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As filed with the Securities and Exchange Commission on February 28, 2011

Registration No. 333-171300

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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Amendment No. 1  
to  
**FORM S-1**  
REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

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**NewLink Genetics Corporation**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>541700</b> (Primary Standard Industrial Classification Code Number)	<b>42-1491350</b> (I.R.S. Employer Identification Number)
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**2503 South Loop Drive  
Ames, IA 50010  
(515) 296-5555**  
(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

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**CHARLES J. LINK, JR.**  
**Chief Executive Officer**  
**NewLink Genetics Corporation**  
**2503 South Loop Drive**  
**Ames, IA 50010**  
**(515) 296-5555**  
(Name, address, including zip code, and telephone number, including area code, of agent for service)

---

*Copies to:*

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**Approximate date of commencement of proposed sale to the public:**  
As soon as practicable after the effective date of this registration statement.

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 under the Securities Exchange Act of 1934. (Check one):

## CALCULATION OF REGISTRATION FEE

<b>Title of Each Class of Securities to be Registered</b>	<b>Proposed Maximum Aggregate Offering Price(1)</b>	<b>Amount of Registration Fee(2)</b>
Common Stock, \$0.01 par value per share	\$86,250,000	\$6,150.00(3)

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
- (3) Previously paid.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 28, 2011

PROSPECTUS



Shares

Common Stock

This is an initial public offering of NewLink Genetics Corporation. We are offering \_\_\_\_\_ shares of our common stock. We currently estimate that the initial public offering price of our common stock will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

Prior to this offering there has been no public market for our common stock. We have filed an application for our common stock to be listed on The NASDAQ Global Market under the symbol "NLNK."

Investing in the common stock involves risks. See "Risk Factors" beginning on page 9.

	<u>Per Share</u>	<u>Total</u>
Initial price to public	\$ _____	\$ _____
Underwriting discounts and commissions	\$ _____	\$ _____
Proceeds, before expenses, to NewLink Genetics Corporation	\$ _____	\$ _____

We have granted the underwriters an option to purchase up to \_\_\_\_\_ additional shares of our common stock to cover over-allotments, if any, exercisable at any time until 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about \_\_\_\_\_, 2011.

**Wells Fargo Securities**

**Cowen and Company**

**Baird**

**Canaccord Genuity**

**Needham & Company, LLC**

Prospectus dated February 28, 2011.

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You should rely only on the information contained in this prospectus and any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized any person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. Neither this prospectus nor any related free writing prospectus is an offer to sell, nor are they seeking an offer to buy, these securities in any jurisdiction where the offer or solicitation is not permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus, and information may have changed since those dates.

For investors outside the United States: Neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

## PROSPECTUS SUMMARY

*The items in the following summary are described in more detail later in this prospectus. This summary does not contain all of the information you should consider. Before investing in our common stock, you should read the entire prospectus carefully, including the "Risk Factors" beginning on page 9, the "Business" section beginning on page 77, which more fully describes our product candidates and the status of our clinical trials and the financial statements and related notes beginning on page F-1. Unless the context indicates otherwise, as used in this prospectus, the terms "NewLink," "the Company," "we," "us" and "our" refer to NewLink Genetics Corporation.*

### Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. Our portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. Our product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. Our lead product candidate, HyperAcute Pancreas cancer immunotherapy, or HyperAcute Pancreas, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating approximately 700 Stage I and Stage II surgically-resected pancreatic cancer patients, according to the American Joint Committee on Cancer classification system, or AJCC system, who have no detectable disease by a CT scan. The clinical trial is being performed under a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA, and as of February 15, 2011, we have enrolled 73 patients at 35 clinical sites in the United States. We launched this trial in May 2010 based on encouraging interim data from a 70-patient Phase 2 clinical trial in surgically-resected pancreatic cancer patients. We have also received Fast Track and Orphan Drug designations from the FDA for HyperAcute Pancreas for the adjuvant treatment of surgically-resected pancreatic cancer.

We completed enrollment of our 70-patient Phase 2 clinical trial for HyperAcute Pancreas in surgically-resected pancreatic cancer in February 2010. In this open label, single arm trial, HyperAcute Pancreas was given in doses of either 100 million cells or 300 million cells approximately twice monthly for six months in combination with the standard-of-care treatment regimen, which consisted of gemcitabine chemotherapy plus 5-FU based chemoradiotherapy. The interim data from this clinical trial indicate that HyperAcute Pancreas may improve disease-free and overall survival when given to patients in combination with standard-of-care following complete resection of detectable disease. As of January 14, 2011, interim efficacy data for all Phase 2 patients predict one-year overall survival of 86% based on Kaplan-Meier analysis. In addition, the interim efficacy data for the 26 patients receiving high dose HyperAcute Pancreas immunotherapy predict median disease-free survival of 15.3 months and a one-year overall survival rate of 96% based on Kaplan-Meier analyses. HyperAcute Pancreas has also demonstrated a favorable safety profile to date.

The American Cancer Society has estimated that approximately 43,000 new cases of pancreatic cancer will be diagnosed in the United States in 2010. Pancreatic cancer has generally been recognized as an aggressive form of cancer that often remains undiagnosed in its earlier stages. As a result, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer Society estimates one-year and five-year survival rates of 24% and 5%, respectively. HyperAcute Pancreas initially targets patients with localized tumors that can be removed surgically, or resected. According to eMedicine, a healthcare reference website run by WebMD containing peer-reviewed articles on diseases and medical topics, approximately 20% of patients in the United States are eligible for resection at initial diagnosis. These earlier stage, resected patients have significantly better prognoses than patients with later-stage disease since they tend to have better nutritional and immune status and significantly lower amounts of micro-metastatic and residual disease. A study published in

the *Journal of the American Medical Association* showed that resection followed by chemotherapy or chemoradiotherapy, known as adjuvant therapy, extends median survival to approximately 18 months. We believe the addition of HyperAcute Pancreas to adjuvant standard-of-care has the potential to improve median disease-free survival and overall survival in resected pancreatic cancer patients.

In addition to HyperAcute Pancreas, we and our collaborators have completed patient enrollment for a Phase 1/2 clinical trial evaluating our HyperAcute Lung cancer immunotherapy product candidate, or HyperAcute Lung, for non-small cell lung cancer, or NSCLC, and a Phase 2 clinical trial for our HyperAcute Melanoma cancer immunotherapy product candidate, or HyperAcute Melanoma. In the Phase 1/2 single arm, open label HyperAcute Lung clinical trial, we administered our product candidate as a monotherapy in 54 patients with refractory, recurrent or metastatic nonresectable NSCLC. In the Phase 2 portion, the 28 patients evaluated for clinical response received injections of 300 million cells every two weeks for up to eight doses. As of September 30, 2010, the interim results for the 28 patients evaluated in the Phase 2 clinical trial group showed a median progression-free survival of 14.6 weeks, median overall survival of 11.3 months, a one-year survival rate of 46%, good tolerability and a favorable safety profile. Based on our analysis of data from comparable precedent clinical trials of similar patients, we would have expected a median overall survival of approximately eight months. We are conducting this Phase 1/2 study at the National Cancer Institute, or NCI. We anticipate announcing results from this trial in the first half of 2011 and initiating a Phase 2B/3 clinical trial in advanced NSCLC patients in the second half of 2011.

HyperAcute Melanoma is being studied in an investigator-initiated, fully-enrolled 25-patient Phase 2 clinical trial for the treatment of advanced melanoma in combination with an eight-week course of PEG-Intron, a man-made immune modulator. The treatment consists of 12 weekly injections of HyperAcute Melanoma with PEG-Intron being co-administered in weeks five through 12. As of October 7, 2010, interim results from the first 12 patients to reach 12 months of follow-up in this trial have been encouraging, with all of the patients developing low levels of autoimmune antibodies and approximately one-third of patients developing vitiligo, an autoimmune condition in which the patient's immune system attacks melanocytes in the skin. In previous melanoma immunotherapy studies, vitiligo has been correlated with favorable response to therapy. HyperAcute Melanoma has demonstrated good tolerability and a favorable safety profile to date. We anticipate announcing the results from this trial in the second half of 2011.

Our HyperAcute Pancreas, Lung and Melanoma product candidates are based on our HyperAcute immunotherapy technology, which is designed to stimulate the human immune system by exploiting a natural barrier present in humans that protects against infection being transmitted from other mammals. This barrier is related to the enzyme, alpha (1,3) galactosyl transferase, or a-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the expression of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or a-Gal, on the surface of affected cells. Introducing a-Gal expressing cells to the human or primate immune system activates an immune response from antibodies against a-Gal. Antibodies directed against the a-Gal epitope are potentially the most abundant natural antibody in humans and represent approximately 1% of circulating human antibodies.

Our HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes a-Gal epitopes. This exposure to a-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which a-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti-a-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens common to both the immunotherapy and the patient's tumor cells.

In addition to our HyperAcute product candidates, we are developing d-1-methyltryptophan, or D-1MT, a small-molecule, orally bioavailable product candidate from our proprietary indoleamine-(2, 3)-dioxygenase, or IDO, pathway inhibitor technology. In preclinical models, IDO pathway inhibitors have

shown anti-tumor effects in combination with radiotherapy, chemotherapy, targeted therapy or immunotherapy. Through our collaboration with the NCI, we are studying D-1MT in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. The first clinical trial has primary endpoints that assess the safety and efficacy of D-1MT in combination with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The second clinical trial has primary endpoints that assess safety and efficacy of D-1MT in combination with Taxotere® for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. We anticipate announcing preliminary data from these trials by the end of 2011.

### **Investment Highlights**

We believe the following are the key attributes of our company:

- Our lead product candidate, HyperAcute Pancreas, is in a Phase 3 clinical trial based on encouraging interim Phase 2 survival data in surgically-resected pancreatic cancer patients.
- Our novel HyperAcute technology has a wide range of anti-cancer applications including two additional product candidates, HyperAcute Lung and HyperAcute Melanoma, in active clinical development.
- We have in-house manufacturing capabilities for our HyperAcute product candidates that we believe are sufficient to support clinical development and initial commercialization of HyperAcute Pancreas in the United States.
- Our lead IDO pathway inhibitor product candidate is in clinical development in combination with multiple alternative therapies, including Taxotere.
- We have an extensive intellectual property portfolio.

### **Our Strategy**

Our strategy is to discover, develop and commercialize immunotherapeutic products for the treatment of cancer where the needs of patients are unmet by current therapies. The critical components of our business strategy include:

- Complete the Phase 3 clinical trial of HyperAcute Pancreas, our lead immunotherapy product candidate, and gain regulatory approval.
- Develop sales and marketing infrastructure to commercialize our HyperAcute Pancreas product candidate in the United States and establish commercial partnerships in other regions.
- Advance our HyperAcute Lung and HyperAcute Melanoma product candidates through additional clinical trials.
- Expand our manufacturing capabilities for our HyperAcute immunotherapy product candidates.
- Investigate our HyperAcute immunotherapy technology in additional oncology indications.
- Develop and commercialize D-1MT, our small-molecule product candidate, for the treatment of various oncology indications.

### **Our Risks**

We are a development stage biopharmaceutical company, and our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide

to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in "Risk Factors" beginning on page 9:

- To date, we have not completed clinical development for any of our products candidates and we do not have a product candidate that has been approved for sale by the FDA.
- Our near term prospects are highly dependent on HyperAcute Pancreas. If we fail to demonstrate efficacy in clinical trials, fail to obtain regulatory approval or fail to successfully commercialize HyperAcute Pancreas, our business would be harmed and the value of our securities would likely decline.
- If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not tested any of our product candidates in controlled clinical trials.
- Our HyperAcute product candidates are based on a novel technology, which may raise development issues we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our product candidates.
- While we have negotiated an SPA with the FDA relating to our HyperAcute Pancreas Phase 3 clinical trial, the SPA does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.
- We may face delays in completing our clinical trials and we may not be able to complete them at all.
- Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.
- Our product candidates are being and will be studied in clinical trials co-sponsored by the NCI and in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.
- We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.
- As of December 31, 2010, we had \$6 million in outstanding debt under a forgivable loan agreement with the Iowa Department of Economic Development, of which \$4.7 million may be accelerated and require repayment as early as March 18, 2012.
- Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.
- We have never manufactured our product candidates at commercial scale, and there can be no assurance that such products can be manufactured in compliance with regulations at a cost or in quantities necessary to make them commercially viable.
- We replicate all biological cells for our products internally and utilize a single manufacturing site to manufacture our clinical product candidates. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing and would result in delays, increased costs or losses.
- The industry within which we operate and our business are subject to extensive regulation, which is costly, time consuming and may subject us to unanticipated delays.



- We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.
- If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.
- We have a history of net losses, including net losses of \$15.7 million and \$9.4 million for the years ended December 31, 2010 and December 31, 2009, respectively. We expect to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.
- We will require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

### Corporate Information

We were incorporated as NewLink Genetics Corporation in Delaware on June 4, 1999. Our principal executive offices are located at 2503 South Loop Drive, Ames, IA 50010, and our telephone number is (515) 296-5555. Our website address is [www.linkp.com](http://www.linkp.com). The information contained in or that can be accessed through our website is not part of this prospectus.

HyperAcute® and NewLink Genetics® are registered trademarks of ours. Other trademarks and tradenames set forth herein are property of their respective owners. Registered trademarks and tradenames will be accompanied by the "®" designation only on their first reference.

### The Offering

**Common stock offered**

shares (or shares if the underwriters' overallotment option is exercised in full).

**Common stock to be outstanding after this offering**

shares (or shares if the underwriters' overallotment option is exercised in full).

**Use of proceeds**

We intend to use the net proceeds from this offering to fund clinical trials and other research and development activities for HyperAcute Pancreas, our other HyperAcute immunotherapy product candidates and our IDO pathway inhibitor product candidate and for working capital and other general corporate purposes.

**Risk factors**

You should read the "Risk Factors" section of this prospectus beginning on page 9 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

**Proposed NASDAQ Global Market symbol**

NLNK

The number of shares of common stock to be outstanding after this offering is based on 7,618,973 shares of common stock outstanding as of December 31, 2010, after giving effect to 276,304 shares of

our Series E preferred stock issued or issuable in connection with our acquisition of the minority interest in our majority-owned subsidiary BioProtection Systems Corporation, or BPS, and excludes:

- 1,167,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Equity Incentive Plan, or 2000 Plan, as of December 31, 2010 having a weighted average exercise price of \$0.90 per share;
- 5,203,250 shares of common stock issuable upon the exercise of outstanding options under our 2009 Equity Incentive Plan, as amended, or 2009 Plan, as of December 31, 2010 having a weighted average exercise price of \$1.49 per share;
- 1,704,750 additional shares of common stock reserved for future issuance under our 2009 Plan, as amended and restated, of which 1,500,000 were added to the shares reserved under this plan on October 29, 2010, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation — Employee Benefit Plans — 2009 Equity Incentive Plan" of this prospectus;
- 950,000 shares of common stock reserved for future issuance under our 2010 Non-Employee Directors' Stock Award Plan, or Directors' Plan, and 2010 Employee Stock Purchase Plan, or 2010 Purchase Plan, each of which will become effective upon the completion of this offering; and
- 106,347 shares of common stock issuable upon the exercise of options that are issuable in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS.

Unless otherwise noted, the information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock into 16,375,568 shares of common stock upon the completion of this offering;
- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws upon the completion of this offering;
- no exercise of the underwriters' over-allotment option; and
- a one-for- reverse stock split of our common stock to be effected before completion of this offering.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

### Summary Financial Data

The following tables summarize certain of our financial data. The summary statement of operations data for the years ended December 31, 2008, 2009 and 2010 are derived from our audited financial statements included elsewhere in this prospectus. Our historical results of operations and financial condition are not necessarily indicative of the results or financial condition that may be expected in the future. The summary financial data set forth below should be read together with our financial statements and related notes, "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	Years Ended December 31,		
	2008	2009	2010
(in thousands, except per share data)			
<b>Statement of operations data:</b>			
Grant revenue	\$ 633	\$ 934	\$ 2,079
<b>Operating expenses:</b>			
Research and development(1)	6,517	7,636	13,249
General and administrative(1)	3,531	3,115	5,023
<b>Total operating expenses</b>	<b>10,048</b>	<b>10,751</b>	<b>18,272</b>
<b>Loss from operations</b>	<b>(9,415)</b>	<b>(9,817)</b>	<b>(16,193)</b>
<b>Other income and expense:</b>			
Miscellaneous income	42	19	71
Interest income	213	132	75
Interest expense	(2)	(9)	(47)
<b>Other income, net</b>	<b>253</b>	<b>142</b>	<b>99</b>
Net loss	(9,162)	(9,675)	(16,094)
<b>Less net loss attributable to noncontrolling interest(2)</b>	<b>—</b>	<b>233</b>	<b>349</b>
<b>Net loss attributable to NewLink</b>	<b>\$ (9,162)</b>	<b>\$ (9,442)</b>	<b>\$ (15,745)</b>
<b>Net loss per share-basic and diluted</b>	<b>\$ (1.40)</b>	<b>\$ (1.42)</b>	<b>\$ (2.24)</b>
<b>Weighted average shares outstanding — basic and diluted</b>	<b>6,542</b>	<b>6,636</b>	<b>7,040</b>
<b>Pro forma as adjusted net loss per share — basic and diluted (unaudited)</b>			<b>\$ ( )</b>
<b>Weighted average pro forma as adjusted shares outstanding (unaudited)</b>			

	As of December 31, 2010		
	Actual	Pro Forma (in thousands)	Pro Forma As Adjusted
<b>Balance sheet data:</b>			
Cash, cash equivalents, and certificates of deposit	\$ 12,841	\$ 12,841	
Working capital	11,438	11,438	
Total assets	20,139	20,139	
Notes payable and obligations under capital leases	7,294	7,294	
Convertible preferred stock	62,775	71,410	
Deficit accumulated during the development stage	(62,707)	(62,707)	
Total equity (deficit)	\$ (51,958)	\$ (60,593)	

- (1) Research and development and general and administrative expenses were corrected for misclassification in 2008 and 2009. See note 2(k) in the notes to the consolidated financial statements included in this prospectus.
- (2) Further explanation is described under the caption "Noncontrolling Interest" in note 2(o) to the consolidated financial statements included in this prospectus.

The summary pro forma and pro forma as adjusted balance sheet data above gives effect to the following transactions as if they had occurred as of December 31, 2010:

- on a pro forma basis the issuance of 276,304 shares of Series E preferred stock in connection with our acquisition of the minority interest in our majority owned subsidiary, BPS of which 221,066 shares were issued on January 7, 2011 and up to 55,238 shares are issuable upon the satisfaction of certain conditions in connection with the acquisition; and
- on a pro forma as adjusted basis (i) the issuance and sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale and (ii) the conversion of all of our outstanding convertible preferred stock into an aggregate of 16,375,568 shares of common stock, which will take place automatically upon the closing of this offering in accordance with the terms of our preferred stock.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and certificates of deposit, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

The table above does not include:

- 1,167,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Plan, as of December 31, 2010 having a weighted average exercise price of \$0.90 per share;
- 5,203,250 shares of common stock issuable upon the exercise of outstanding options under our 2009 Plan as of December 31, 2010 having a weighted average exercise price of \$1.49 per share; and
- 1,704,750 additional shares of common stock reserved for future issuance under our 2009 Plan, as amended and restated, of which 1,500,000 were added to the shares reserved under this plan on October 29, 2010, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation — Employee Benefit Plans — 2009 Equity Incentive Plan" section of this prospectus;
- 950,000 shares of common stock reserved for future issuance under our Directors' Plan and 2010 Purchase Plan, each of which will become effective upon the completion of this offering; and
- 106,347 shares of common stock issuable upon the exercise of options that are issuable in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve risks and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.*

### Business Risks

#### Risks Relating to Clinical Development and Commercialization of Our Product Candidates

***Our near term prospects are highly dependent on HyperAcute Pancreas. If we fail to complete, or demonstrate safety and efficacy in, clinical trials, fail to obtain regulatory approval or fail to successfully commercialize HyperAcute Pancreas, our business would be harmed and the value of our securities would likely decline.***

We must be evaluated in light of the uncertainties and complexities affecting a development stage biopharmaceutical company. We have not completed clinical development for any of our products. Our most advanced product candidate is HyperAcute Pancreas. The United States Food and Drug Administration, or FDA, must approve HyperAcute Pancreas before it can be marketed or sold. Our ability to obtain FDA approval of HyperAcute Pancreas depends on, among other things, completion of our Phase 3 clinical trial, whether our Phase 3 clinical trial of HyperAcute Pancreas demonstrates statistically significant achievement of the clinical trial endpoints with no significant safety issues and whether the FDA agrees that the data from our Phase 3 clinical trial of HyperAcute Pancreas is sufficient to support approval. The final results of our Phase 3 clinical trials of HyperAcute Pancreas may not meet the FDA's requirements to approve the product for marketing, and the FDA may otherwise determine that our manufacturing processes, facilities or raw materials are insufficient to warrant approval. We may need to conduct more clinical trials than we currently anticipate. Furthermore, even if we do receive FDA approval, we may not be successful in commercializing HyperAcute Pancreas. If any of these events occur, our business could be materially harmed and the value of our common stock would likely decline.

***If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not tested any of our product candidates in controlled clinical trials.***

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints.

In particular, there have been no control groups in our clinical trials conducted to date. While comparisons to results from other reported clinical trials can assist in predicting the potential efficacy of our HyperAcute Pancreas product candidate, there are many factors that affect the outcome for patients in clinical trials, some of which are not apparent in published reports, and results from two different trials cannot always be reliably compared. As a result, we are studying HyperAcute Pancreas in combination with the current standard-of-care in direct comparison to the current standard-of-care alone in the same trial and will need to show a statistically significant benefit when added to the current standard-of-care in order for HyperAcute Pancreas to be approved as a marketable drug. Patients in our Phase 3 study who do not receive HyperAcute Pancreas may not have results similar to patients studied in the other studies we have used for comparison to our Phase 2 studies. If the patients in our Phase 3 study who receive standard-of-care without HyperAcute Pancreas have results which are better than the results predicted by the other large studies, we may not demonstrate a sufficient benefit from the HyperAcute Pancreas to allow the FDA to approve it for marketing.

***Our HyperAcute product candidates are based on a novel technology, which may raise development issues we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our product candidates.***

Our HyperAcute product candidates are based on our novel HyperAcute immunotherapy technology. In the course of developing this technology and these product candidates, we have encountered difficulties in the development process. There can be no assurance that additional development problems will not arise in the future which we may not be able to resolve or which may cause significant delays in development.

Regulatory approval of novel product candidates such as ours can be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to our and regulatory agencies' lack of experience with them. This may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. For example, the two cell lines that comprise HyperAcute Pancreas are novel and complex therapeutics that we have endeavored to better characterize so that their identity, strength, quality, purity and potency may be compared among batches created from different manufacturing methods. We currently lack the manufacturing capacity necessary for larger-scale production. If we make any changes to our current manufacturing methods or cannot design assays that satisfy FDA's expectations regarding the equivalency of such therapeutics in the laboratory, the FDA may require us to undertake additional clinical trials.

The novel nature of our product candidates also means that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel for research, development and manufacturing positions.

***Our Special Protocol Assessment, or SPA, with the FDA relating to our HyperAcute Pancreas Phase 3 clinical trial does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.***

The protocol for our HyperAcute Pancreas Phase 3 clinical trial was reviewed by the FDA under its SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a New Drug Application, or NDA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval, the FDA retains the right to require additional Phase 3 testing and we cannot be certain that the design of, or data collected from, the HyperAcute Pancreas Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of HyperAcute Pancreas for the treatment of patients with pancreatic cancer, or otherwise be sufficient to

support FDA or any foreign regulatory approval. In addition, the survival rates, duration of response and safety profile required to support FDA approval are not specified in the HyperAcute Pancreas Phase 3 clinical trial protocol and will be subject to FDA review. Although the SPA agreement calls for review of interim data at certain times prior to completion, there is no assurance that any such review, even if such interim data is positive, will result in early approval. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement was entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the HyperAcute Pancreas Phase 3 clinical trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the HyperAcute Pancreas Phase 3 clinical trial, or whether HyperAcute Pancreas will receive any regulatory approvals as a result of the SPA agreement or the HyperAcute Pancreas Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for HyperAcute Pancreas for the treatment of patients with pancreatic cancer.

Interim data from our HyperAcute Pancreas Phase 2 clinical trial, or NLG-0205, has shown statistically significant differential responses to HyperAcute Pancreas immunotherapy between the 300 million cell dose cohort and the 100 million cell dose cohort. We recently amended our HyperAcute Pancreas Phase 3 clinical trial protocol to extend treatment duration based upon this and other maturing data emerging from NLG-0205. This amendment was approved by the FDA and does not affect the status of our SPA. However, the clinical sites participating in the HyperAcute Pancreas Phase 3 clinical trial must approve this amendment before we can incorporate these changes into the protocol. If this approval process is prolonged or we are unable to obtain approval from some of these sites, our enrollment goals may not be reached, which could delay or prevent the successful completion of our HyperAcute Pancreas Phase 3 clinical trial.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle including by allowing Investigational New Drug applications, or INDs, to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. If we do not accurately evaluate the scientific and commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

***We may face delays in completing our clinical trials, and we may not be able to complete them at all.***

We have not completed all the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- slower than expected patient enrollment or lack of a sufficient number of patients that meet the enrollment criteria for our clinical trials;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our study protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in achieving study endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for the HyperAcute product candidates, D-1MT or other product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize the HyperAcute product candidates, D-1MT or other future product candidates will be adversely affected.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.***

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;



- design of the trial protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

In particular, the inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events for reasons that may not be related to the product candidate we are testing or, in those trials where our product candidate is being tested in combination with one or more other therapies, for reasons that may be attributable to such other therapies, but which can nevertheless negatively affect clinical trial results. In addition, we have experienced difficulties enrolling patients in certain of our smaller clinical trials due to lack of referrals and may experience similar difficulties in the future.

If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

***Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.***

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA; should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change

requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

***We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.***

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices, or cGCP, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices, or cGMP, and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our HyperAcute product candidates, D-1MT and other product candidates could take a significantly longer time to gain regulatory approval for any additional indications than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating the commercialization of our HyperAcute product candidates, D-1MT and other product candidates for additional indications.

***Our product candidates are being and will be studied in clinical trials co-sponsored by the National Cancer Institute, or NCI, and in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.***

Our D-1MT product candidate is being studied in a two Phase 1B/2 clinical trials co-sponsored by the National Cancer Institute. We are also currently providing clinical supply of our HyperAcute Melanoma product candidate in support of a Phase 2 investigator-initiated clinical trial. We expect to continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

***If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.***

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

***Even if approved, the HyperAcute product candidates, D-1MT or any other product we may commercialize and market may be later withdrawn from the market or subject to promotional limitations.***

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to fulfill. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our products.

***We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.***

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and

- expand existing operational, financial and management information systems.

We plan to increase our manufacturing capacity and seek FDA approval for our production process simultaneously with seeking approval for sale of our HyperAcute Pancreas product candidate. Should we not receive timely approval of our production process, our ability to produce the immunotherapy products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.***

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we market and sell any products that we develop ourselves.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales, marketing and distribution capabilities depends on the progress towards commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to partner with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

***Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.***

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff, particularly Dr. Charles J. Link, Jr. The loss of his services might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit a significant number of additional personnel in order to achieve our operating goals. In order to pursue our product development and marketing and sales plans, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. If the personnel that have contingently agreed to join us do not join us it will be difficult or impossible for us to execute our business plan in a timely manner. Additionally, our facilities are located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. We have two forgivable loans totaling \$6.4 million that are contingent on us creating jobs in Iowa. If we leave Iowa or fail to create the required number of jobs in Iowa, we may be required to pay back some or all of those loans. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

#### **Risks Relating to Manufacturing Activities**

***We have never manufactured our product candidates at commercial scale, and there can be no assurance that such products can be manufactured in compliance with regulations at a cost or in quantities necessary to make them commercially viable.***

We have no experience in commercial-scale manufacturing, the management of large-scale information technology systems or the management of a large-scale distribution system. We may develop our manufacturing capacity in part by expanding our current facilities. This activity would require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing facilities that are sufficient to produce materials for additional later-stage clinical trials or commercial use.

If we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes or our relationships with other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of our Biologics License Application, or BLA, or New Drug Application, or NDA, on a timely basis and must adhere to Good Laboratory Practice, or GLP and cGMP regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA approval of the products will not be granted.

***We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.***

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing contract manufacturer for D-1MT and the components used in the HyperAcute product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval

inspection for compliance with the applicable regulations as a condition of regulatory approval of the HyperAcute product candidates, D-1MT or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of the HyperAcute product candidates, D-1MT or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

***We currently rely on relationships with third-party contract manufacturers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates in the near-term.***

We will rely upon contract manufacturers for D-1MT, and for components of the HyperAcute product candidates, for commercial sale if any are approved for sale. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of antigen, components or finished HyperAcute product candidates or D-1MT. This could delay or reduce commercial sales and materially harm our business. We do not currently have experience with the manufacture of products at commercial scale, and may incur substantial costs to develop the capability to manufacture products at commercial scale. Any prolonged delay or interruption in the operations of our facilities or our contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in regulatory requirements or standards that require modifications to our manufacturing processes, action by the regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of drug substances could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to timely meet market demand for any products that are approved for sale.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

***We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.***

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and

Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

***We replicate all biological cells for our products internally and utilize a single manufacturing site to manufacture our clinical product candidates. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing and would result in increased costs and losses.***

We have thus far elected to replicate all biological cells for our products internally using a complex process. The disruption of our operations could result in manufacturing delays due to the inability to purchase the cell lines from outside sources. We have only one manufacturing facility in which we can manufacture clinical products. In the event of a physical catastrophe at our manufacturing or laboratory facilities, we could experience costly delays in reestablishing manufacturing capacity, due to a lack of redundancy in manufacturing capability.

Our current manufacturing facility contains highly specialized equipment and utilizes complicated production processes developed over a number of years, which would be difficult, time-consuming and costly to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. We may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or any losses may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

We recently transferred our manufacturing operation to a new facility. We have experienced bacterial and mycoplasma contaminations in lots produced at the previous facility and we destroyed the contaminated lots and certain overlapping lots. We may have contaminated lots at our new facility and we will destroy any contaminated lots that we detect.

***Our facilities are located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.***

Our facilities are located in Ames, Iowa, which is susceptible to floods and tornados, and our facilities are therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business personal property insurance in the amount of \$6.25 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

## Risks Relating to Regulation of Our Industry

***The industry within which we operate and our business are subject to extensive regulation, which is costly, time consuming and may subject us to unanticipated delays.***

The research, design, testing, manufacturing, labeling, marketing, distribution and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe, pure, potent and effective, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations.

There can be no assurance that clinical studies for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. There can be no assurance that we will not encounter problems in clinical trials that will cause us to delay or suspend clinical trials.

Regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate. To date, the FDA has approved only one active cellular cancer immunotherapy product, even though several have been, and currently are in, clinical development. Further, even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer.

We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. Once we submit our potential products for review, there can be no assurance that regulatory approvals for any pharmaceutical products developed by us will be granted on a timely basis, if at all.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted BLA and NDA. A delay in obtaining or failure to obtain such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record keeping and reporting of adverse experiences and other



information. In addition, we would be required to comply with federal and state anti-kickback and other health care fraud and abuse laws that pertain to the marketing of pharmaceuticals. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Non-compliance with these requirements could result in enforcement actions or penalties or could delay introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

***The availability and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payors may reimburse for our potential product, are uncertain.***

In both United States and foreign markets, sales of our proposed products will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third party payors to contain or reduce the costs of health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations.

In addition, in both the United States and elsewhere, sales of prescription drugs are dependent in part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials.

***The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing.***

In addition to FDA restrictions on marketing of biopharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

***Multi-jurisdictional regulations, including those establishing our ability to price products, may negatively affect our sales and profit margins.***

We expect to face pricing pressure globally from managed care organizations, institutions and government agencies and programs, which could negatively affect the sales and profit margins for our HyperAcute product candidates, D1-MT or any other of our product candidates that are approved for marketing. For example, in the United States, the Medicare Modernization Act contains a prescription drug benefit for individuals who are eligible for Medicare. The prescription drug benefit became effective on January 1, 2006 and has resulted in increased use of generics and increased purchasing power of those negotiating on behalf of Medicare recipients, which in turn may result in increased pricing pressure on our products.

***Health care reform measures could adversely affect our business.***

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. Most recently, in March 2010 the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, was enacted, which includes measures to significantly change the way

health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;
- new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending beginning by January 1, 2011.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA to our HyperAcute product candidates. The FDA is only now soliciting public comment and conducting hearings to assist them in drafting regulations under the PPACA. It is not certain that we will receive 12 years of marketing exclusivity for any of our products. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively,

in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

## **Financial Risks**

***We have a history of net losses. We expect to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.***

We are not profitable and have incurred significant net losses in each year since our inception, including net losses of \$15.7 million, \$9.4 million and \$9.2 million for the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010, we had an accumulated deficit of \$62.7 million. Our losses have resulted principally from costs incurred in our discovery and development activities. We anticipate that our operating losses will substantially increase over the next several years as we expand our discovery, research and development activities, including the Phase 2 and Phase 3 clinical development of the HyperAcute product candidates and Phase 2 clinical development of D-1MT.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

***We will require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.***

Development of our HyperAcute product candidates, D-1MT and any other product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);

- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish collaborative arrangements to the extent necessary;
- revenues received from any existing or future products; and
- payments received under any future strategic partnerships.

We anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, develop our pipeline and expand our corporate infrastructure. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, will allow us to fund our operating plan through at least the end of 2012. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. Pursuant to most of these license agreements, we are obligated to make aggregate payments ranging from around \$200,000 to \$2.8 million per license (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors are subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborative partners, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when

needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

***We have outstanding debt which may be accelerated as early as March 18, 2012.***

In March 2005, we entered into a \$6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there will be no principal or interest payments due until the completion date for the project, which is March 18, 2012, under the current one-year extension granted by the IDED. The project is to provide us with financial assistance for research and product development activities at our Iowa State University Research Park facility. The project calls for the creation of 315 jobs at the time of commercialization and retention of 35 jobs with total project expenditures of \$189.9 million for clinical trials, research and development activities, building construction, equipment purchases, and other working capital needs. As of December 31, 2010, we believe we had created 45 jobs, retained 35 jobs and incurred \$61.4 million of project expenditures. If, as of March 18, 2011, the IDED determines we have fulfilled all the job creation and maintenance terms and project expenditure requirements of the loan agreement, the loan will be forgiven. However, on the project completion date we will be required to repay the greater of either approximately \$17,000 for each of the 350 jobs we fail to create and maintain as of that date or a percentage of the \$6.0 million advanced under the agreement equal to the percentage of any shortfall in our obligation to expend \$189.9 million of project expenditures. Five years following the project completion date, we will be required to repay approximately \$17,000 for each of the 350 jobs the IDED determines we failed to maintain as of that date. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6% interest per annum beginning at the date of default. We are also obligated to maintain our business in the State of Iowa while amounts remain outstanding under this loan.

We have not currently fulfilled the requirements for loan forgiveness under this agreement. Absent an amendment granted by the IDED, we would have to repay up to \$4.7 million on or after March 18, 2012. There is no guarantee that the IDED will agree to further extend the completion date under the agreement. If the amounts under the loan become due in March 2012, it would likely have a material adverse affect on our cash position. Additionally, under the agreement, we are obligated to pay a minimum of 0.25% royalties on all gross revenues of any products we bring to market with a cumulative maximum royalty amount due of \$3.2 million. Substantially all of our assets are pledged to secure this loan.

In March 2010, we entered into a \$400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, in order to help finance the construction of new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015. The project calls for us to create or retain at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and to create or retain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for us to enter into a five-year building lease with option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, we have failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, we will be required to repay approximately \$3,100 per job not created or retained following the respective date. As of December 31, 2010, we had created or retained an aggregate of 76 full-time jobs in Ames, Iowa. As of December 31, 2010, \$300,000 of the total \$400,000 forgivable loan was advanced to us with the final \$100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6.5% interest per annum beginning at the date of default.

We have not met the full job creation requirements of these loans as of the present date. If we cannot or do not comply with these and all other requirements under these loans, we may be obligated

to pay principal and interest on these loans immediately. If we are unable to meet our obligations to service our debt and fund our business, we may be forced to reduce or delay capital expenditures, seek additional debt financing or equity capital, restructure or refinance our debt or sell assets. We cannot assure you that we would be able to obtain additional financing, refinance existing debt or sell assets on satisfactory terms or at all.

***Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.***

We have received significant financial assistance from state and local governments, primarily in the form of forgivable loans. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

Through our subsidiary, BioProtection Systems Corporation, or BPS, we also have ongoing contracts and grants with the United States Department of Defense and National Institutes of Health, respectively. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

### **Risks Relating to Competitive Factors**

***We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.***

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We will face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

***Our competitors may develop and market products that are less expensive, more effective, safer or reach the market sooner than our product candidates, which may diminish or eliminate the commercial success of any products we may commercialize.***

The biopharmaceutical industry is highly competitive. There are many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. Given the significant unmet patient need for new therapies, oncology is an area of focus for large and small companies as well as research institutions. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates, and several large public biopharmaceutical companies have approved or are developing cancer immunotherapy products, including Dendreon Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline plc, Merck & Co., Merck KGaA and Sanofi-Aventis.

There are several marketed products indicated for pancreatic cancer, including Eli Lilly and Company's Gemzar®, Astellas Pharma's Tarceva®, Teva's streptozocin, and fluorouracil, or 5-FU, and mitomycin which are marketed by several generic pharmaceutical firms. There are numerous marketed therapeutics indicated for NSCLC, including Roche AG's Avastin®, Eli Lilly's Alimta® and Gemzar, Astellas Pharma's Tarceva, AstraZeneca's Iressa®, and Sanofi-Aventis' Taxotere, as well as generically available platinum-based chemotherapeutics (cisplatin and carboplatin) and mitotic inhibitors (paclitaxel and venorelbine). There are also several marketed therapeutics indicated for advanced melanoma, including Merck's Intron A and Novartis/Prometheus Laboratories' Proleukin®, as well as cisplatin and dacarbazine, which are available generically. Bristol-Myers Squibb's immunotherapy ipilimumab is pending FDA approval for use as a monotherapy against advanced melanoma.

In addition, there are a number of companies with active clinical trials ongoing in pancreatic cancer including AB Science SA, Amgen Inc., Astellas Pharma, Baxter, BioSante, Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics Inc., Sanofi-Aventis and Threshold Pharmaceuticals, Inc., a number of companies with active clinical trials ongoing in NSCLC, including Abbott Laboratories, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, BioNumerik Pharmaceuticals, Inc., Celgene, GlaxoSmithKline, Onyx Pharmaceuticals, Inc., Pfizer Inc. and Regeneron Pharmaceuticals, Inc., and a number of companies with active clinical trials ongoing in advanced melanoma, including Astellas Pharma, Eli Lilly, Onyx, Plexxikon Inc., Roche, Synta Pharmaceuticals Corp. and Vical Inc.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the significant expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

There are many different approaches to using immunotherapies to treat cancer, including anti-idiotypic, whole cell, DNA, peptide/antigen, viral, tumor lysate, shed antigens, and dendritic cell. Cancer immunotherapies are also distinguished by whether or not they are derived from autologous or allogeneic sources. Each of the various approaches to cancer immunotherapy have potential advantages and disadvantages based on factors such as their immunostimulatory mechanisms, formulation characteristics, manufacturing requirements, and treatment regimens.

We also compete with other clinical-stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Delay in recruiting clinical



trial participants could adversely affect our ability to bring a product to market prior to our competitors. Further, research and discoveries by others may result in breakthroughs that render our HyperAcute product candidates, D-1MT or our other potential products obsolete even before they begin to generate any revenue.

In addition, our competitors may obtain patent protection or FDA approval and commercialize products more rapidly than we do, which may impact future sales of any of our products that receive marketing approval. If the FDA approves the commercial sale of any of our products, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval, but cannot compete effectively in the marketplace.

If any of our product candidates are approved and commercialized, we may face competition from generic products if the product candidate is a small molecule drug, or biosimilars if the product candidate is a biologic. The route to market for generic versions of small molecule drugs was established with the passage of the Hatch-Waxman Amendments in 1984 and for biosimilars with the passage of the PPACA in March 2010. The PPACA establishes a pathway for the FDA approval of follow-on biologics and provides 12 years of marketing exclusivity for reference products and an additional six months of exclusivity if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

Our biodefense product candidates face significant competition for United States government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. Competitors include Emergent BioSolutions, SIGA Technologies, AVI Biopharma, Pharmathene, Acambis, Bavarian Nordic AS, and Novartis. Academic institutions, government agencies, private research organizations and public research organizations are also conducting research and filing patents toward commercialization of products. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

***Our products may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any.***

Even if the HyperAcute product candidates, D-1MT or any of our other potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our products, if successfully developed, will compete with a number of traditional products and immunotherapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and reimbursement by government and private third party payors.

## Risks Relating to Our Arrangements with Third Parties

***We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.***

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, to conduct our preclinical studies and clinical trials. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and cGCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with cGCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

***If we fail to enter into any needed collaboration agreements for our product candidates, we may be unable to commercialize them effectively or at all.***

To successfully commercialize the HyperAcute product candidates or D-1MT, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with another company that can provide some or all of such physical resources and systems as well as financial resources and expertise. Such collaborations are complex and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the HyperAcute product candidates and D-1MT, the costs and complexities of manufacturing and delivering the HyperAcute product candidates and D-1MT to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for the HyperAcute product candidates or D-1MT is necessary and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the HyperAcute product candidates or D-1MT in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the HyperAcute product candidates or D-1MT;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the HyperAcute product candidates or D-1MT reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the HyperAcute product candidates or D-1MT; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the HyperAcute product candidates or D-1MT.

If we enter into one or more collaborations for our HyperAcute product candidates, D-1MT or any of our other product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates that are difficult and costly to resolve, or may not be resolved. In addition, a collaborator for the HyperAcute product candidates or D-1MT may have the right to terminate the collaboration at its discretion. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or require us to delay or scale back the commercialization efforts. The occurrence of any of these events could adversely affect the commercialization of the HyperAcute product candidates or D-1MT and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

***We rely on a single manufacturer for a key component used in the manufacture of our HyperAcute immunotherapy product candidates, which could impair our ability to manufacture and supply our products.***

The manufacturing process for our HyperAcute immunotherapy product candidates has one component that we obtain from a single manufacturer. If we utilize an alternative manufacturer, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use. The loss of our current supplier could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays.

***We may explore strategic partnerships that may never materialize or may fail.***

We may, in the future, periodically explore a variety of possible strategic partnerships in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic partnership might take. We are likely to face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

***If we enter into one or more strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.***

Any future strategic partnerships we enter into could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement;
- strategic partners could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

#### **Risks Relating to Protecting Our Intellectual Property**

***If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.***

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the actual products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted hereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office, or USPTO. The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

***We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.***

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. Under the Abbreviated New Drug Application provisions of U.S. law, after four years from the date marketing approval is granted to us by the FDA for a patented drug, a generic drug company may submit an Abbreviated New Drug Application to the FDA to obtain

approval to market in the United States a generic version of the drug patented by us. If approval were given to the generic drug company, we would be required to promptly initiate patent litigation to prevent the marketing of such generic version prior to the normal expiration of the patent. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any generic drug would be found to infringe our patents.

In addition, if our competitors file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy, are costly to defend and involve complex questions of law and fact the outcomes of which are difficult to predict. An adverse outcome with respect to a third party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property become known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

### **Risks Relating to Our Exposure to Litigation**

***We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.***

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan, and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death.

We currently carry clinical trial liability insurance in the amount of \$5 million in the aggregate, but there can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any products by us or our partners.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

***We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.***

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biopharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this "Risk Factor," section of this prospectus, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

### **Offering Risks**

***We do not know whether a market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.***

Before this offering, there was no public trading market for our common stock and there can be no assurance that a regular trading market will develop and continue after this offering or that the market price of our common stock will not decline, perhaps substantially, below the initial public offering price. The initial public offering price has been determined through negotiations between us and the representatives of the underwriters and may not be indicative of the market price of our common stock following this offering. Among the factors considered in such negotiations were prevailing market conditions; our results of operations and financial condition; financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable or similar to us; the present state of our development; and our future prospects. See the "Underwriting" section of this prospectus for additional information. If you purchase shares of our common stock, you may not be able to resell those shares at or above the initial public offering price. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the NASDAQ Global Market or otherwise or how liquid that market might become. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

***The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.***

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section in this prospectus and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic partners, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, including our Phase 3 clinical trial of our HyperAcute Pancreas product candidate, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts; actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst ratings downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation



has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

As of December 31, 2010, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 45% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after December 31, 2010, and we expect that upon completion of this offering, that same group will continue to hold at least % of our outstanding common stock. Accordingly, even after this offering, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares will may be distributed and subsequently voted.

***A significant portion of our total outstanding shares may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time after the expiration of the lock-up agreements described in the "Underwriting" section of this prospectus. These sales, or the market perception that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have shares of common stock outstanding based on the number of shares outstanding as of December 31, 2010. This includes the shares that we are selling in this offering, which may be resold in the public market immediately. The remaining shares, or % of our outstanding shares after this offering, are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future as set forth below.

**Number of Shares and % of Total Outstanding**

**Date Available for Sale into Public Market**

shares, or %

On the date of this prospectus

shares, or %

180 days after the date of this prospectus, subject to extension in specified instances, due to lock-up agreements between the holders of these shares and the underwriters. However, the representatives of the underwriters can waive the provisions of these lock-up agreements and allow these stockholders to sell their shares at any time.

In addition, as of December 31, 2010, there were 6,370,322 shares subject to outstanding options and an additional 1,704,750 shares reserved for future issuance under our employee benefit plans that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, the lock-up agreements and Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act. Moreover, after this offering, holders of an aggregate of shares

of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If such holders, by exercising their registration rights, cause a large number of securities to be registered and sold into the public market, these sales could have an adverse effect on the market price for our common stock. We also intend to register all shares of common stock that we may issue under our employee benefit plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements and the restrictions imposed on our affiliates under Rule 144.

***You will incur immediate and substantial dilution as a result of this offering.***

If you purchase common stock in this offering, you will incur immediate and substantial dilution of \$ \_\_\_\_\_ per share, representing the difference between the assumed initial public offering price of \$ \_\_\_\_\_ per share and our pro forma net tangible book value per share after giving effect to this offering and the conversion of all outstanding shares of our convertible preferred stock upon the closing of this offering. Moreover, we issued warrants and options in the past to acquire common stock at prices significantly below the assumed initial public offering price. As of December 31, 2010, there were 6,370,322 shares subject to outstanding options with a weighted average exercise price of \$1.34 per share. To the extent that these outstanding options are ultimately exercised, you will incur further dilution.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to meet compliance obligations.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Stock Market, or NASDAQ, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

***Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required to publish a report by our management on our internal control over financial reporting. We have not been subject to these requirements in the past. The internal control report must contain (a) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (b) a statement identifying the framework used by management to conduct the required evaluation of the

effectiveness of our internal control over financial reporting, (c) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective, and (d) a statement that our independent registered public accounting firm has issued an attestation report on internal control over financial reporting.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan to (a) assess and document the adequacy of internal control over financial reporting, (b) take steps to improve control processes where appropriate, (c) validate through testing that controls are functioning as documented, and (d) implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we can provide no assurance as to our, or our independent registered public accounting firm's, conclusions with respect to the effectiveness of our internal control over financial reporting under Section 404. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***We do not expect to pay any cash dividends for the foreseeable future. Investors in this offering may never obtain a return on their investment.***

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, our ability to pay cash dividends is currently prohibited by the terms of one of our debt financing arrangements, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

***We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.***

We expect to use the net proceeds from this offering primarily to fund the development activities for our HyperAcute immunotherapy product candidates. We also expect to use a portion of the proceeds to support the research and development of our other product candidates and the balance, if any, for working capital and other general corporate purposes, and any of the purposes described in the "Use of Proceeds" section of this prospectus. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.***

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- limitation on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

***Our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options and warrants or by future issuances of securities by us.***

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options or warrants are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options or warrants would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of the securities purchased in this offering.

***Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code.***

Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research audits) to offset any future taxable income if the corporation experiences a cumulative ownership change of more than 50%, as interpreted by the Internal Revenue Service, or IRS, over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the

absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on a preliminary analysis, we believe that, from its inception through December 31, 2009, NewLink experienced Section 382 ownership changes in September 2001 and March 2003. These two ownership changes limit NewLink's ability to utilize its federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the 2003 ownership change. In addition, the net operating loss carryforwards (and certain other tax attributes) of our subsidiary may be limited by Sections 382 and 383 as a result of a prior ownership change of the subsidiary.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2009 and/or changes in our ownership that will result from this offering have caused or will cause another ownership change to occur, and the conclusions will depend on the terms of this offering and other information that may not be available to us until after this offering has occurred. Any such change could result in significant limitations on all of our net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

***Accounting pronouncements may impact our reported results of operations and financial position.***

United States generally accepted accounting principles, or GAAP, and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock, publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- our plans to develop and commercialize our product candidates;
- our ongoing and planned preclinical studies and clinical trials, including the timing for completion of enrollment and outcome of our Phase 3 clinical trial for HyperAcute Pancreas;
- the timing of release of data from ongoing clinical studies;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our products;
- our plans to leverage our existing technologies to discover and develop additional product candidates;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should,

therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that our internal estimates and research and the industry publications, studies and surveys are reliable, this data involves a number of assumptions and you are cautioned not to give undue weight to such estimates, research, publications, studies and surveys.

## USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of \_\_\_\_\_ shares of common stock in this offering will be approximately \$ \_\_\_\_\_ million (or approximately \$ \_\_\_\_\_ million if the underwriters' over-allotment option is exercised in full), assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this preliminary prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) our net proceeds from this offering by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this preliminary prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use approximately \$ \_\_\_\_\_ million of the net proceeds from this offering to fund to completion our Phase 3 clinical trial and related development activities for HyperAcute Pancreas, approximately \$ \_\_\_\_\_ million to fund clinical and related development activities for our other HyperAcute immunotherapy product candidates, approximately \$ \_\_\_\_\_ million to fund clinical and related development activities for our IDO pathway inhibitor product candidates and the remainder for working capital and other general corporate purposes. Our other HyperAcute immunotherapy product candidates have either started or completed Phase 1 clinical trials or completed the patient enrollment portion of Phase 2 clinical studies. Our IDO pathway inhibitor product candidates are in Phase 1 clinical trials and in multiple Phase 1/2 clinical trials. We intend to use the net proceeds from this offering to fund the completion of each of these ongoing studies. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, will allow us to fund our operations through at least the end of 2012.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures depend on numerous factors, including the ongoing status and enrollment and site participation rates of, standard of care applicable to and results from clinical trials and other studies, as well as any strategic collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending use of the proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

## DIVIDEND POLICY

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future.



## CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2010:

- on an actual basis;
- on a pro forma basis to give effect to the issuance of 276,304 shares of Series E preferred stock in connection with our acquisition of the minority interest in our majority owned subsidiary, BPS, on January 7, 2011, of which 221,066 were issued and up to 55,238 are issuable upon the satisfaction of certain conditions in connection with the acquisition; and
- on a pro forma as adjusted basis to give further effect to (i) the issuance and sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale and (ii) the conversion of all of our outstanding convertible preferred stock into an aggregate of 16,375,568 shares of common stock, which will take place automatically upon the closing of this offering in accordance with the terms of our preferred stock. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our consolidated financial statements and the related notes appearing at the end of this prospectus, the sections entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	<b>As of December 31, 2010</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma As Adjusted (1)(2)</b>
	<b>(in thousands, except per share data)</b>		
Cash, cash equivalents, and certificates of deposit	\$ 12,841	\$ 12,841	\$
Redeemable preferred stock, \$0.01 par value:			
Series AA preferred stock: 1,217,175 shares issued and outstanding actual and pro forma; no shares issued or outstanding, pro forma as adjusted	\$ 2,191	\$ 2,191	\$
Series AAA preferred stock: 377,410 shares issued and outstanding, actual and pro forma; no shares issued or outstanding, pro forma as adjusted	849	849	
Series B preferred stock: 2,191,193 shares issued and outstanding, actual; no shares issued or outstanding, pro forma as adjusted	5,478	5,478	
Series BB preferred stock: 1,883,337 shares issued and outstanding, actual and pro forma; no shares issued or outstanding, pro forma as adjusted	8,004	8,004	
Series C preferred stock: 6,000,000 shares issued and outstanding, actual and pro forma; no shares issued or outstanding, pro forma as adjusted	30,000	30,000	
Series D preferred stock: 1,500,000 shares issued and outstanding, actual and pro forma; no shares issued or outstanding, pro forma as adjusted	7,500	7,500	
Series E preferred stock: 248,320 shares issued and outstanding actual; 524,624 shares issued and outstanding, pro forma; no shares issued or outstanding pro forma as adjusted	7,723	16,358	
Equity:			
Series A preferred stock, \$0.01 par value: 420,000 shares issued and outstanding, actual and pro forma; no shares issued or outstanding, pro forma as adjusted	1,030	1,030	
Common stock, \$0.01 par value: 7,618,973 shares issued and outstanding, actual and pro forma; and shares issued and outstanding, pro forma as adjusted	76	76	
Additional paid-in capital	6,713	1,021	
Notes receivable for common stock	(13)	(13)	
Deficit accumulated during the development stage	(62,707)	(62,707)	
Total NewLink Genetics shareholders' (deficit) equity	(54,901)	(60,593)	
Equity attributable to noncontrolling interests	2,943	—	
Total (deficit) equity	(51,958)	(60,593)	
Total capitalization	\$ 9,787	\$ 9,787	\$

- (1) A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on

the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

- (2) Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such exercise and conversion will likely differ from the respective number of shares set forth above.

The table above does not include:

- 1,167,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Equity Incentive Plan, or 2000 Plan, as of December 31, 2010 having a weighted average exercise price of \$0.90 per share;
- 5,203,250 shares of common stock issuable upon the exercise of outstanding options under our 2009 Equity Incentive Plan, as amended, or 2009 Plan, as of December 31, 2010 having a weighted average exercise price of \$1.49 per share;
- 1,704,750 additional shares of common stock reserved for future issuance under our 2009 Plan, as amended and restated, of which 1,500,000 were added to the shares reserved under this plan on October 29, 2010, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation — Employee Benefit Plans — 2009 Equity Incentive Plan" section of this prospectus;
- 950,000 shares of common stock reserved for future issuance under our 2010 Non-Employee Directors' Stock Award Plan, or Directors' Plan, and 2010 Employee Stock Purchase Plan, or 2010 Purchase Plan, each of which will become effective upon the completion of this offering; and
- 106,347 shares of common stock issuable upon the exercise of options that are issuable in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of December 31, 2010 was \$(53.0) million or \$(6.95) per share of our common stock. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets less total liabilities and convertible preferred stock, divided by the number of shares of common stock outstanding.

Our pro forma net tangible book value (deficit) as of December 31, 2010 was \$(61.6) million or \$(8.09) per share of our common stock. Pro forma net tangible book value (deficit) per share represents the amount of our total tangible assets less total liabilities and convertible preferred stock, divided by the total number of shares of common stock outstanding after giving effect to the issuance of 276,304 shares of Series E preferred stock in connection with our acquisition of the minority interest in BPS on January 7, 2011, of which 221,066 were issued and up to 55,238 are issuable upon the satisfaction of certain conditions in connection with the acquisition.

After giving effect to the issuance and sale by us of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, less underwriting discounts and commissions and estimated offering expenses payable by us, and the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 16,375,568 shares of common stock upon the closing of this offering. Our pro forma as adjusted net tangible book value as of December 31, 2010 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma net tangible book value per share of \$ \_\_\_\_\_ to existing stockholders and immediate dilution of \$ \_\_\_\_\_ in pro forma net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share of common stock	\$
Pro forma net tangible book value per share as of December 31, 2010	
Increase per share attributable to new investors	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to new investors	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) our pro forma net tangible book value per share by approximately \$ \_\_\_\_\_, our pro forma as adjusted net tangible book value per share by approximately \$ \_\_\_\_\_ and dilution per share to new investors by approximately \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

If the underwriters exercise their over-allotment option, the pro forma as adjusted net tangible book value will increase to \$ \_\_\_\_\_ per share, representing an immediate increase to existing stockholders of \$ \_\_\_\_\_ per share and an immediate dilution of \$ \_\_\_\_\_ per share to new investors. If

any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.

The following table summarizes, on the pro forma as adjusted basis described above as of December 31, 2010, the difference between the number of shares of common stock purchased from us, the total effective cash consideration paid to us and the average price per share paid to us by our existing stockholders and by investors purchasing shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors purchasing shares of our common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percentage	Amount	Percentage	Share
Existing stockholders		%	\$	%	\$
New investors					
<b>Total</b>		<b>100%</b>	<b>\$</b>	<b>100%</b>	<b>\$</b>

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) the total consideration paid by new investors by \$ \_\_\_\_\_ million and increase (decrease) the percentage of total consideration paid by new investors by approximately \_\_\_\_\_ %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

The number of shares purchased from us by existing stockholders is based on 7,618,973 shares of common stock outstanding as of December 31, 2010, after giving effect to 276,304 shares of our Series E preferred stock issued in connection with our acquisition of the minority interest in our majority-owned subsidiary, BPS on January 7, 2011, of which 221,066 were issued and up to 55,238 are issuable upon the satisfaction of certain conditions in connection with the acquisition, and excludes:

- 1,167,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Plan as of December 31, 2010 having a weighted average exercise price of \$0.90 per share;
- 5,203,250 shares of common stock issuable upon the exercise of outstanding options under our 2009 Plan as of December 31, 2010 having a weighted average exercise price of \$1.49 per share;
- 1,704,750 additional shares of common stock reserved for future issuance under our 2009 Plan as amended and restated, of which 1,500,000 were added to the shares reserved under this plan on October 29, 2010, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation — Employee Benefit Plans — 2009 Equity Incentive Plan" section of this prospectus;
- 950,000 shares of common stock reserved for future issuance under our 2010 Non-Employee Directors' Stock Award Plan, or Directors' Plan, and 2010 Employee Stock Purchase Plan, or 2010 Purchase Plan, each of which will become effective upon the completion of this offering; and

- 106,347 shares of common stock issuable upon the exercise of options that are issuable in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS.

To the extent that outstanding options or warrants are exercised, you will experience further dilution. If all our outstanding stock options and outstanding warrants had been exercised as of December 31, 2010, assuming the treasury stock method, our pro forma net tangible book value as of December 31, 2010 would have been approximately \$            million or \$            per share of our common stock, and the pro forma net tangible book value after giving effect to this offering would have been \$            per share, representing dilution in our pro forma net tangible book value per share to new investors of \$            .

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

## SELECTED FINANCIAL DATA

You should read the following selected consolidated financial data together with our financial statements, the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

We derived the annual consolidated financial data from our audited financial statements, the last three years of which are included elsewhere in this prospectus. We derived the summary statement of operations data for the years ended December 31, 2006 and 2007 and the balance sheet data as of December 31, 2006, 2007 and 2008 from our audited financial statements not included in this prospectus.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year.

	Years Ended December 31,				
	2006	2007	2008	2009	2010
(in thousands, except per share data)					
<b>Statement of operations data:</b>					
Grant revenue	\$ 198	\$ —	\$ 633	\$ 934	\$ 2,079
<b>Operating expenses:</b>					
Research and development(1)	4,326	5,756	6,517	7,636	13,249
General and administrative(1)	1,897	2,364	3,531	3,115	5,023
<b>Total operating expenses</b>	<u>6,223</u>	<u>8,120</u>	<u>10,048</u>	<u>10,751</u>	<u>18,272</u>
<b>Loss from operations</b>	<u>(6,025)</u>	<u>(8,120)</u>	<u>(9,415)</u>	<u>(9,817)</u>	<u>(16,193)</u>
<b>Other income and expense:</b>					
Miscellaneous income	72	87	42	19	71
Forgiveness of debt	224	—	—	—	—
Interest income	414	454	213	132	75
Interest expense	(3)	(1)	(2)	(9)	(47)
<b>Other income, net</b>	<u>707</u>	<u>540</u>	<u>253</u>	<u>142</u>	<u>99</u>
Net loss	(5,318)	(7,580)	(9,162)	(9,675)	(16,094)
<b>Less net loss attributable to noncontrolling interest(2)</b>	<u>—</u>	<u>—</u>	<u>—</u>	<u>233</u>	<u>349</u>
<b>Net loss attributable to NewLink</b>	<u>\$ (5,318)</u>	<u>\$ (7,580)</u>	<u>\$ (9,162)</u>	<u>\$ (9,442)</u>	<u>\$ (15,745)</u>
<b>Net loss per share-basic and diluted</b>	<u>\$ (0.83)</u>	<u>\$ (1.17)</u>	<u>\$ (1.40)</u>	<u>\$ (1.42)</u>	<u>\$ (2.24)</u>
<b>Weighted average shares outstanding — basic and diluted</b>	<u>6,369</u>	<u>6,460</u>	<u>6,542</u>	<u>6,636</u>	<u>7,040</u>

	As of December 31,				
	2006	2007	2008	2009	2010
(in thousands)					
<b>Balance sheet data:</b>					
Cash, cash equivalents, and certificates of deposit	\$ 8,825	\$ 16,238	\$ 8,126	\$ 17,209	\$ 12,841
Working capital	5,421	(1,007)	6,923	15,657	11,438
Total assets	10,054	17,358	10,576	22,667	20,139
Notes payable and obligations under capital leases	5,001	6,000	6,008	6,113	7,294
Convertible preferred stock	17,664	17,664	35,583	55,164	62,775
Deficit accumulated during the development stage	(20,778)	(28,358)	(37,520)	(46,962)	(62,707)
Total deficit	\$ (15,331)	\$ (22,833)	\$ (31,830)	\$ (40,786)	\$ (51,958)

- (1) Research and development and general and administrative expenses were corrected for misclassification in 2008 and 2009. See note 2(k) in the notes to the consolidated financial statements included in this prospectus.
- (2) Further explanation is described under the caption "Noncontrolling Interest" in note 2(o) in the consolidated financial statements included in this prospectus.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of our operations together with our financial statements and the related notes to those statements included later in this prospectus. In addition to historical financial information, this discussion contains forward-looking statements reflecting our current plans, estimates, beliefs and expectations that involve risks and uncertainties. As a result of many important factors, particularly those set forth under the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this prospectus, our actual results and the timing of events may differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients. Our portfolio includes biologic and small-molecule immunotherapy product candidates to treat a wide range of oncology indications. Our lead product candidate, HyperAcute Pancreas, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients that is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. We launched this trial based on encouraging Phase 2 data that suggests improvement in both disease-free and overall survival. We have three additional product candidates in clinical development, including HyperAcute Lung, which is being studied in a Phase 1/2 clinical trial conducted at the National Cancer Institute, or NCI, and HyperAcute Melanoma, which is being studied in an investigator-initiated Phase 2 clinical trial. To date, our HyperAcute product candidates have been dosed in more than 200 cancer patients, either as a monotherapy or in combination with other therapies, and have demonstrated a favorable safety profile.

Our HyperAcute product candidates are based on our proprietary HyperAcute immunotherapy technology, which is designed to stimulate the human immune system. Our product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens without incremental toxicity. We are also conducting small-molecule based research and development with an aim to produce new drugs capable of breaking the immune system's tolerance to cancer through inhibition of the indoleamine-(2,3)-dioxygenase, or IDO, pathway. We are currently studying our lead IDO pathway inhibitor product candidate, d-1-methyltryptophan, or D-1MT, in collaboration with the National Cancer Institute, or NCI, in multiple Phase 1B/2 clinical trials. We believe that our immunotherapeutic technologies will enable us to discover, develop and commercialize multiple product candidates that can be used either alone or in combination to enhance or potentially replace current therapies to treat cancer with underserved patient populations and significant market potential.

We are a development stage company and have incurred significant losses since our inception. As of December 31, 2010, we had an accumulated deficit of \$62.7 million. We incurred a net loss of \$15.7 million, \$9.4 million and \$9.2 million for the years ended December 31, 2010, December 31, 2009, and December 31, 2008, respectively. We expect our losses to increase over the next several years as we advance into late-stage clinical trials and pursue regulatory approval of our product candidates. In addition, if one or more of our product candidates are approved for marketing, we will incur significant expenses for the initiation of commercialization activities.

### Financial Overview

#### Revenues

From our inception through December 31, 2010, we have not generated any revenue from product sales. We have generated \$3.8 million in grant revenue from our inception through December 31, 2010, which is primarily attributable to research and development being performed by our subsidiary,



BioProtection Systems Corporation, or BPS, under contracts and grants with the Department of Defense, or DOD, and the National Institutes of Health, or NIH.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, and milestone, research and development and royalty payments in connection with strategic collaborations or licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments we may receive under potential strategic collaborations, and the amount and timing of payments we may receive upon the sale of any products, if approved, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales for several years, if ever. If we fail to complete the development of our product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

### ***Research and Development Expenses***

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries, bonuses, benefits and share-based compensation;
- the cost of acquiring and manufacturing clinical trial materials;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment;
- license fees for and milestone payments related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development expenses as incurred.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, duration and complexity of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidates, and to further advance our earlier-stage research and development projects. From our inception through December 31, 2009, and December 31, 2010, we have incurred \$35.0 million and \$48.3 million,

respectively, in research and development expenses. The following tables summarize our research and development expenses for the periods indicated:

**Research and Development Expenses by Product  
(in thousands)**

	Years Ended December 31,			Cumulative from June 4, 1999 (inception) through
	2008	2009	2010	December 31, 2010
HyperAcute immunotherapy technology	\$ 3,480	\$ 4,799	\$ 8,916	\$ 33,815
IDO pathway inhibitor technology	2,173	1,908	2,936	9,743
Other research and development	864	929	1,397	4,701
Total research and development expenses	<u>\$ 6,517</u>	<u>\$ 7,636</u>	<u>\$ 13,249</u>	<u>\$ 48,259</u>

**Research and Development Expenses by Category  
(in thousands)**

	Years Ended December 31,			Cumulative from June 4, 1999 (inception) through
	2008	2009	2010	December 31, 2010
Compensation	\$ 2,861	\$ 3,698	\$ 5,915	\$ 23,550
Equipment, supplies and occupancy	1,805	1,976	4,275	15,190
Outside clinical and other	1,851	1,962	3,059	9,519
Total research and development expenses	<u>\$ 6,517</u>	<u>\$ 7,636</u>	<u>\$ 13,249</u>	<u>\$ 48,259</u>

At this time, we cannot accurately estimate or know the nature, specific timing or costs necessary to complete clinical development activities for our product candidates. We are subject to the numerous risks and uncertainties associated with developing biopharmaceutical products including the uncertain cost and outcome of ongoing and planned clinical trials, the possibility that the FDA or another regulatory authority may require us to conduct clinical or non-clinical testing in addition to trials that we have planned, rapid and significant technological changes, frequent new product and service introductions and enhancements, evolving industry standards in the life sciences industry and our future need for additional capital. In addition, we currently have limited clinical data concerning the safety and efficacy of our product candidates. A change in the outcome of any of these variables with respect to the development of any of our product candidates could result in a significant change in the costs and timing of our research and development expenses.

**General and Administrative Expenses**

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise associated with research and development expenses, intellectual property prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will continue to increase over the next several years for, among others, the following reasons:

- we expect our general and administrative expenses to increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, auditing and tax services and investor relations costs, and director and officer insurance premiums associated with being a public company;
- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect to expand as we continue to advance the clinical development of our product candidates; and
- we may also begin to incur expenses related to the planned sales and marketing of our product candidates in anticipation of commercial launch before we receive regulatory approval, if any, of a product candidate.

### ***Interest Income and Interest Expense***

Interest income consists of interest earned on our cash and cash equivalents and certificates of deposit. The primary objective of our investment policy is capital preservation. We expect our interest income to increase as we invest the net proceeds from the offering pending their use in our operations.

Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with our loans payable.

### **Tax Loss Carryforwards**

The valuation allowance for deferred tax assets as of December 31, 2010, 2009 and 2008 was \$15.0 million, \$11.6 million and \$10.0 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2010, 2009 and 2008 was an increase of \$3.4 million, \$1.6 million and \$2.5 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of December 31, 2010, 2009 and 2008, due to the uncertainty of future recoverability.

As of December 31, 2010, we had federal net operating loss carryforwards of \$62.1 million and federal research credit carryforwards of \$2.1 million that expire at various dates from 2020 through 2030. Tax loss carryforwards are subject to limitations by Section 382 of the Internal Revenue Code. Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research audits) to offset any future taxable income if the corporation experiences a cumulative ownership change of more than 50%, as interpreted by the Internal Revenue Service, or IRS, over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on a preliminary analysis, we believe that, from its inception through December 31, 2009, NewLink experienced Section 382 ownership changes in September 2001 and March 2003. These two ownership changes limit NewLink's ability to utilize its federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the 2003 ownership change. In addition, the net operating loss carryforwards (and certain other tax attributes) of our subsidiary may be limited by Sections 382 and 383 as a result of a prior ownership change of the subsidiary.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2009 and/or changes in our ownership that will result from this offering have caused or will cause another ownership change to occur, and the conclusions will depend on the terms of this offering and other information that may not be available to us until after this offering has occurred. Any such change could result in significant limitations on all of our net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

We incurred no income tax expense for the years ended December 31, 2010, 2009 and 2008. Income tax expense differs from the amount that would be expected after applying the statutory United States federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

### **Critical Accounting Policies and Significant Judgments and Estimates**

We have prepared our financial statements in accordance with United States generally accepted accounting principles. Our preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in note 2 to our financial statements included later in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

#### ***Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued clinical expenses include:

- fees paid to contract research organizations in connection with clinical trials;
- fees paid to investigator sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- fees paid to vendors in connection with preclinical development activities.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments

under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

### **Stock-Based Compensation**

*Stock Option Valuation.* We are required to estimate the grant-date fair value of stock options issued to employees and recognize this cost over the period these awards vest. We estimate the fair value of each option granted using the Black-Scholes option pricing model. Generally, we have issued employee awards that vest over time. For these awards, we record compensation cost on a straight-line basis over the vesting period. We issue awards which typically vest 20% to 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 months, as determined by the Board of Directors at the time of grant.

We have issued awards to nonemployee consultants and advisers. All grants to nonemployees are valued using the same fair value method that we use for grants to employees. The compensation cost on these awards is recognized through the later of the vesting of the award or completion of services by the nonemployee.

The following table summarizes our assumptions used in the Black-Scholes model for option grants during the last three years:

#### **Black-Scholes Model Assumptions**

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2009</b>	<b>2010</b>
Exercise price	\$1.00	\$1.00-\$1.41	\$1.46-\$3.41
Expected volatility	52.0%-52.1%	44.7%-62.5%	57.4%-62.5%
Expected term (in years)	5.5-7.5	7.0-7.5	5.0-7.5
Risk-free interest rate	2.2%-3.3%	1.6%-2.2%	2.3%-3.5%
Expected dividend yield	0.0%	0.0%	0.0%

*Exercise Price.* Our stock options are granted with an exercise price at or above the then current fair value of our common stock as determined by the Board of Directors. As an input to making this determination, the Board of Directors obtained a third-party valuation. See "Common Stock Fair Value" below.

*Expected Volatility.* Since prior to this offering we were a privately-held company, the estimated future expected volatility for each stock option valuation utilizes volatility rates of similar publicly traded companies considered to be in the same peer group. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

*Expected Term (in Years).* The expected term of a stock option is the period of time for which the option is expected to be outstanding. We have a large number of options outstanding. There is no secondary market for our outstanding stock options and they contain only basic terms. Therefore, we used a simplified method of determining expected term by selecting the midpoint between the date upon which they would be fully vested in accordance with their terms and the anticipated forfeiture date as the expected term for the employee and non-employee director grants. For other non-employee grants, the contractual life of the option was used.

*Risk-Free Interest Rate.* We use the average yield on current United States Treasury instruments with terms that approximate the expected term of the stock options being valued.

*Expected Dividend Yield.* The expected dividend yield for all of our stock option grants is 0%, as we have not declared a cash dividend since inception, and do not expect to do so in the foreseeable future.

*Forfeitures.* The stock-based compensation expense recognized has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of our option plan, which we expect to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock-based award over its vesting period will only be for those shares that actually vest.

*Common Stock Fair Value.* Due to the absence of an active market for our common stock, the fair value of our common stock for purposes of determining the exercise price for stock option grants was determined by our Board of Directors, with the assistance of our management, in good faith based on a number of objective and subjective factors including:

- the prices of our convertible preferred stock sold to outside investors in arms-length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preference of our convertible preferred stock;
- our results of operations, financial position and the status of our research and development efforts;
- our stage of development and business strategy;
- the lack of liquidity of our private stock as a private company;
- valuations performed by an unrelated valuation specialist prepared in accordance with methodologies outlined in the AICPA Technical Practice Aid, "*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*";
- the likelihood of achieving a liquidity event for the shares of our common stock and underlying stock options, such as an initial public offering, given prevailing market conditions;
- the material risks related to our business; and
- the composition of and changes to our management team.

Common Stock Valuations. After taking into account management's recommendations based on the valuation reports prepared by the Mentor Group, Inc., a third-party valuation specialist, our Board of Directors adopted valuations of our common stock as of December 31, 2007, 2008 and 2009, March 31, 2010, June 30, 2010, and September 30, 2010. The valuations used the probability-weighted expected return method, or PWERM, to allocate our estimated enterprise value between our preferred stock and common stock. This method is generally considered appropriate to use when there are several distinct liquidity scenarios to be considered. Under the PWERM, we analyzed the value of our company using several scenarios, which included an initial public offering ("IPO Scenario"), sale of the Company ("Sale Scenario"), remaining a private enterprise ("Private Company Scenario") and a liquidation of the assets ("Liquidation Scenario").

In determining the value of the equity under each scenario, the traditional approaches to valuation were considered. We utilized the discounted cash flow method to provide a reliable means of representing the fair value of the equity through the potential operating results of the Company on a going concern basis. This method was utilized in the Private Company Scenario. We also considered the capital market approach. This approach was utilized because we were able to identify publicly traded guideline companies we considered sufficiently comparable to the Company. The capital market approach was used in the IPO Scenario. The asset accumulation approach was considered and utilized

in the Liquidation Scenario. The business transaction approach was utilized because data was available on the sale of entire businesses that we considered to be comparable to the Company. We used this approach in the Sale Scenario.

We determined the value of our preferred stock and common stock under each scenario by allocating the equity value to each class of stock and discounting the value back to the present using a risk-adjusted discount rate. We then weighted the present value of the common stock under each scenario based upon the probability of each scenario occurring in order to determine a final indication of value for the common stock.

After calculating the estimated values of our preferred stock and common stock in each scenario, we then tested our expected pre-money enterprise values for our IPO and Sale Scenarios using the guideline public company, or GPC, method within the market approach. We believe this two-step approach is consistent with the guidance set forth by the American Institute of Certified Public Accountants in the AICPA Technical Practice Aid, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation," which we refer to as the AICPA Practice Aid.

As described in the AICPA Practice Aid, the market approach is one of three generally accepted valuation approaches. The market approach, and more specifically the GPC method within that approach, considers market transactions in businesses to develop measures that can be used in the valuation of the subject business. We believe that this method is useful if adequate information is available. Guideline public companies are publicly traded companies that provide a reasonable basis for comparison to the characteristics of the company being valued. Once these guideline companies have been identified, the GPC method then consists of developing ratios of value, or market multiples, based on the traded market value of each selected public company, as well as operating performance and financial condition indicators such as revenues, earnings and cash flow.

Valuation models require the input of highly subjective assumptions, and the valuation model we used is not the only valuation model available. Therefore, we cannot assure the accuracy of any particular valuation of our stock. Because our common stock has characteristics significantly different from that of publicly traded common stock and because changes in the subjective input assumptions can materially affect the fair value estimate, the models we used do not, in management's opinion, necessarily provide a reliable, single measure of the fair value of our common stock, and we will not use them to value our common stock once this offering is complete.

The Mentor Group, Inc. performed two distinct valuations for two different purposes. The valuation described below was performed for the purpose of calculating compensation expense for options grants pursuant to FAS 123R. A separate valuation was performed for purposes of determining the fair market value of our common stock for purposes of Section 409A of the Code, and was used to establish the exercise price of stock options. The valuations resulted in different fair values for accounting and tax purposes, reflecting differences in the applicable standards and guidance.

Liquidity Scenarios. For all of the valuations we considered a number of different liquidity scenarios, including an initial public offering of our common stock and an acquisition of our company. In all of these scenarios, the proceeds of the liquidation event were sufficient to provide a return to the holders of common stock. For each of the acquisition scenarios, we assumed different enterprise valuations and different dates and, consistent with the PWERM, in the acquisition scenarios we took into account the liquidation preferences that would be payable to the shares of our convertible preferred stock before any distribution of proceeds to holders of our common stock. We also considered that the holders of certain series of the convertible preferred stock would have the right to participate, after payment of the convertible preferred stock liquidation preference, in receiving their pro rata share of remaining proceeds payable to the common stock, up to a maximum amount per share of convertible preferred stock set forth in our certificate of incorporation. We also assigned a probability to an additional scenario in which we would be dissolved for no value and no proceeds would be available for any stockholder. In this scenario, we assumed that the common stock had a value of zero, since no

proceeds would be available for distribution to the holders of common stock. The probability weightings assigned to these scenarios for our 2009 valuation were lower than those used in the prior retrospective valuations because, by that time, we had determined that an initial public offering or sale of the Company at a higher valuation was more likely.

**IPO and Acquisition Scenarios in which Holders of Common Stock Will Realize a Return.** For all of the valuations, we assigned probabilities to successful IPO Scenarios and to Sale Scenarios that would result in a return to the holders of our common stock. We considered that our success in completing either an initial public offering or sale that resulted in a return to the holders of our common stock would be dependent upon our realization of clinical milestones, together with our execution of our business plan and a receptive marketplace. For each of the valuations, the assumptions as to our enterprise value in the acquisition scenarios were the same as in the IPO Scenarios but, consistent with the PWERM, in the acquisition scenarios we took into account the liquidation preferences that would be payable to the shares of our convertible preferred stock before any distribution of proceeds to holders of our common stock. We also considered that the holders of the convertible preferred stock would have the right to participate, after payment of the convertible preferred stock liquidation preference, in receiving their pro rata share of remaining proceeds payable to the common stock, up to a maximum amount per share of convertible preferred stock set forth in our certificate of incorporation. As a result, the values per share of our common stock in the acquisition scenarios were less than the corresponding values per share of common stock in the IPO Scenarios.

**Guideline Public Companies Analysis.** We have completed an analysis using a set of guideline public companies. We noted that the assumed values for our company we used in our IPO Scenarios fell within the observed range of initial public offering values for the identified companies. We selected a subset of the public companies we considered to be most similar to our company. We determined that each of the selected public companies was comparable to our company at the respective valuation dates because they are small capitalization companies engaged in either small molecule research or vaccines that are generally either in a pre-commercial stage or in the early stages of commercialization. As of each valuation date, we evaluated the market value of these companies' equity, excluding cash, and noted that these values were consistent with the enterprise values that we assumed as part of our IPO Scenarios and acquisition scenarios under the PWERM.

To analyze our valuation for each of our acquisition scenarios, we utilized the guideline transaction method. In this analysis, we reviewed approximately 20 companies in the biotechnology industry and compared the multiples from these transactions to the implied multiples for the acquisition scenarios. We calculated the median multiples of the transactions for enterprise value to sales, enterprise value to earnings before interest, taxes, depreciation and amortization and enterprise value to earnings before interest and taxes. We believe that the proprietary product mix and potential growth will increase the multiples from normalized multiples paid in the industry. However, we utilized multiples at or below the median multiples. Consequently, we have kept the market multiples within a reasonable range of the median market multiples for similar companies.

**Discount Rate.** Once we had allocated the per share values to our common stock and to each series of our convertible preferred stock at each of the future dates in our various scenarios, we calculated the present values of each per share amount to the valuation date, using a discount rates ranging from 46% to 67%. We believe that the discount rates selected are consistent with the required rates of return described in the AICPA Practice Aid for companies in a similar stage of development to us. Under the criteria set forth in the AICPA Practice Aid, for the valuations for the years ending December 31, 2007, 2008 and 2009, we determined that our company was no longer in the start-up stage but had generally not progressed beyond the first or early stage of development. Under the criteria set forth in the AICPA Practice Aid, for the periods ending March 31, 2010, June 30, 2010, and September 30, 2010, we determined that the Company was in the first or early stage of development



from a technology-risk point of view and the bridge or initial public offering stage of development from a time-to-liquidity point of view.

Additionally, for the December 31, 2009 valuation, the discount rate we used to determine the value of the common stock was lower than in the prior retrospective valuations because we believed that our stage of development had progressed during 2009 under the framework described in the AICPA Practice Aid. For example, we made additional progress in our product development during 2009, including the receipt of interim data from our Phase 2 clinical trial of HyperAcute Pancreas. We closed our \$7.5 million Series D preferred stock financing and had the final closing of our \$30 million Series C preferred stock financing in July 2009 and September 2009, respectively.

#### *Fair Value Estimates*

After taking into account all of the assumptions and estimates described in our application of the PWERM and the GPC method within the market approach, we determined the fair value of our common stock to be approximately \$0.96 per share as of December 31, 2007, approximately \$0.95 per share as of December 31, 2008, approximately \$2.02 per share as of December 31, 2009, approximately \$2.08 per share as of March 31, 2010, approximately \$2.25 per share as of June 30, 2010, approximately \$4.02 per share as of September 30, 2010 and approximately \$4.77 per share as of December 31, 2010. The following table lists grants of options to purchase shares of common stock with GAAP measurement dates in 2009, 2010 and 2011.

<b>Options Granted on Shares of Common Stock</b>					
<b>GAAP</b>					
<b>Approval Date</b>	<b>Measurement Date</b>	<b>Number of shares</b>	<b>Exercise price per share</b>	<b>Common Stock values</b>	<b>Intrinsic value per share</b>
July 16, 2008	September 2, 2009	364,000	1.00	0.95	0
August 6, 2008	September 2, 2009	490,000	1.00	0.95	0
May 13, 2009	September 2, 2009	2,267,000	1.00	0.95	0
December 4, 2009(1)	March 3, 2010	1,706,500	1.41	2.02	0.61
March 3, 2010	June 2, 2010	1,005,250	1.46	2.08	0.62
June 2, 2010	October 8, 2010	13,000	1.91	2.25	0.34
October 8, 2010(2)	January 19, 2011	26,500	3.41	4.02	0.61
November 23, 2010(2)	—	25,000	—	—	—
December 9, 2010(2)	—	160,000	—	—	—

- (1) The options granted on December 4, 2009 are not reflected in the disclosure in note 12 of the financial statements for the period ending December 31, 2009 as the grant measurement date had not yet occurred under GAAP.
- (2) The options granted on October 8, 2010, November 23, 2010 and December 9, 2010, are not reflected in the disclosure in note 12 of the financial statements for the period ending December 31, 2010 as the grant measurement date had not yet occurred under GAAP.

The following table summarizes the significant assumptions used by our valuation consultant in the PWERM pricing model used to determine the fair value of our common stock as of the date indicated.

	<u>12/31/2008</u>	<u>12/31/2009</u>	<u>3/31/2010</u>	<u>6/30/2010</u>	<u>9/30/2010</u>	<u>12/31/2010</u>
<b>PWERM weightings</b>						
Private company	20.0%	20.0%	20.0%	20.0%	25.0%	30.0%
Merger or acquisition	30.0%	30.0%	30.0%	30.0%	25.0%	15.0%
Initial Public Offering	5.0%	30.0%	30.0%	30.0%	40.0%	45.0%
Liquidation	45.0%	20.0%	20.0%	20.0%	10.0%	10.0%
<b>Value by method</b>						
Private company scenario	0.71	1.66	1.78	2.10	4.22	4.67
Merger or acquisition	2.25	2.95	2.92	3.09	4.68	5.81
Initial Public Offering	2.65	2.67	2.82	2.99	4.48	5.55
Liquidation	—	—	—	—	—	—
<b>Weighted value</b>						
Private company scenario	0.14	0.33	0.36	0.42	1.06	1.40
Merger or acquisition	0.68	0.89	0.88	0.93	1.17	0.87
Initial Public Offering	0.13	0.80	0.85	0.90	1.79	2.50
Liquidation	—	—	—	—	—	—
	<u>0.95</u>	<u>2.02</u>	<u>2.08</u>	<u>2.25</u>	<u>4.02</u>	<u>4.77</u>
<b>Lack of marketability discount</b>	<u>45%</u>	<u>30%</u>	<u>30%</u>	<u>15%</u>	<u>15%</u>	<u>0%</u>

The estimated per share fair value of our common stock increased from January 1, 2009 to December 31, 2009 from \$0.95 to \$2.02. This increase in estimated fair value primarily reflected operational factors, including advancement of Hyperacute Lung, Hyperacute Pancreas and Hyperacute Melanoma Phase 2 clinical trials and concurrent increases in our enrollment for these trials from 20 patients in 2008 to 71 patients in 2009. We also initiated the treatment phase of our Phase 1 clinical trial in D-1MT. Data on D-1MT was presented at the annual meeting of the American Society of Clinical Oncologists, or ASCO, during this period. The increase is also due to our improving financial strength. During this period, BPS signed a \$3.7 million contract with the federal government to study HyperAcute technology in the infectious disease setting. We also raised an additional \$12 million in our existing Series C preferred stock financing and \$7.5 million in a new Series D preferred stock financing. External factors that increased the estimated fair value included Dendreon Corporation's announcement that its Provenge immunotherapy product candidate demonstrated a survival benefit in its Phase 3 clinical trial.

The estimated per share fair value of our common stock increased from January 1, 2010 to March 31, 2010 from \$2.02 to \$2.08. This increase primarily reflected continued progress in our ongoing clinical trials, including the receipt of the FDA's letter of concurrence related to our Special Protocol Assessment request for our HyperAcute Pancreas Phase 3 clinical trial.

The estimated per share fair value of our common stock increased from April 1, 2010 to June 30, 2010 from \$2.08 to \$2.25 per share. This increase primarily reflected the encouraging data received from our ongoing HyperAcute Pancreas and HyperAcute Melanoma Phase 2 clinical trials and acceptance for presentation at the ASCO annual meeting in June 2010. We also treated our first patient in our HyperAcute Pancreas Phase 3 clinical trial during this period. In addition, prior to 2010, we had manufactured all of our HyperAcute cancer immunotherapy product candidates in a small good manufacturing practice, or GMP, laboratory setting and in April 2010, we began to occupy our first commercial scale GMP manufacturing facility. External factors that affected estimated fair value during this period included the FDA's May 2010 approval of Dendreon Corporation's Provenge.

The estimated per share fair value of our common stock increased from July 1, 2010 to September 30, 2010 from \$2.25 to \$4.02 per share. This increase was primarily due to our initiating the process associated with this offering with an organizational meeting on September 8, 2010. Additionally, in July 2010, we negotiated acceleration of the development milestones associated with our prior acquisition of OncoRx Corporation.

The estimated per share fair value of our common stock increased from October 1, 2010 to December 31, 2010 from \$4.02 to \$4.77 per share. This increase is due to many factors. As of December 31, 2010, we had nearly completed follow-up data on the HyperAcute Pancreas Phase 2 clinical trial, which was used to support our ongoing HyperAcute Pancreas Phase 3 clinical trial. In December 2010, we negotiated the acquisition of the noncontrolling interest in BPS. In October 2010, we received both Orphan Drug and Fast Track designations from the FDA for HyperAcute Pancreas. In December 2010, we raised \$7.7 million in a new Series E preferred stock financing and completed the initial filing of our Registration Statement on Form S-1 associated with this offering. As of December 31, 2010, we had enrolled 60 patients and initiated 30 sites in our ongoing HyperAcute Pancreas Phase 3 clinical trial.

The estimated per share fair value of our common stock from January 1, 2011 through March 31, 2011 from \$ to \$ per share. In January 2011, we received encouraging 12 month follow-up data on the full patient cohort of our HyperAcute Pancreas Phase 2 clinical trial, which was accepted for presentation at the ASCO Gastro-Intestinal clinical symposium. In addition we closed the acquisition of the noncontrolling interest in BPS.

Based on an assumed initial public offering price of \$ per share, which is the midpoint of the range set forth on the cover page of this prospectus, the intrinsic value of stock options outstanding at December 31, 2010, would have been \$ million, of which \$ million and \$ million related to stock options that were vested and unvested, respectively, at that date.

## Results of Operations

### *Years Ended December 31, 2010, 2009 and 2008*

*Revenues.* Revenues for the year ended December 31, 2010 were \$2.1 million, increasing from \$934,000 for the same period in 2009. The increase in revenue of \$1.1 million was due to an increase in billings of \$860,000 by BPS under various DOD contracts and NIH grants and the receipt of \$240,000 in section 48D income tax credits by NewLink.

Revenues for the year ended December 31, 2009 were \$934,000, increasing from \$633,000 for the same period in 2008. The increase in revenue of \$301,000 was primarily due to increased billings by BPS under various DOD contracts and NIH grants.

The DOD contracts and NIH grants provide us with cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. Revenues are recognized in the period during which the related costs are incurred, provided that the conditions under which the cost reimbursement was provided have been met and we have only perfunctory obligations outstanding. As of December 31, 2010, \$3.3 million in funding remained under the terms of these agreements.

*Research and Development Expenses.* Research and development expenses for the year ended December 31, 2010 were \$13.2 million, increasing from \$7.6 million for the same period in 2009. The \$5.6 million increase was due to a \$2.3 million increase in equipment, supplies and occupancy costs including the acquisition of in-process research and development, accompanied by a \$2.2 million increase in personnel-related expenses and a \$1.1 million increase in outside clinical and other expenses including direct development expenses for our clinical trial activities.

Research and development expenses for the year ended December 31, 2009 were \$7.6 million, increasing from \$6.5 million for the same period in 2008. The \$1.1 million increase was primarily due to a \$837,000 increase in personnel-related expenses, accompanied by a \$171,000 increase in equipment, supplies, and occupancy costs, and a \$111,000 increase in outside clinical and other costs.

Research and development and general and administrative expenses were corrected for misclassification in 2008 and 2009. See note 2(k) in the notes to the consolidated financial statements included in this prospectus.

*General and Administrative Expenses.* General and administrative expenses for the year ended December 31, 2010 were \$5.0 million, increasing from \$3.1 million for the same period in 2009. The \$1.9 million increase was primarily due to a \$867,000 increase in personnel-related expenses, a \$129,000 increase in equipment, supplies and occupancy costs, a \$647,000 increase in professional fees, and a \$257,000 increase in other costs.

General and administrative expenses for the year ended December 31, 2009 were \$3.1 million, decreasing from \$3.5 million for the same period in 2008. The \$416,000 decrease was primarily due to a \$284,000 decrease in personnel-related expenses accompanied by a \$136,000 decrease in other expenses offset by a \$4,000 increase in equipment, supplies and occupancy costs.

*Interest Income and Expense.* Interest expense for the year ended December 31, 2010 was \$47,000, compared to \$9,000 for the same period in 2009. The \$38,000 increase was due to increased borrowings under notes payable and capital lease obligations. Interest income for the year ended December 31, 2010 was \$75,000, compared to \$132,000 for the same period in 2009. The \$57,000 decrease was primarily due to a decrease in interest rates, partially offset by an increase in our average cash balances.

Interest expense for the year ended December 31, 2009 was \$9,000, compared to \$2,000 for the same period in 2008. Interest income for the year ended December 31, 2009 was \$132,000, compared to \$213,000 for the same period in 2008. The \$81,000 decrease was primarily due to a decrease in interest rates.

*Other Income (Expense).* Miscellaneous income, net for the year ended December 31, 2010 was \$71,000, compared to \$19,000 for the same period in 2009. Miscellaneous income, net for the year ended December 31, 2009 was \$19,000, compared to \$42,000 for the same period in 2008.

## **Liquidity and Capital Resources**

We have funded our operations principally through the private placement of equity securities, debt financing and interest income. As of December 31, 2010, we have received proceeds, net of offering costs, of \$62.7 million from the issuance of convertible preferred stock, including \$7.5 million from the sale of 1.5 million shares of Series D preferred stock in July 2009, \$30.0 million from the sale of 6.0 million shares of Series C preferred stock in during the course of 2008 and 2009, and \$7.8 million from the sale of 248,320 shares of Series E preferred stock in December, 2010. As of December 31, 2010,

we had cash, cash equivalents and certificates of deposit of approximately \$12.8 million. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

**Sources and Uses of Cash**  
(in thousands)

	Years Ended December 31,		
	2008	2009	2010
Net cash used in development activities	\$ (8,885)	\$ (9,140)	\$ (13,270)
Net cash used in investing activities	(3,127)	(1,545)	(2,709)
Net cash provided by financing activities	17,930	19,626	11,334
Net increase (decrease) in cash and cash equivalents	<u>\$ 5,918</u>	<u>\$ 8,941</u>	<u>\$ (4,645)</u>

During 2010, 2009 and 2008, our development activities used cash of \$13.3 million, \$9.1 million and \$8.9 million, respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. The increase in cash used for the year ended 2010 resulted from an increase in research and development activities and general and administrative expenses. The increase in cash used for the year ended 2009 resulted from an increase in research and development activities offset by a decrease in general and administrative expenses.

During 2010, 2009 and 2008, our investing activities used cash of \$(2.7) million, \$(1.5) million and \$(3.1) million, respectively. The use of cash for the year ended December 31, 2010 was primarily the result of the purchases of property and equipment of \$2.9 million related to the expansion of our manufacturing facilities at our corporate headquarters. The use of cash for the years ended 2009 and 2008 was primarily the net result of the purchase of investments accompanied by the purchases of property and equipment of \$1.4 million and \$427,000, respectively.

During 2010, 2009 and 2008, our financing activities provided \$11.3 million, \$19.6 million and \$17.9 million, respectively. The cash provided by financing activities in the year ended December 31, 2010 was primarily due to the sale and issuance of Series E preferred stock for net proceeds of \$7.8 million along with the exercise of a warrant for net proceeds of \$2.0 million, proceeds from loans payable of \$1.1 million and cash received from noncontrolling interest investment of \$911,000. The cash provided in 2009 was primarily a result of the continued sale and issuance of Series C preferred stock along with 1.5 million shares of Series D preferred stock for net proceeds of \$19.6 million. The cash provided by financing activities in 2008 was primarily due to the sale and issuance of Series C preferred stock for net proceeds of \$17.9 million.

#### ***Series E Preferred Stock***

On December 13, 2010 we completed the sale of 248,320 shares of our Series E preferred stock at a price per share of \$31.25, which resulted in aggregate proceeds of \$7.8 million. The Series E preferred stock is convertible into common stock at a 15% discount to the price to the public in an initial public offering if the offering results in at least \$20 million in gross proceeds to us and occurs prior to September 1, 2011, or \$6.25 per common share under any other conversion scenario.

On January 7, 2011, we acquired the minority interest in BPS. We will issue up to 276,304 shares of our Series E preferred stock as consideration for this acquisition of which 221,066 shares were issued on January 7, 2011 and up to 55,238 shares are issuable upon the satisfaction of certain conditions in connection with the acquisition.

## **Loan Agreements**

### *March 2005 Iowa Department of Economic Development Loan*

In March 2005, we entered into a \$6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDEED. Under the agreement, in the absence of default, there will be no principal or interest payments due until the completion date for the project, which is March 18, 2012, under the current one-year extension granted by the IDEED. The project is to provide assistance to the Company for research and product development activities at its Iowa State University Research Park facility. The project calls for the creation of 315 positions and retention of 35 positions with total project expenditures of \$189.9 million for clinical trials, research and development activities, building construction, equipment purchases, and other working capital needs. As of December 31, 2010, we believe we have created 45 jobs, retained 35 jobs and incurred approximately \$61.4 million of project expenditures.

If, as of March 18, 2012, which is the current project completion date under the agreement, the IDEED determines we have fulfilled all the job creation and maintenance terms and project expenditure requirements of the loan agreement, the loan will be forgiven. However, on the project completion date we will be required to repay the greater of approximately \$17,000 for each of the 350 jobs we fail to create and maintain as of that date or a percentage of the \$6 million advanced under the agreement equal to the percentage of any shortfall in our obligation to expend \$189.9 million of project expenditures. As of December 31, 2010, we had \$4.7 million in outstanding debt subject to repayment. Five years following the project completion date, we will be required to repay approximately \$17,000 for each of the 350 jobs the IDEED determines we fail to maintain as of that date. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6% interest per annum beginning at the date of default.

Under the agreement, we are obligated to pay a minimum of 0.25% royalties on all gross revenues of our products with a cumulative maximum royalty amount due of \$3.2 million. Royalties we pay will first offset amounts we are required to repay for amounts of the loan not forgiven and then go toward reducing the total cumulative royalty to be paid. We are also obligated to maintain our business in the State of Iowa while amounts remain outstanding under the loan. Substantially all of our assets are pledged against this loan and we are required to submit audited financial statements within 90 days of year-end. We have failed to meet this covenant each year and have obtained a waiver from the IDEED each year.

The original project completion date for the project was March 18, 2010 and was initially extended to March 18, 2011 by amendment to the agreement approved by the IDEED. Based on our progress on the project we requested and received a second extension of the project completion date to March 18, 2012.

### *September 2007 IDEED High Quality Job Creation Program Tax Credit*

In September 2007, we entered into a master contract and associated funding agreement, or HQJC Agreement, with the IDEED under its high quality job creation program. We amended the HQJC Agreement in 2010 to extend the dates by which certain job creation and investment requirements were to be met to March 18, 2011.

The terms of the HQJC Agreement, as amended, require us by March 18, 2012, to make a qualifying investment in real estate or depreciable assets of at least \$2.0 million, to finalize the lease of our new executive offices and manufacturing facilities and to create at least 45 new full time equivalent jobs in Iowa of which at least 14 must be high quality, or HQJC jobs. In order to qualify as high quality jobs, the jobs created must be at a compensation levels that exceed the county average hourly wage of \$17.31. We fulfilled two of the three requirements by March 18, 2010. We have made a qualified investment in real estate and finalized the lease of our new offices and manufacturing facility. As of December 31, 2010 we have created 44 new jobs of which 27 were HQJC jobs. In addition, we are

required to retain the HQJC jobs through March 18, 2013. If we fail to meet this requirement we will be required to repay all tax credits received under the HQJC Agreement. As of December 31, 2010, we had maintained our base employment of 34 full time equivalent jobs in addition to the 44 newly created jobs.

Under the HQJC Agreement, we received a tax credit of \$414,000, which was refunded to us between March 2006 and October 2009. Under the HQJC Agreement, the IDED may require us to repay the entire amount of the tax credit upon certain events of default, which include our experiencing a substantial layoff, relocating a substantial portion of our business or our research and development outside of Iowa, failing to offer certain employee benefits or failing to reinvest at least 1.0% of our pre-tax profits from our Iowa facility in research and development in Iowa. In addition, prior notice and consent of the IDED is required during the term of the HQJC Agreement for any material changes in our business or our research and development activities.

#### *March 2010 City of Ames Forgivable Loan*

In March 2010, we entered into a \$400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provides us with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015.

The project calls for our creating or retaining at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and the creating or maintaining at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for our entering into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, we have failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, we will be required to repay approximately \$3,100 per job not created or retained following the respective date. As of December 31, 2010, we had created or retained an aggregate of 76 full-time jobs in Ames, Iowa. As of December 31, 2010, \$300,000 of the total \$400,000 forgivable loan was advanced to us with the final \$100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

#### **Operating Capital Requirements**

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses related to the research and development of our HyperAcute immunotherapy and IDO pathway inhibitor product candidates, build commercial capabilities and expand our corporate infrastructure. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and certificates of deposit, will allow us to fund our operations through at least the end of 2012.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to

reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biopharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

### ***Contractual Obligations and Commitments***

The following table summarizes our contractual obligations at December 31, 2010:

	<b>Contractual Obligations Due (in thousands)</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 to 3 Years</b>	<b>3 to 5 Years</b>	<b>More than 5 Years</b>
Short and long-term debt (including interest)	\$ 7,127	\$ 113	\$ 6,225	\$ 528	\$ 261
Operating lease obligations	1,100	266	540	294	—
Capital lease obligations	289	135	154	—	—
Total contractual cash obligations	<u>\$ 8,516</u>	<u>\$ 514</u>	<u>\$ 6,919</u>	<u>\$ 822</u>	<u>\$ 261</u>

Under the license agreements described below in "Financial Obligations Related to Licensing and Development—In-Licensing Agreements," we are obligated to make potential milestone payments as



listed in the following table. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined.

<b>Licensor</b>	<b>Aggregate potential milestone payments</b>
Drexel University	\$1 million per licensed product
Lankenau Institute for Medical Research under the IDO-1 Agreement(1)	\$1.36 million per licensed product
Lankenau Institute for Medical Research under the LIMR IDO-2 Agreement(1)	\$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement
Lankenau Institute for Medical Research under the 2009 LIMR Agreement(1)	\$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement
Medical College of Georgia	\$2.8 million per licensed product
University of British Columbia	\$1.8 million per licensed product
Regents of the University of California(2)	\$285,000 per licensed product
Her Majesty the Queen in Right of Canada(2)	C\$205,000 per licensed product

(1) As defined below in "Financial Obligations Related to Licensing and Development — In-Licensing Agreements."

(2) As described in the "Business — Licensing Agreements" section of this prospectus.

Under some of the in-licensing agreements below, we are obligated to pay annual license maintenance fees in amounts we believe to be immaterial.

## **Financial Obligations Related to Licensing and Development**

### ***In-Licensing Agreements***

We are subject to a number of licensing agreements with respect to certain of the technologies that underlie our intellectual property. Unless otherwise noted, these agreements typically provide that we have exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to us meeting our financial and other contractual obligations under the agreements. Certain of the key licensing agreements with significant financial obligations include the following:

*Central Iowa Health Systems.* We are a party to a license agreement, or the CIHS Agreement, dated August 2, 2001, with the Central Iowa Health System, or CIHS. The CIHS Agreement grants to us an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information and know-how relating to our HyperAcute immunotherapy technology. In partial consideration of the license under the CIHS Agreement, we entered into a stock purchase agreement with CIHS, under which we issued to CIHS shares of our common stock and granted CIHS certain rights related to ownership of such shares.

In addition, we must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If we commercialize a licensed product, we also have the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments we must make to third parties. If we grant a

sublicense under the licenses granted by CIHS, we must pay to CIHS a percentage of certain consideration paid by the sublicensee to us. Under the CIHS Agreement, we must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets.

*Drexel University.* We are party to a license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel. The Drexel Agreement grants us, and our affiliates, an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on a-Gal epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease.

In consideration of our license under the Drexel Agreement, we have paid and are obligated to continue to pay specified license fees, potential milestone payments in an aggregate amount up to approximately \$1 million for each licensed product, annual license maintenance fees, reimbursement of patent prosecution costs, and royalty payments as a low single-digit percentage of "net sales" of any licensed product that is commercialized, subject to minimum royalty payments. Royalty rates vary depending on the type of licensed product, the territory where it is sold and whether the licensed product is combined with other technologies. In addition, if we grant a sublicense under the license granted by Drexel, we must pay Drexel a percentage of the consideration paid by the sublicensee to us. In accordance with a development plan included in the Drexel Agreement, we are obligated to use commercially reasonable efforts to develop and market products covered by the license as soon as practicable.

*Lankenau Institute for Medical Research — IDO-1.* We are a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, import, sell and offer for sale products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics.

In consideration of the license grant, we are obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if we grant a sublicense under the IDO-1 Agreement, we must to pay to LIMR a percentage of the consideration received by us from the sublicensee. Under the IDO-1 Agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines.

*Medical College of Georgia.* We are a party to a License Agreement dated September 13, 2005, or the MCGRI Agreement, with Medical College of Georgia Research Institute, or MCGRI, which was amended on April 27, 2006 and February 13, 2007. The MCGRI Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified MCGRI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

In consideration of such license grant, we are obligated to pay to MCGRI specified license fees (including issuing shares of our common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by MCGRI, we must pay to MCGRI a percentage of the consideration we receive from the sublicensee. Under the agreement, we are obligated to make certain investments toward the further development of licensed products within specified time periods.

*University of British Columbia.* We are a party to a license agreement dated February 1, 2007, or the UBC License, with the University of British Columbia, or UBC. The UBC License grants us an exclusive, worldwide license, under specified UBC patent rights relating to IDO-1 inhibitors and related technology, to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology. In addition, the UBC License grants us an option to obtain an exclusive, worldwide license to new IDO-1 inhibitors related technology developed during the term of the agreement.

In consideration of the license grant, we must pay to UBC specified license fees, annual payment and license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$1.8 million per licensed product, and royalties in a range of 10% or less of net revenue of the licensed product if a licensed product is commercialized, which royalty rate varies depending on the type of license product and field of use. In addition, if we grant a sublicense under the licenses granted by UBC, we may be required to pay to UBC a percentage of certain consideration we receive from the sublicensee. We are obligated to use our commercially reasonable efforts to develop and market the licensed products, and to achieve certain specific development milestones by agreed-upon deadlines.

*LIMR — IDO-2.* We are a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target indoleamine 2,3 dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses.

In consideration of the license grant, we have paid to LIMR an upfront license fee and annual license maintenance fees, and are obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately \$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us. Under the LIMR IDO-2 Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license.

*2009 LIMR Exclusive License Agreement.* We are a party to a license agreement, or the 2009 LIMR Agreement, dated April 23, 2009 with LIMR. The 2009 LIMR Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. In consideration of such license grant, we are obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately \$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

*Bresagen Patent License Agreement.* We are a party to a license agreement, or the Bresagen Agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants us a non-exclusive, non-sublicensable license to specified Bresagen patent rights for use in testing microbial and cancer vaccines. In consideration of such license grant, we are obligated to pay Bresagen an up front license fee and an annual license fee.

### ***Collaborative Agreements with Medical Institutions***

We have entered into numerous agreements with various medical institutions for the performance of clinical trials for various products. They typically call for the payment of fees by us for the performance of the clinical trials and the maintenance of confidentiality as to the associated technology.

We have entered into a letter of intent, or LOI, dated May 7, 2007 for a Cooperative Research & Development Agreement, or CRADA, with the NCI regarding certain IDO development efforts, which have consisted to date of primarily preclinical and Phase 1 clinical development of D-1MT. The LOI permits us to conduct informal joint research with the NCI pending formal approval of the CRADA. In the absence of an approved CRADA, we do not have any rights to inventions or raw data generated by NCI. We do have the right to use any clinical data generated under the LOI for exclusive use in obtaining regulatory approval.

If the CRADA is approved, it will have retroactive effect to the date that the last party executed the LOI, which is May 23, 2007, for any inventions that may be made pursuant to the joint research under the LOI. The financial obligations under the LOI will be defined in the CRADA when and if one is executed relating to this program. The term of the LOI has been extended until May 23, 2011. The CRADA is currently under active negotiation and the informal joint research is continuing. If the NCI discontinued support under the LOI, we would take over completing the development of D-1MT without federal support.

### **Patents and Trademarks**

As noted above, we presently have an extensive portfolio of patents and patent applications (and certain trademark registrations) with the United States Patent and Trademark Office. During the fiscal years ending December 31, 2010, 2009 and 2008, we incurred expenses related to the filing, maintenance and initiation of our patent portfolio of \$722,000, \$424,000 and \$457,000. These expenses increased by \$298,000 or 70% for 2010 compared to 2009. We anticipate these expenses to continue and increase into 2011.

### **OncoRx Acquisition**

On June 21, 2005, we acquired all of the stock of OncoRx Corporation for \$120,000 in cash and an agreement to deliver 780,611 shares of the our common stock, due in four installments upon successful completion of specified milestones as set forth in the agreement. On July 29, 2010, we entered into an amendment of this stock purchase agreement to reduce the remaining shares payable under the third and fourth installments by accelerating the payment of such installments to the effective date of the amendment. In consideration for our accelerated stock payment, we received a 30% discount on the remaining shares payable, reducing our total shares payable under the agreement by 156,122 shares. Through this acquisition, we acquired the fundamental technology for our IDO pathway inhibitor product candidates, subject to the licensing agreement with LIMR as set forth in "In-Licensing Agreements," above.

### **BioProtection Systems Corporation**

We formed BioProtection Systems Corporation, or BPS, as a subsidiary in 2005 to research, develop and commercialize vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid response prophylactic and therapeutic treatment for pathogens that might be targeted to the human population through acts of bioterrorism. At December 31, 2010, we owned shares of Series A common stock representing approximately 64% of BPS's common stock on an as-converted basis, assuming conversion into Series B common stock of all outstanding Series A and Series B preferred stock. On December 1, 2010, we entered into an agreement to acquire all of the noncontrolling interest in BPS, as described in more detail below.

BPS has financed its operations since inception through a combination of stock sales to and loans from the Company, sales of preferred stock to investors, and government contracts. We hold 7,000,000 shares of Series A common stock in BPS. These shares have a preference of \$0.10 per share over the Series B common stock, which is held primarily by officers and current and former employees. BPS has raised an aggregate of \$3.5 million from the sale of 1,444,721 shares of Series A preferred stock and 555,930 shares of Series B preferred stock. Each share of BPS Series B preferred stock and each share of Series A preferred stock is entitled to receive \$1.75 in preference to the shares of common stock upon a liquidation or sale of BPS.

BPS borrowed \$2.5 million from us pursuant to a convertible secured promissory note dated September 1, 2009. On December 1, 2010, the note was converted into 1,785,714 shares of BPS Series B preferred stock at a price of \$1.40 per share, which represents a 20% discount to the price per share paid by other purchasers of Series B preferred stock. Upon conversion of the note into Series B preferred stock, the Company owned 64% of the common stock assuming the conversion of all Series A and Series B preferred stock into Series B common stock.

BPS has entered into government contracts under which it recognized revenue of \$734,000 in 2009 and \$1.6 million in 2010.

BPS maintains an independent stock option plan. Pursuant to its plan, Gordon Link was granted an option to purchase up to 30,000 shares of Series B common stock at an exercise price of \$0.10 per share on September 18, 2008 and Ken Lynn was granted an option to purchase up to 30,000 shares of Series B common stock at an exercise price of \$0.10 per share on January 20, 2009. The following options to purchase Series B common stock were exercised at \$0.05 per share in September 2006 and purchased by the following officers and/or directors of the Company:

<u>Name</u>	<u>Shares</u>
Charles J. Link, Jr., M.D.	1,500,000
Nicholas N. Vahanian, M.D.	400,000
Thomas A. Raffin, M.D.	50,000
Ernest J. Talarico, III	50,000

Dr. Charles Link and Dr. Vahanian delivered notes to BPS in the principal amounts of \$75,000 and \$20,000, respectively, in September 2006, bearing interest at 5.01% per annum, in order to purchase their shares of BPS Series B common stock under the stock options. As of November 17, 2010, Dr. Link and Dr. Vahanian had repaid the remaining principal and interest owed under the notes. For a more detailed description of these loans, see "Executive and Director Compensation — Indebtedness of Management and Related Agreements." Dr. Link serves as CEO of BPS, and Dr. Vahanian serves as Chief Medical Officer of BPS.

#### **Acquisition of BioProtection Systems Corporation**

On January 7, 2011, we acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of ours with BPS, with BPS as the surviving corporation. In connection with this transaction, we will issue up to an aggregate of 276,304 shares of our Series E preferred stock to the former holders of BPS Series B common stock, Series A preferred stock and Series B preferred stock (other than the Company). 221,066 of the shares of our Series E preferred stock were issued to the holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of our Series E preferred stock were held back to satisfy any indemnity obligations under the merger agreement. If there are no indemnity obligations payable under the merger agreement by June 30, 2011, those shares will be issued to the former holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock. As a result of this transaction, BPS became a wholly-owned subsidiary of the Company and our note was converted into

Series B preferred stock of BPS. All options to purchase shares of BPS stock became options to purchase a total of 106,347 shares of our common stock.

In connection with this transaction, shares of our Series E preferred stock were issued to our officers and directors as follows:

<b>Name</b>	<b>Shares of Series E Preferred Stock Issued at Closing of the Merger</b>	<b>Shares of Series E Preferred Stock Potentially Issuable in the Future</b>
Charles J. Link, Jr., M.D.	41,568	10,392
Nicholas N. Vahanian, M.D.	11,085	2,771
Thomas A. Raffin, M.D.	1,386	346
Ernest J. Talarico, III	1,386	346

In addition, the following directors and officers of NewLink who are also directors or officers of BPS exchanged their BPS stock options for options to acquire shares of NewLink common stock as follows:

<b>Name</b>	<b>Options to Acquire BPS Series B Common Stock</b>	<b>Options to Acquire NewLink Common Stock</b>
Charles J. Link, Jr., M.D.	20,000	5,385
Nicholas N. Vahanian, M.D.	20,000	5,385
Thomas A. Raffin, M.D.	50,000	13,462
Ernest J. Talarico, III	45,000	12,116

The acquisition of BPS was recommended by a special committee of our Board of Directors consisting of Dr. Alexander and Messrs. Lundquist and Saluri, none of whom served as directors of BPS. Dr. Alexander and Mr. Saluri did not own any shares or options in BPS. The David Lundquist Revocable Trust owned shares of Series A Preferred Stock in BPS.

#### **Related Party Transactions**

In connection with his employment with us, Mr. Gordon Link was required to relocate from Colorado to Iowa. Pending the sale of his home in Colorado, we agreed to loan him the funds necessary to purchase a new home. He borrowed \$500,000 from us on July 28, 2008, which bore interest at the IRS applicable federal rate of 2.42% per annum. As of May 11, 2010, Mr. Link had repaid the principal on the loan and accrued interest of \$10,052 was forgiven.

On May 2, 2008, Dr. Charles Link borrowed \$225,000 from us at an interest rate of 6% per annum, with all accrued interest and principal due May 1, 2009. On January 22, 2009, we granted Dr. Link a bonus of \$78,149, which was applied to the principal due on the loan. On April 24, 2009, Dr. Link repaid the remaining principal and accrued interest on the loan.

On April 24, 2009, Dr. Link borrowed \$350,000 from us at an interest rate of 6% per annum, with all accrued interest and principal due May 1, 2011. On May 7, 2010, the note plus accrued interest of \$25,170 was forgiven, effective as of July 2, 2010, and an additional bonus of \$180,226 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options held by Dr. Link to purchase our common stock were modified to increase the aggregate exercise price by an amount equal to the amount of the forgiveness plus the bonus paid, and Dr. Link agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

Dr. Vahanian borrowed \$31,500 from us at an interest rate of 6.71% per annum. On July 1, 2010, the note plus accrued interest of \$10,000 was forgiven, effective as of July 2, 2010, and a bonus of \$12,010

was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options held by Dr. Vahanian to purchase our common stock were modified to increase the aggregate exercise price by an amount equal to the amount of the forgiveness plus the bonus paid, and Dr. Vahanian agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

On August 20, 2008, Dr. Vahanian borrowed \$125,000 from us at an interest rate of 6% per annum, with all accrued interest and principal due March 1, 2009. On January 22, 2009, we granted Dr. Vahanian a bonus of \$55,037, which was applied to the principal due on the loan. On April 24, 2009, Dr. Vahanian repaid the remaining principal and accrued interest on the loan.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission, or SEC, rules.

#### **Recent Accounting Pronouncements**

In April 2009, the Financial Accounting Standards Board, or FASB, issued guidance that expands the fair value disclosures required for financial instruments to interim reporting periods for publicly traded companies, including disclosure of the significant assumptions used to estimate the fair value of financial instruments. We adopted this guidance effective June 30, 2010. The adoption did not impact our financial position or results of operations.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The amended guidance requires disclosure of transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy, including the reasons and the timing of the transfers and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of the assets and liabilities measured under Level 3 of the fair value measurement hierarchy. The Company adopted the new disclosure requirements on January 1, 2010, except for the requirement concerning gross presentation of Level 3 activity, which is effective for fiscal years beginning after December 15, 2010. The adoption of the Level 1 and Level 2 disclosure guidance did not have an impact on the Company's consolidated financial position or results of operations.

In recent exposure drafts, the International Accounting Standards Board (IASB) and the FASB proposed a new approach to the accounting for leases. From a lessee's perspective, the exposure drafts propose to abolish the distinction between operating and finance/capital leases. In its place, a right-of-use model would be used. This proposal, as currently written, would require the lessee to recognize an asset for its right to use the underlying leased asset and a liability for its obligation to make lease payments. This would lead to an increase in assets and liabilities for leases currently classified as an operating lease and could also lead to a change in timing as to when the expense is recognized. This exposure draft is not yet finalized.

#### **Internal Control Over Financial Reporting**

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting.

For the year ending December 31, 2011, pursuant to Section 404 of the Sarbanes-Oxley Act, management will be required to deliver a report that assesses the effectiveness of our internal control

over financial reporting. Under current SEC rules, our independent registered public accounting firm will also be required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ending December 31, 2011, unless we qualify for an exemption as a non-accelerated filer under the Dodd-Frank Wall Street Reform and Consumer Protection Act, enacted on July 21, 2010.

### **Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share**

We calculated net loss per share in accordance with Accounting Standards Codification (ASC) 260, *Earnings per Share*. We have determined that the Series A, Series AA, Series AAA, Series B, Series BB, Series C and Series D preferred stock represent participating securities in accordance with ASC 260. However, since we operate at a loss, and losses are not allocated to the preferred stock, the two class method does not affect our calculation of earnings per share. We had a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive.

Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents. Potentially dilutive common stock equivalents total approximately 20.2 million, 17.9 million and 11.4 million as of ended December 31, 2010, 2009 and 2008, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same.

### **Quantitative and Qualitative Disclosures About Market Risks**

We are exposed to market risk related to changes in interest rates. As of December 31, 2010 and December 31, 2009, we had cash and cash equivalents and certificates of deposit of \$12.8 million and \$17.2 million, respectively, consisting of money market funds and bank certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term marketable securities. Our certificates of deposit are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our certificates of deposit until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial (or no) impact on our financial statements.



## BUSINESS

### Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. Our portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. Our lead product candidate, HyperAcute Pancreas cancer immunotherapy, or HyperAcute Pancreas, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients that is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. We launched this trial based on encouraging interim Phase 2 data that suggests improvement in both disease-free and overall survival. We have also received Fast Track and Orphan Drug designations from the FDA for this product candidate for the adjuvant treatment of surgically-resected pancreatic cancer. We have three additional product candidates in clinical development, including our HyperAcute Lung cancer immunotherapy, or HyperAcute Lung, which is being studied in a Phase 1/2 clinical trial conducted at the National Cancer Institute, or NCI, and our HyperAcute Melanoma cancer immunotherapy, or HyperAcute Melanoma, which is being studied in an investigator-initiated Phase 2 clinical trial. To date, our HyperAcute product candidates have been dosed in more than 200 cancer patients either as a monotherapy or in combination with other therapies and have demonstrated a favorable safety profile.

Our HyperAcute product candidates are based on our proprietary HyperAcute immunotherapy technology, which is designed to stimulate the human immune system. Our product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. We are also conducting small-molecule based research and development with an aim to produce new drugs capable of breaking the immune system's tolerance to cancer through inhibition of the indoleamine-(2,3)-dioxygenase, or IDO, pathway. We are currently studying our lead IDO pathway inhibitor product candidate, d-1-methyltryptophan, or D-1MT, in collaboration with the NCI, in two Phase 1B/2 clinical trials. We believe that our immunotherapeutic technologies will enable us to discover, develop and commercialize multiple product candidates that can be used either alone or in combination with current therapies to treat cancer.

### *Our HyperAcute Cancer Immunotherapy Product Candidates*

We initiated our Phase 3 clinical trial for HyperAcute Pancreas in May 2010. We expect to evaluate approximately 700 surgically-resected pancreatic cancer patients in this clinical trial and have enrolled 73 patients at 35 clinical sites in the United States as of February 15, 2011. The interim data from our fully-enrolled 70-patient Phase 2 pancreatic cancer clinical trial suggests that HyperAcute Pancreas may improve disease-free and overall survival when given in addition to standard-of-care treatment to patients following complete resection of detectable disease. As of January 14, 2011, 68 patients had reached at least 12-months of follow-up with a median follow-up period of 18.6 months. As of January 14, 2011, interim efficacy data for the 26 patients receiving high dose therapy predict median disease-free survival of 15.3 months and a one-year overall survival rate of 96% based on Kaplan-Meier analyses. To date, HyperAcute Pancreas has demonstrated good tolerability and a favorable safety profile. The most common treatment-related adverse reactions (reported by at least 5% of patients) for HyperAcute Pancreas were injection site reaction (58%), fatigue (20%), induration (17%), nausea (8%), pruritus (7%), fever (7%), urticaria (6%), anemia (6%) and decreased white blood cell count (6%). There have been no reported grade four adverse events attributed to HyperAcute Pancreas, and less than 8% of the patients treated with HyperAcute Pancreas have experienced a grade three serious adverse event characterized by the investigators as possibly or probably attributable to our product candidate. The NCI's common terminology criteria, or CTC, categorizes adverse events into five grades, where grade one is mild, grade two is moderate, grade three is severe, grade four is life-threatening and grade five is death.

Our second most advanced product candidate, HyperAcute Lung, is in a Phase 1/2 clinical trial that is fully enrolled with 54 patients for the treatment of refractory, recurrent or metastatic nonresectable non-small cell lung cancer, or NSCLC. Survival analysis completed as of September 30, 2010 for the 28 patients evaluated in the Phase 2 portion of the study suggests median overall survival of 11.3 months and a one-year survival rate of 46%. Based on our analysis of data from comparable precedent clinical trials of similar patients, we would have expected a median overall survival of approximately eight months. In an interim analysis of 45 patients who had reached median follow-up of 30 months as of September 30, 2010, HyperAcute Lung demonstrated a favorable safety profile and no dose limiting toxicities. The most common treatment-related adverse reactions (reported by at least 5% of patients) for HyperAcute Lung were injection site reaction (92%), induration (56%), fatigue (25%), urticaria (12%), anemia (7%), pruritus (7%), lymphopenia (7%), elevated serum amylase (5%), edema (5%), skin pain (5%) and dyspnea (5%). There have been no reported CTC grade four adverse events attributed to HyperAcute Lung and less than 13% of the patients treated with HyperAcute Lung have experienced a CTC grade three serious adverse event characterized by the investigators as possibly or probably attributable to our product candidate. This trial is being conducted at the NCI. We anticipate announcing the results of the completed clinical trial in the first half of 2011.

Our HyperAcute Melanoma product candidate is being studied in an investigator-initiated, fully enrolled 25 patient Phase 2 clinical trial for the treatment of advanced melanoma in combination with an eight-week course of PEG-Intron, a man-made immune modulator. As of October 7, 2010, interim results from the first 12 patients to reach 12 months of follow-up in this clinical trial have been encouraging, with all of the patients developing low levels of autoimmune antibodies and approximately one-third of patients developing vitiligo. Vitiligo is an autoimmune condition in which the patient's immune system attacks melanocytes in the skin, which are the cells that may turn into melanoma cancer cells. Vitiligo has previously been correlated with a favorable response to therapy in other melanoma immunotherapy studies. To date, HyperAcute Melanoma has demonstrated good tolerability and a favorable safety profile, with no systemic, drug-related serious adverse events characterized by the investigators as possibly or probably attributable to our product candidate. The most common non-serious adverse events reported were local injection site skin reactions, induration, diarrhea and nausea. We anticipate announcing results of the completed clinical trial in the second half of 2011.

### ***Our HyperAcute Cancer Immunotherapy Technology***

We believe our HyperAcute immunotherapies operate by exploiting a natural barrier present in humans that protects against infection being transmitted from other mammals. This barrier is related to the enzyme, alpha (1,3) galactosyl transferase, or a-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the expression of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or a-Gal, on the surface of affected cells. Introducing a-Gal-expressing cells to the human or primate immune system activates an immune response from antibodies against a-Gal. Antibodies directed against the a-Gal epitope are potentially the most abundant natural antibody in humans and represent approximately 1% of circulating human antibodies.

Our HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes a-Gal epitopes. This exposure to a-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which a-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti a-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens, or TAAs, common to both the immunotherapy and the patient's tumor cells.

We believe our proprietary HyperAcute immunotherapy technology offers several advantages over prior immunotherapy approaches. Specifically, our HyperAcute immunotherapy technology is designed to:

- harness the human body's innate immune response to a-Gal to fight cancer;
- utilize a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- use allogeneic (non-patient specific) cells from previously-established cell lines, which enables a simpler, more consistent and scalable manufacturing process than therapies based on autologous (patient specific) tissues or cells.

### ***Our IDO Pathway Inhibitor Product Candidate***

In addition to our HyperAcute product candidates, we are developing D-1MT, a small-molecule, orally bioavailable product candidate designed to inhibit the IDO pathway. In preclinical models, IDO pathway inhibitors have shown anti-tumor effects in combination with radiotherapy, chemotherapy, targeted therapy or immunotherapy. Through our collaboration with the NCI, we are studying D-1MT in two Phase 1B/2 safety and efficacy clinical trials in various chemotherapy and immunotherapy combinations. One clinical trial combines D-1MT with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The other clinical trial involves the combined use of D-1MT and Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care treatment, such as metastatic breast, prostate, ovarian and lung cancers. We anticipate announcing preliminary data from these clinical trials by the end of 2011.

### **Investment Highlights**

We are a biopharmaceutical company with a pipeline of product candidates based on our proprietary immunotherapeutic technologies that are intended to address significant unmet medical needs in the treatment of cancer. We believe the following are the key attributes of our company:

*Our lead product candidate, HyperAcute Pancreas, is in a Phase 3 clinical trial based on encouraging interim Phase 2 survival data in surgically-resected pancreatic cancer patients.* We are currently enrolling patients in a Phase 3 clinical trial of our lead product candidate, HyperAcute Pancreas, which is being performed under an SPA with the FDA. If approved, we believe the addition of HyperAcute Pancreas as an adjuvant therapy has the potential to be an important component of treatment for surgically-resected pancreatic cancer, an indication with high mortality rates and limited treatment alternatives. As of January 14, 2011, interim efficacy data in our HyperAcute Pancreas Phase 2 clinical trial for patients receiving high dose therapy predict median disease-free survival of 15.3 months and a one-year overall survival rate of 96% based on Kaplan-Meier analyses after 26 patients in the high dose group had reached 12 months of follow-up. Median overall survival has not yet been reached for this population. We have also received Fast Track and Orphan Drug designations for this product candidate.

*Our novel HyperAcute immunotherapy technology has a wide range of anti-cancer applications including two additional product candidates, HyperAcute Lung and HyperAcute Melanoma, in active clinical development.* We believe our technology is broadly applicable to many types of solid tumors. We have fully enrolled both a 54-patient Phase 1/2 clinical trial for our HyperAcute Lung product candidate in NSCLC at the NCI as well as an investigator-initiated, 25-patient Phase 2 clinical trial for our HyperAcute Melanoma product candidate in advanced melanoma. In addition, we are evaluating our HyperAcute technology in preclinical models for the treatment of other cancer types. To date, our HyperAcute product candidates have been dosed in more than 200 cancer patients and have demonstrated good tolerability and a favorable safety profile.

*We have in-house manufacturing capabilities for our HyperAcute product candidates that we believe are sufficient to support clinical development and initial commercialization of HyperAcute Pancreas in the United States.* Our HyperAcute product candidates rely on established cell lines and can be produced at our current facility in Ames, Iowa through a cost-effective and scalable production process. Our HyperAcute product candidates do not require patients to donate cellular material, which permits an easier scale-up of the manufacturing process as compared to autologous therapies. We believe that our current and planned manufacturing facilities will be adequate to supply the initial commercial quantities of HyperAcute Pancreas, if approved, in the United States.

*Our lead IDO pathway inhibitor product candidate is in clinical development in combination with multiple alternative therapies, including Taxotere.* Our lead IDO pathway inhibitor drug candidate is D-1MT, which is currently being evaluated in two Phase 1B/2 clinical trials co-sponsored by the NCI. The first clinical trial combines D-1MT with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The second clinical trial combines D-1MT with Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. D-1MT has shown favorable drug-like properties and has demonstrated anti-tumor activity in animal models in combination with traditional chemotherapy. We are also conducting preclinical research to identify new IDO pathway inhibitors.

*We have an extensive intellectual property portfolio.* We own or license 65 issued/granted patents, including those validated internationally, and 68 pending United States and foreign patent applications covering six patent families relating to HyperAcute technology, 19 patent families relating to IDO inhibitor immune response modulators and five other patent families not related to either our HyperAcute technology or IDO product candidates. We believe the intellectual property pertaining to our HyperAcute technology offers broad protection in this field. In addition, we believe we have broad protection pertaining to immune response modulators, with market exclusivity for the use of D-1MT to treat cancer until 2024 in the United States.

## **Our Strategy**

Our strategy is to discover, develop and commercialize immunotherapeutic products for the treatment of cancer where the needs of patients are unmet by current therapies. The critical components of our business strategy include:

*Complete the Phase 3 clinical trial of HyperAcute Pancreas, our lead immunotherapy product candidate, and gain regulatory approval.* HyperAcute Pancreas is currently in Phase 3 clinical development in patients with surgically-resected pancreatic cancer. This clinical trial, which was initiated in May 2010, is an approximately 700-patient randomized clinical trial being performed under an SPA with the FDA. We plan to complete patient enrollment in 2013 and complete the first interim analysis by late 2013. We received Fast Track designation on October 1, 2010 and we received Orphan Drug designation on October 21, 2010 from the FDA for this product candidate.

*Develop sales and marketing infrastructure to commercialize our HyperAcute Pancreas product candidate in the United States and establish commercial partnerships in other regions.* We currently own or exclusively license all rights to our HyperAcute product candidates. We intend to commercialize some or all of our HyperAcute product candidates, including HyperAcute Pancreas, in the United States by building an initial specialty sales force of approximately 50 to 100 representatives with a focused marketing effort directed to medical and surgical oncologists. We intend to seek collaborations to develop and commercialize our HyperAcute product candidates outside of the United States, and may seek collaborations for selected indications within the United States.

*Advance our HyperAcute Lung and HyperAcute Melanoma product candidates through additional clinical trials.* Based on the clinical trial data generated to date by HyperAcute Lung and HyperAcute

Melanoma, we plan to pursue further clinical development of these product candidates. We have convened a panel of thought leaders in lung cancer to assist us in planning a Phase 2B/3 clinical trial for NSCLC with an adaptive design, which we plan to initiate during the second half of 2011. We are also currently working to develop clinical trial designs to further study the efficacy of HyperAcute Melanoma either as a stand-alone or combination therapy.

*Expand our manufacturing capabilities for our HyperAcute product candidates.* We manufacture HyperAcute Pancreas at our facility in Ames, Iowa and believe our current and planned manufacturing facilities will be adequate to support the initial U.S. commercialization efforts for that product. We intend to maintain control over manufacturing for our HyperAcute product candidates for the U.S. market and may need to expand our manufacturing capacity in the future if more than one of our products are approved.

*Investigate our HyperAcute technology in additional oncology indications.* We have developed a process to discover and develop new tumor-specific HyperAcute cancer immunotherapies. In addition to our lead programs in pancreatic cancer, lung cancer and melanoma, we intend to pursue clinical development of this technology in other tumor types.

*Develop and commercialize D-1MT, a small-molecule product candidate, in cancer.* In collaboration with the NCI, we have initiated two Phase 1B/2 clinical trials to evaluate use of D-1MT in combination with other approved therapies for solid tumor indications. We also plan to initiate multiple clinical trials of our D-1MT product candidate in combination with other approved and development-stage cancer therapies, including immunotherapies such as our HyperAcute Lung and HyperAcute Melanoma product candidates.

## **Cancer Market Overview**

Cancer is the second-leading cause of death in the United States with an estimated 569,000 deaths in 2010 according to the American Cancer Society. Despite a number of advancements in the diagnosis and treatment of cancer over the past decade, overall five-year survival rates from all cancer types is 68% for the period spanning 1999-2005 according to the American Cancer Society.

Cancer is characterized by abnormal cells that grow and proliferate, forming masses called tumors. Under certain circumstances, these proliferating cells can metastasize, or spread, throughout the body and produce deposits of tumor cells called metastases. As the tumors grow, they may cause tissue and organ failure and, ultimately, death. To be effective, cancer therapies must eliminate or control the growth of the cancer.

The specialized cells of the immune system recognize specific chemical structures called antigens. Generally, foreign antigens trigger an immune response that results in the removal of disease-causing agents from the body. Cancer cells, however, frequently display antigens that are also found on normal cells. The immune system may not be able to distinguish between tumors and normal cells and, thus, may be unable to mount a strong anti-cancer response. Tumors also have various defense mechanisms that may prevent the immune system from fully activating.

Current therapies, such as surgery, radiation, hormone treatments and chemotherapy, do not address this evasive characteristic of cancer and may not have the desired therapeutic effect. Active immunotherapies stimulate the immune system, the body's natural mechanism for fighting disease, and may overcome some of the limitations of current standard-of-care cancer therapies.

## Limitations of Current Cancer Therapies

We believe current cancer treatment alternatives suffer from a number of limitations that impair their effectiveness in improving patient survival and overall quality of life including:

- *Toxicity.* Chemotherapeutic agents are highly toxic to the human body and often cause a variety of side effects, which may include nausea and vomiting, bleeding, anemia and mucositis. Targeted therapeutics may have fewer systemic toxicities, but still tend to have off-target effects such as gastrointestinal inflammation, severe skin reactions and breathing difficulties. These effects limit a patient's ability to tolerate treatment thereby depriving the patient of the potential benefit of additional treatments or treatment combinations that might otherwise destroy or prevent the growth of cancer cells. Once educated as to the limited efficacy, limited increased survival and potentially significant toxicity of existing treatment alternatives, patients diagnosed with terminal cancer often choose to limit or forego therapy in order to avoid further compromising their quality of life. Patients with advanced stage cancer often cannot tolerate cancer therapy, and certain therapies have been shown to hasten death in some cases as the patient's health deteriorates.
- *Mechanism of action.* While many current therapeutic approaches may be effective against a particular target, the overall impact of these therapies on treating cancer is limited because the abundance and diversity of tumor cells are believed to enable cancers to adapt and become resistant to these treatments over time resulting in reduced longer-term efficacy.
- *Short-term approach.* Incremental survival benefit is the primary objective of many currently marketed and development-stage cancer therapeutics. In general, many drugs show modest impact on overall survival or only affect progression-free survival. Other than surgical tumor removal, curative intent is often not a focus or realistic potential outcome of many current cancer therapies.
- *Immune system suppression.* Cancer is difficult to treat in part because cancer cells use sophisticated strategies to evade the immune system. Current approaches to cancer treatment generally involve introduction of an agent, such as a chemical, an antibody or radiation. These agents cause cell apoptosis (programmed cell death) or inhibit the proliferation of all cells, including immune cells, thereby indirectly suppressing the immune system. A weakened immune system not only further inhibits the body's natural ability to fight cancer, but also causes patients to become more susceptible to infections and other diseases.

## Our Potential Solution: HyperAcute Immunotherapy

We believe our HyperAcute immunotherapy has the following advantages over existing therapies, which may enable us to develop commercial products that extend both survival and quality of life for cancer patients:

- *Robust, innate immune response.* Our HyperAcute immunotherapy technology is designed to fight cancer by activating the human body's naturally protective and rapid immune response to the a-Gal carbohydrate.
- *Complex, multi-targeted approach.* We believe our HyperAcute immunotherapy technology attacks cancer through several mechanisms. Initially, by introducing allogeneic, whole cancer cells incorporating a-Gal to the body, our HyperAcute immunotherapy is designed to teach the immune system to attack specific cancer cells, such as pancreas, lung or melanoma cancer cells, with both antibody mediated and cellular immune responses. Secondly, by using multiple whole cancer cell lines, our HyperAcute immunotherapy targets multiple tumor proteins simultaneously, which we believe increases the probability of stimulating an effective immune response to the heterogeneous cells that are present in cancer.

- *Favorable safety profile.* We have not observed significant additional systemic toxicities when HyperAcute immunotherapy has been added to chemotherapy regimens. There have been no CTC grade four serious adverse events attributed to HyperAcute Pancreas, HyperAcute Lung or HyperAcute Melanoma. Our HyperAcute immunotherapy technology is designed to stimulate a natural immune response to specific cancer cells with the objective to decrease the risks of off-target effects. Data generated to date suggests that patients can tolerate the addition of our HyperAcute product candidates to standard chemotherapy and radiation therapy.
- *Broad applicability.* We believe that the novel mechanism of action, good tolerability and favorable safety profile will enable our HyperAcute product candidates to have potential benefits across multiple disease stages and tumor types and in combination with other therapies. Our HyperAcute immunotherapy technology can be targeted to additional specific tumor types by modifying cells from the cancer type of interest.
- *Potential application as single agent adjuvant therapy.* We believe many patients who are too ill to tolerate chemotherapy due to the associated toxicities may be able to benefit from our HyperAcute product candidates. We also believe that the safety profile of our HyperAcute immunotherapies may make them suitable for use in patients with low risk of recurrence or metastasis who choose not to receive chemotherapy due to its toxicity relative to the potential therapeutic benefits.

**Our Product Pipeline**

The chart below summarizes our current product candidates and their stages of development.

<b>Product Candidate</b>	<b>Phase of Development</b>	<b>Indication</b>	<b>Upcoming Milestone</b>
<i>HyperAcute Immunotherapy Technology</i>			
HyperAcute Pancreas	Phase 3	Adjuvant to standard-of-care in surgically-resected pancreatic cancer	1st quarter 2013: 1st interim analysis
HyperAcute Lung	Phase 2 enrollment complete	Adjuvant to standard-of-care in surgically-resected pancreatic cancer	1st half 2011: Announce Phase 1/2 clinical trial results  2nd half 2011: Initiate Phase 2B/3 clinical trial
	Phase 1/2 enrollment complete	Advanced NSCLC	
HyperAcute Melanoma	Phase 2 enrollment complete(1)	Advanced melanoma in combination with PEG-Intron	2nd half 2011: Update Phase 2 clinical trial results
Additional HyperAcute cancer immunotherapies	Lead optimization	To be determined	End of 2011: Initiate Phase 1 clinical trial
<i>IDO Pathway Inhibitor Technology</i>			
D-1MT	Phase 1B/2(2)	2nd-line metastatic solid tumors in combination with p53 adenovirus	End of 2011: Announce preliminary data
	Phase 1B/2(2)	2nd-line metastatic solid tumors in combination with Taxotere	End of 2011: Announce preliminary data
Additional IDO Pathway Inhibitor Candidates	Lead optimization	To be determined	To be determined

(1) Investigator-initiated

(2) Co-sponsored by the National Cancer Institute



## **Our HyperAcute Pancreas Cancer Immunotherapy Product Candidate**

Our lead product candidate, HyperAcute Pancreas, is in a Phase 3 clinical trial being performed under an SPA with the FDA. We have also received Fast Track and Orphan Drug designations for this product candidate for the adjuvant treatment of surgically-resected pancreatic cancer. HyperAcute Pancreas consists of equal doses of two separate allogeneic pancreatic cancer cell lines engineered to express a-Gal. Although cells making up naturally occurring pancreatic tumors in patients do not express a-Gal, the tumor cells share other molecules, called tumor-specific or tumor-associated antigens, with the genetically altered pancreatic cancer cells contained in HyperAcute Pancreas. We believe the molecules that are shared by both the patient's tumor cells and HyperAcute Pancreas immunotherapy cells allow the antibodies and immune cells that develop against the HyperAcute Pancreas immunotherapy cells to target and destroy the patient's own tumor cells as well. Each of the modified cell lines is grown in large cultures, harvested, irradiated and packaged. Approximately 150 million cells of each HyperAcute Pancreas cell line are given by intradermal injection with each treatment. A series of up to 12 treatments using both cell lines over a period of six months was used in our Phase 2 clinical trial. In our Phase 3 protocol, we are adding an additional series of six maintenance treatments, to be given during the next six months.

### ***Market Opportunity***

The American Cancer Society estimates that approximately 43,000 new cases of pancreatic cancer will be diagnosed in the United States in 2010. Pancreatic cancer has generally been recognized as an aggressive form of cancer with non-specific initial symptoms, making it difficult to diagnose at an early stage. Due to the difficulty in diagnosis and the aggressive nature of this cancer, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer Society estimates one-year and five-year overall survival rates of about 24% and 5%, respectively.

Pancreatic cancer can generally be divided into three broad categories: (1) local disease, in which the cancer is confined to the pancreas and can be removed surgically, which is called resection; (2) locally advanced disease, in which the cancer has spread locally and may or may not be eligible for resection because it has invaded tissues that should not be removed, such as key nerves and arteries; and (3) metastatic disease, in which the tumor has spread beyond the region of the pancreas.

According to eMedicine, a healthcare reference website run by WebMD containing peer-reviewed articles on diseases and medical topics, approximately 20% of pancreatic cancer patients in the United States are eligible for resection at initial diagnosis. These earlier stage, resected patients have significantly better prognoses than patients with later stage disease since they tend to have better nutritional and immune status and significantly lower amounts of micro-metastatic and residual disease. A study published in the *Journal of the American Medical Association*, or *JAMA*, in March 2008 showed that resection followed by chemotherapy or chemoradiotherapy, known as adjuvant therapy, extends median survival to approximately 18 months. We believe the addition of HyperAcute Pancreas to adjuvant standard-of-care has the potential to improve median disease-free survival and overall survival in resected pancreatic cancer patients.

Patients with locally advanced nonresectable disease represent an additional 30% of patients at diagnosis and are generally treated with chemotherapy or chemoradiotherapy. We plan to initiate a clinical trial to test the safety and efficacy of HyperAcute Pancreas in locally advanced, nonresectable pancreatic cancer patients. We believe patients with locally advanced nonresectable disease may also benefit from the addition of HyperAcute Pancreas to standard-of-care.

## Clinical Trials

### *Phase 3 Clinical Trial*

In May 2010, we initiated our Phase 3 clinical trial for HyperAcute Pancreas. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating approximately 700 Stage I and Stage II surgically-resected pancreatic cancer patients, according to the American Joint Committee on Cancer classification system, or AJCC system, who have no detectable disease by a CT scan. The primary endpoint of the clinical trial is overall survival, with secondary endpoints of disease-free survival, safety, toxicity and immunological responses. Based on our discussions with the FDA, we plan to enroll up to 722 patients and believe this number of patients will enable us to demonstrate statistically significant improvement in median overall survival at the end of the trial. Additional patients will be accrued, if needed, to maintain adequate numbers for statistical significance. As of February 15, 2011, 73 patients had been enrolled at 35 U.S. based clinical sites. We are actively recruiting additional major medical centers, where a large number of pancreatic cancer surgeries occur, to participate in this clinical trial.

Current adjuvant standard-of-care regimens for post-resection pancreatic cancer patients include gemcitabine chemotherapy alone or a combination of gemcitabine plus 5-FU based chemoradiotherapy. In our Phase 3 clinical trial, 50% of the patients will receive standard adjuvant therapy with HyperAcute Pancreas and 50% will receive standard adjuvant therapy without HyperAcute Pancreas. The treatment schedule for HyperAcute Pancreas is being amended to administer up to 18 treatments given every two weeks over a period of approximately six months followed by monthly injections for an additional six months. Patients in the study are monitored with periodic imaging to check for recurrences for at least five years after surgery or until death occurs. We have selected the 300 million cell dose as the treatment dose for this clinical trial based on the analysis of data from our Phase 2 clinical trial.

The clinical trial includes interim evaluations for both overall survival and disease-free survival when approximately one-half of the expected number of deaths have occurred and, if needed, again when approximately three-quarters of the expected number of deaths have occurred. Our SPA specifies that if results show a highly statistically significant effect on survival we may stop the trial and apply for marketing approval. Our statistical modeling indicates that a 45% or 30% improvement in overall survival, relative to controls through the period when one-half or three-quarters, respectively, of the expected number of deaths have occurred, would be highly statistically significant. Overall survival refers to the duration of life after surgery. Disease-free survival refers to the period of time after surgical resection when no evidence of disease is detected.

When initially diagnosed, patients eligible for our Phase 3 clinical trials have localized tumors that can potentially be completely removed based upon strict imaging criteria. In addition, the patients are generally strong enough to survive a major surgical procedure that involves an inherent significant risk of death. Patients are not eligible to participate in this trial until pathology and post-operative imaging studies indicate that they are without clinical evidence of residual tumor as observed by a CT scan. As a result, patients admitted to the trials have minimal residual tumor burden and possess generally intact immune systems, characteristics that we believe improve the likelihood of meaningful response.

### *Phase 2 Clinical Trial*

We have completed enrollment of a 70-patient open-label, single arm Phase 2 clinical trial in which HyperAcute Pancreas was given in doses of either 100 million cells or 300 million cells approximately twice monthly for six months in combination with the standard-of-care treatment regimen, which consisted of gemcitabine chemotherapy plus 5-FU based chemoradiotherapy. We enrolled patients for this clinical trial at 16 different sites including some of the leading cancer centers in the United States. Patients in this clinical trial had been diagnosed with Stage I and Stage II pancreatic adenocarcinoma, according to the AJCC system, and subsequently underwent surgical resection to remove all visible tumors with curative intent. There were no other exclusion criteria relative to pre-operative disease

status. The primary endpoint of this clinical trial was to evaluate disease-free survival with secondary endpoints of overall survival and toxicity. We enrolled the final patient in March 2010 and expect to report 12-month analysis of all 70 patients in January 2011.

We designed this clinical trial to add HyperAcute Pancreas immunotherapy to the standard-of-care treatment regimen defined in RTOG 97-04 (Regine et al., 2008) as adjuvant 5-FU chemoradiotherapy plus gemcitabine and to perform a dose-finding analysis of cohorts receiving bi-weekly HyperAcute Pancreas doses of 100 million or 300 million cells. Our objectives are to demonstrate a clinical benefit by addition of HyperAcute Pancreas to RTOG 97-04 standard adjuvant therapy alone and to determine if a superior dosing regimen can be identified.

We enrolled 44 patients in the 100 million cell dose cohort, or low dose group, and 26 patients in the 300 million cell dose cohort, or high dose group. The high dose group represented the first 26 patients enrolled in the clinical trial. The baseline patient characteristics of both cohorts were similar in terms of age, gender and disease state.

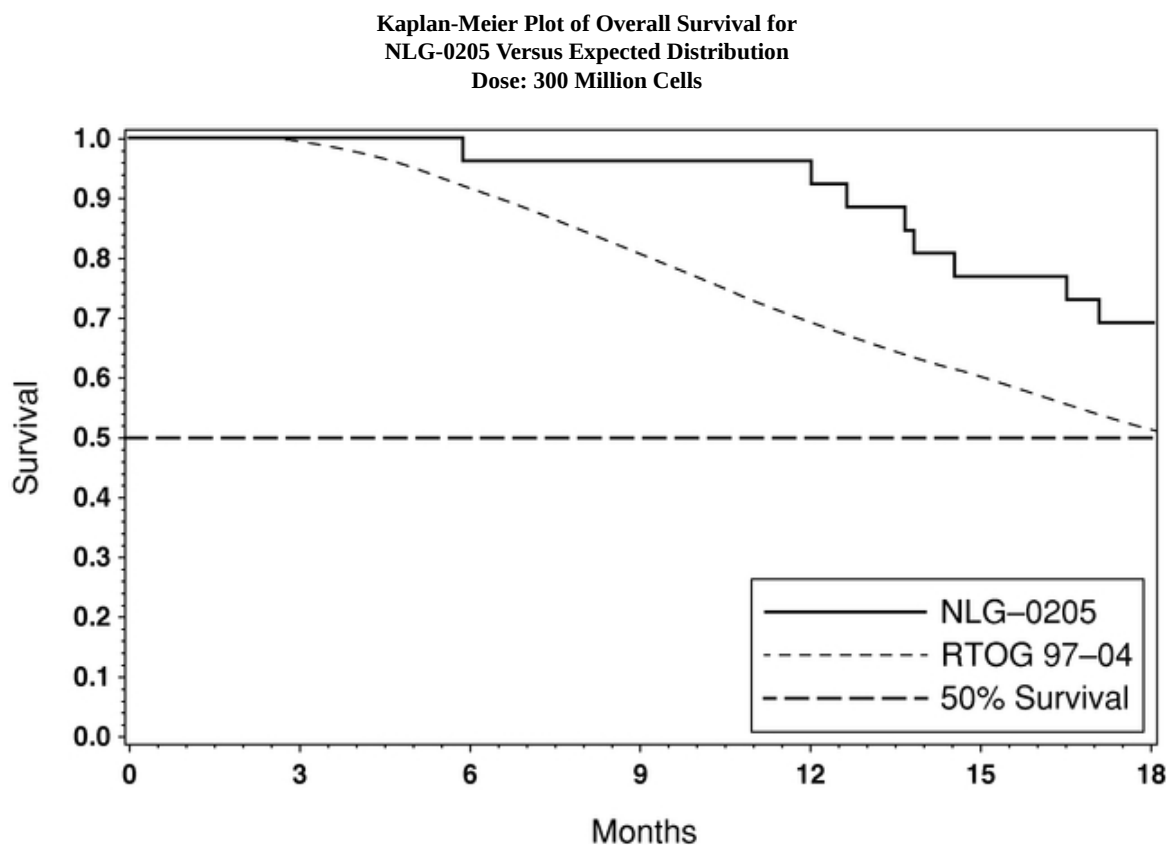
As of January 14, 2011, 68 patients had reached at least 12 months of follow-up with a median follow-up period of 18.6 months. To date, HyperAcute Pancreas has demonstrated good tolerability and a favorable safety profile. There have been no reported CTC grade four adverse events attributed to HyperAcute Pancreas, and less than 8% of the patients treated with HyperAcute Pancreas have experienced a CTC grade three serious adverse event characterized by the investigators as possibly or probably attributable to the product candidate. The most common non-serious adverse events observed were fatigue, local injection site skin reactions and injection site pain. The nature and frequency of the adverse events observed in this clinical trial are consistent with the adverse events observed in all clinical trials for HyperAcute Pancreas. When HyperAcute Pancreas was given in combination with gemcitabine and 5-FU based chemoradiotherapy, approximately 4% of patients experienced CTC grade three lymphopenia, 3% of patients experienced CTC grade three pain, less than 2% of patients experienced CTC grade three pancreatitis and less than 2% experienced CTC grade three fatigue, adverse events possibly or in the case of fatigue, probably attributable to our product candidate according to the principal investigators.

As of January 14, 2011, interim efficacy data for all treatment groups combined predict 12 month disease-free survival of 63% and 12 month overall survival of 86% based on Kaplan-Meier analyses. Data from the high and low dose HyperAcute Pancreas treatment groups predict 12 month disease-free survival of 81% and 52%, and a one-year overall survival rate of 96% and 80% for the respective cohorts based on Kaplan-Meier analyses. These results compare favorably to the outcomes of prior clinical trials in surgically resected pancreatic cancer patients. Of these clinical trials, we believe the study known as RTOG 97-04, a 451-patient clinical trial conducted by the Radiation Therapy Oncology Group, is the most comparable with respect to baseline patient characteristics and treatment regimen. One treatment arm in RTOG 97-04 received the current standard-of-care treatment regimen, or gemcitabine chemotherapy plus 5-FU based chemoradiotherapy. In RTOG 97-04, patients in the standard-of-care treatment arm had one-year disease-free survival of less than 50% and a one-year overall survival rate of 69% based on Kaplan-Meier analysis.

### ***Kaplan-Meier Analysis***

Kaplan-Meier analysis is a statistical method of predicting survival rates. As shown in the graph below, the Kaplan-Meier-calculated overall survival in our Phase 2 clinical trial, referred to as NLG-0205, compares favorably to data from RTOG 97-04. The dotted line depicts overall survival of successfully resected pancreatic cancer patients derived from the published data of RTOG 97-04 in which the one year survival rate was 69% for patients. The solid line represents the Kaplan-Meier estimated survival

curve for patients in our Phase 2 clinical trial as of January 14, 2011. At 12 months after surgery overall survival for the combined patient population in NLG-0205 is 86%.



Data from the NLG-0205 study has been stratified into high dose and low dose groups on the basis of statistically significant differential responses to HyperAcute Pancreas immunotherapy. We believe 300 million cells is the largest practically attainable treatment dose based on clinician observation; however, we have tested a 100 million cell dose as a means to reduce the number of injections needed during therapy. The patterns of response in patients treated with these two doses have become increasingly distinct during the study.

Patients in the high dose group of NLG-0205 demonstrated an improved disease-free survival projection compared to patients in the low dose group or the current standard-of-care RTOG 97-04 chemoradiotherapy protocol alone. The median disease-free survival in NLG-0205 high dose patients is projected to be 15.3 months based on data as of January 14, 2011 versus an estimated median disease-free survival of 11.4 months in RTOG 97-04. The apparent difference in disease progression is most prominent at earlier time points during active immunotherapy and persists beyond the completion of treatment. Conversely, although some benefit may occur with administration of low dose HyperAcute Pancreas during the period when the drug is administered, the effect is of lesser magnitude and is less durable beyond the active treatment phase.

The maturing data from NLG-0205 do not yet allow calculation of median overall survival but demonstrate a statistically significant difference between high and low dose groups in terms of disease-free survival ( $p=0.02$ ). In addition, an increased overall survival at one year for 300 million cell dose patients is approaching (but has not yet achieved) the level of statistical significance observed compared to low dose patients (96% vs. 80%,  $p=0.053$ ). These data demonstrate that patients in the high dose group have both a higher disease-free survival and a trend towards higher overall survival at one year compared to patients in the low dose group. Notably, patients treated at both dose levels in NLG-0205

compare favorably to the 69% one year overall survival observed in the RTOG 97-04 study. Furthermore, both dose levels in NLG-0205 compare favorably to the 63% one year overall survival calculated by the Memorial Sloan Kettering Cancer Center nomogram (Brennan et al., 2005), as discussed below, of the NLG-0205 patient population.

	<b>Disease-Free Survival at 1 year</b>	<b>Overall Survival at 1 year</b>
Brennan et al., 2005 nomogram	Not Applicable	63%
RTOG 97-04 (all patients)	<50%*	69%
NLG-0205 — 100 million cell dose group	52%	80%
NLG-0205 — 300 million cell dose group	81%	96%

\* Disease-free survival at 1 year was not reported. However, from the median disease-free survival of 11.4 months, we have inferred that disease-free survival at 1 year is less than 50%.

After reviewing these data that cumulatively suggest a significant dosage effect, we have amended our Phase 3 clinical trial protocol to increase the duration of therapy to 12 months in an effort to further delay recurrence and improve overall survival.

### ***Analysis of Historical Controls***

Baseline patient characteristics are key factors to consider in reviewing clinical trials. Not all patients have an identical disease state and, in the context of surgically-resected pancreatic cancer patients, certain patient characteristics have been shown to have a significant impact on a patient's prognosis of disease progression and survival. These characteristics include:

**Nodal status**: refers to the presence of cancer in the nearby lymph nodes. When cancer enters the lymph nodes, there is an increased risk that the cancer will spread, or metastasize, to other regions of the body via the lymphatic system. As such, nodal status is an indicator of disease progression and thereby a prognostic indicator of survival. A study completed by Hsu et al. and published in the *Annals of Surgical Oncology* in 2010 reported that resected pancreatic cancer patients who received adjuvant chemoradiotherapy with positive lymph nodes prior to resection had a median overall survival 8.5 months less than that of patients with negative nodes. Further, a study conducted by Lim et al. published in *Annals of Surgery* in 2003 demonstrated that patients with greater than four positive lymph nodes had median overall survival 9.4 months less than that of patients with no positive lymph nodes.

**Degree of local invasion**: refers to the extension of tumors into peripancreatic tissues including neural, vascular, or lymphatic structures or surrounding organs. Larger, higher-staged tumors are associated with a higher degree of local invasion, advanced disease and a poorer prognosis. As it relates to pancreatic cancer, patients with smaller, less invasive tumors have a greater median overall survival as reported by Gebhardt et al. in *Langenbeck's Archives of Surgery* in 2000. In the Gebhardt study, patients with pancreatic cancer that had invaded the lymph vessels, blood vessels and perineural tissues had a median overall survival of 16.8 months, 7.2 months and 4.8 months less, respectively, than patients with cancer that had not invaded these tissues.

**Tumor stage**: refers to the size and peripancreatic extension of pancreatic cancer. T1 is defined as less than two centimeters in diameter and limited to the pancreas; T2 is defined as greater than two centimeters in diameter and limited to the pancreas; T3 is defined as a tumor that has extended beyond the pancreas; and T4 tumors are defined as unresectable. The T3 tumor stage is associated with poorer prognosis and increased risk of death compared to T1-T2 tumors in resected pancreatic cancer patients who receive adjuvant chemoradiotherapy as reported by Hsu et al., where T3 patients had a median overall survival that was 8.3 months less than T1-T2 patients.

Tumor grade: refers to abnormalities of cancer cells relative to healthy cells. Tumor cells considered undifferentiated, or having a higher tumor grade, have little to no resemblance to the cells from which they originated (in this case pancreatic cells). Tumors classified as G1 or G2 are considered low grade tumors with well and moderately differentiated cells, respectively. Tumors classified as G3 or G4 are considered high grade tumors with poorly or undifferentiated cells, respectively. Many factors are considered in determining tumor grade, including the structure and growth pattern of the cells. Tumor grade is determined by a pathologist via biopsy of the tumor. Higher degrees of cancer cell abnormality are associated with a poorer disease prognosis; in fact, high tumor grade is an independent predictor of survival. The study conducted by Lim et al. referred to above showed that patients with poorly differentiated (G3), or higher grade, tumors of the pancreas had median overall survival of 22.8 months less than patients with well differentiated (G1), or lower grade, tumors.

Ca 19-9 markers: refers to the post-operative concentration of the tumor marker carbohydrate antigen 19-9. The concentration of Ca 19-9 markers is associated with significant risk of early, distant metastasis. A study conducted by Kinsella et al. published in *American Journal of Clinical Oncology* in 2008 reported that pancreatic cancer patients with high post-operative Ca 19-9 levels, defined as greater than 70 units per milliliter, had a median overall survival 16.8 month less than patients with Ca 19-9 marker levels lower than 70 units per milliliter.

Our Phase 2 clinical trial did not compare the outcomes of patients who received HyperAcute Pancreas plus the standard-of-care treatment regimen to the standard-of-care alone. Therefore, we believe it is important to evaluate the patient characteristics and clinical results of NLG-0205 relative to those of prior clinical trials in surgically-resected pancreatic cancer patients. We have reviewed baseline patient characteristics and outcomes from the following clinical trials conducted in surgically-resected Stage I/II pancreatic cancer:

ESPAC-1: This clinical trial initially recruited 541 patients at 53 hospitals in 11 European countries from February 1994 to June 2000. The final data analysis published in March 2004 was based on an evaluation of 289 patients. The objective of ESPAC-1 was to evaluate potential survival benefits of post-surgical adjuvant therapy: chemotherapy, chemoradiotherapy, chemoradiotherapy followed by chemotherapy and no-treatment/observation. The investigators in this clinical trial concluded that adjuvant chemotherapy with 5-FU has a significant survival benefit in patients with resected pancreatic cancer while chemoradiotherapy may have had a negative impact on survival. We believe ESPAC-1 lacked adequate statistical power to draw any meaningful conclusions regarding superiority of any of the treatment arms. Results of ESPAC-1 were published in the *New England Journal of Medicine* in March 2004.

ESPAC-3: This clinical trial enrolled a total of 1,088 patients at 159 pancreatic cancer centers in Europe, Australasia, Japan, and Canada from July 2000 to January 2007. The objective of ESPAC-3 was to determine whether treatment with 5-FU/FA or gemcitabine is superior in terms of overall survival as adjuvant treatment following resection of pancreatic cancer. ESPAC-3 is the largest adjuvant trial conducted in pancreatic ductal adenocarcinoma. This study concluded that gemcitabine alone did not result in improved overall survival in completely resected pancreatic cancer versus 5-FU/FA chemotherapy. The results of ESPAC-3 were presented at the 2009 annual meeting of the American Society of Clinical Oncology, or ASCO, and published in *JAMA* in September 2010.

We believe that there were several confounding elements of the ESPAC-3 trial design that limit the applicability of its conclusions to clinical practice. First, the treatment regimens lacked standardization in terms of dosing and schedule. Also, ESPAC-3 was conducted primarily in Europe where standard surgical practices differ from the United States. Finally, the investigators determined not to include an observation arm in this study following the results of ESPAC-1. The

lack of a treatment control arm does not allow investigators to define a baseline patient risk profile for enrollees in this trial.

**CONKO-001:** This clinical trial enrolled a total of 368 patients at 88 academic and community-based oncology centers in Germany and Austria from July 1998 to December 2004. The objective of CONKO-001 was to test the hypothesis that adjuvant chemotherapy with gemcitabine administered after complete resection of pancreatic cancer improves disease-free survival by six months or more relative to best supportive care. In their analysis of 354 eligible patients, the CONKO-001 investigators concluded that adjuvant gemcitabine delayed the development of recurrent disease compared to observation alone. However, a statistically significant benefit in overall survival was not observed. CONKO-001 results were published in *JAMA* in January 2007.

**RTOG 97-04:** This clinical trial enrolled 538 patients at 164 U.S. and Canadian institutions from July 1998 to July 2002 with follow-up through August 2006. The objective of RTOG 97-04 was to determine if the addition of gemcitabine to adjuvant 5-FU chemoradiation would improve survival for patients with resected pancreatic adenocarcinoma. In their primary analysis of a 451 patient sub-population, the RTOG 97-04 investigators determined that the addition of gemcitabine to adjuvant 5-FU-based chemoradiation was associated with a survival benefit for patients with resected pancreatic cancer, although this benefit was not statistically significant. Based on the subpopulation analysis of this study, we believe that this study demonstrated limited benefit. The results of RTOG 97-04 were presented at the 2006 ASCO annual meeting and published in *JAMA* in March 2008.

The table below shows baseline patient characteristics for several key prognostic indicators and outcomes from these clinical trials. The same prognostic indicators are not always reported at baseline in each clinical trial. Prognostic indicators for Stage I/II pancreatic cancer have been analyzed during the development of the AJCC TNM (Tumor size, lymph Nodes affected, Metastases) system. The principal prognostic indicators have been validated and demonstrate that baseline data on tumors, nodal involvement and metastasis inform meaningful predictions of likely outcomes for patients.

Study	Nodal Status (% N+)	Local Invasion	Tumor Stage (T3/T4)	High Tumor Grade	Ca 19-9 (≥ 180 U/mL)	Disease-Free Survival Median (Months)	Overall Survival Median (Months)	Overall Survival at 1 Year
<b>ESPAC-1 (289 patients) 2004(1)</b> Treatment Arm: 5-FU (147 patients)	52%*	18%*	Not Reported	18%*	Not Reported	Not Reported	20.1	67%
<b>CONKO-001(354 patients) 2007(2)</b> Treatment Arm: Gemzar (179 patients)	71%	Not Reported	86%	36%*	0%	13.4	22.1	73%
<b>RTOG 97-04 (451 patients) 2008(3)</b> Treatment Arm: Gemcitabine+5-FU+Radiation (221 patients)	68%	Not Reported	81%	32%*	14%	11.4(6)	20.5(6)	69%
<b>ESPAC-3 (1088 patients) 2010(4)</b> Treatment Arm: Gemcitabine (537 patients)	73%	43%	64%	24%	Not Reported(5)	14.3	23.6	80%
<b>NLG-0205 (70 patients)</b> Gemcitabine + 5-FU + Radiation + HyperAcute Pancreas	81%	90%*	83%	35%*	17%*	—(7)	—(7)	86%(8)

- (1) Neoptolemos et al., *New England Journal of Medicine* 2004; 350:1200-1210.
- (2) Oettle et al., *JAMA* 2007; 297(3): 267-277.
- (3) Regine et al., *JAMA* 2008; 299(9): 1019-1026.
- (4) Neoptolemos et al., *JAMA* 2010; 304(10):1073-1081.

- (5) Postoperative levels of CA 19-9 were recorded in 373 of the 537 Gemcitabine treatment arm patients. Only patients with CA 19-9 levels in the interquartile (25th to 75th percentile) range of recorded events were reported, with a reported range of 9 to 62 units per milliliter and a median of 22 units per milliliter.
- (6) Regine et al. study in *JAMA* only reports overall survival and disease-free survival for patients with pancreatic head tumors. The median overall survival of all cancer patients treated in RTOG 97-04 is 18.8 months.
- (7) Not estimable as of January 14, 2011.
- (8) Determined by Kaplan-Meier estimation of overall survival at 1 year (68/70 patients evaluable) as of January 14, 2011.
- \* Calculation excludes unknowns

We believe that patient characteristics and treatment regimens used in these prior clinical trials are relevant when comparing NLG-0205 to historical controls; however, variability between patient populations as well as variability in data collection and presentation for these different trials makes direct comparisons complex. Foremost, differences in patient selection may exist between trials due to differences in surgical approaches between United States and Europe. For example, according to Picozzi, in *Business Briefing: US Gastroenterology Review* in 2005, less than 3% of Stage I/II pancreatic cancer patients receive surgery in the United Kingdom versus up to 15% in the United States and up to 40% in Japan. As a result, the baseline characteristics for the RTOG 97-04 and NLG-0205 clinical trials are different compared to the three European trials. Furthermore, the studies do not follow harmonized or standardized study regimens. Nonetheless, the table above demonstrates that whether considering either individual or collective prognostic indicators, patients in NLG-0205 are higher risk patients in comparison to those treated in other clinical trials. The NLG-0205 data gathered to date suggest that these higher risk patients have longer disease-free survival and higher overall survival at 12-months than patients from the other comparator studies.

ESPAC-1, ESPAC-3, CONKO-001 were studies conducted in Europe and thus have notable differences compared to NLG-0205 in terms of patient selection and therapies administered. Relative to NLG-0205, baseline patient characteristics of both ESPAC studies show lower risk profiles as evidenced by substantially lower levels of local invasion as an individual risk factor and by a higher percentage of patients with T1-T2 stage tumors in ESPAC-3 compared to NLG-0205. Furthermore, ESPAC-1 and ESPAC-3 study subjects had lower grade tumors compared to NLG-0205. In terms of historical comparisons between NLG-0205 and other resectable pancreatic cancer trials with curative intent, we believe RTOG 97-04 represents the most appropriate comparator study. RTOG 97-04 baseline patient characteristics are the most similar to NLG-0205 baseline patient characteristics, both studies enrolled patients primarily at major medical centers in the United States and there is minimal difference in treatment regimens between these two trials; specifically, NLG-0205 incorporates the addition of HyperAcute Pancreas to a chemoradiotherapy protocol highly similar to that used in RTOG 97-04.

Since comparisons between specific studies can have distinct limitations, other approaches have been created to evaluate the likely impact of therapies on overall survival. To expand prognostication beyond the TNM system, researchers have developed statistical tools such as multi-component nomograms that incorporate large numbers of independent variables, including adjuvant therapy, to permit calculations of likely outcomes for post-surgical pancreatic cancer patients. One such nomogram has been developed for surgically resected Stage I/II patients based on the interaction of multiple prognostic indicators identified at Memorial Sloan Kettering Cancer Center over a 17-year period. We have evaluated our entire patient population using this nomogram. The nomogram analysis of the NLG-0205 patients predicted a 63% overall survival at one year following standard therapy. This is in contrast to one-year Kaplan-Meier estimated survival rates of 86% for all patients and 96% for high dose patients in our clinical trial. We believe this represents an additional demonstration that the survival data from NLG-0205 is consistent with an improvement in survival arising from the use of HyperAcute Pancreas in the adjuvant setting.



## **Our HyperAcute Lung Cancer Immunotherapy Product Candidate**

Our HyperAcute Lung product candidate is being studied in a combined Phase 1/2 clinical trial that is fully enrolled with 54 patients for the treatment of refractory, recurrent or metastatic nonresectable NSCLC. This trial is being conducted at the NCI. HyperAcute Lung consists of a group of three separate allogeneic lung tumor cell lines that were modified to express the gene that makes a-GT. These three cell lines are representative of the three major types of NSCLC. Each of the modified cell lines is grown in large cultures, harvested, irradiated, and packaged. Approximately 100 million cells of each HyperAcute Lung cell line are given by intradermal injection with each treatment.

### ***Market Opportunity***

According to the American Cancer Society, lung cancer is the leading cause of cancer-related death in the United States. The NCI estimates that over 157,000 Americans will die of the disease in 2010, accounting for approximately 28% of all cancer deaths. Lung cancer is most often diagnosed at advanced stages when it is difficult to treat. According to the American Cancer Society, about 85% to 90% of lung cancers are classified as NSCLC. The remainder are called small cell lung cancer. The American Cancer Society also reports that about 80% of NSCLC cases are detected when they have progressed to stages III or IV. A study published in the *Journal of Clinical Oncology* in 2004 states that the current expected overall survival for a nonresectable stage IIIB or IV NSCLC patient who has failed first line treatment is approximately eight months.

### **Clinical Trials**

#### ***Phase 1/2 Clinical Trial***

HyperAcute Lung is currently in a Phase 1/2, single-arm, open-label clinical trial that is fully enrolled with 54 patients at the NCI. This clinical trial is for patients with refractory, recurrent or metastatic NSCLC. Its primary endpoint is to assess tumor response rate after administration of HyperAcute Lung, and the secondary endpoint is to assess overall survival. For the Phase 1 portion of this clinical trial, a positive response included stable disease for 16 weeks in patients who had enrolled after having previously shown progressive disease. A total of 17 patients in the Phase 1 portion and 37 patients in the Phase 2 portion were injected with HyperAcute Lung. Of the 37 patients in the Phase 2 portion, only 28 were evaluated for clinical response. In the Phase 1 portion, four cohorts of patients each received injections of 3 million, 10 million, 30 million, or 100 million cells every four weeks for four doses, and one cohort of three patients received an initial dose of 500 million cells, followed by injections of 300 million cells every two weeks for up to seven doses. In the Phase 2 portion, the 28 patients evaluated received injections of 300 million cells every two weeks for up to eight doses.

The interim results of our Phase 1/2 clinical trial for HyperAcute Lung based on an interim analysis of 45 patients who had reached median follow-up of 30 months as of September 30, 2010, were encouraging. The interim results for the 28 patients evaluated in the Phase 2 clinical trial group showed a median progression-free survival of 14.6 weeks, median overall survival of 11.3 months, and a one-year survival rate of 46%. Median overall survival data from the Phase 2 clinical trial group was better than the Phase 1 clinical trial group (11.3 versus 7.6 months), a comparison that would be consistent with study drug dose dependency. Overall survival of patients in our Phase 1/2 clinical trial trended with the persistent elevation of anti-a-Gal immunoglobulin (IgG) antibodies. Some patients with longer overall survival demonstrated increased secretion of interleukin-5 (IL-5) and gamma-interferon (IFN $\gamma$ ).

Prior Phase 3 studies suggest that in the refractory, recurrent or metastatic NSCLC setting (second line therapy), the median overall survival of patients receiving best supportive care was 4.6 months and the median overall survival of patients receiving pemetrexed or docetaxel (Taxotere) therapy was approximately eight months. We believe the data from our Phase 1/2 clinical trial is encouraging and suggests that further studies are warranted. The initial Phase 1/2 clinical trial was amended to collect lung biopsies before and after administration of the immunotherapy to study in detail immunological

responses to the therapy within the lung. Data from this analysis should be available in 2011. We are currently evaluating alternative designs for a Phase 2B/3 clinical trial in NSCLC with an adaptive design, which we plan to initiate in the second half of 2011. The following table shows comparative results for second-line treatment in advanced NSCLC with pemetrexed, docetaxel and HyperAcute Lung.

#### Treatment Options and Clinical Outcomes in 2<sup>nd</sup> Line Advanced Stage NSCLC

Therapy	Overall Survival (Months)	12 Month Survival	Serious Adverse Events (CTC Grade 3 or 4) Attributed to Therapy			
			Nausea	Fatigue	Anemia	Neutropenia
Docetaxel(1)	7.9	30%	1.8%	5.4%	4.3%	40.2%
Pemetrexed(2)	8.3	30%	2.6%	5.3%	4.2%	5.3%
HyperAcute Lung(3)	11.3	46%	0%	0%	0%	0%

- (1) Prospective Randomized Trial of Docetaxel versus Best Supportive Care in Patients with Non-Small-Cell Lung Cancer Previously Treated With Platinum-Based Chemotherapy. Frances A. Shepherd et al., *Journal of Clinical Oncology*, Volume 18, No. 10 (May), 2000: pp 2095-2103
- (2) Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients with Non-Small-Cell Lung Cancer Previously Treated with Chemotherapy. Hanna N. Shepherd et al., *Journal of Clinical Oncology* 2004 May 1; 22(9):1589-97
- (3) Data from NLG0101 clinical trial Patients 18-45

The Phase 1 portion of our Phase 1/2 clinical trial for our HyperAcute Lung demonstrated a favorable safety profile, with no dose limiting toxicities at any of the five escalating dose levels. There have been no reported CTC grade four adverse events attributed to HyperAcute Lung and only one serious adverse event (CTC grade three lymphopenia) characterized by investigators as possibly or probably attributable to HyperAcute Lung. The most common treatment-related adverse reactions (reported by at least 5% of patients) for HyperAcute Lung were injection site reaction (92%), induration (56%), fatigue (25%), urticaria (12%), anemia (7%), pruritus (7%), lymphopenia (7%), elevated serum amylase (5%), edema (5%), skin pain (5%) and dyspnea (5%). The clinical trial involved a dose escalation from approximately three million up to 300 million cells in repeat dosing. Only a single dose escalation has been required by the FDA in all subsequent clinical trials of our other HyperAcute product candidates conducted to date.

#### Our HyperAcute Melanoma Immunotherapy Product Candidate

Our HyperAcute Melanoma product candidate is being studied in an investigator-initiated Phase 2 clinical trial in 25 patients with advanced melanoma. In this trial, HyperAcute Melanoma is being administered in combination with an eight-week course of PEG-Intron, a man-made immune modulator that has been tested for the treatment of melanoma. HyperAcute Melanoma consists of a group of three allogeneic melanoma tumor cell lines that were modified to express the gene that makes a-GT. These three cell lines each possess collections of known melanoma antigens so that the immune response they stimulate will provide broad coverage. Each of the modified cell lines is grown separately in large cultures, harvested, irradiated and packaged. Approximately 50 million cells of each HyperAcute Melanoma cell line are given by intradermal injection with each treatment.

#### Market Opportunity

Melanoma is an often lethal form of skin cancer. If it is not recognized and treated early, the cancer can advance and spread to other parts of the body, where it becomes hard to treat and can be fatal. While it is not the most common of the skin cancers, it causes the most deaths. The American Cancer Society estimates that in 2009 there were 8,650 deaths from melanoma in the United States and there will be approximately 68,000 new cases of melanoma in the United States in 2010.

## **Phase 2 Clinical Trial**

We are currently providing HyperAcute Melanoma product to, and collaborating with, Dr. Adam Riker at the Ochsner Cancer Institute in New Orleans, Louisiana, in support of a Phase 2 investigator-initiated clinical trial studying HyperAcute Melanoma in combination with an eight week course of PEG-Intron for patients with advanced melanoma. The treatment consists of 12 weekly injections of HyperAcute Melanoma with PEG-Intron being co-administered in weeks five through 12. This is the first time that one of our HyperAcute immunotherapies has been combined with another approved immunotherapy, in this case PEG-Intron. The primary objective of this clinical trial is to conduct correlative scientific studies of patient tumor and peripheral blood samples to determine the mechanism of any observed anti-tumor effect involving the innate and cell-mediated host immune response to HyperAcute immunotherapy alone and combined with PEG-Intron. Although the number of patients in this clinical trial is modest, the results to date are encouraging.

We continue to look for immunological evidence that our HyperAcute immunotherapies are working as expected. All of the patients in the clinical trial developed low levels of autoimmune antibodies as a result of the immunotherapy and approximately one-third of the patients developed a condition called vitiligo. Both of these observations suggest an immunological response to the HyperAcute Melanoma. Vitiligo is an autoimmune condition in which the patient's immune system attacks melanocytes, the cells responsible for skin pigmentation and potential melanoma cancer cells. Other than vitiligo, no other clinically apparent autoimmune disorder has been reported in any patient to date. Patient outcomes of two prior clinical trials of immunotherapies not conducted by us indicated that the development of vitiligo was correlated with a favorable response to therapy in melanoma patients. Two of the eight patients with metastatic disease in our Phase 2 clinical trial had complete responses to therapy. To date, HyperAcute Melanoma has demonstrated good tolerability and a favorable safety profile, with no systemic, drug-related serious adverse events characterized by the investigators as possibly or probably attributable to our product candidate. The most common non-serious adverse events reported were injection site reactions, induration, diarrhea and nausea. The small scale of this clinical trial and the fact that it was performed at a single institution limit our ability to draw significant conclusions from the data; however, durable complete responses to metastatic disease in this setting are rarely seen.

The investigator-initiated Phase 2 clinical trial of our HyperAcute Melanoma product reached its 25-patient enrollment goal in September 2010, and we anticipate updating the data from this clinical trial in the second half of 2011. While preliminary analysis of the data from this Phase 2 clinical trial is encouraging, we are in the process of further evaluating the optimal clinical settings and drug combinations that may maximize the potential benefits of HyperAcute Melanoma. Therefore, we are currently developing clinical trial designs to further evaluate the efficacy of HyperAcute Melanoma either as a stand-alone or combination therapy.

## **Our Other HyperAcute Cancer Immunotherapy Product Candidates and Indications**

We believe we have developed a process to efficiently discover and develop new tumor-specific HyperAcute immunotherapies for other solid tumor types. We have initiated clinical development for our HyperAcute Prostate and HyperAcute Breast product candidates and are developing our HyperAcute immunotherapy technology for other indications.

### ***Our HyperAcute Prostate Cancer Immunotherapy Product Candidate***

Prostate cancer is one of the most common forms of cancer affecting men. According to the American Cancer Society, there will be over 217,000 patients diagnosed with prostate cancer in the United States in 2010. Increased screening over the past few decades has enabled physicians to detect prostate cancer in its early, more treatable stages. Nonetheless, while overall five-year survival rates for cases of prostate cancer approach 100%, the outlook for advanced, metastasized cases is poor with five-year survival rate of 31%, according to the American Cancer Society.

We have completed an open-label, single-center Phase 1 clinical trial for our HyperAcute Prostate product candidate. This clinical trial enrolled eight patients with hormone refractory prostate cancer that had recurred or no longer responded to standard treatment. Study participants received 12 bi-weekly intradermal injections of HyperAcute Prostate, which consists of two separate allogeneic prostate cancer cell lines that were selected based on antigen profiles and modified to express the gene that makes a-GT. The primary endpoint for this clinical trial was safety and efficacy of administration. We successfully completed this clinical trial in August 2008. We observed no dose-limiting toxicities and only one serious adverse event (CTC grade three anemia) was reported by the investigator as possibly attributable to HyperAcute Prostate. Median survival was 25.1 months (range 5-60 months) with one treated patient remaining alive at 60 months with stable Prostate Specific Antigen and unchanged bone metastasis since 2007. Although we currently do not have an active IND for this indication due to resource constraints, we believe HyperAcute Prostate could provide a valuable treatment alternative for many prostate cancer patients.

#### ***Our HyperAcute Breast Cancer Immunotherapy Product Candidate***

According to the American Cancer Society, carcinoma of the breast is the second leading cause of cancer death in women in the United States with over 207,000 new cases and 39,800 deaths estimated in 2010. Increased access to improved screening methods has had a major impact on reducing deaths from this disease; however, despite these interventions, patients continue to present with nodal or metastatic lesions that carry poor prognoses.

We initiated an open-label, single-center Phase 1 clinical trial for our HyperAcute Breast product candidate. Three patients were enrolled in this clinical trial. Due to resource constraints, the clinical trial was suspended.

HyperAcute Breast consists of two allogeneic breast cancer cell lines genetically modified to express the gene that makes a-GT. The cell lines selected for inclusion in this drug represent both estrogen receptor positive and estrogen receptor negative examples of disease. The cell lines of the drug are manufactured with growth nutrient in media by concentrating, irradiating and compounding in a cryopreservative solution. Although we currently do not have an active IND for this indication, we believe HyperAcute Breast could provide a valuable treatment alternative for many breast cancer patients.

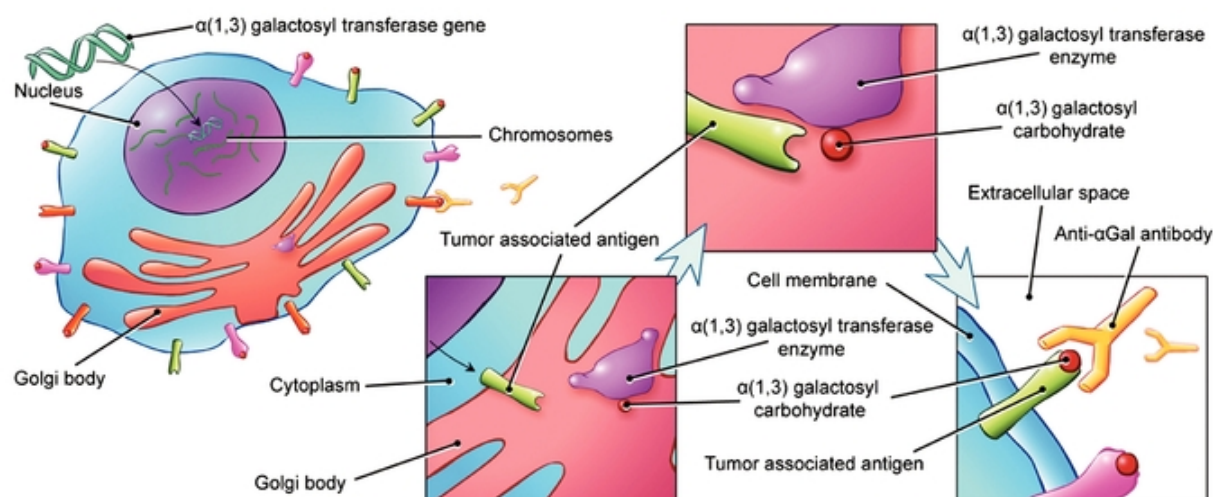
#### **Our HyperAcute Cancer Immunotherapy Technology**

Compared to prior immunotherapy approaches, our proprietary HyperAcute immunotherapy technology offers several distinct advantages including:

- a robust innate immune response that harnesses the human body's naturally protective and rapid immune reaction to the a-Gal carbohydrate to fight cancer;
- a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- an allogeneic, or non-patient specific, approach, in which we manufacture products from genetically modified, allogeneic cells from previously established cell lines, which permits an easier scale-up of the manufacturing process compared to an autologous, or patient specific, approach involving a patient's own cells.

We believe our HyperAcute immunotherapies operate by exploiting a natural barrier present in humans that protects against infections being transmitted from other mammals. This barrier is related to the enzyme a-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the expression of a non-human form of carbohydrate called a-Gal on the surface of affected cells. Introducing a-Gal expressing cells to the human or primate immune system activates an immune response from antibodies against a-Gal.

Antibodies directed against the a-Gal epitope are potentially the most abundant antibody in humans and represent approximately 1% of circulating human antibodies.



The figure above represents our HyperAcute Immunotherapy process. The a-GT gene is inserted into the chromosome within the cancer cell. The gene then yields a protein called a-GT enzyme which is located within the Golgi body of the cell where macromolecules, such as proteins and lipids, are processed and packaged. Proteins, like the illustrated tumor associated antigen, that are processed through the Golgi, are tagged with a-Gal carbohydrate and placed on the surface of the cell. The a-Gal carbohydrate located on the surface of the tumor associated antigen is now targeted by anti-aGal antibodies causing the hyperacute immune response to be initiated.

HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes a-Gal epitopes. This exposure to a-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which a-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti a-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens common to both the immunotherapy and the patient's tumor cells.

In the early 1990s, the NCI conducted experiments in brain cancer patients involving the implantation of mouse cells that had been engineered to produce a virus to genetically attack cancer cells in the brains of cancer patients. Promising results in these clinical trials led our founder and others to attempt a similar experiment in ovarian cancer patients in 1995. However after that therapy, genetic testing of biopsies from these patients demonstrated that this gene transfer approach was ineffective. Nonetheless, the clinical trial suggested clinical benefit in four of nine evaluated patients. During the clinical trial, it was observed that the ovarian cancer patients had a vigorous immune response to the infusion of the mouse cells, characterized by fever and abdominal pain. Further study and comparison to the work of transplant scientists who were attempting to understand the mechanism of xenotransplant rejection (the rejection of tissues transplanted from a different species) identified a carbohydrate on the surface of mouse cells known as a-Gal that may have triggered the ovarian cancer patient's immune systems to mount an attack on the mouse cells. This immune response was led by existing anti-a-Gal antibodies in a manner very similar to "hyperacute rejection," the rapid destruction of tissues transplanted from lower animals.

Evolutionary biologists believe that the ancestors of humans lost the functional gene to produce a-Gal about 25 million years ago. Because the cells or pathogens originating in nonhuman species (for example domestic pets) contain a-Gal, they are rapidly destroyed by anti- a-Gal antibodies present in substantially all humans. This process likely helps humans to defeat infection from other species.

Humans develop these antibodies as a result of constant exposure to a-Gal from the beneficial bacteria normally found in the digestive system and through exposure to cells carrying a-Gal on the meat in the diets of humans. We believe the cancer cells in the ovarian cancer patients were immunologically destroyed as a result of being adjacent to the mouse cells carrying the a-Gal gene, and we term this the "hyperacute" response.

In the case of a HyperAcute cancer immunotherapy, this process results in immune cells that are educated to attack a patient's own cancer cells by virtue of the antigens which the immunotherapy and these tumor cells share and by a more generalized activation of the immune system. Our scientists have shown in mouse models of cancer that the immune system responds after a HyperAcute injection by attacking all similar cancer cells, including those that have no a-Gal carbohydrate. In the case of a HyperAcute viral immunotherapy, because of the high concentration of anti-a-Gal antibodies, there is a clearance and processing of immunotherapy containing the a-Gal epitope, significantly boosting immune responses to some target pathogens.

HyperAcute immunotherapies are designed to break tolerance and enable longer duration of anti-tumor effect. We believe that our HyperAcute immunotherapy technology induces a unique combination of advantageous immunologic effects. Our current understanding of the mechanism of HyperAcute immunotherapy includes the following concepts, although our understanding of this technology continues to evolve. The immune response is triggered by formation of immunocomplexes between the a-Gal-containing cells or viral vaccines and pre-existing, naturally occurring, high-titer antibodies to a-Gal that are present in every patient screened by us to date. Formation of immunocomplexes by complement-fixing anti-Gal antibodies activates complement-mediated cell lysis, which generates immune system "danger signals" that elicit activation and recruitment of antigen presenting cells, or APCs, of multiple lineages. The anti-a-Gal-dependent generation of immune responses involves activation of multiple types of immune system effector cells, such as dendritic cells, macrophages and natural killer (NK) cells. These cells which have taken up the lysed or fragmented HyperAcute immunotherapy cells have responses against multiple tumor targets and act by different modes of action, both cellular and antibody mediated. The process of FcγR-mediated phagocytosis, whereby antibodies bind to the immunotherapy cells and form a connection to a specific region that facilitates uptake by APCs, results in activation of certain immune cells called cytotoxic CD8<sup>+</sup> T-cells and CD4<sup>+</sup> helper T-cells, as well as stimulation of tumor antigen-specific B-cells. Hyperacute immunotherapy has produced long-term complete responses in an animal model of metastatic disease. Further study in human cancer patients will need to be correlated with observations in preclinical models.

### **Our IDO Pathway Inhibitor Product Candidate**

We are developing d-1-methyltryptophan, or D-1MT, a small-molecule, orally bioavailable product candidate based on our proprietary IDO pathway inhibitor technology. Preclinical experiments have demonstrated a strong, synergistic anti-tumor effect without increased toxicity when D-1MT was administered in combination with a number of currently available chemotherapeutic agents. D-1MT is currently being evaluated for the treatment of a broad range of solid tumors in chemotherapeutic and immunotherapeutic combinations in two Phase 1B/2 clinical trials.

### **Clinical Trials**

#### ***Phase 1B/2 Clinical Trials***

We currently have two Phase 1B/2 clinical trials enrolling patients to evaluate D-1MT in combination with other approved therapies. The first clinical trial has primary endpoints that assess safety and efficacy of D-1MT in combination with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. As of October 10, 2010, eight patients have been enrolled in the Phase 1B dose escalation portion of this clinical trial. The Phase 2 clinical trial portion of the D-1MT/Ad-p53 study will expand primarily to enroll patients with metastatic

breast cancer. The second clinical trial has primary endpoints that assess safety and efficacy of D-1MT in combination with Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. As of October 10, 2010, patients are being screened for enrollment in the Phase 1B dose escalation portion of this clinical trial. The Phase 2 clinical trial portion of the D-1MT/Taxotere study will expand primarily to enroll patients with metastatic breast cancer. We believe D-1MT has the potential to have a synergistic therapeutic effect in combination with Ad-p53 or Taxotere without adding systemic safety complications. The clinical trials are being co-sponsored by the NCI's Division of Cancer Treatment and Diagnosis under a Cooperative Research and Development Agreement and letter of intent and are taking place at the Moffitt Cancer and Research Institute in Tampa, Florida.

According to the American Cancer Society, in the United States, breast cancer is the most common cancer among women, other than skin cancer. According to the American Cancer Society, there are projected to be approximately 207,000 new cases in 2010, and approximately 39,800 patients are expected to die of the disease. The disease comes in different forms depending on whether the tumor is driven by signaling through the estrogen receptor (approximately 70% of patients), the HER2/neu receptor (approximately 15-20% of patients), or neither. In the early stages, breast cancer may have no symptoms and can be detected only through mammography screening. During the later phases, symptoms may include tenderness, swelling, lumps, and skin irritation. Treatment of breast cancer typically includes surgery to remove tumors and lymph nodes. Usually a combination of radiation, chemotherapy or hormonal therapy is used post-surgery. Although the use of mammography screening has driven a trend toward earlier-stage diagnosis and decreased mortality, approximately 5% of new breast cancer cases will be Stage IV at the time of diagnosis in 2010. Metastatic breast cancer can be treated with a variety of monotherapy or combination drug regimens. According to the NCI, the overall five-year survival rate for breast cancer is 89%, but the outlook for advanced metastasized cases is poor with five-year survival rates of 23.4%.

### ***Phase 1 Clinical Trials***

We have nearly completed two Phase 1 clinical trials of D-1MT as a single agent. These Phase 1 clinical trials were open to all tumor types and enrolled patients with a wide variety of cancers. The principal goal of these trials was to demonstrate that patients can tolerate the drug and that increasing quantities of the drug can be administered without inducing toxicity that would prevent the attainment of efficacy. We have observed an encouraging safety profile, with one reported CTC grade four (cerebrovascular ischemia) and two reported CTC grade three (lymphopenia) serious adverse events characterized by the investigators possibly, probably or definitely attributable to D-1MT in the clinical trial combining D-1MT with Ad-p53. There have been no reported serious adverse events characterized by the investigators as attributable to D-1MT in the clinical trial combining D-1MT with Taxotere. We may reach the end of the clinical trial without demonstrating dose-limiting toxicity or maximum tolerated dose. In addition to toxicity data, we have completed pharmacokinetic studies demonstrating that drug concentrations in the ranges anticipated to have biologic effects can be reached with the doses we are administering in our on-going Phase 1B/2 clinical trials. Finally, we have observed significant biologic effects in a small group of patients previously sensitized to immunotherapy. The drug appears to produce detectable immune system activation.

### ***Our IDO Pathway Inhibitor Technology***

IDO pathway inhibitors, including D-1MT, represent a potential breakthrough approach to cancer therapy using small-molecule, anti-toleragenic product candidates intended to combat the mechanisms by which tumors evade immune-mediated destruction. IDO is an enzyme that regulates immune response by suppressing T-cell function and creating local tumor immune escape. Recent studies have demonstrated that IDO is overexpressed in many cancers, within both tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor draining lymph nodes whereby IDO promotes peripheral tolerance to TAAs. When hijacked by developing cancers in this manner, IDO



may facilitate the survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system as foreign.

We believe that immune system failure is a fundamental reason for the inability of the human body to successfully fight cancer cells. Research into the inability of the immune system to respond to cancerous tumors indicates that tumors can induce the human immune system to tolerate the existence of the tumor. This immune tolerance and suppression represents a major barrier to successful treatment of cancer and is a significant target for new therapeutics.

Scientific understanding of the process leading to immune tolerance is in its early stages. We believe IDO is part of a system that may be used by some tumors as a mechanism to evade the immune system. IDO is an enzyme that regulates immune response by suppressing effector T-cell function by breaking down the essential amino acid tryptophan. Expression of IDO, either directly by tumors or by dendritic cells in tumor-draining lymph nodes, has been shown in animal studies to induce immune tolerance to tumors, and inhibition of IDO has been shown in these studies to prevent this induction of tolerance. IDO is rarely expressed by the majority of normal tissues, but it is overexpressed in many types of human tumors.

Cytotoxic chemotherapy places substantial stress on established, tumor-induced tolerance. Several factors can potentially contribute to this result: (1) dying tumors cells release waves of TAAs for processing and presentation, (2) many chemotherapeutic regimens induce a period of transient lymphopenia and homeostatic recovery during which T-cells may become more susceptible to breaking tolerance, and (3) certain regimens can transiently deplete or inactivate tumor-protective T-regulatory cells. Despite producing these challenges to tolerance, most chemotherapeutic agents do not appear to trigger a protective immune response against established tumors. This shortcoming of traditional chemotherapy has been attributed, in part, to the ability of tumors to rapidly reestablish tolerance following each cycle of chemotherapy. We believe a potential mechanism underlying the failed opportunity is IDO expression by APCs in tumor-draining lymph nodes, which are thereby converted to an immunosuppressive and tolerance-inducing milieu. Preclinical data have demonstrated that IDO pathway inhibitors have anti-tumor effects in combination with a number of radiotherapy, chemotherapeutic drugs or other immunotherapy drug candidates and may work better together than either type of treatment alone.

The ability to acutely eliminate the protective IDO mechanism by administering IDO pathway inhibitor drugs, such as D-1MT, may provide a therapeutic window in which to break tolerance in tumors and reverse the inhibition of immune cells. Additionally, we believe that once immune cells are restored to normal function, they can assist in the rejection of tumors.

We believe our IDO pathway inhibitor technology has the following potential advantages in combating cancers:

- *Potential to break immune tolerance.* The immune tolerance to cancerous cells represents a key barrier to the treatment of cancer. To date, few available therapies have addressed the immune escape mechanisms of cancer. We believe inhibition of the IDO pathway has the potential to break a key immune escape mechanism of cancer cells and significantly enhance patient outcomes.
- *Tolerability.* In early-stage clinical development, we have observed an encouraging safety profile. We believe inhibition of the IDO pathway will selectively enhance the immune response against cancer cells given the limited expression of IDO in normal cells.
- *Oral bioavailability.* Unlike many cancer therapies which require intravenous administration, our D-1MT IDO pathway inhibitor is orally bioavailable, a significant advantage in ease of administration for patients and physicians.
- *Synergy with existing cancer therapies.* Inhibiting the IDO pathway in conjunction with chemotherapy has the potential to enhance the therapeutic effect of chemotherapy by delaying



or disrupting the reacquisition of immune tolerance to tumor antigens during the period following chemotherapy. We believe our IDO pathway inhibitors could also have therapeutic synergy with targeted therapeutics, radiation and immunotherapy. The safety profile in humans is conducive to exploring combination therapy and the available animal data does not indicate significant additive or synergistic toxicities with many common oncology therapies.

### **BioProtection Systems Corporation**

BioProtection Systems Corporation, or BPS, was founded by the Company as a subsidiary in 2005 to research, develop and commercialize vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid-response prophylactic and therapeutic treatment for pathogens likely to be targeted to the human population through acts of bioterrorism. In 2010, we owned a majority of BPS's common stock on an as-converted basis. On January 7, 2011, we acquired the minority interest in BPS and BPS became a wholly-owned subsidiary of the Company.

BPS is based upon three core technologies, each of which can be leveraged into the biodefense field. The first is our HyperAcute immunotherapy technology, which has been licensed from us for the biodefense field. The second technology, based on a yellow fever virus, is in licensed from the University of California at San Francisco. The third technology is replication competent recombinant Vesicular Stomatitis Vaccine, or rVSV, an advanced vaccine technology developed for the Marburg and Ebola viruses.

### ***BPS Grants and Contracts with the United States Government***

On August 26, 2009, BPS received a grant from the NIH for the study of Rift Valley fever virus in the aggregate amount of \$536,000, of which BPS has billed \$446,000 through January 31, 2011 (\$446,000 through December 31, 2010). This grant provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. The project period for this grant is from July 1, 2005 to June 30, 2011.

On April 06, 2010, BPS received a grant from the NIH for the study of yellow fever and arena viruses in the aggregate amount of \$300,000, of which BPS has billed \$176,000 through January 31, 2011 (\$153,000 through December 31, 2010). This grant provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. BPS retains the principal worldwide patent rights to any invention developed with support of the grant and the United States receives a royalty free license to use such inventions. The project period for this grant is from April 6, 2010 to March 31, 2012.

Contract between BPS and the DOD, dated July 31, 2009, as amended on April 21, 2010, for the study of Venezuelan equine encephalitis virus in the aggregate amount of \$750,000, of which BPS has billed \$520,000 through January 31, 2011 (\$500,000 through December 31, 2010). This contract provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. The period of performance for this contract is from July 31, 2009 through July 30, 2011.

Contract between BPS and the DOD, dated May 5, 2008, as amended February 12, 2009, for the study of adjuvant technology in the aggregate amount of \$100,000, of which BPS has billed \$100,000 through January 31, 2011 (\$100,000 through December 31, 2010). This contract provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. The period of performance for this contract was from May 5, 2008 through May 1, 2009.

On September 25, 2009, BPS entered into a research and development contract with DOD for the study of a-Gal adjuvant technology for the biodefense field. The contract provides for reimbursements to BPS for certain research and development activities on a cost-plus-fixed-fee basis. The contract involves an initial two-year contract period during which BPS may receive reimbursements for aggregate amounts of up to approximately \$3.7 million. Following the initial two-year period, DOD may exercise an option

to extend the contract for an additional one-year period during which BPS may receive reimbursements for aggregate amounts of up to an additional approximately \$7.0 million. As of December 31, 2010, BPS had submitted reimbursement requests for approximately \$929,000 for research and development performed under the contract during the initial contract period. BPS is permitted to retain ownership of inventions made by BPS under the contract subject to BPS's compliance with certain specified procedures.

## **Manufacturing**

To date, we have manufactured our HyperAcute immunotherapies in our facilities in Ames, Iowa. We are in the process of transferring all of our manufacturing to a new facility also located in Ames. We believe this facility is adequate to supply all of the Phase 3 clinical trial drug requirements for at least the first two of our HyperAcute product candidates and initial commercial quantities of HyperAcute Pancreas in the United States. We are in the process of finalizing manufacturing process improvements that have the potential to significantly increase our production capacity.

We currently contract with Sigma-Aldrich Fine Chemicals, a division of Sigma-Aldrich Corporation, for the manufacture of our D-1MT product candidate. We believe that many suppliers would be available for the production of this product, if required. We currently have no plans to build our own manufacturing capacity to support this product.

## **Sales and Marketing**

We currently own exclusive worldwide commercial rights to our HyperAcute and D-1MT immunotherapy product candidates. If we obtain approval for any of these product candidates, we intend to build a commercial infrastructure targeting oncologists and cancer centers in the United States. In addition, we may pursue partnerships or co-promotion arrangements with pharmaceutical and biotechnology companies to complement these efforts or for particular indications.

We expect that our commercial infrastructure would be comprised of a targeted specialty sales force led by several experienced sales management personnel, an internal marketing and medical affairs staff and a specialty distribution team. For our lead product candidate, HyperAcute Pancreas, we estimate that an initial sales force of approximately 50 to 100 representatives will be necessary to drive utilization at key institutions and cancer centers treating pancreatic cancer patients. Our sales infrastructure will also include managed markets personnel to establish and direct reimbursement activities with third-party payors, such as managed care organizations, group-purchasing organizations, oncology group networks and government accounts. We may need to hire personnel to fill some of these functions in advance of the approval of any of our product candidates. We currently have no sales and marketing or distribution capabilities or in-house personnel specializing in these functions.

Outside the United States, we may enter into out-licensing agreements with other pharmaceutical or biotechnology firms to develop and commercialize our product candidates in foreign markets.

## **Competition**

The biopharmaceutical industry is highly competitive. Given the significant unmet patient need for new therapies, oncology is an area of focus for many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

### ***Immunotherapy Products for Cancer***

The cancer immunotherapy landscape is broad but still in the early stages of development as a class of therapeutics with only one FDA-approved active cellular immunotherapy product, Dendreon Corporation's Provenge for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. We estimate that there are over 100 cancer immunotherapy products in clinical development by approximately 70 public and private biotechnology and pharmaceutical companies. Altogether, trials of these product candidates target at least 23 different cancer types. Of this universe, several large public biopharmaceutical companies have approved or are developing cancer immunotherapy products, including Dendreon Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline plc, Merck & Co., Inc., Merck KGaA and Sanofi-Aventis. The cancer immunotherapy product landscape includes numerous immunotherapeutic approaches including but not limited to anti-idiotype, whole cell, DNA, peptide/antigen, viral, tumor lysate, shed antigens, and dendritic cell. To the extent applicable, cancer immunotherapies are also distinguished by whether or not they are derived from autologous or allogeneic sources. Different approaches to cancer immunotherapy design have the potential to confer corresponding advantages and disadvantages based on their respective immunostimulatory mechanisms, formulation characteristics, manufacturing requirements, and logistical demands.

### ***HyperAcute Pancreas***

There are several marketed products indicated for pancreatic cancer including Eli Lilly and Company's Gemzar, Astellas Pharma Inc.'s Tarceva, Teva Pharmaceutical Industries Limited's streptozocin, and fluorouracil, or 5-FU, and mitomycin which are marketed by several generic pharmaceutical firms. In addition, there are a number of companies with active clinical trials ongoing in pancreatic cancer including AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics Inc., Sanofi-Aventis, and Threshold Pharmaceuticals, Inc. among other companies.

### ***HyperAcute Lung***

There are numerous marketed therapeutics indicated for NSCLC including Roche Holding AG's Avastin, Eli Lilly's Alimta and Gemzar, Astellas Pharma's Tarceva, AstraZeneca PLC's Iressa, Sanofi-Aventis' Taxotere and Eloxatin, as well as generically available platinum-based chemotherapeutics

(cisplatin and carboplatin) and mitotic inhibitors (paclitaxel and vinorelbine) which are marketed by several generic pharmaceutical firms. In addition, there are a number of companies with active clinical trials ongoing in lung cancer including to Abbott Laboratories, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim GmbH, BioNumerik Pharmaceuticals, Inc., Celgene, GlaxoSmithKline, NovaRx Corporation, Onyx Pharmaceuticals, Inc., Pfizer Inc., Regeneron Pharmaceuticals, Inc. among other companies.

### ***HyperAcute Melanoma***

Excision is the preferred treatment for early stage, localized melanoma, and there are several marketed therapeutics indicated for advanced melanoma including Merck's Intron A, Novartis AG / Prometheus Laboratories Inc.'s Proleukin as well as cisplatin and dacarbazine, which are available through several generic pharmaceuticals firms. Bristol-Myers Squibb's immunotherapy ipilimumab is pending FDA approval for use as a monotherapy. In addition, there are a number of companies with active clinical trials ongoing in advanced melanoma including Astellas Pharma, Eli Lilly, Onyx, Plexxikon Inc., Roche, Synta Pharmaceuticals Corp., and Vical Inc., among other companies.

### **Intellectual Property**

We believe that patent protection and trade secret protection are important to our business and that our future success will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain and maintain patents and operate without infringing the proprietary rights of others both in the United States and abroad. We believe that obtaining identical patents and protection periods for a given technology throughout all markets of the world will be difficult because of differences in patent laws. In addition, the protection provided by non-U.S. patents, if any, may be weaker than that provided by United States patents. We have established and continue to build proprietary positions for our HyperAcute Technology and our IDO pathway inhibitor technology in the United States and abroad. As of September 30, 2010, our patent portfolio included six patent families relating to our HyperAcute Technology and nineteen patent families relating to our IDO pathway inhibitor technology.

There are two principal families of patents and patent applications relating to our HyperAcute product candidates and HyperAcute Technology. The first patent family is exclusively licensed from Central Iowa Health System and includes five pending patent applications and 20 registered U.S. and foreign patents related to the HyperAcute Technology. This patent family is expected to provide basic composition of matter patent protection extending until 2023 and has already resulted in a granted patent in Europe (EP 1549353 B1) and in Mexico (278681) both covering pharmaceutical compositions for inhibiting pre-established tumor growth comprising attenuated allogeneic tumor cells modified with a-Gal. Similar composition claims as well as methods of use for treating pre-established tumors are currently being pursued in the U.S., China, Japan and Canada. One patent recently issued from this family in the U.S. and contains claims to methods of making master cell banks of HyperAcute allogeneic cells (US 7,763,461).

The second principal family of patents is exclusively licensed from Drexel University and includes two U.S. patents (US 6,361,775 and US 5,879,675) relating to the use of a-Gal in viral and cancer vaccines. These patents expire in 2014 and 2016, respectively, in the United States. Related patents in this family have also been granted in Canada and Europe and expire in 2014. We exclusively license from Central Iowa Health System or own several other patents relating to a-Gal technology, which we believe provide additional barriers to entry in the space occupied by our HyperAcute Technology. Additional coverage includes issued patents relating to gene therapy technology and the use of xenogeneic cells having a-Gal expiring in 2016 and 2020, respectively; and a pending application in the United States and Europe covering isolated tumor antigens comprising a-Gal residues and projected to expire in 2027.

Our IDO pathway inhibitor technology patent portfolio contains several key U.S. patent families exclusively licensed from the Medical College of Georgia. The first patent family contains three issued

U.S. patents and two pending applications, all expiring in 2018. This family contains patents having claims to methods of increasing T cell activation (US 6,451,840) and methods of augmenting rejection of tumor cells (US 6,482,416) by administering an IDO inhibitor. The second patent family contains four pending applications and an issued U.S. patent (US 7,598,287) to methods of using D-1MT to treat cancer and provides exclusivity for this use until 2024. We are also actively pursuing pharmaceutical composition claims to D-1MT in the U.S. in a pending application from this family, and also claims to the use of D-1MT to activate T cells in Europe, Australia and Canada out of another Medical College of Georgia patent family that if granted, will provide exclusivity for this use in validated European countries until 2022. Related applications are pending in Australia and Canada. We believe additional barriers to entry in the IDO space are provided through exclusive licenses with Lankenau Institute for Medical Research and various NewLink-owned inventions, in which we are pursuing patent protection for specific combination therapies targeting the IDO pathway, as well as protection for novel inhibitor compounds and potential second generation products.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also oblige our employees, consultants, advisors and collaborators to assign or license to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products or new technologies that may be competitive with those being developed by us. Therefore, our product candidates may give rise to claims that it infringes the patents or proprietary rights of other parties now or in the future. Furthermore, to the extent that we, our consultants, or manufacturing and research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights to such intellectual property or in related or resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that we are prevented from the development, manufacture or sale of products requiring such licenses. In addition, we could incur substantial costs in defending ourselves in legal proceedings instituted before patent and trademark offices in the United States, the European Union, or other ex-U.S. territories, or in a suit brought against us by a private party based on such patents or proprietary rights, or in a suit by us asserting our patent or proprietary rights against another party, even if the outcome is not adverse to us.

## **Licensing Agreements**

Following are licensing agreements covering technologies and intellectual property rights useful to our HyperAcute product candidates and technologies:

### ***Central Iowa Health System License Agreement***

We are a party to a license agreement, or the CIHS Agreement, dated August 2, 2001 with the Central Iowa Health System, or CIHS. The CIHS Agreement grants to us an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information and know-how relating to our HyperAcute immunotherapy technology. The license is subject to CIHS's retained right to use, and to permit other academic and research institutions to use, the CIHS patent rights and information for non-commercial bona fide research

purposes. The license is also subject to certain rights of and obligations to the United States government under applicable law, to the extent that such intellectual property was created using funding provided by a United States federal agency. We may grant sublicenses under the license, so long as the sublicense is subordinate to, and complies with, the CIHS Agreement.

In partial consideration of the license under the CIHS Agreement, we entered into a stock purchase agreement with CIHS, under which we issued to CIHS shares of our common stock and granted CIHS certain rights related to ownership of such shares. In addition, we must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If we commercialize a licensed product, we also have the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments we must make to third parties. If we grant a sublicense under the licenses granted by CIHS, we must pay to CIHS a percentage of certain consideration paid by the sublicensee to us.

Under the CIHS Agreement, we must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets. As part of such efforts, we must deliver to CIHS certain information including an annual progress report detailing our progress towards commercial use of licensed products. At specific dates after the effective date we must satisfy certain obligations to conduct specified development on the licensed product, expend specified amounts on development of the licensed technology, or raise specific minimum amounts of equity capital. We are obligated to use commercially reasonable efforts to negotiate appropriate sponsored research programs with researchers at CIHS. If CIHS concludes that we have not met any of these obligations, and we fail to cure such failure, CIHS may either terminate the agreement or convert the license to a non-exclusive license. In addition, if CIHS determines that we have failed to use commercially reasonable efforts to, or to grant sublicenses to, develop or commercialize a licensed product in a particular field within the licensed field of use, CIHS may terminate, or convert the license to a non-exclusive license with respect to such particular field.

Unless terminated earlier, the CIHS Agreement shall remain in effect until the expiration of all of our royalty obligations under the agreement. We may terminate the agreement, or specific patents covered by the agreement, on written notice to CIHS or for CIHS' uncured material breach of the agreement. CIHS has the right to terminate for our uncured material breach of the agreement after written notice. Upon termination of the agreement we may sell our existing inventory of licensed products for a period of three months after such termination. We have the right to assign the CIHS Agreement to any affiliate or in connection with the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires CIHS' written consent, which consent shall not be unreasonably withheld.

#### ***Drexel University License Agreement***

We are party to a license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel. The Drexel Agreement grants us, and our affiliates, an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on a-Gal epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease. The license is subject to Drexel's retained right to use, and to permit other non-profit organizations to use, those patent rights and technical information for educational and non-commercial research purposes. The license is also subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that certain of such intellectual property were created using funding provided by a U.S. federal agency. We may grant sublicenses under the license, pursuant to a sublicense agreement in form acceptable to Drexel and subject to certain additional conditions and obligations.

In consideration of our license under the Drexel Agreement, we have paid and are obligated to continue to pay specified license fees, potential milestone payments in an aggregate amount up to approximately \$1 million for each licensed product, annual license maintenance fees, reimbursement of patent prosecution costs, and royalty payments as a low single-digit percentage of "net sales" of any licensed product that is commercialized, subject to minimum royalty payments. Royalty rates vary depending on the type of licensed product, the territory where it is sold and whether the licensed product is combined with other technologies. In addition, if we grant a sublicense under the license granted by Drexel, we must pay Drexel a percentage of the consideration paid by the sublicensee to us.

In accordance with a development plan included in the Drexel Agreement, we are obligated to use commercially reasonable efforts to develop and market products covered by the license as soon as practicable. In addition, we must either market licensed products within five years of the date of the agreement, or demonstrate that we have made and continue to make bona fide, good faith, ongoing efforts to develop and market licensed products.

Unless terminated earlier, the Drexel Agreement shall remain in effect until the expiration or abandonment of all the licensed Drexel patents. We may terminate the Drexel Agreement on written notice to Drexel. Drexel has the right to terminate for the uncured breach of our obligations under the agreement or for certain other reasons. If the Drexel Agreement terminates we may, in certain circumstances, sell any remaining inventory of licensed products for a period of six months after termination. We may not assign the Drexel Agreement except with Drexel's written consent, not to be unreasonably withheld or delayed.

Following are licensing agreements covering technologies and intellectual property rights useful to our IDO pathway inhibitor technology and product candidate:

***LIMR Exclusive License Agreement (IDO-1)***

We are a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, import, sell and offer for sale products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics. Such license is subject to LIMR's retained right to use such LIMR patent rights and technology for its non-commercial educational and research purposes. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under the LIMR Licenses, provided that each sublicense materially conforms to the IDO-1 Agreement and is expressly subject to its terms.

In consideration of such license grant, we are obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if we grant a sublicense under the IDO-1 Agreement, we must to pay to LIMR a percentage of the consideration received by us from the sublicensee.

Under the IDO-1 Agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If we breach our obligations and fail to cure such breach, LIMR may reduce our license to a non-exclusive license or revoke the license in its entirety.

Unless terminated earlier, the IDO-1 Agreement shall remain in effect until the expiration of the last licensed LIMR patents. LIMR may terminate the agreement for our failure to make payments due, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current

inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We have the right to assign the IDO-1 Agreement in connection with an acquisition, merger, consolidation, operation of law or the transfer of all or substantially all of our assets or equity relating to the agreement, but any other assignment requires the express prior written consent of LIMR, not to be unreasonably withheld.

#### ***Medical College of Georgia Research Institute License Agreement***

We are a party to a License Agreement dated September 13, 2005, or the MCGRI Agreement, with Medical College of Georgia Research Institute, or MCGRI which was amended on April 27, 2006 and February 13, 2007. The MCGRI Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified MCGRI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

Such license is subject to MCGRI's retained right to use, and to permit its academic research collaborators to use, such MCGRI patent rights and technology for research and educational purposes. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under such license, subject to the prior approval of MCGRI, not to be unreasonably withheld or delayed.

In consideration of such license grant, we are obligated to pay to MCGRI specified license fees (including issuing shares of our common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by MCGRI, we must pay to MCGRI a percentage of the consideration we receive from the sublicensee.

Under the agreement, we are obligated to make certain investments toward the further development of licensed products within specified time periods. If we fail to make the required investment, MCGRI may convert our license in the oncology field to a non-exclusive license. In addition, if we fail to develop the licensed products in a non-cancer field, specifically infectious disease or diagnostics, MCGRI may convert our license in such field to a non-exclusive license.

Unless terminated earlier, the MCGRI Agreement will remain in effect until the expiration of the last licensed MCGRI patents. MCGRI may terminate this agreement for our uncured material breach, bankruptcy or similar proceedings. For a period of one year following the termination of the agreement, we may sell our licensed products that are fully manufactured and part of our normal inventory at the date of termination. We have the right to assign the MCGRI Agreement to our affiliates or in connection with the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires the prior written consent of MCGRI.

#### ***University of British Columbia License Agreement***

We are a party to a license agreement dated February 1, 2007, or the UBC License, with the University of British Columbia, or UBC. The UBC License grants us an exclusive, worldwide license, under specified UBC patent rights relating to IDO-1 inhibitors and related technology, to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology. In addition, the UBC License grants us an option to obtain an exclusive, worldwide license to new IDO-1 inhibitors related technology developed during the term of the agreement.



Such license is subject to UBC's retained right to use such UBC patent rights and technology for research, scholarly publication, educational and non-commercial uses. We may grant sublicenses, other than naked cross-licenses, under the UBC license, provided that each sublicense is consistent with the terms and conditions of the UBC License and contains certain mandatory sublicensing provisions.

In consideration of such license grant, we must pay to UBC specified license fees, annual payment and license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$1.8 million per licensed product, and royalties in a range of less than 10% of net revenue of the licensed product if a licensed product is commercialized, which royalty rate varies depending on the type of license product and field of use. In addition, if we grant a sublicense under the licenses granted by UBC, we may be required to pay to UBC a percentage of certain consideration we receive from the sublicensee.

We are obligated to use our commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If we breach our obligations and fail to cure such breach, UBC may terminate this agreement. If we are diligently developing the licensed product in some therapeutic fields, but not in other therapeutic fields, UBC may require us to grant a sublicense in such other fields not being exploited by us to a third party that is able to develop the licensed product in such other fields.

Unless terminated earlier, the UBC License will remain in effect for 20 years or until the expiration of the last licensed UBC patents, whichever is later. UBC may terminate this agreement for our uncured material breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may not sell any inventory of the licensed product without the prior written consent of UBC. We have the right to assign the UBC Agreement to our affiliates or in connection with a merger, acquisition, or the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires the prior written consent of UBC, not to be unreasonably withheld.

#### ***LIMR Exclusive License Agreement (IDO-2)***

We are a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target Indoleamine 2,3 Dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. Such license is subject to LIMR's retained non-exclusive right to use such LIMR patent rights and technical information for internal non-commercial, educational and research purposes only. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under the LIMR IDO-2 license, provided that each sublicense complies with the terms of the LIMR IDO-2 Agreement.

In consideration of such license grant, we have paid to LIMR an upfront license fee and annual license maintenance fees, and are obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately \$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us. The payment provisions of the LIMR IDO-2 Agreement provide that, in the event a product for which we have payment obligations under the LIMR IDO-2 Agreement is also covered by payment obligations under the LIMR IDO-1 Agreement, we will not be obligated to pay both such obligations but rather will pay to LIMR the higher of the amounts owed under the two agreements.

Under the LIMR IDO-2 Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license. We have the obligation, at our expense and in our reasonable discretion, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement. In addition, LIMR granted us the exclusive option to obtain exclusive, worldwide licenses on commercially reasonable terms to future inventions and discoveries of LIMR related to IDO-2 or inhibitors of IDO-2.

Concurrently with, and as an obligation under, the LIMR IDO-2 Agreement, we entered into a cooperative research and development agreement with LIMR, or the CRADA Agreement. Under the CRADA agreement, we agree to provide funding to LIMR in support of IDO research for one year and renewable at our option.

Unless terminated earlier, the LIMR IDO-2 Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. We may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for our uncured breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We may assign the LIMR Agreement in connection with the transfer of all or substantially all of our assets or equity, or by reason of acquisition, merger, consolidation or operation of law, but any other assignment requires LIMR's written consent, which shall not be unreasonably withheld.

#### ***LIMR Exclusive License Agreement (IDO)***

We are a party to a license agreement, or the LIMR IDO Agreement, dated April 23, 2009 with LIMR. The LIMR IDO Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. Such license is subject to LIMR's retained non-exclusive right to use such LIMR patent rights and technical information for internal non-commercial, educational and research purposes only. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under the LIMR IDO license, provided that each sublicense complies with the terms of the LIMR IDO Agreement.

In consideration of such license grant, we are obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately \$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Under the LIMR IDO Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license. We have the right and responsibility, at our expense and in our reasonable discretion, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement.

Unless terminated earlier, the LIMR IDO Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. We may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for our uncured breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We may assign the LIMR IDO Agreement in connection with the transfer of all or substantially all of our assets or equity, or by reason of acquisition, merger, consolidation or operation of law, but any other assignment requires LIMR's written consent, which shall not be unreasonably withheld.

### ***Bresagen Patent License Agreement***

We are a party to a license agreement, or the Bresagen Agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants us a non-exclusive, non-sublicensable license to specified Bresagen patent rights for use in testing microbial and cancer vaccines. In consideration of such license grant, we are obligated to pay Bresagen an up-front license fee and an annual license fee.

Unless terminated earlier, the Bresagen Agreement shall continue for an initial period of eight years, which may be extended an additional five years upon agreement of the parties. We may terminate the Agreement upon agreement in writing with Bresagen. Bresagen has the right to terminate for our uncured breach, insolvency, change of control without consent or similar proceedings. Upon termination of the agreement, all of our rights under the license are terminated. We may assign the Bresagen Agreement in connection with the transfer of all or substantially all of our assets by reason of acquisition, merger, purchase or otherwise with notice to Bresagen, but any other assignment requires Bresagen's written consent.

Following are licensing agreements to which BPS is a party covering technologies and intellectual property rights applicable to BPS's development of vaccines for the biodefense field:

### ***Regents of the University of California License Agreement***

BPS is a party to a license agreement dated July 29, 2008, or the California License, with the Regents of the University of California, or California. The California License grants BPS an exclusive, worldwide license, under specified California patent rights relating to technology based on yellow fever virus, to make, use, import, sell and offer for sale products that are covered by licensed patent rights in the field of human healthcare. The license is subject to California's retained right to use the California patent rights and technology for research purposes. The license is also subject to certain rights of and obligations to the United States government under applicable law. BPS may grant sublicenses under the California license, provided that each sublicense is consistent with the terms and conditions of the California License.

In consideration of the license grant, BPS must pay to California a specified license issue fee, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$285,000 per licensed product, and royalties as a low single-digit percentage of net sales of the licensed product, which royalty rate varies depending on the territory. In addition, if BPS grants a sublicense under the licenses granted by California, BPS may be required to pay to California a percentage of certain consideration BPS receives from the sublicensee. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If BPS breaches its obligations and fails to cure the breach, California may terminate the California License or reduce BPS's rights under the license.

Unless terminated earlier, the California License will remain in effect until the expiration or abandonment of the last of the California patent rights. This agreement will terminate automatically upon the filing, by or against BPS, for relief under the United States Bankruptcy Code or upon the filing of a legal action, by or on behalf of BPS, claiming that any portion of the California License is invalid or unenforceable. California may terminate this agreement for BPS's uncured material breach. BPS may terminate this agreement upon written notice to California. Upon termination of the agreement, BPS may sell any previously made licensed product for a period of 120 days after termination. BPS has the right to assign the California License to its affiliates or in connection with a merger, acquisition, or the transfer of all or substantially all of its assets relating to the agreement, but any other assignment requires the prior written consent of California.

## ***Her Majesty the Queen in Right of Canada License Agreement***

BPS is a party to a license agreement dated May 4, 2010, or the Canada License, with the Her Majesty the Queen in Right of Canada, or Canada. The Canada License grants BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license for commercialization of specified Canada patent rights relating to technology based on rVSV. The license is subject to Canada's retained right to use the Canada patent rights and technology to improve the patent rights, carryout educational purposes, and development of the patent rights where BPS cannot obtain regulatory approval or meet demand. BPS may grant sublicenses under the Canada license, provided that each sublicense is consistent with the terms and conditions of the Canada License and contain certain mandatory sublicensing provisions.

In consideration of the license grant, BPS must pay to Canada a specified patent and signing fees, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C\$205,000 per licensed product, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, which royalty rate varies depending on the type of licensed product. In addition, if BPS grants a sublicense under the licenses granted by Canada, BPS is required to pay to Canada a percentage of certain consideration BPS receives from the sublicensee. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products. If BPS breaches its obligations and fails to cure the breach, Canada may terminate the Canada License.

Unless terminated earlier, the Canada License will remain in effect until the expiration of the last of the Canada patent rights. Canada may terminate this agreement for BPS's failure to use commercially reasonable efforts to commercialize, failure to pay, breach of confidentiality, cessation of business, criminal conviction or other breach of its obligations under the agreement. BPS may not assign the Canada License to a third party without the prior written consent of Canada, not to be unreasonably withheld. This agreement will terminate automatically if BPS assigns the Canada License without prior written consent or if BPS files for bankruptcy or similar proceedings.

### **Government Regulation**

We operate in a highly regulated industry that is subject to significant federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug, and Cosmetic Act, or FDC Act, and the Public Health Service Act, among others.

The FDC Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these laws and regulations, product development and product approval processes are very expensive and time consuming.

### **FDA Approval Process**

In the United States, pharmaceutical products, including biologics, are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or biologic license applications, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation as well as animal trials to assess the characteristics and potential pharmacology and toxicity of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not objected to the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices, or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs, which are applications for marketing approval, are typically conducted in three sequential Phases, but the Phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Before proceeding with a Phase 3 clinical trial, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment, or SPA. SPAs help establish up front agreement with the FDA about the adequacy of the design of a clinical trial to support a regulatory approval, but the agreement is not binding if new circumstances arise. In addition, even if an SPA remains in place and the trial meets its endpoints with statistical significance, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support

approval, or only justifies approval for a narrow set of clinical uses or approval with restricted distribution or other burdensome post-approval requirements or limitations.

In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these trials are frequently referred to as Phase 1B clinical trials. Additionally, when product candidates can do damage to normal cells, it is not ethical to administer such drugs to healthy patients in a Phase 1 clinical trial. After completion of the required clinical testing, an NDA or, in the case of a biologic, a BLA, is prepared and submitted to the FDA. FDA approval of the marketing application is required before marketing of the product may begin in the U.S. The marketing application must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of marketing applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider new information submitted during the review or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a marketing application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices, or cGMPs, is satisfactory and the marketing application (the NDA or, in the case of biologics, the BLA) contains data that provide substantial evidence that the drug is safe and effective in the indication studied. Manufacturers of biologics also must comply with FDA's general biological product standards.

After the FDA evaluates the marketing application and the manufacturing facilities, it issues an approval letter, or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed in a resubmission of the marketing application, FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. It is not unusual for the FDA to issue a complete response letter because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval of the marketing application, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

### ***Fast Track Designation***

Congress enacted the Food and Drug Administration Modernization Act of 1997, or the Modernization Act, in part to ensure the availability of safe and effective drugs, biologics and medical devices by expediting the development and review for certain new products. The Modernization Act establishes a statutory program for the review of Fast Track products, including biologics. A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the Fast Track program, the sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a Fast Track product at any time during the development of the product, prior to a new drug application submission. Fast Track designation enables a company to file their application for approval on a rolling basis and potentially qualify for priority review.

The FDA may condition approval of an application for a Fast Track product on a commitment to do post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and require prior review of all promotional materials. In addition, the FDA may withdraw approval of a Fast Track product in an expedited manner on a number of grounds, including the sponsor's failure to conduct any required post-approval study in a timely manner. On October 1, 2010 the FDA approved our application for Fast Track product designation for HyperAcute Pancreas.

### ***Orphan Drug Designation***

The Company was granted Orphan Drug designation for HyperAcute Pancreas on October 21, 2010 by the FDA. The FDA grants Orphan Drug designation to drugs intended to treat a rare disease or condition, which for this program is defined as having a prevalence of less than 200,000 individuals in the United States. Now that the FDA has granted us Orphan Drug designation, the generic identity of our therapeutic agent and its potential orphan use will be disclosed publicly by the FDA. Orphan drug exclusive marketing rights may be lost if the FDA determines that our request for designation was materially defective or if we are unable to assure sufficient quantity of our drug.

Orphan drug designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives the first approval for the indication for which it has designation, the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the United States. Additional benefits of Orphan Drug designation include clinical tax research incentives and exemption from application filing fees. Although obtaining approval to market a product with orphan drug exclusivity may be advantageous, we cannot be certain:

- that we will be the first to obtain approval for any other drugs or indications for which we obtain Orphan Drug designation;
- that Orphan Drug designation will result in any commercial advantage or reduce competition; or
- that the limited exceptions to this exclusivity will not be invoked by the FDA.

### ***Accelerated Approval Based on Surrogate Endpoint***

The Modernization Act provides that the FDA can base approval of a marketing application for a Fast Track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical

endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. We do not intend to seek approval for HyperAcute Pancreas based on a surrogate endpoint, but may seek approval based on surrogate endpoints for other indications in the future.

### ***The Hatch-Waxman Act***

In seeking approval for marketing of a drug or biologic through an NDA or BLA, respectively, applicants are required to list with the FDA each patent with claims that cover the applicant's product or FDA approved method of using this product. Upon approval of a product, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification notification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.



### ***Other Regulatory Requirements***

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement, or in the case of biologics, a new BLA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs. We cannot be certain that the FDA or any other regulatory agency will grant approval for our product candidates for any other indications or any other product candidate for any indication on a timely basis, if at all.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### ***Priority Review***

Under the FDA policies, a drug or biologic candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA or BLA is submitted, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A Fast Track designated drug or biologic candidate would ordinarily meet the FDA's criteria for priority review.

### ***U.S. Foreign Corrupt Practices Act***

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

### ***Federal and State Fraud and Abuse Laws***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

In addition, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record keeping and control procedures. Any failure to comply with the regulations may result in significant criminal and civil penalties as well as damage to our credibility in the marketplace.

### ***Regulation in the European Union***

Drugs are also subject to extensive regulation outside of the United States. In the E.U., for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in Europe). If this procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under two simplified application processes, the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, pricing and reimbursement approvals are also required in most countries.

Similar to the United States, a system for Orphan Drug designation exists in the E.U. Orphan designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has designation, the relevant regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for ten years in the E.U.

### **Price Controls**

In many of the markets where we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to reimbursement programs with varying price control mechanisms. In the United States, the Medicare program is administered by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. Coverage and reimbursement for products and services under Medicare are determined pursuant to regulations promulgated by CMS and pursuant to CMS's subregulatory coverage and reimbursement determinations. It is difficult to predict how CMS may apply those regulations and subregulatory determinations to newly approved products, especially novel products, and those regulations and interpretive determinations are subject to change. Moreover, the methodology under which CMS makes coverage and reimbursement determinations is subject to change, particularly because of budgetary pressures facing the Medicare program. For example, the Modernization Act provides for a change in reimbursement methodology that reduces the Medicare reimbursement rates for many drugs, including oncology therapeutics. Medicare regulations and interpretive determinations also may determine who may be reimbursed for certain services.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

### **Other Regulations**

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances and biological materials. We may incur significant costs to comply with such laws and regulations now or in the future.

### **Legal Proceedings**

We are not currently a party to any legal proceedings.

### **Employees**

As of December 31, 2010, we had 82 employees. None of our employees are subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees are good.

### **Facilities**

Our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. In June 2010, we completed the expansion of a 22,500 square foot facility, which includes executive offices as well as approximately 14,000 feet dedicated to manufacturing, testing and product storage. The manufacturing portion of the facility became operational on October 17, 2010. The lease expires January 31, 2015, and we have the option to extend the lease for three additional five-year periods upon the same terms as the base lease. In addition, we continue to occupy a small pilot manufacturing and office facility in the same research park, which we lease on a month-to-month basis.

**MANAGEMENT**

The following table sets forth the name, age and position of each of our executive officers and directors as of December 31, 2010.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive Officers</b>		
Charles J. Link, Jr., M.D.	51	Chief Executive Officer, Chief Scientific Officer, Chairman of the Board
Nicholas N. Vahanian, M.D.	43	President, Chief Medical Officer
Gordon H. Link, Jr.	57	Chief Financial Officer
Kenneth Lynn	57	Executive Vice President of Business Development
<b>Significant Employees</b>		
Mario Mautino, Ph.D.	44	Vice President — Drug Discovery Module, Intellectual Property Officer
W. Jay Ramsey, M.D., Ph.D.	53	Quality Assurance Officer
<b>Non-Employee Directors</b>		
Thomas A. Raffin, M.D.	64	Director, (1), (2) and (4)
Sarah Alexander, M.D., F.A.C.P.	67	Director, (2)
David J. Lundquist	68	Director, (3)
Joseph Saluri	44	Director, (1), (2) and (3)
Ernest J. Talarico, III	40	Director, (1) and (3)

- (1) Member of the Compensation Committee.
- (2) Member of the Nominating and Governance Committee.
- (3) Member of the Audit Committee.
- (4) Lead Independent Director.

**Executive Officers**

*Charles J. Link, Jr., M.D.* founded the Company in 1999 and has served as Chairman of the Board and Chief Scientific Officer since inception in 1999. He served as President from 2001 to 2009 and has served as Chief Executive Officer since 2003. Dr. Link has also served as Chairman and Chief Executive Officer of BioProtection Systems Corporation from 2005 and was its Chief Scientific Officer from 2005 to 2009. Dr. Link has been a practicing oncologist at the Medical Oncology and Hematology Associates of Iowa since 1995. From 1995 to 2003, Dr. Link served as the Director of the John Stoddard Cancer Research Institute, which he co-founded. Dr. Link served as a Medical Oncology Clinical Fellow at the NCI, National Institutes of Health, or NIH, from 1988 to 1991. Dr. Link attended the U.S. Air Force Academy from 1977 to 1980. Dr. Link holds a B.A. from Stanford University, an M.D. from Stanford University School of Medicine and is certified in Internal Medicine by the American Board of Internal Medicine and has previously been certified in Medical Oncology.

The Nominating and Corporate Governance Committee believes that Dr. Link's extensive experience with the Company, as founder and as Chief Scientific Officer and Chairman of the Board since inception, brings both strategic vision and continuity to the Board. In addition, the Nominating and Corporate Governance Committee believes that Dr. Link's prior experience as a NCI trained oncologist and Director of the Stoddard Cancer Research Institute provides him with substantial expertise in drug discovery and development, which are important to the Board.

*Nicholas N. Vahanian, M.D.* has served as our Chief Medical Officer since 2001, Chief Operations Officer since 2003 and President since 2009. Dr. Vahanian served as a research scientist at the NCI from 1992 to 1994 and at the National Center for Human Genome Research, NIH from 1994 to 1995. He

completed his Molecular Oncology Fellowship at the John Stoddard Cancer Research Institute from 1999 to 2000. Dr. Vahanian holds a B.S. in Biology from Virginia Commonwealth University. Dr. Vahanian attended St. Bartholomew's and Royal London Hospital Medical College. He also holds an M.B.A. from the University of Notre Dame.

*Gordon H. Link, Jr.* has served as our Chief Financial Officer since 2008. Previously, Mr. Link worked for Tapestry Pharmaceuticals, Inc., or Tapestry, as Chief Executive Officer from April to July 2008, Senior Vice President and Chief Financial Officer from 2002 through 2008, President of the Genomics Division from 2000 to 2002 and Vice President and Chief Financial Officer from 1993 to 2002. At Tapestry, Mr. Link directed a staff of five to ten individuals in areas of accounting, cash management, financial planning and analysis, risk management, financial reporting and investor relations. Mr. Link also worked with Tapestry's Board of Directors on financial, business and corporate development matters and coordinated Tapestry's initial public offering and subsequent follow-on public offerings of common stock. On April 4, 2008, the Tapestry Board of Directors appointed Mr. Link as Chief Executive Officer to manage the winding up of Tapestry in bankruptcy. Tapestry filed a petition for relief under Chapter 11 of the U.S. Bankruptcy Code on March 19, 2009. Prior to joining Tapestry, Mr. Link served as Corporate Controller of Synergen, Inc., Treasurer of the Syntex-Synergen Neuroscience Joint Venture, Treasurer of Synergen Development Corporation and Audit Manager with Deloitte & Touche USA LLP. Mr. Link received a B.S. from Rensselaer Polytechnic Institute and a B.A. in accounting from Metropolitan State College. Mr. Link is not related to our Chief Executive Officer, Dr. Charles Link.

*Kenneth Lynn* joined the Company as Senior Vice President of Business Development in February 2008 and has served as Executive Vice President of Business Development since February 2009. From 2006 to 2008, Mr. Lynn was employed as Executive Vice President, Strategy and Policy, of Kansas Technology Enterprise Corporation. From 2004 to 2006, Mr. Lynn worked for the Kauffman Foundation, where he served as President of the Kauffman Innovation Network, a nonprofit corporation established and supported by the Kauffman Foundation to promote the advancement of science and technology-based innovation generated by university researchers. Mr. Lynn was Senior Vice President of Corporate Development and Legal Affairs with RxKinetix, Inc. from 2000 to 2002, where he led the opportunities assessment and strategic planning process, coordinated development of the business plan, and evaluated and negotiated partnership and licensing agreements. He was Senior Vice President, Corporate Development and Legal Affairs with Valentis, Inc. from 1999 to 2000, where he supervised the business development and legal staff, evaluated and negotiated corporate transactions and partnering opportunities, and managed existing strategic alliances. From 1993 to 1998, Mr. Lynn worked for Cortech, Inc., a publicly traded company, where he progressed from Vice President of Business Development and General Counsel to Chairman and Chief Executive Officer. From 1991 to 1993, Mr. Lynn was Vice President and General Counsel of U.S. Bioscience, Inc. From 1984 to 1991, he served as Corporate Counsel with Marion Laboratories (now Sanofi-Aventis). Mr. Lynn holds a B.A. degree in history from Washburn University, a J.D. from the University of Kansas, and an M.B.A. from Rockhurst University.

#### **Significant Employees**

*Mario Mautino, Ph.D.* has served as our Vice President for the Drug Discovery Module since 2007 and as our Intellectual Property Officer since 2002, and served as a Senior Scientist at NewLink Genetics from 2001 to 2007. He received his Licenciante in Biological Chemistry in 1990 and his Ph.D. in Molecular Genetics at the University of Cordoba, Argentina in 1995. He performed one year of post-doctoral training at the National University of Cordoba and five years of post-doctoral work in human gene therapy at the Clinical Gene Therapy Branch, NIH.

*W. Jay Ramsey, M.D., Ph.D.* has served as our Clinical and Regulatory Compliance Officer since 2006 and served as our Senior Medical Scientist from 2000 to 2006. Prior to joining the Company, Dr. Ramsey served as Clinical Fellow of the Clinical Gene Therapy Branch, National Human Genome Research Institute, NIH from 1995 to 2000, and Clinical Fellow of the Metabolism Branch of the NCI

from 1992 to 1995. Dr. Ramsey received his Ph.D. in Cell Biology from the Baylor College of Medicine in Houston, TX and his M.D. from University of Texas Medical Branch at Galveston.

### **Non-Employee Directors**

*Thomas A. Raffin, M.D.* has served as a member of the Board of Directors since 1999. Dr. Raffin has spent 30 years on the faculty at Stanford University School of Medicine, where he is the Colleen and Robert Haas Professor Emeritus of Medicine and Biomedical Ethics. Over the past two decades, Dr. Raffin has worked extensively in the healthcare and medical device business sectors and was an advisor to Cell Therapeutics Inc. (1993-1997), Broncus Technologies (1997-2004), Medica (1998-2002), and Inhale Technologies (1998-2001). He co-founded Rigel Pharmaceuticals, a publicly traded company, in 1996. In 2001, he co-founded Telegraph Hill Partners, a San Francisco life sciences private equity firm as a General Partner. Dr. Raffin has been a director of the following Telegraph Hill Partners private portfolio companies: AngioScore, Confirma, Freedom Innovations, LDR, and PneumRK. Dr. Raffin received a B.A. from Stanford University and an M.D. from Stanford University School of Medicine and did his medical residency at the Peter Bent Brigham Hospital (now Brigham and Women's Hospital) in Boston.

The Nominating and Corporate Governance Committee believes that Dr. Raffin's experience with the Company, as a director since inception, brings continuity to the Board. In addition, the Nominating and Corporate Governance Committee believes that Dr. Raffin's prior experience as a founder of Rigel Pharmaceuticals and as a venture capitalist and board member of development stage biotechnology companies provides important background to the Board in drug development, finance, corporate development, and overall strategy.

*Sarah Alexander, M.D., F.A.C.P.* has served as a director since 2006. Dr. Alexander is certified by the American Board of Internal Medicine in Internal Medicine, Hematology and Medical Oncology. She has been a practicing hematologist and oncologist since 1975 and worked with the Medical Oncology and Hematology Associates in Des Moines since 1989. At present, she is a Medical Oncologist and Hematologist at the Des Moines Veterans Administration Hospital. Dr. Alexander's undergraduate work was completed at Christian Medical College, Vellore, Madras, India, her residency in Internal Medicine was completed at the V. A. Hospital in New Orleans, Louisiana, and her fellowship in Medical Oncology and Hematology was completed in at Emory University School of Medicine.

The Nominating and Corporate Governance Committee believes that Dr. Alexander's experience as a practicing medical oncologist and as an investigator in clinical trials brings an important perspective to the Board, as most of our product candidates under development are targeted at cancer.

*David J. Lundquist* has served as a director since 2005. Since 1996, Mr. Lundquist has served as a Partner of Lundquist, Schiltz & Associates, a firm in the fee-only investment advisory business. From 1991 to 1996, Mr. Lundquist was Vice Chairman of New Heritage Associates, a company engaged in the acquisition and operation of cable television systems. From 1980 to 1990, Mr. Lundquist was Executive Vice President — Finance of Heritage Communications, Inc. Mr. Lundquist is currently a director of Da-Lite Screen Company, Genesis Systems Group, Marketlink and G-Sky. Mr. Lundquist holds a B.A. from the University of Minnesota and an M.B.A. from Stanford University Graduate School of Business.

The Nominating and Corporate Governance Committee believes that Mr. Lundquist's ten years of experience as a Executive Vice President — Finance of a public company provides important experience in corporate finance and provides the background necessary for Mr. Lundquist to chair our Audit Committee and to serve as an "audit committee financial expert." In addition, Mr. Lundquist's operational experience in rapidly growing companies and transactional experience in both financing and strategic transactions may be helpful to the Company in the future.

*Joseph Saluri* has served as a director since May 2010. Mr. Saluri has served as Vice President and General Counsel for Stine Seed Company and its affiliates since July 1999. As part of his duties for Stine, he works to establish collaborative licensing, research and marketing alliances with international

biotechnology and agribusiness companies, in addition to managing the legal and intellectual property affairs for the Stine Companies. Previous to his employment with Stine, Mr. Saluri was an attorney and solicitor at law with Nicholas Critelli Associates, PC, in Des Moines and London. Mr. Saluri received a B.S./B.A. from Drake University and a J.D. from Drake University Law School.

The Nominating and Corporate Governance Committee believes that Mr. Saluri's extensive experience as legal counsel to a large private company provides important experience in corporate finance and provides the background necessary for Mr. Saluri to serve as a member of our Audit Committee and our Nominating and Corporate Governance Committee. In addition, Mr. Saluri's operational experience in rapidly growing companies and transactional experience in both financing and strategic transactions may be helpful to the Company in the future.

*Ernest J. Talarico, III* has served as a director since 1999. Mr. Talarico has worked for Mesirow Financial Holdings, Inc., a diversified financial services firm headquartered in Chicago, Illinois since 1998, where he has been a Managing Director since June 2008. Prior to becoming Managing Director, Mr. Talarico served as Senior Vice President from 2005 to 2008, Vice President from 2003 to 2005 and Investment Executive from 1998 to 2003. Mr. Talarico specializes in financial planning and asset allocation, as well as other wealth accumulation and preservation strategies for individuals and businesses. Mr. Talarico sits on several boards and committees, including the Mutual Fund Committee at Mesirow Financial and the Select Advisory Board and Committee at Mesirow Financial. Mr. Talarico has also been the Chairman for the local chapter of the Cystic Fibrosis Foundation and the Founder and Chairman of the Talarico Ataxia Foundation. Mr. Talarico holds a bachelor's degree from the University of Iowa as well as licenses in equities, options and managed futures.

The Nominating and Corporate Governance Committee believes that Mr. Talarico's experience with the Company, as a director since inception, brings continuity to the Board. In addition, the Nominating and Corporate Governance Committee believes that Mr. Talarico's extensive experience in the investment management business provides important experience in corporate finance and investor relations and provides the background necessary for him to serve as a member of our Audit Committee.

### **Scientific Advisors**

We have established a scientific advisory board comprised of leading experts in their fields. We regularly seek advice and input from these experienced scientific leaders on matters related to our research and development programs. The members of our scientific advisory board consist of experts across a range of key disciplines relevant to our programs and science. We intend to continue to leverage the broad expertise of our advisors by seeking their counsel on important topics relating to our drug discovery and development programs. Some members of our scientific advisory board enter into consulting agreements with us covering their respective financial arrangements and confidentiality, non-disclosure and proprietary rights matters and own or have owned shares of our common stock or options to purchase shares of our common stock.

All of the scientific advisors are employed by or have consulting arrangements with other entities and devote only a small portion of their time to us. Our current advisors are:

<b>Name</b>	<b>Professional Affiliation</b>
Robert B. Belshe, M.D.	Director of the Division of Infectious Diseases and Immunology at Saint Louis University.
Michael Blaese, M.D.	Research Director of the Fund for Inherited Disease Research, Founder and President of PreGentis, Medical Director of the Immune Deficiency Foundation and Administrator of the U.S. Immunodeficiency Network Research Consortium.
Richard Burt, M.D.	Director of Allogeneic Bone Marrow Transplantation for Northwestern Medical Center in Chicago, Illinois and Assistant Professor at Northwestern University School of Medicine.
Richard C. Larock, Ph.D.	Distinguished Professor of Organic Chemistry at Iowa State University.
Kevin Legge, Ph.D.	Assistant Professor of Pathology at the University of Iowa Carver College of Medicine.
Andrew Mellor, Ph.D.	Professor of Medicine and Georgia Research Alliance Eminent Scholar in Immunogenetics at the Medical College of Georgia.
David Munn, M.D.	Professor of Pediatric Hematology-Oncology at the Medical College of Georgia. Head of the Cancer Immunotherapy program in the Cancer Research Center at MCG.
Nicola Pohl, Ph.D.	Associate Professor and Caldwell Chair of Chemistry at Iowa State University.
George Prendergast, Ph.D.	Professor and President/CEO of the Lankenau Institute for Medical Research.

### **Board Composition and Election of Directors**

Our Board of Directors currently consists of five non-employee members and our Chief Executive Officer, Dr. Charles Link. Our Board of Directors has determined that all of our directors, other than Dr. Link, are independent within the meaning of applicable NASDAQ listing standards.

We have initiated the process of recruiting an additional director. Among other qualifications, we are seeking a director who could serve as a member of our Audit Committee.

Effective upon the completion of this offering, we will divide our Board of Directors into three classes, as follows:

- Class I, which will consist of Dr. Alexander and Mr. Talarico, and whose terms will expire at our first annual meeting of stockholders to be held after the completion of this offering;
- Class II, which will consist of Mr. Lundquist and Mr. Saluri, and whose terms will expire at our second annual meeting of stockholders to be held after the completion of this offering; and
- Class III, which will consist of Dr. Charles Link and Dr. Raffin, and whose terms will expire at our third annual meeting of stockholders to be held after the completion of this offering.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of the Board of Directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as



possible, each class will consist of one-third of the directors. This classification of the Board of Directors may have the effect of delaying or preventing changes in our control or management. Under our certificate of incorporation to be in effect upon the closing of this offering, our directors may be removed only for cause, which may be effected by the affirmative vote of the holders of 66<sup>2</sup>/<sub>3</sub>% of our voting stock.

## **Board Committees**

Upon the completion of this offering, our Board of Directors will have an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. At that time, each of these committees will have adopted a written charter that will be available on our corporate website. The composition and primary responsibilities of each committee are described below.

### ***Audit Committee***

Upon the completion of this offering, the members of our Audit Committee will be Mr. Lundquist, Mr. Saluri and Mr. Talarico. Mr. Lundquist will serve as chairman of the Audit Committee. Our Board of Directors has determined that each member of the Audit Committee meets the independence requirements of Rule 10A-3 of the Securities Exchange Act of 1934, or the Exchange Act, and NASDAQ listing standards, except for Mr. Talarico. Our Board of Directors has also determined that Mr. Lundquist qualifies as an audit committee financial expert within the meaning of Securities and Exchange Commission, or SEC, regulations.

The primary purpose of the Audit Committee is to discharge the responsibilities of our Board of Directors with respect to our accounting, financial and other reporting and internal control practices and to oversee our independent registered public accounting firm. Specific responsibilities of our Audit Committee include:

- evaluating the performance of our independent registered public accounting firm and determining whether to retain or terminate their services;
- determining and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services, other than immaterial aggregate amounts of non-audit services as excepted under applicable laws and rules;
- reviewing and discussing with management and our independent registered public accounting firm the results of the annual audit and the independent registered public accounting firm's review of our annual and quarterly financial statements and reports;
- reviewing with management and our independent registered public accounting firm significant issues that arise regarding accounting principles and financial statement presentation;
- conferring with management and our independent registered public accounting firm regarding the scope, adequacy and effectiveness of our internal control over financial reporting; and
- establishing procedures for the receipt, retention and treatment of any complaints we receive regarding accounting, internal control or auditing matters.

### ***Compensation Committee***

Upon the completion of this offering, the members of our Compensation Committee will be Dr. Raffin, Mr. Saluri and Mr. Talarico. Dr. Raffin will serve as chairman of the Compensation Committee. Our Board has determined that each member of the Compensation Committee is independent within the meaning of applicable NASDAQ listing standards, is a non-employee director as defined in Rule 16b-3 under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the Internal Revenue Code of 1986. The purpose of our Compensation Committee is to discharge the responsibilities of our Board of Directors to oversee our compensation policies, plans

and programs and to review and determine the compensation to be paid to our executive officers and other senior management. Specific responsibilities of our Compensation Committee include:

- determining the compensation and other terms of employment of our executive officers and reviewing and approving corporate performance goals and objectives relevant to such compensation;
- evaluating and recommending to our Board of Directors the compensation plans and programs advisable for us, and evaluating and recommending the modification or termination of existing plans and programs; and
- reviewing and approving the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for our executive officers.

#### ***Nominating and Corporate Governance Committee***

The members of our Nominating and Corporate Governance Committee are Dr. Alexander, Dr. Raffin and Mr. Saluri. Dr. Raffin serves as chairman of the Nominating and Corporate Governance Committee. Each member of the Nominating and Corporate Governance Committee is independent within the meaning of applicable NASDAQ listing standards. The specific responsibilities of our Nominating and Corporate Governance Committee include:

- identifying, reviewing, evaluating and recommending for selection candidates for membership to our Board of Directors;
- reviewing, evaluating and considering the recommendation for nomination of incumbent members of our Board of Directors for reelection to our Board of Directors and monitoring the size of our Board of Directors;
- evaluating nominations by stockholders of candidates for election to our Board of Directors;
- reviewing, discussing and reporting to our Board of Directors an assessment of our board's performance; and
- determining adherence to our corporate governance documents.

#### **Lead Independent Director**

Dr. Raffin has been appointed as our lead independent director. As lead independent director, Dr. Raffin will work with our Chief Executive Officer to develop the agenda for meetings of the Board of Directors and with committee chairs to develop the agendas for meetings of committees. He will also chair the executive session of Board meetings at which officers are not present and will oversee the Board's annual evaluation of our Chief Executive Officer's performance.

#### **Compensation Committee Interlocks and Insider Participation**

For the fiscal year ended December 31, 2009, members of the Board's Compensation Committee consisted of Dr. Raffin and Mr. Talarico. None of the members of the Compensation Committee is currently, or has ever been at any time since the Company's formation, one of the Company's officers or employees. None of our officers currently serve, nor have they served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more officers serving as a member of our Board of Directors or Compensation Committee.

#### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer and controller, or persons performing similar functions. Following this offering, a current copy of the code will be posted on the Corporate Governance section of our website, [www.linkp.com](http://www.linkp.com).

## EXECUTIVE AND DIRECTOR COMPENSATION

*The following discussion and analysis of compensation arrangements of our named executive officers for our fiscal years ended December 31, 2009 and 2010 should be read together with the compensation tables and related disclosures set forth below. This discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion.*

### **Compensation Discussion and Analysis**

Our executive compensation program is designed to help us attract talented individuals to manage and operate our business, to reward those individuals fairly over time and to retain those individuals who continue to meet our high expectations. The goals of our executive compensation program are to align our executive officers' compensation with our business objectives and the interests of our stockholders, to incentivize and reward our executive officers for our success and to reflect the teamwork philosophy of our executive management team. To achieve these goals, we have established executive compensation and benefit packages that are based on a mix of base salary, cash incentive payments and equity-based awards and severance and change in control benefits. Our executive compensation program is also intended to make us competitive in the biopharmaceutical industry, where there is significant competition for talented employees, and to be fair relative to other professionals within our organization.

### **Compensation Objectives**

Our compensation program is designed to enable us to attract and retain executives with the skills and experience necessary to execute our business plan, to provide short-term incentives to accomplish specific annual goals defined by the Board of Directors, and to provide long-term incentives to build shareholder value.

### **Role of Our President and Chief Executive Officer in Setting Executive Compensation**

We initially establish executive officers' compensation arrangements when negotiating the terms of employment when they join the Company. We generally include these initial compensation terms in an offer letter with the executive. Each year we review executive compensation and the mix of elements used to compensate our executive officers. In connection with each annual review cycle, Dr. Charles Link, our Chief Executive Officer, meets with those officers who report directly to him to discuss the Company's accomplishments during the year and the individual's performance and contributions over the prior year. Based on these discussions, our Chief Executive Officer then develops a set of compensation recommendations for submission to our Compensation Committee. The Compensation Committee uses these recommendations, its own judgment and experience, and the resources and tools described below to determine the appropriate mix of compensation for each of our executive officers. Our Chief Executive Officer does not participate in the determination of his own compensation.

### **Role of Our Board and Compensation Committee in Setting Executive Compensation**

Our Board of Directors has established a Compensation Committee for the purpose of making recommendations to the full Board of Directors regarding compensation decisions for our executive officers. The Compensation Committee currently consists of Dr. Raffin, Mr. Saluri and Mr. Talarico. In carrying out its responsibilities, our Compensation Committee receives and evaluates the compensation recommendations made by our Chief Executive Officer. None of our executive officers participates in the discussions regarding his own compensation. Based on the evaluation of management's suggestions, the Compensation Committee then makes formal recommendations regarding executive compensation decisions to the full Board of Directors. In making these recommendations, the Compensation Committee does not delegate any of its functions to others.

Our Compensation Committee has retained independent compensation consultants to advise on selected aspects of executive and Board compensation as follows:

- In 2007, Syzygy Consulting Group was retained to make recommendations regarding equity awards to Dr. Charles Link, who was then serving as our Chief Executive Officer, and Dr. Vahanian, who was then serving as our Chief Medical and Operating Officer, and to provide recommendations concerning Board compensation. The consultant's report was based on 34 United States-based life sciences and biotechnology companies that were managed by founders and had financing histories and valuations deemed similar to the company.
- In 2009, our Compensation Committee retained two compensation consultants, Syzygy Consulting Group and Radford, to provide recommendations on all aspects of executive compensation. The Syzygy report was based on a proprietary database of 160 private life sciences and biotechnology-related companies and its Pre-IPO and Private Technology Company Total Compensation Survey that covered compensation practices at 341 private companies. From those databases, Syzygy identified a group of similarly-situated, founder-managed companies based on cumulative capital raised and valuation. The Radford analysis was based on the 2009 Radford Global Life Sciences Pre-IPO Survey. These reports covered both the Company and our subsidiary BioProtection Systems Corporation, or BPS.
- In 2010, our Compensation Committee retained Syzygy Consulting Group to provide recommendations regarding the establishment and size of initial share reserves for an Employee Stock Purchase Plan and Non-Employee Directors' Stock Award Plan, and the addition of an "evergreen" provision to our 2009 Equity Incentive Plan. The Syzygy report was based on an analysis of the following 34 public biotechnology companies that were considered to be similar to us with respect to market capitalization:

- |   |                                 |                               |                                 |
|---|---------------------------------|-------------------------------|---------------------------------|
| • Alnylam Pharmaceuticals, Inc.           | • Clinical Data, Inc.           | • Idenix Pharmaceuticals Inc. | • Obagi Medical Products, Inc.  |
| • Ariad Pharmaceuticals Inc.              | • Codexis, Inc.                 | • Immunogen Inc.              | • Optimer Pharmaceuticals, Inc. |
| • Array BioPharma, Inc.                   | • Corcept Therapeutics Inc.     | • Jazz Pharmaceuticals, Inc.  | • Osiris Therapeutics, Inc.     |
| • AVEO Pharmaceuticals, Inc.              | • Cornerstone Therapeutics Inc. | • Ligand Pharmaceuticals Inc. | • Sequenom Inc.                 |
| • BioCryst Pharmaceuticals, Inc.          | • Cytokinetics Inc.             | • Medivation, Inc.            | • Vanda Pharmaceuticals, Inc.   |
| • BioTime, Inc.                           | • Cytori Therapeutics, Inc.     | • Nabi Biopharmaceuticals     | • Xenoport, Inc.                |
| • Cadence Pharmaceuticals Inc.            | • Dyax Corp.                    | • Neurocrine Biosciences Inc. | • ZIOPHARM Oncology, Inc.       |
| • Cell Therapeutics, Inc.                 | • Exact Sciences Corporation    | • Novavax, Inc.               |                                 |
| • Chelsea Therapeutics International Ltd. | • Exelixis, Inc.                | • NPS Pharmaceuticals, Inc.   |                                 |

In addition to relying on the consultants' reports, the committee members also have relied on the Ernst & Young 2008, 2009, and 2010 Compensation and Entrepreneurship Report in Life Sciences and on their own experience and observations in the marketplace in assessing and making recommendations regarding executive compensation. Our Board of Directors evaluates the recommendations from the Compensation Committee and makes final decisions regarding executive compensation.

Our Compensation Committee consists solely of directors who are "outside directors" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and "non-employee directors" for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended.

Prior to our pending acquisition of the minority interest in our subsidiary BPS, it had its own compensation committee, consisting of Dr. Raffin and Mr. Talarico, who are also directors of the Company, and Mr. Steve Stahley, who is not a director, officer, employee or affiliate of the Company. Dr. Charles Link, our Chief Executive Officer, and Dr. Vahanian, our President and Chief Medical Officer have equity ownership positions in BPS. Neither Dr. Link nor Dr. Vahanian receives any salary from BPS. In September 2006, Drs. Link and Vahanian delivered notes to BPS in the principal amounts of \$75,000

and \$20,000, respectively, bearing interest at 5.01% per annum, in order to purchase their shares of BPS Series B common stock under stock options. As of November 17, 2010, Dr. Link and Dr. Vahanian had repaid the remaining principal and interest owed under the notes. For a more detailed description of these loans, see "Executive and Director Compensation — Indebtedness of Management and Related Agreements."

### **Basis for Historical and Future Compensation Policies and Decisions**

We use a mix of short-term compensation, consisting of base salaries and cash incentive bonuses, and long-term compensation, consisting of equity incentive compensation, to provide a total compensation structure that is designed to achieve our corporate objectives.

In arriving at the amount and types of initial compensation for each of our named executive officers, we consider the following factors:

- the individual's particular background and circumstances, including prior relevant work experience and compensation paid prior to joining us;
- the individual's role with us and the compensation paid to similar persons in the similarly situated companies represented in the compensation data that we review;
- the demand for people with the individual's specific expertise and experience;
- performance goals and other expectations for the individual's position;
- comparison to other executives within the Company having similar levels of expertise and experience; and
- recommendations from our compensation consultants.

We annually re-assess the compensation of our named executive officers and determine whether any adjustments should be made. In determining whether to adjust the compensation of any of our named executive officers, we generally take into account the following factors:

- our understanding of compensation generally paid by similarly situated companies to their executives with similar roles and responsibilities;
- formal market data regarding base salary, cash incentives and equity compensation from surveys conducted by our compensation consultants of biopharmaceutical and biotechnology companies, as well as the Ernst & Young report cited above;
- the roles and responsibilities of our executives, including any increases or decreases in responsibilities; and
- the contributions and performance of each named executive officer.

### ***Elements of our Executive Compensation Program***

*General.* Our executive compensation program consists of four principal components: base salary, performance-based cash bonus payments, long-term incentive compensation in the form of equity-based awards and severance and change-in-control benefits. Each component of our executive compensation program is designed to address specific compensation objectives. The Compensation Committee has not established any formal policies or guidelines for allocating compensation between the components, although it seeks to maintain an appropriate balance between fixed compensation, in the form of base salary, and performance-based compensation, in the form of cash bonuses and long-term incentive compensation. As a general matter, our executive officers are also eligible to participate, on the same basis as other employees, in our 401(k) plan and our other benefit programs generally available to all employees, and with limited exceptions relating to the relocation of executive officers, we do not provide

perquisites or benefits for our named executive officers on a basis that is different from other eligible employees.

We view each of the elements of our compensation program as related but distinct. Our decisions about each individual element generally do not affect the decisions we make about other elements. For example, we do not believe that significant compensation derived from one element of compensation, such as equity appreciation, should adversely affect compensation from other elements, such as salary or bonus.

*Base Salary.* Base salary is the primary fixed component of our executive compensation program. We use base salary to compensate executives for services rendered during the calendar year, and to ensure that we remain competitive in attracting and retaining executive talent.

Upon joining the Company, each of our executive officers received an offer letter that provided for an initial base salary. These initial salaries are the product of negotiation with the executive, but we generally seek to establish salaries that we believe are commensurate with the salaries paid to industry peers with comparable qualifications, experience, responsibilities and performance at similar companies. In addition to the Radford and Syzygy reports in 2009, we reviewed the Ernst & Young reports cited above. Our Compensation Committee has also relied on its members' collective experience in the marketplace for determining what they believe to be the market rate of salaries for executives of comparable companies.

Shortly before the end of each calendar year, we review company and individual performance to, among other things, determine whether adjustments in base salary are necessary or appropriate. In establishing the 2009 and 2010 base salaries of our executive officers, our Compensation Committee and Board of Directors took into account a number of factors, including the executive's seniority, position, functional role and level of responsibility and individual performance during the previous year.

<u>Named Executive Officer</u>	<u>2009 Base Salary (\$)</u>	<u>2010 Base Salary (\$)</u>
Charles J. Link, Jr., M.D.	354,895	440,682
Nicholas N. Vahanian, M.D.	256,316	312,322
Gordon H. Link, Jr.	228,375	239,794
Kenneth Lynn	231,750	243,338
W. Jay Ramsey, M.D., Ph.D.	162,225	240,000

For 2009, base salaries increased by 3% from 2008 levels for Dr. Charles Link, Dr. Vahanian, Mr. Lynn and Dr. Ramsey, and increased by 1.5% for Mr. Gordon Link.

We will continue to review base salaries of our executive officers on an annual basis and make adjustments to reflect individual performance-based factors, as well as our financial status. Historically, we have not applied, nor do we intend to apply, specific formulas to determine base salary increases.

*Performance-Based Cash Bonuses.* Our performance-based cash bonus program is designed to promote the interests of the Company and its stockholders by providing executive officers with the opportunity to earn annual cash bonuses based upon the achievement of pre-specified corporate and individual performance objectives, and to assist the Company in attracting and retaining executive talent.

Our annual cash bonus amounts are recommended by our Compensation Committee and approved by our Board, and these bonuses are ordinarily paid in a single installment in the first quarter of each year for performance in the prior year. Each executive officer is eligible for a discretionary annual cash incentive payment up to a specified percentage of the executive officer's salary. The Board of Directors sets these target percentages at levels that, upon achievement of the target percentage, are likely to result in cash bonus payments that the Board believes to be approximately the level paid to high-performing executives of comparable companies in the biopharmaceutical industry.

At the end of each year, our Chief Executive Officer develops bonus recommendations for each of our executive officers, based on the company's corporate accomplishments and the individual's performance and contributions to those accomplishments during the year. These recommendations are subjective determinations which may vary, from time to time, depending on our overall strategic objectives and the job responsibilities of each executive officer, but relate generally to factors such as development and progression of our existing product candidates, achievement of clinical and regulatory milestones, operational goals such as the expansion of our manufacturing capabilities, and financial factors such as raising and maintaining capital. However, these recommendations may be more or less than the established target percentages for the executive officers, depending on individual and corporate performance, as well as our financial position. The Compensation Committee assesses the bonuses recommended by management and makes its bonus recommendations to the full Board of Directors. Based on its consideration of the recommendations of the Compensation Committee, the full Board then makes a final decision regarding cash bonus payments, if any, for the year. Whether or not a cash bonus is paid for any year is solely within the discretion of the Board.

For 2009, based upon recommendations of the Compensation Committee, the Board of Directors established target bonus amounts for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey equal to 50%, 40%, 25%, 20% and 15% of their 2010 base salaries. As a basis for these performance bonuses, the Compensation Committee established corporate and individual performance objectives in January 2009, which were communicated to the named executive officers at that time. The corporate goals for the year included:

- receiving approval from the FDA for the launch of our Phase 3 trial for HyperAcute Pancreas;
- developing Phase 2 clinical trial plans for D-1MT; and
- raising additional funding

Dr. Charles Link's performance goals for 2009 included leading the Company through the significant corporate developments referenced above. Dr. Vahanian's performance goals for 2009 included his role in running our day-to-day operations, including the achievements referenced above. Mr. Gordon Link's performance goals for 2009 included his primary responsibility, as our principal financial and accounting officer, for our Series C and Series D preferred stock financings that closed in 2009. Mr. Lynn's performance goals for 2009 included his role in establishing third party relationships and presenting our Company to outside companies for potential future collaborations. Dr. Ramsey's performance goals for 2009 included his role in regulatory and compliance accomplishments concerning clinical trials, manufacturing and quality assurance.

The Board determined that each of the 2009 corporate performance goals had been met or exceeded. The Compensation Committee determined that Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey had all met their individual 2009 performance goals. Taking all corporate and personal achievements into consideration, the Compensation Committee, in its discretion, made bonus recommendations for each executive officer in December 2009 and the Board of Directors adopted those bonus recommendations. The bonuses paid to Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey were equal to 50%, 40%, 25%, 20%, and 15% of their 2010 base salaries, respectively.

For 2010, based upon recommendations of the Compensation Committee, the Board of Directors established target bonus amounts for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey equal to 50%, 35%, 25%, 40% and 25% of their 2010 base salaries. The Compensation Committee also established corporate and individual performance objectives in June 2010, which were communicated to the named executive officers at that time. The corporate goals for the year included:

- launching a Phase 3 clinical trial for HyperAcute Pancreas and meeting specific targets for patient enrollment and number of clinical centers;

- launching a Phase 1B/2 clinical trial for D-1MT; and
- raising additional funding.

Each officer's individual goals consisted of one or more corporate goals and, in most cases, separate individual goals. Dr. Charles Link's performance goals for 2010 were the foregoing corporate goals. Dr. Vahanian's performance goals for 2010 included the corporate goals pertaining to the HyperAcute Pancreas and D-1MT trials and design of a HyperAcute Lung clinical study. Mr. Gordon Link's performance goals for 2010 included the corporate goal with respect to financing, raising additional funding and preparation for this offering. Mr. Lynn's performance goals for 2010 included the corporate goal with respect to financing, progress towards strategic third-party partnerships, and establishing an intellectual property committee. Dr. Ramsey's performance goals for 2010 included the corporate goal with respect to HyperAcute Pancreas trial, obtaining Orphan Drug and Fast Track approvals for HyperAcute Pancreas, validating the new HyperAcute immunotherapy production facility and initiating production of HyperAcute immunotherapy product candidates in that facility.

The Board determined that each of the 2010 corporate performance goals had been met or exceeded. The Compensation Committee determined that Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link and Dr. Ramsey had all met their individual 2010 performance goals. The Compensation Committee determined that Mr. Lynn achieved substantially all of his stated objectives, but did not fully satisfy his individual performance goals with respect to progress towards strategic partnerships. Taking all corporate and personal achievements into consideration, the Compensation Committee, in its discretion, made bonus recommendations for each executive officer in December 2010 and the Board of Directors adopted those bonus recommendations. The bonuses paid to Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey were equal to 50%, 35%, 25%, 28%, and 25% of their 2010 base salaries, respectively.

We have not determined whether we would seek to recover cash bonus payments paid to our executive officers if the performance objectives that led to the determination of such payments were to be restated or found not to have been met to the extent that we originally believed.

*Equity Compensation.* Equity incentives represent the largest at-risk component of our executive compensation program. Our equity incentives are designed to align the interests of our executive officers with those of our stockholders by creating an incentive for our executive officers to maximize stockholder value and to remain employed with us despite a competitive labor market through the grant of time-vested stock options.

Initial option grants to our executive officers are generally set forth in an offer letter. These initial option grants are the product of negotiation with the executive, but we generally seek to establish equity ownership levels that we believe are commensurate with the equity stakes of industry peers with comparable qualifications, experience, responsibilities and performance at similar companies. In addition, as part of our annual compensation review process, we provide subsequent option grants to those executive officers determined to be performing well.

In May 2009, we granted Dr. Charles Link a stock option for 1,538,275 shares and Dr. Vahanian a stock option for 695,725 shares, each at an exercise price of \$1.00 per share. These options vest over five years beginning on June 29, 2007, and expire on December 13, 2017. These grants had been initially approved by the Compensation Committee and the Board in June 2007, but the Company did not have sufficient shares authorized under its 2000 Equity Incentive Plan at that time. In 2009 the Company adopted the 2009 Equity Incentive Plan and these options were approved and granted by the Board under that plan. In December 2009, we granted Dr. Charles Link a stock option for 900,000 shares of common stock, and Dr. Vahanian a stock option for 800,000 shares of common stock, each at an exercise price of \$1.41 per share. These options vest as to 25% on the first anniversary of the date of grant and as to the remainder in equal monthly increments over the following 36 months. These options expire December 3, 2019. In March 2010, we granted Dr. Vahanian a stock option for 400,000 shares,



Mr. Gordon Link a stock option for 10,000 shares and Dr. Ramsey a stock option for 108,000 shares, each at an exercise price of \$1.46 per share. These options vest as to 25% on December 4, 2010 for Dr. Vahanian and March 3, 2011 for Mr. Gordon Link and Dr. Ramsey, and as to the remainder in equal monthly increments over the following 36 months. These options expire on March 2, 2020. All of these grants were recommended to the Board by our Compensation Committee, which considered the advice of our independent compensation consultants regarding executive equity ownership. Our independent compensation consultants compared our executives' ownership positions with other similarly-situated biopharmaceutical companies and, in recommending these grants, the Compensation Committee considered the executives' roles and responsibilities within the company, and their ownership positions in relation to similarly-situated companies as defined by our Compensation Committee. The December 2009 grants to Dr. Link and Dr. Vahanian and March 2010 grant to Dr. Vahanian resulted in equity ownership percentages above the median of the companies in the group of companies analyzed by our compensation consultant. The Compensation Committee and Board approved these grants in recognition of the leadership of Dr. Link and Dr. Vahanian in achieving company goals and raising capital.

*Severance and Change of Control Benefits.* We enter into employment agreements with our executives in select cases, generally when it is necessary to secure the services of a newly hired executive. We entered into employment agreements with each of Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey, as well as certain other officers. These agreements provide for severance compensation to be paid if the officers are terminated under certain conditions, such as in connection with a change-in-control of the Company or a termination without cause by us, each as defined in the agreements. The severance compensation payable under the employment agreements are described in more detail beginning on page 141 of this prospectus under the heading "Potential Payments Upon Termination or Change in Control."

In our experience, post-termination protection for executive officers is common among our peer group, and the Compensation Committee believes that providing this protection is essential to our ability to attract and retain talented executives capable of providing the leadership, vision and execution necessary to achieve our business objectives. In addition, the employment agreements and the related post-termination compensation provisions are designed to meet the following objectives:

- *Change in control:* As part of our normal course of business, we engage in discussions with other pharmaceutical companies about possible collaborations, licensing and/or other ways in which the companies may work together to further our respective long-term objectives. In addition, many larger established pharmaceutical companies consider companies at similar stages of development to ours as potential acquisition targets. In certain scenarios, the potential for a merger or being acquired may be in the best interests of our stockholders. We provide post-termination compensation if an officer is terminated as a result of a change-in-control transaction to promote the ability of our officers to act in the best interests of our stockholders even though they could be terminated as a result of the transaction.
- *Termination Without Cause:* In certain instances, if we terminate the employment of an officer "without cause" or the officer resigns for "good reason," each as defined in the applicable agreement, we are obligated to pay the officers certain severance benefits under their employment agreements. We believe this is appropriate because the terminated officer is bound by confidentiality and non-competition provisions covering one year after termination and because we and the officer have a mutually agreed-to severance package that is in place prior to any termination event. This provides us with more flexibility to make a change in senior management if such a change is in our and our stockholders' best interest.

*401(k) Plan.* Our employees, including our executive officers, are eligible to participate in our 401(k) plan. Our 401(k) plan is intended to qualify as a tax qualified plan under Section 401 of the Code. Our 401(k) plan provides that each participant may contribute a portion of his or her pretax

compensation, up to a statutory limit, which for most employees was \$16,500 in 2009 and 2010, with a larger "catch up" limit for older employees. Employee contributions are held and invested by the plan's trustee. We provide a contribution of 3% of each participant's salary with a possibility of an additional discretionary contributions.

*Other Benefits and Perquisites.* We pay a portion of the premiums for medical insurance, dental insurance, life insurance and accidental death and dismemberment insurance benefits to all full-time employees, including our executive officers. These benefits are available to all employees, subject to applicable laws. Our executive officers have not historically received perquisites valued in aggregate at more than \$10,000 per year per person, with the exception of Dr. Charles Link, who received perquisites totalling \$18,443 in 2009 and \$14,846 in 2010. The Compensation Committee will evaluate perquisites annually as an element of overall compensation. From time to time, we have provided relocation expenses in connection with the relocation of executive officers to the geographic area of our corporate headquarters in Ames, Iowa. We intend to continue to provide relocation expenses in the future, as necessary, to obtain the services of qualified individuals.

*Executive Loans.* Between September 2006 and October 2010, the Company and its subsidiary BPS extended loans to Dr. Charles Link, Dr. Vahanian and Mr. Gordon Link. The loans made by the Company were extended to Dr. Charles Link and Dr. Vahanian for personal purposes and to Mr. Gordon Link to facilitate purchase of a home in Ankeny, Iowa. In light of the Company's planned initial public offering, and in accordance with the recommendation of its compensation consultants, the Company's Compensation Committee recommended and the Company's Board agreed in May 2010 to forgive Dr. Charles Link's and Dr. Vahanian's loans and pay a bonus equal to the resulting tax liability in exchange for the executives' agreement to increase the exercise price of certain outstanding stock options. As of July 2, 2010, the aggregate exercise price of these options was increased by an amount equal to the principal and accrued interest on the loans forgiven plus the bonuses paid to cover the resulting tax liability. Mr. Gordon Link repaid his loan in full on May 11, 2010.

In September 2006, Dr. Charles Link and Dr. Vahanian delivered notes to BPS in the principal amounts of \$75,000 and \$20,000, respectively, bearing interest at 5.01% per annum, in order to purchase their shares of BPS Series B common stock under stock options. As of November 17, 2010, Dr. Link and Dr. Vahanian had repaid the remaining principal and interest owed under the notes. For a more detailed description of these loans, see "Executive and Director Compensation — Indebtedness of Management and Related Agreements." No loans to executives of the company or BPS are currently outstanding and it is the policy of the Company and BPS not to extend loans to officers or directors in the future.

*Other Compensation.* We intend to continue to maintain the current benefits for our executive officers, which are also available to all of our other employees; however, our Compensation Committee, in its discretion, may in the future revise, amend or add to the benefits of any executive officer if it deems it advisable.

#### ***Federal Tax Considerations Under Sections 162(m) and 409A***

Section 162(m) of the Code limits our deduction for federal income tax purposes to not more than \$1 million of compensation paid to specified executive officers in a calendar year. Compensation above \$1 million may be deducted if it is performance-based compensation within the meaning of Section 162(m). Our Compensation Committee has not yet established a policy for determining which forms of incentive compensation awarded to our executive officers will be designed to qualify as performance-based compensation. To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, our Compensation Committee has not adopted a policy that requires all compensation to be deductible. However, the committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the Compensation Committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders.

Section 409A of the Code addresses the tax treatment of nonqualified deferred compensation benefits and provides for significant taxes and penalties in the case of payment of nonqualified deferred compensation. We currently intend to structure our executive compensation programs to avoid triggering these taxes and penalties under Section 409A.

### ***Accounting Considerations***

Under ASC 718, we are required to estimate and record an expense for each award of equity compensation, including stock options, over the vesting period of the award. Our Board of Directors has determined to retain for the foreseeable future our stock option program as the sole component of its long-term compensation program, and, therefore, to record this expense on an ongoing basis according to ASC 718. Our Compensation Committee may in the future consider the grant of restricted stock or other equity-based awards to our executive officers in lieu of stock option grants, in light of the accounting impact of ASC 718 with respect to stock option grants.

### **Compensation Policies and Practices as They Relate to Risk Management**

The Company believes that risks arising from its compensation policies and practices for its employees are not reasonably likely to have a material adverse effect on the Company. In addition, the Compensation Committee believes that the mix and design of the elements of executive compensation do not encourage management to assume excessive risks.

The Compensation Committee has reviewed the elements of executive compensation to determine whether any portion of executive compensation encouraged excessive risk taking and concluded:

- significant weighting towards long-term incentive compensation discourages short-term risk taking, including use of multi-year vesting for equity awards which compromise the majority of compensation awards;
- goals are set to focus mainly on key events related to the overall success of the Company's product development rather than individual components;
- vesting conditions imposed on option awards after performance targets are reached discourage short-term risk taking;
- incentive awards are benchmarked to calculate reasonable overall compensation; and
- as a biopharmaceutical business, the Company does not face the same level of risks associated with compensation for employees at financial services companies (traders and instruments with a high degree of risk).

Furthermore, as described above in "Compensation Discussion and Analysis," compensation decisions include subjective considerations, which help to constrain the influence of formulae or objective factors on excessive risk taking.

**Summary Compensation Table**

The following table sets forth information regarding compensation earned during the years ended December 31, 2010 and 2009, by our principal executive officer, our principal financial officer and our three other most highly compensated executive officers serving as executive officers at December 31, 2010 whose total compensation exceeded \$100,000 for the year ended December 31, 2009. We refer to these persons as our named executive officers.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus(1) (\$)</b>	<b>Option Awards(2) (\$)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Charles J. Link, Jr., M.D.	2010	440,682	285,341(4)	—	643,609(5)	1,369,632
Chairman of the Board and Chief Executive and Scientific Officer	2009	354,895	298,490(6)	307,655	57,073(7)	1,018,113
Nicholas N. Vahanian, M.D.	2010	312,322	124,313(8)	—	78,571(9)	515,206
President and Chief Medical Officer	2009	256,316	179,966(10)	139,145	34,496	609,923
Gordon H. Link, Jr.	2010	239,794	59,949	—	23,345(11)	323,088
Chief Financial Officer	2009	228,375	59,948	52,500	13,294(12)	354,117
Kenneth Lynn	2010	243,338	68,135	—	13,190	324,663
Executive Vice President of Business Development	2009	231,750	48,668	52,500	14,350	347,268
W. Jay Ramsey, M.D., Ph.D.	2010	240,000	60,000	—	12,827	312,827
Quality Assurance Officer	2009	162,225	36,000	8,400	13,597	220,222

- (1) Performance bonuses are based on a percentage of 2010 base salary. For 2010 and 2009, Dr. Charles Link was awarded cash performance bonuses of 50% of his 2010 base salary, which was \$440,682. For 2010 and 2009, Dr. Vahanian was awarded cash performance bonuses of 35% and 40%, respectively, of his 2010 base salary, which was \$312,332. For 2010 and 2009, Mr. Gordon Link was awarded cash performance bonuses of 25% of his 2010 base salary, which was \$239,794. For 2010 and 2009, Mr. Lynn was awarded cash performance bonuses of 28% and 20%, respectively, of his 2010 base salary, which was \$243,338. For 2010 and 2009, Dr. Ramsey was awarded cash performance bonuses of 25% and 15%, respectively, of his 2010 base salary, which was \$240,000.
- (2) The assumptions we used in valuing options are described under the caption "Stock Option Valuation" in note 2(n) to our financial statements included in this prospectus. This column reflects compensation expense that would be recorded under ASC 718 as stock-based compensation in our financial statements for the indicated year in connection with options we granted in the indicated year and in prior years, adjusted to disregard the effects of any estimate of forfeitures related to service-based vesting, if we had adopted the modified-prospective transition method of ASC 718. As a result, unlike our financial statements for the indicated year, the amounts in the table include values associated with stock options that were granted prior to January 1, 2006 and that had not fully vested prior to the indicated year, and assume that the executive will perform the requisite service for the award to vest.
- (3) Unless otherwise indicated, amounts in this column represent Company contributions under our 401(k) plan.
- (4) Amount includes the performance bonus discussed in footnote (1) and bonuses of \$50,000 and \$15,000 received by Dr. Charles Link from BPS.
- (5) Amount includes: (i) a \$29,850 contribution under the Company's 401(k) plan; (ii) \$14,846 in perquisites and personal benefits received by Dr. Charles Link that we reimbursed or paid on his

behalf in 2010, including insurance, memberships, a medical license and various other Company provided benefits; (iii) \$43,517 in loan and accrued interest forgiveness by BPS; and (iv) \$555,396 in loan and accrued interest forgiveness by the Company and a tax gross-up, which was offset by increasing the exercise price of options to purchase 555,396 shares of common stock held by Dr. Link from \$1.00 per share to \$2.00 per share, as described in more detail on page 154 of this prospectus.

- (6) Amount includes the performance bonus discussed in footnote (1) and a \$78,149 bonus received by Dr. Charles Link from the Company.
- (7) Amount includes (i) a \$38,630 contribution under the Company's 401(k) plan and (ii) \$18,443 in perquisites and personal benefits received by Dr. Charles Link that we reimbursed or paid on his behalf in 2009, including insurance, memberships, a medical license and various other Company provided benefits.
- (8) Amount includes the performance bonus discussed in footnote (1) and a \$15,000 bonus received by Dr. Vahanian from BPS.
- (9) Amount includes: (i) a \$19,600 contribution under the Company's 401(k) plan; (ii) \$10,357 of loan interest forgiveness; (iii) \$11,604 in loan and accrued interest forgiveness by BPS; and (iv) \$37,010 in loan and accrued interest forgiveness by the Company and a tax gross-up, which was offset by increasing the exercise price of options to purchase 37,010 shares of common stock held by Dr. Vahanian from \$1.00 per share to \$2.00 per share, as described in more detail on page 155 of this prospectus.
- (10) Amount includes the performance bonus discussed in footnote (1) and a \$55,037 bonus received by Dr. Vahanian from the Company.
- (11) Amount includes (i) a \$13,345 contribution under the Company's 401(k) plan, of which \$5,995 is non-vested and subject to Mr. Link's continued service with the Company through 2011, and (ii) \$10,000 in loan and accrued interest forgiveness by the Company.
- (12) Amount represents a \$13,294 contribution under the Company's 401(k) plan, of which \$7,000 is non-vested and subject to Mr. Link's continued service with the Company through 2011.

**2010 Grants of Plan-Based Awards**

The following table lists grants of plan-based awards made to our named executive officers in 2010:

<b>Grants Of Plan-Based Awards</b>				
<b>Name</b>	<b>Grant Date</b>	<b>All Other Option Awards: Number of Securities Underlying Options (#)</b>	<b>Exercise or Base Price of Option Awards (\$/Sh)</b>	<b>Fair Value of Shares Available Under Grant</b>
Nicholas N. Vahanian	3/3/2010	400,000(1)	\$ 1.46	\$ 584,000
Gordon H. Link, Jr.	3/3/2010	10,000(2)	\$ 1.46	\$ 14,600
W. Jay Ramsey	3/3/2010	108,000(2)	\$ 1.46	\$ 157,680

- (1) The vesting commencement date of these options was December 4, 2009. See "Executive and Director Compensation — Elements of our Executive Compensation Program — Equity Compensation" for further discussion of this option grant.
- (2) The vesting commencement date of these options was March 3, 2010. See "Executive and Director Compensation — Elements of our Executive Compensation Program — Equity Compensation" for further discussion of this option grant.

**Outstanding Equity Awards at End of 2010**

The following table provides information about outstanding stock options held by each of our named executive officers at December 31, 2010. All of these options were granted under our 2000 Equity Incentive Plan. Our named executive officers did not hold any restricted stock or other stock awards at the end of 2010.

Name	Number of Shares Underlying Unexercised Options(1)		Option Vesting Commencement Date	Option Exercise Price	Option Expiration Date
	(#) Exercisable	(#) Unexercisable(2)			
Charles J. Link, Jr., M.D.	688,015(4)(6)	294,864	6/1/2007	\$ 1.00	5/12/2019
	388,777(4)(6)	166,619	6/1/2007	\$ 2.00	5/12/2019
	225,000(3)	675,000	12/4/2009	\$ 1.41	12/3/2019
	2,064(4)(8)	3,321	1/1/2009	\$ 0.38	1/20/2019
Nicholas N. Vahanian, M.D.	5,000(5)	0	10/18/2002	\$ 1.00	7/15/2018
	75,000(3)	0	10/18/2002	\$ 1.00	7/15/2018
	461,100(4)(7)	197,615	6/1/2007	\$ 1.00	5/12/2019
	25,907(4)(7)	11,103	6/1/2007	\$ 2.00	5/12/2019
	200,000(3)	600,000	12/4/2009	\$ 1.41	12/3/2019
	100,000(3)	300,000	12/4/2009	\$ 1.46	3/2/2010
	2,064(4)(8)	3,321	1/1/2009	\$ 0.38	1/21/2009
Gordon H. Link, Jr.	116,666(3)	83,334	8/4/2008	\$ 1.00	8/5/2018
	10,000(5)	0	3/3/2010	\$ 1.46	3/2/2020
	4,712(3)(8)	3,366	8/1/2008	\$ 0.38	9/11/2018
Kenneth Lynn	148,750(3)	61,250	2/25/2008	\$ 1.00	8/5/2018
	4,577(4)(8)	3,501	2/25/2008	\$ 0.38	1/20/2019
W. Jay Ramsey, M.D., Ph.D.	28,000(4)	12,000	6/29/2007	\$ 1.00	6/28/2017
	5,000(3)	0	10/18/2002	\$ 1.00	7/15/2018
	5,000(3)	0	9/1/2004	\$ 1.00	7/15/2018
	2,000(4)	0	4/4/2005	\$ 1.00	7/15/2018
	0(3)	108,000	3/3/2010	\$ 1.46	3/2/2020

- (1) Unless otherwise indicated, these options have a 10-year term.
- (2) This column shows options that were unvested as of December 31, 2010.
- (3) These options vest over a four-year period, with 25% of the options vesting on the first anniversary of the vesting commencement date and the remaining 75% of the options vesting in equal monthly installments thereafter over the next three years, subject to the recipient's continued employment with the Company through such vesting dates.
- (4) These options vest over a five-year period, with 20% of the options vesting on the first anniversary of the vesting commencement date and the remaining 80% of the options vesting in equal monthly installments thereafter over the next four years, subject to the recipient's continued employment with the Company through such vesting dates.
- (5) These options and were fully vested as of the date of grant.
- (6) Dr. Charles Link was granted a total option of 1,538,275 shares at \$1.00 per shares, which was amended on July 1, 2010 and split into separate grants of 982,879 with a price of \$1.00 and 555,396 with a price of \$2.00.
- (7) Dr. Nicholas Vahanian was granted a total option of 695,725 shares at \$1.00 per shares, which was amended on July 1, 2010 and split into separate grants of 658,715 with a price of \$1.00 and 37,010 with a price of \$2.00
- (8) This number represents outstanding stock options to purchase stock in the Company that were issued on January 7, 2011 in exchange for options to purchase stock in our subsidiary, BPS.

**2010 Option Exercises and Stock Vested**

The following table lists exercise of stock options during 2010 for each of the named executive officers:

<b>Name</b>	<b>Option Awards</b>	
	<b>Number of Shares Acquired on Exercise (#)</b>	<b>Value Realized on Exercise (\$)</b>
Nicholas N. Vahanian, M.D.	75,000	18,750
Gordon H. Link, Jr.	10,000	10,000

**Employment Agreements**

The Company has entered into employment agreements with each of the named executive officers. The material terms of the agreements are summarized below.

**Employment Agreement with Dr. Charles Link**

On December 6, 2010, the Company entered into an employment agreement with Dr. Charles Link in connection with his employment as Chief Executive Officer. Pursuant to the employment agreement, Dr. Link earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Dr. Link earns an annual base salary of \$440,682. Dr. Link is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Dr. Link's target bonus is set at 50% of his annual base salary.

The employment agreement with Dr. Link also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Link or the Company at any time. However, if the Company terminates Dr. Link's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Dr. Link executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

The employment agreement with Dr. Link further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Link's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Dr. Link executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

**Employment Agreement with Dr. Nicholas Vahanian**

On November 22, 2010, the Company entered into an employment agreement with Dr. Nicholas Vahanian in connection with his employment as President and Chief Medical Officer. Pursuant to the employment agreement, Dr. Vahanian earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Dr. Vahanian earns an annual base salary of \$312,332. Dr. Vahanian is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Dr. Vahanian's target bonus is set at 35% of his annual base salary.

The employment agreement with Dr. Vahanian also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Vahanian or the Company at any

time. However, if the Company terminates Dr. Vahanian's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Dr. Vahanian executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

The employment agreement with Dr. Vahanian further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Vahanian's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Dr. Vahanian executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

***Employment Agreement with Mr. Gordon Link***

On November 22, 2010, the Company entered into an employment agreement with Mr. Gordon Link in connection with his employment as Chief Financial Officer. Pursuant to the employment agreement, Mr. Link earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Mr. Link earns an annual base salary of \$239,794. Mr. Link is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Mr. Link's target bonus is set at 25% of his annual base salary.

The employment agreement with Mr. Link also provides that his employment with the Company is at-will and may be altered or terminated by either Mr. Link or the Company at any time. However, if the Company terminates Mr. Link's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Mr. Link executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

The employment agreement with Mr. Link further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Link's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Mr. Link executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

***Employment Agreement with Mr. Kenneth Lynn***

On November 22, 2010, the Company entered into an employment agreement with Mr. Kenneth Lynn in connection with his employment as Executive Vice President, Business Development. Pursuant to the employment agreement, Mr. Lynn earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Mr. Lynn earns an annual base salary of \$243,338. Mr. Lynn is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Mr. Lynn's target bonus is set at 40% of his annual base salary.

The employment agreement with Mr. Lynn also provides that his employment with the Company is at-will and may be altered or terminated by either Mr. Lynn or the Company at any time. However, if the Company terminates Mr. Lynn's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Mr. Lynn executes a general release in favor of the Company, he will be entitled to receive certain payments and other



benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

The employment agreement with Mr. Lynn further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Lynn's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Mr. Lynn executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

***Employment Agreement with Dr. W. Jay Ramsey***

On November 22, 2010, the Company entered into an employment agreement with Dr. W. Jay Ramsey in connection with his employment as Quality Assurance and Quality Control Officer. Pursuant to the employment agreement, Dr. Ramsey earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Dr. Ramsey earns an annual base salary of \$240,000. Dr. Ramsey is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Dr. Ramsey's target bonus is set at 25% of his annual base salary.

The employment agreement with Dr. Ramsey also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Ramsey or the Company at any time. However, if the Company terminates Dr. Ramsey's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Dr. Ramsey executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

The employment agreement with Dr. Ramsey further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Ramsey's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Dr. Ramsey executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 141 of this prospectus.

***Potential Payments Upon Termination or Change in Control***

Under the terms of employment agreements with our named executive officers, if the Company terminates a named executive officer's employment for "cause" or a named executive officer resigns without "good reason," such named executive officer is entitled to the following: (i) any salary earned but unpaid prior to termination, (ii) any benefits accrued prior to termination, (iii) all accrued but unused vacation and (iv) any business expenses that were incurred but not reimbursed as of the date of termination (collectively, the "Accrued Obligations"). Following such termination, vesting of such named executive officer's then outstanding stock options shall cease on the date of such termination.

Under the terms of employment agreements with the named executive officers, if the Company terminates a named executive officer's employment without just cause or a named executive officer resigns with good reason (other than in connection with a change in control of the Company), and in each case such named executive officer signs a general release and written acknowledgment of his continuing obligations under his confidentiality and inventions assignment agreement with the Company, such named executive officer is entitled to the following: (i) payment of the Accrued Obligations; (ii) depending on the named executive officer and as described in the tables below, the equivalent of 24, 12 or 6 months of such named executive officer's base salary as in effect immediately

prior to the termination date, payable on the same basis and at the same time as previously paid and subject to employment tax withholdings and deductions; and (iii) depending on the named executive officer and as described in the tables below, payment of such named executive officer's COBRA premiums for 24, 12 or 6 months to be paid in order for such named executive officer to maintain medical insurance coverage that is substantially equivalent to that which such named executive officer received immediately prior to the termination payment of premiums for his group health insurance. In the event that such named executive officer breaches his confidentiality, non-compete or non-solicitation obligations under his confidentiality and inventions assignment agreement with the Company, the payments described above, except for the Accrued Obligations, shall cease, and the Company shall have no further obligations to such named executive officer with respect thereto. The Company's obligation to pay such named executive officer's COBRA premiums ceases upon such named executive officer's eligibility for comparable coverage provided by a new employer.

Under the terms of the employment agreements with the named executive officers, if the Company (or any surviving or acquiring corporation) terminates a named executive officer's employment without cause or a named executive officer resigns with good reason within one month prior to or 13 months following the effective date of a change in control of the Company (either constituting a "Change of Control Termination"), and in each case such named executive officer signs a general release and written acknowledgment of his continuing obligations under his confidentiality and inventions assignment agreement with the Company, such named executive officer is entitled to the following: (i) payment of the Accrued Obligations; (ii) depending on the named executive officer and as described in the tables below, the equivalent of 24, 12 or 6 months of such named executive officer's base salary as in effect immediately prior to the termination date, payable on the same basis and at the same time as previously paid and subject to employment tax withholdings and deductions; (iii) depending on the named executive officer and as described in the tables below, payment of such named executive officer's COBRA premiums for 24, 12 or 6 months to be paid in order for such named executive officer to maintain medical insurance coverage that is substantially equivalent to that which such named executive officer received immediately prior to the termination payment of premiums for his group health insurance; and (iv) the Company will vest 100% of the shares subject to such named executive officer's options and such vesting shall occur upon the occurrence of the change of control in the case of a Change of Control Termination occurring prior to the change in control or upon termination in the case of a Change of Control Termination occurring after the change of control. If a named executive officer breaches his confidentiality, non-compete or non-solicitation obligations under his confidentiality and inventions assignment agreement with the Company, the payments described above, except for the Accrued Obligations, shall cease, and the Company shall have no further obligations to such named executive officer with respect thereto. The Company's obligation to pay such named executive officer's COBRA premiums ceases upon such named executive officer's eligibility for comparable coverage provided by a new employer.

The following tables reflect the estimated potential payments that would be payable to each named executive officer upon a termination or change-in-control of the Company under the terms of his employment agreement. The amounts shown reflect only the additional payments or benefits that each named executive officer would have received upon the occurrence of the respective triggering events listed below; they do not include the value of payments or benefits that would have been earned, or any amounts associated with equity awards that would have vested, absent the triggering event. For purposes

of calculating the potential payments set forth in the tables below, we have assumed that (i) the date of termination was December 31, 2010 and (ii) the stock price was \$4.77.

	<b>Termination For Just Cause or Resignation Without Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)</b>
<b>Charles J. Link, Jr., M.D.</b>			
<i>Cash Payments</i>			
Cash Severance	\$ —	\$ 881,364(1)	\$ 881,364(1)
<i>Long-Term Incentives</i>			
Stock Options (Unvested and Accelerated)	—	—	1,136,483(2)
<i>Benefits and Perquisites</i>			
Accrued Obligations	39,449(3)	39,449(3)	39,449(3)
Benefits Continuation	—	21,753(4)	21,753(4)
<b>Total Payments Upon Termination</b>	<b>\$ 39,449</b>	<b>\$ 942,566</b>	<b>\$ 2,079,049</b>

- (1) Amount represents 24 months of his base salary then in effect.
- (2) Amount represents the in-the-money value of unvested NewLink stock options as of December 31, 2010, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options — Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at End of 2010" table set forth on page 138 of this prospectus. Amount excludes the in-the-money value of 12,334 unvested BPS stock options as of December 31, 2010, which equals \$1,233 using the value of BPS's Series B common stock on December 31, 2010 based on the value of BPS's Series B common stock used for purposes of calculating compensation expense under ASC 718.
- (3) Amount represents (i) a \$22,500 contribution under the Company's \$401(k) plan and (ii) \$16,949 in accrued vacation.
- (4) Amount represents 24 months of COBRA premiums.

	<b>Termination For Just Cause or Resignation Without Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)</b>
<b>Nicholas N. Vahanian, M.D.</b>			
<i>Cash Payments</i>			
Cash Severance	\$ —	\$ 312,332(1)	\$ 312,332(1)
<i>Long-Term Incentives</i>			
Stock Options (Unvested and Accelerated)	—	—	1,492,718(2)
<i>Benefits and Perquisites</i>			
Accrued Obligations	24,262(3)	24,262(3)	24,262(3)
Benefits Continuation	—	10,876(4)	10,876(4)
<b>Total Payments Upon Termination</b>	<b>\$ 24,262</b>	<b>\$ 347,470</b>	<b>\$ 1,840,188</b>

- (1) Amount represents 12 months of his base salary then in effect.
- (2) Amount represents the in-the-money value of unvested NewLink stock options as of December 31, 2010, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options — Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at End of 2010" table set forth on page 138 of this prospectus. Amount excludes the in-the-money value of 12,334 unvested BPS stock options as of December 31, 2010, which equals \$1,233 using the value of BPS's Series B common stock on December 31, 2010 based on the value of BPS's Series B common stock used for purposes of calculating compensation expense under ASC 718.
- (3) Amount represents (i) a \$12,250 contribution under the Company's \$401(k) plan and (ii) \$12,012 in accrued vacation.
- (4) Amount represents 12 months of COBRA premiums.

	<b>Termination For Just Cause or Resignation Without Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)</b>
<b>Gordon H. Link, Jr.</b>			
<i>Cash Payments</i>			
Cash Severance	\$ —	\$ 119,897(1)	\$ 119,897(1)
<i>Long-Term Incentives</i>			
Stock Options (Unvested and Accelerated)	—	—	83,334(2)
<i>Benefits and Perquisites</i>			
Accrued Obligations	9,223(3)	9,223(3)	9,223(3)
Benefits Continuation	—	5,438(4)	5,438(4)
<b>Total Payments Upon Termination</b>	<b>\$ 9,223</b>	<b>\$ 134,558</b>	<b>\$ 217,892</b>

- (1) Amount represents six months of his base salary then in effect.
- (2) Amount represents the in-the-money value of unvested NewLink stock options as of December 31, 2010, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The

number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options — Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at End of 2010" table set forth on page 138 of this prospectus. Amount excludes the in-the-money value of 12,500 unvested BPS stock options as of December 31, 2010, which equals \$1,250 using the value of BPS's Series B common stock on December 31, 2010 based on the value of BPS's Series B common stock used for purposes of calculating compensation expense under ASC 718.

- (3) Amount represents \$9,223 in accrued vacation.
- (4) Amount represents six months of COBRA premiums.

<b>Kenneth Lynn</b>	<b>Termination For Just Cause or Resignation Without Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)</b>
<i>Cash Payments</i>			
Cash Severance	\$ —	\$ 121,669(1)	\$ 121,669(1)
<i>Long-Term Incentives</i>			
Stock Options (Unvested and Accelerated)	—	—	61,250(2)
<i>Benefits and Perquisites</i>			
Accrued Obligations	15,199(3)	15,199(3)	15,199(3)
Benefits Continuation	—	5,438(4)	5,438(4)
<i>Total Payments Upon Termination</i>	<u>\$ 15,199</u>	<u>\$ 142,306</u>	<u>\$ 203,556</u>

- (1) Amount represents six months of his base salary then in effect.
- (2) Amount represents the in-the-money value of unvested NewLink stock options as of December 31, 2010, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options — Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at End of 2010" table set forth on page 138 of this prospectus. Amount excludes the in-the-money value of 13,000 unvested BPS stock options as of December 31, 2010, which equals \$1,300 using the value of BPS's Series B common stock on December 31, 2010 based on the value of BPS's Series B common stock used for purposes of calculating compensation expense under ASC 718.
- (3) Amount represents (i) a \$5,840 contribution under the Company's \$401(k) plan and (ii) \$9,359 in accrued vacation.
- (4) Amount represents six months of COBRA premiums.

<b>W. Jay Ramsey, M.D., Ph.D.</b>	<b>Termination For Just Cause or Resignation Without Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason Termination</b>	<b>Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)</b>
<i>Cash Payments</i>			
Cash Severance	\$ —	\$ 120,000(1)	\$ 120,000(1)
<i>Long-Term Incentives</i>			
Stock Options (Unvested and Accelerated)	—	—	169,680(2)
<i>Benefits and Perquisites</i>			
Accrued Obligations	12,869(3)	12,869(3)	12,869(3)
Benefits Continuation	—	3,354(4)	3,354(4)
<i>Total Payments Upon Termination</i>	<u>\$ 12,869</u>	<u>\$ 136,223</u>	<u>\$ 305,903</u>

- (1) Amount represents six months of his base salary then in effect.
- (2) Amount represents the in-the-money value of unvested NewLink stock options as of December 31, 2010, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options — Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at End of 2010" table set forth on page 138 of this prospectus.
- (3) Amount represents (i) a \$5,477 contribution under the Company's \$401(k) plan and (ii) \$7,392 in accrued vacation.
- (4) Amount represents six months of COBRA premiums.

***Option Acceleration Under Equity Incentive Plans***

Under our 2009 Equity Incentive Plan, the vesting of stock options granted to our employees and officers may be accelerated in connection with specified corporate transactions and change in control transactions.

Under the terms of the employment agreements with the named executive officers, if the Company (or any surviving or acquiring corporation) terminates a named executive officer's employment without just cause or a named executive officer resigns with good reason within one month prior to or 13 months following the effective date of a change in control of the Company, the Company will vest 100% of the shares subject to such named executive officer's options.

In addition, in the event of a change in control of the Company, the Company will vest 100% of the shares subject to each Director's options.

Other than as set forth above, none of our other option grants provide for acceleration of vesting of any options in connection with such a transaction, unless the acquirer does not assume outstanding option grants.

***Confidential Information and Inventions Agreement***

Each of our named executive officers has entered into a form agreement with respect to confidential information and inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our confidential information received during the course of employment and, with some exceptions, to assign to us any inventions conceived or developed during the course of employment.

## **Employee Benefit Plans**

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate qualified service providers, and encourages them to devote their best efforts to our business and financial success. The material terms of our equity incentive plans are described below.

### ***2000 Equity Incentive Plan***

On April 10, 2000, the stockholders approved the Company's 2000 Equity Incentive Plan, or the 2000 Plan. As of July 15, 2009, no additional stock awards have been granted under the 2000 Plan and the 2000 Plan terminated according to its terms on March 2, 2010. As of December 31, 2010, options to purchase 1,167,072 shares of common stock at a weighted average exercise price per share of \$0.90 were outstanding under the 2000 Plan.

### ***2009 Equity Incentive Plan***

On July 16, 2009, the stockholders approved the Company's 2009 Equity Incentive Plan, or the 2009 Plan, as the successor to and continuation of the 2000 Plan. The options still outstanding under the 2000 Plan will continue to be governed by their existing terms, but any shares subject to outstanding options granted under the 2000 Plan that expire or terminate for any reason prior to exercise or settlement, or are forfeited because of the failure to meet a contingency or condition required to vest such shares, will become available for issuance pursuant to awards granted under the 2009 Plan. In anticipation of our initial public offering, the 2009 Plan was amended by our Board of Directors on October 29, 2010.

*Available Awards.* The 2009 Plan provides for the discretionary grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards to our employees, directors and consultants. Incentive stock options may be granted only to employees of the Company or our affiliates.

*Administration.* Our Board of Directors has delegated its authority to administer the 2009 Plan to our Compensation Committee. Subject to the terms of the 2009 Plan, our Board of Directors or an authorized committee, referred to as the "plan administrator," determines: grant recipients, when and how each award will be granted, what type or combination of types of award will be granted, the provisions of each award granted (including the time or times when a person will be permitted to receive cash or common stock pursuant to a stock award), the number of shares of common stock with respect to which a stock award will be granted, and the fair market value applicable to a stock award.

The plan administrator also has the authority, under appropriate circumstances, to engage in any action that is treated as a repricing under United States generally accepted accounting principles, to reduce the exercise price of any outstanding option or the strike price of any outstanding stock appreciation right, and to cancel any outstanding option or stock appreciation right and to grant in exchange one or more of the following: (i) new options or stock appreciation rights covering the same or a different number of shares of common stock; (ii) new stock awards; (iii) cash, and/or (iv) other valuable consideration.

*Amendment and Termination.* The plan administrator has the authority to amend the 2009 Plan, provided that certain changes require the approval of our stockholders. The 2009 Plan is scheduled to terminate on May 12, 2019, unless terminated earlier by the plan administrator.

*Share Reserve.* Subject to the provisions of the 2009 Plan relating to adjustments upon changes in stock, the aggregate number of shares of common stock that are available for issuance pursuant to

stock awards (including incentive stock options) under the 2009 Plan is 8,385,000 shares. This amount will be increased pursuant to an "evergreen provision" on January 1 of each year, from 2012 to (and including) 2019, in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year. However, our Board of Directors will have the authority to designate a lesser number of shares by which the share reserve will be increased. As of December 31, 2010, options to purchase 5,203,250 shares of common stock at a weighted average exercise price per share of \$1.49 were outstanding under the 2009 Plan. As of December 31, 2010, 1,704,750 shares of common stock remained available for future issuance.

If a stock award (a) granted under the 2009 Plan expires or otherwise terminates without all of the shares covered by such stock award having been issued or (b) granted under the 2009 Plan is settled in cash (i.e., the holder of the stock award receives cash rather than stock), such expiration, termination or settlement will not reduce or otherwise offset the number of shares of the common stock that may be issued pursuant to the 2009 Plan. In addition, if any shares of common stock issued pursuant to a stock award granted under the 2009 Plan are forfeited back to or repurchased by the Company because of the failure to vest, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the 2009 Plan. In addition, if any shares subject to a stock award are not delivered to a participant because the shares are reacquired by the Company to satisfy withholding obligations upon the exercise of an option, or as consideration for the exercise of an option, the number of shares subject to the stock award that are not delivered to the participant will also be available for subsequent issuance under the 2009 Plan. Subject to the provisions of the 2009 Plan relating to capitalization adjustments, the aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options will be 8,385,000 shares of common stock.

The stock issuable under the 2009 Plan may be shares of authorized but unissued or reacquired common stock, including shares repurchased by the Company on the open market.

*Stock Options.* Incentive and nonstatutory stock options are granted pursuant to incentive and nonstatutory stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2009 Plan, provided that the exercise price of an incentive stock option and nonstatutory stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2009 Plan vest at the rate specified by the plan administrator.

Generally, the plan administrator determines the term of stock options granted under the 2009 Plan, up to a maximum of 10 years, except in the case of specified incentive stock options, as described below. Unless the terms of an optionee's stock option agreement provide otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than a termination for cause or a termination because of disability or death, the optionee may exercise the vested portion of any options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a specified period following cessation of service), the optionee or a beneficiary may exercise the vested portion of any options for a period of 12 months or 18 months, respectively. In the event of a termination of an optionee's services for cause, the unexercised portion of any outstanding stock option held by the optionee will be forfeited and may not be exercised. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include cash or check, a broker-assisted cashless exercise, the tender of common stock previously owned by the optionee, a net exercise of the option, and other legal consideration approved by the plan administrator.



Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionee may designate a beneficiary, however, who may exercise the option following the optionee's death.

*Tax Limitations on Incentive Stock Options.* Incentive stock options may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year under all of our equity incentive plans may not exceed \$100,000. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and the term of the incentive stock option does not exceed five years from the date of grant.

*Restricted Stock Awards.* Restricted stock is stock that is subject to certain restrictions, such as vesting or a holding period. The plan administrator may award restricted stock in consideration for past or future services without the payment of a purchase price, or in consideration for a cash payment or other legal consideration. Even while the restricted stock award is unvested, the award holder will have the same general rights as a stockholder with respect to those shares, including the right to vote those shares in any matter put to our stockholders for a vote.

*Restricted Stock Unit Awards.* A restricted stock unit award represents the right to receive consideration in the future based on the value of our common stock when the shares of common stock subject to the award have vested or are subsequently deliverable. Restricted stock unit awards may be settled by the delivery of shares of our common stock, their cash equivalent, a combination thereof, or any other form of consideration determined by the plan administrator and detailed in the award recipient's restricted stock unit award agreement. Unlike restricted stock, a holder of a restricted stock unit award does not have any rights as a stockholder until shares subject to the award are actually issued. Specifically, award holders do not have rights to vote the shares subject to their awards and will not have rights to receive dividends with respect to the shares subject to their awards, unless and until those shares are actually issued.

*Performance Stock Awards.* The 2009 Plan permits the grant of performance stock awards that may qualify as performance-based compensation that is not subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To assure that the compensation attributable to one or more performance stock awards will so qualify, our Compensation Committee can structure one or more such awards so that stock will be issued or paid pursuant to such award only upon the achievement of certain pre-established performance goals during a designated performance period. The maximum benefit to be received by a participant in any calendar year attributable to performance stock awards may not exceed 500,000 shares of our common stock.

*Other Stock Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award and all other terms and conditions of such awards.

*Adjustment Provisions.* Transactions not involving our receipt of consideration, such as certain mergers, consolidations, reorganizations, stock dividends, or stock splits, may change the type, class and number of shares of our common stock subject to the 2009 Plan and outstanding awards. In that event, the 2009 Plan will be appropriately adjusted as to the type, class and the maximum number of shares of our common stock subject to the 2009 Plan, and outstanding awards will be adjusted as to the type, class, number of shares and price per share of common stock subject to such awards.

*Corporate Transactions; Changes in Control.* Unless otherwise determined by the Board of Directors at the time of grant, in the event of (i) a sale or other disposition of all or substantially all of

the consolidated assets of our company and our subsidiaries, (ii) a sale or disposition of at least 90% of our outstanding securities, (iii) a merger consolidation or similar transaction after which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction after which we are the surviving corporation but our shares of common stock immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, any unvested portion of a stock award granted under the 2009 Plan held by those in continuous service as of the effective time of the corporate transaction will become fully vested, unless the surviving or acquiring corporation assumes or continues such outstanding stock award or substitutes a similar stock award for such outstanding stock award.

If a change in control occurs under the 2009 Plan, an individual stock award may provide for accelerated vesting upon the change in control. A change in control includes a transaction or series of related transactions, in each case, where persons who were not our stockholders immediately prior to acquiring our capital stock as part of such transaction become the owners of our capital stock that represents more than 50% of the combined voting power of our outstanding capital stock.

### **2010 Employee Stock Purchase Plan**

On October 29, 2010, our Board of Directors adopted our 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, and our stockholders approved the 2010 Purchase Plan on January 7, 2011. The 2010 Purchase Plan will become effective upon the closing of the initial public offering.

*Share Reserve.* Subject to the provisions of the 2010 Purchase Plan relating to capitalization adjustments, the shares of common stock that may be sold pursuant to purchase rights shall not exceed in the aggregate 450,000 shares of common stock. If any purchase right granted under the 2010 Purchase Plan will for any reason terminate without having been exercised, the shares of common stock not purchased under such purchase right will again become available for issuance under the 2010 Purchase Plan. The 2010 Purchase Plan is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

*Administration.* Our Board of Directors has delegated its authority to administer the 2010 Purchase Plan to our Compensation Committee. Subject to the terms of the 2010 Purchase Plan, our Board of Directors or an authorized Committee, referred to as the "plan administrator," determines the provisions of each offering of rights to purchase our common stock and whether employees of any of our parent or subsidiary companies will be eligible to participate in the 2010 Purchase Plan. The 2010 Purchase Plan will be implemented through a series of offerings of such duration as determined by the plan administrator to eligible employees, provided that in no event may an offering exceed 27 months. Each offering will consist of one or more purchase periods as determined by the plan administrator prior to the commencement of that offering. The plan administrator has the authority to alter the duration of subsequent offerings or change the number of purchase dates within each such offering. The provisions of separate offerings need not be identical. When an eligible employee elects to join an offering, he or she will be granted a purchase right to acquire shares of common stock on each purchase date within the offering. On the purchase date, all payroll deductions collected from the participant are automatically applied to the purchase of common stock, subject to certain limitations. The plan administrator has not yet established the terms of any offering.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of any of our parent or subsidiary companies designated by the plan administrator may contribute, normally through payroll deductions, up to 15% of their eligible cash compensation (or such lesser amount set by the plan administrator for a specific offering) for the purchase of common stock under the 2010 Purchase Plan. Amounts deducted and accumulated for a participant are used to purchase shares of our common stock on the purchase dates established by the plan administrator. All payroll deductions made for a participant are credited to his or her account under the 2010 Purchase Plan and deposited with our general funds. A participant may make additional payments into such

account only as specifically provided for in the offering and only if the participant has not exceeded certain limitations under the 2010 Purchase Plan or under the terms of such offering. The 2010 Purchase Plan permits common stock to be purchased at a price per share no less than the lower of (i) 85% of the fair market value of a share of our common stock on the offering date, or (ii) 85% of the fair market value of a share of our common stock on the applicable purchase date.

*Purchase of Stock.* An eligible employee must sign and return an agreement in order to participate in the 2010 Purchase Plan. In connection with offerings made under the 2010 Purchase Plan, the plan administrator may specify a maximum number of shares of common stock a participant may purchase and the maximum aggregate number of shares of common stock that may be purchased by all participants in such offering. In addition, in connection with each offering that contains more than one purchase date, the plan administrator may specify a maximum aggregate number of shares of common stock that may be purchased by all participants on any purchase date under the offering. If the aggregate number of shares to be purchased upon exercise of outstanding purchase rights in the offering would exceed the maximum aggregate number of shares of common stock available, the plan administrator will make a pro rata allocation of available shares in a uniform and equitable manner. Unless the employee's participation is discontinued, his or her right to purchase shares is exercised automatically at the next purchase date at the applicable price.

*Withdrawal.* During an offering, a participant may cease making contributions and withdraw from the offering by delivering a notice of withdrawal and terminating his or her payroll deductions in such form as we may require. Such withdrawal may occur at any time prior to the end of an offering except as otherwise provided by the plan administrator. Upon such withdrawal, we will refund accumulated payroll deductions without interest to the employee, and such employee's right to participate in that offering will terminate. However, an employee's withdrawal from an offering does not generally affect such employee's eligibility to participate in subsequent offerings under the 2010 Purchase Plan.

*Reset Feature.* The plan administrator has the authority to provide that if the fair market value of the shares of our common stock on the first day of a new purchase period within a particular offering is less than the fair market value of the shares of common stock on the start date of that offering, then the participants in that offering will automatically be transferred and enrolled in a new offering which will begin on the first day of that purchase period and the participant's purchase rights in the original offering will terminate.

*Limitations.* The plan administrator may limit participation in the 2010 Purchase Plan to those persons who are customarily employed more than 20 hours per week and five months per calendar year by us (or by any of our parent or subsidiary companies designated by the plan administrator) on the first day of an offering. The plan administrator may also provide that a person must have been employed for such continuous period preceding the first day of the offering as the plan administrator may require, but in no event may the required period of continuous employment be greater than two years. In addition, the plan administrator may provide in any offering that certain of our employees who are "highly compensated" as defined in the Code are not eligible to participate in the 2010 Purchase Plan. The plan administrator may also provide that each person who, during the course of an offering, first becomes an eligible employee will, on a date or dates specified in the offering, receive a purchase right under that offering at a price equal to the market price of our common stock at that time, which purchase right will be deemed to be a part of that offering, and such purchase right will generally have the same characteristics as any purchase rights originally granted under that offering. No employee is eligible to participate in the 2010 Purchase Plan if, immediately after the grant of purchase rights, the employee would own, directly or indirectly, stock possessing 5% or more of the total combined voting power or value of all classes of our stock or of any of our parent or subsidiary companies (including any stock which such employee may purchase under all outstanding purchase rights and stock options). In addition, no employee may purchase more than \$25,000 worth of our common stock (valued at the time each purchase right is granted) for each calendar year during which those purchase rights are outstanding.

*Termination of Employment.* Purchase rights granted pursuant to any offering under the 2010 Purchase Plan terminate upon cessation of employment for any reason, and we will refund all accumulated payroll deductions to the terminated employee without interest.

*Restrictions on Transfer.* A participant may not transfer rights granted under the 2010 Purchase Plan other than by will, the laws of descent and distribution, or by a beneficiary designation as provided in the 2010 Purchase Plan. During a participant's lifetime, purchase rights will be exercisable only by such participant.

*Changes to Capital Structure.* In the event that there is any change to the outstanding common stock (whether by reason of merger, consolidation, reorganization, recapitalization, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or other transaction not involving the receipt of consideration by the Company), appropriate adjustments will be made to (a) the class and maximum number of securities subject to the 2010 Purchase Plan, (b) the class and maximum number of securities by which the share reserve is to increase automatically each year, (c) the class and number of securities subject to outstanding purchase rights, and (d) the class and number of securities imposed by purchase limits under each ongoing offering.

*Corporate Transactions.* In the event of certain significant corporate transactions, any surviving or acquiring corporation may assume, continue or substitute similar purchase rights for those outstanding under the 2010 Purchase Plan. If the surviving or acquiring corporation does not assume or continue such rights or substitute similar rights, then the participants' accumulated payroll deductions will be used to purchase shares of common stock within ten business days prior to the corporate transaction under any ongoing offerings, and such purchase rights will terminate immediately thereafter.

*Termination and Amendment.* The plan administrator may amend, suspend or terminate the 2010 Purchase Plan at any time. Any amendment of the 2010 Purchase Plan must be approved by our shareholders to the extent shareholder approval is necessary for the 2010 Purchase Plan to satisfy Sections 423 of the Code or other applicable laws and regulations. Purchase rights granted before amendment, suspension or termination of the 2010 Purchase Plan generally may not be altered or impaired by any amendment, suspension or termination of the 2010 Purchase Plan without consent of the employee to whom such purchase rights were granted. No purchase rights may be granted under the 2010 Purchase Plan while the 2010 Purchase Plan is suspended or after it is terminated.

#### **2010 Non-Employee Directors' Stock Award Plan**

Our Board of Directors adopted the Non-Employee Directors' Stock Award Plan, or Directors' Plan, on October 29, 2010 and our stockholders approved the Directors' Plan on January 7, 2011. The Directors' Plan will become effective immediately upon the execution and delivery of the underwriting agreement for this offering. The Directors' Plan will terminate at the discretion of our Board of Directors. The purpose of the Directors' Plan is to retain the services of new non-employee directors and provide incentives for such persons to exert maximum efforts towards our success by giving them an opportunity to benefit from increases in value of our common stock. The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of our common stock to our non-employee directors. The Directors' Plan also provides for the discretionary grant of stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards.

*Share Reserve.* An aggregate of 500,000 shares of our common stock are reserved for issuance under the Directors' Plan. Shares of our common stock subject to stock awards that have expired or otherwise terminated under the Directors' Plan without having been exercised in full will again become available for grant under the Directors' Plan. Shares of our common stock issued under the Directors' Plan may be previously unissued shares or reacquired shares bought on the market or otherwise. If the exercise of any stock option granted under the Directors' Plan is satisfied by tendering shares of our common stock held by the participant, then the number of shares tendered will again become available

for the grant of awards under the Directors' Plan. In addition, any shares reacquired to satisfy income or employment withholding taxes will again become available for the grant of awards under the Directors' Plan.

*Administration.* Our Board of Directors has delegated its authority to administer the Directors' Plan to our Compensation Committee. The Compensation Committee must consist of two or more "non-employee directors" pursuant to the Rule 16b-3 of the Securities Exchange Act of 1934, as amended.

*Stock Options.* Stock options will be granted pursuant to stock option agreements. The exercise price of the options granted under the Directors' Plan will be equal to 100% of the fair market value of our common stock on the date of grant.

In general, the term of stock options granted under the Directors' Plan may not exceed ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any affiliate of ours, ceases due to death or disability, the optionholder or his or her beneficiary may then exercise any vested options for a period of 12 months in the event of disability, or 18 months in the event of death. If an optionholder's service with us or any affiliate ceases for any other reason, the optionholder may exercise the vested options for up to three months following cessation of service.

Acceptable consideration for the purchase of our common stock issued under the Directors' Plan may include cash, a net exercise, common stock previously owned by the optionholder or a program developed under Regulation T as promulgated by the Federal Reserve Board.

Generally, an optionholder may not transfer a stock option other than by will or the laws of descent and distribution. However, an optionholder may transfer an option under certain circumstances with our written consent if a Form S-8 registration statement is available for the exercise of the option and the subsequent resale of the shares. In addition, an optionholder may designate a beneficiary who may exercise the option following the optionholder's death.

#### *Non-discretionary Grants*

- *Initial Grant.* Any person who becomes a non-employee director for the first time after the completion of this offering will automatically receive an initial grant of an option to purchase 25,000 shares of our common stock upon his or her election or appointment, subject to adjustment by our Board of Directors from time to time. Twenty percent of the shares subject to the initial grants will vest on the first anniversary of the date of such person's election or appointment to the Board of Directors and the remainder will vest monthly over four additional years. These initial grants may also be issued in the form of stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, or other stock awards if so determined by our Board of Directors.
- *Annual Grant.* In addition, on the date of the annual meeting of our stockholders, commencing with our first annual meeting after the completion of this offering, any person who is a non-employee director on such date automatically will be granted an option to purchase 15,000 shares of our common stock, plus an additional 7,500 shares of our common stock for service as chair of the Audit, Compensation or Nominating and Corporate Governance Committee, or as Lead Independent Director as of such date, plus 5,000 shares of our common stock for service as a member of the Audit, Compensation or Nominating and Corporate Governance Committee as of such date, subject to adjustment by our Board of Directors from time to time. Fifty percent of the shares subject to the annual grants will vest on the first anniversary of the date of grant and the remainder will vest monthly over one additional year, subject to continued employment. These annual grants may also be issued in the form of SARs, restricted stock awards, restricted stock unit awards, or other stock awards if so determined by our Board of Directors.

### *Discretionary Grants*

In addition to the non-discretionary grants noted above, our Board of Directors may grant stock awards to one or more non-employee directors in such numbers and subject to such other provisions as it shall determine. These awards may be in the form of stock options, SARs, restricted stock awards, restricted stock units, or other stock awards and will vest pursuant to vesting schedules to be determined by our Board of Directors in its sole discretion.

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure not involving the receipt of consideration by us, such as a stock split or stock dividend, the number of shares reserved under the Directors' Plan, the maximum number of shares by which the share reserve may increase automatically each year, the number of shares subject to the initial and annual grants and the number of shares and exercise price of all outstanding stock options will be appropriately adjusted.

*Change in Control Transactions.* In the event of a change in control transaction, the vesting of options held by non-employee directors whose service is terminated may be accelerated in full according to the provisions of the award agreement. A change in control is the occurrence of one or more of the following events:

- a transaction in which one person or a group acquires stock that, combined with stock previously owned, controls more than 50% of our value or voting power;
- a merger, consolidation or similar transaction involving us (directly or indirectly) in which the our stockholders immediately before the transaction do not own more than 50% of the outstanding securities following such transaction;
- our complete liquidation or dissolution;
- a sale, lease, license or other disposition of substantially all of our assets; or
- a majority of the Board of Directors is replaced by persons whose appointment or election is not endorsed by a majority of the Board of Directors.

*Plan Amendments.* Our Board of Directors will have the authority to amend, suspend or terminate the Directors' Plan. However, no amendment or termination of the directors' plan will adversely affect any rights under awards already granted to a participant unless agreed to by the affected participant. We will obtain stockholder approval of any amendment to the Directors' Plan that is required by applicable law.

### **Indebtedness of Management and Related Agreements**

In 2008, in connection with his commencement of employment and relocation to Ames, Iowa, we entered into a loan agreement with Mr. Gordon Link, our Chief Financial Officer. Pursuant to the terms of this agreement, we loaned Mr. Link \$500,000 for the purchase of a principal residence. This note was secured by Mr. Link's residence and had an interest rate of 2.42% per year. In May 2010, Mr. Link repaid the loan in full and we forgave accrued interest of \$10,052.

In 2008, we entered into a loan agreement with Dr. Charles Link, our Chief Executive Officer. Pursuant to this agreement, we loaned Dr. Link \$225,000 for personal purposes. This loan had an interest rate of 6% per year. In January 2009, we granted Dr. Link a bonus of \$78,149, which was applied to the principal due on the loan. In April 2009, Dr. Link repaid the remaining principal and accrued interest on the loan.

In 2009, we entered into another loan agreement with Dr. Link. Pursuant to this agreement, we loaned Dr. Link \$350,000 for personal purposes. This loan had an interest rate of 6% per year. In July 2010, we forgave the loan and accrued interest of \$25,170 and granted Dr. Link a \$180,226 bonus to pay the taxes incurred as a result of such extinguishment. To offset the forgiveness and the bonus payment, the exercise price of options to purchase 555,396 shares of common stock held by Dr. Link from was increased from \$1.00 per share to \$2.00 per share and Dr. Link agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

In 2000, we loaned Dr. Vahanian, our President and Chief Medical Officer \$31,500. This loan had an interest rate of 6.71% per year. In July 2010, we forgave the remaining balance of \$25,000 and all accrued interest and granted Dr. Vahanian a \$12,010 bonus to pay the taxes incurred as a result of such extinguishment. To offset the forgiveness and the bonus payment, the exercise price of options to purchase 37,010 shares of common stock held by Dr. Vahanian from was increased from \$1.00 per share to \$2.00 per share and Dr. Vahanian agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

In 2008, we entered into another loan agreement with Dr. Vahanian. Pursuant to this agreement, we loaned Dr. Vahanian \$125,000 for personal purposes. This loan had an interest rate of 6% per annum. In January 2009, we granted Dr. Vahanian a bonus of \$55,037, which was applied to the principal due on the loan. In April 2009, Dr. Vahanian repaid the remaining principal and all accrued interest on the loan.

In 2006, BPS entered into a loan agreement with Dr. Charles Link. Pursuant to this agreement, BPS loaned Dr. Link \$75,000 to facilitate the exercise of stock options. The loan had an interest rate of 5.01% per annum. In March 2010 and May 2010, BPS forgave a total of \$30,000 of the principal amount of the loan plus \$13,517 of interest accrued on the loan. In March 2010, BPS paid Dr. Link a cash bonus of \$15,000 to cover related tax liability. In October 2010, BPS paid Dr. Link a bonus of \$50,000 gross, of which \$33,775 was net and was applied to the principal due on the loan. In November 2010, Dr. Link repaid the remaining principal and all accrued interest on the loan.

In 2006, BPS entered into a loan agreement with Dr. Vahanian. Pursuant to this agreement, BPS loaned Dr. Vahanian \$20,000 to facilitate the exercise of stock options. The loan had an interest rate of 5.01%. In March 2010 and May 2010, BPS forgave a total of \$8,000 of the principal amount of the loan plus \$3,604 of interest accrued on the loan and paid Dr. Vahanian a cash bonus, a portion of which was used to cover the related tax liability. In October 2010, Dr. Vahanian repaid the remaining principal and all accrued interest on the loan.

### **Limitation of Liability and Indemnification**

Our amended and restated bylaws to be in effect upon the closing of this offering require us to indemnify our directors to the fullest extent not prohibited by law and permit us to indemnify our officers, employees and other agents as set forth under Delaware law. We will indemnify any such person in connection with a proceeding initiated by such person only if such indemnification is expressly required by law, the proceeding was authorized by our Board of Directors, the indemnification is provided by us, in our sole discretion, pursuant to the Delaware General Corporation Law or other applicable law or is otherwise expressly required by our amended and restated bylaws. Section 145 of the Delaware General Corporation Law permits indemnification of officers, directors and other agents under specified circumstances and subject to specified limitations. Delaware law also permits a corporation to not hold its directors personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for:

- breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity. We have obtained directors' and officers' liability insurance to cover certain liabilities described above.

We have entered into indemnity agreements with each of our directors that require us to indemnify such persons against any and all expenses, including attorneys' fees, witness fees, judgments, fines, settlements and other amounts incurred, including expenses of a derivative action, in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of our company, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to us or our stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors of our company.

At present, there is no pending litigation or proceeding involving a director or officer of our company for which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted by directors, executive officers or persons controlling us, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### Non-Employee Director Compensation

The following table shows certain information with respect to the compensation of all non-employee directors of the Company for the fiscal year ended December 31, 2010.

#### 2010 Director Compensation

Name	Option Awards\$(1)	Total(\$)
Thomas A. Raffin, M.D.	\$ 330,725(2)	\$ 330,725
Sarah Alexander M.D., F.A.C.P.	\$ 153,800(3)	\$ 153,800
David J. Lundquist	\$ 187,625(4)	\$ 187,625
Joseph Saluri	\$ 218,050(5)	\$ 218,050
Ernest J. Talarico, III	\$ 289,100(6)	\$ 289,100

- (1) Unless otherwise indicated, these options have a 10-year term and vest over a two-year period, with 50% of the options vesting on the first anniversary of the vesting commencement date and the remaining 50% of the options vesting in equal monthly installments thereafter over the next year, subject to the recipient's continued service with the Company through such vesting dates.
- (2) Represents (i) 55,000 options exercisable at \$1.46 per share with a vesting commencement date of March 3, 2010, (ii) 15,000 options exercisable at \$4.77 per share with a vesting commencement date of December 9, 2010 and (iii) 37,500 options exercisable at \$4.77 per share with a vesting commencement date of January 1, 2011.
- (3) Represents (i) 40,000 options exercisable at \$1.46 per share with a vesting commencement date of March 3, 2010 and (ii) 20,000 options exercisable at \$4.77 per share with a vesting commencement date of January 1, 2011.
- (4) Represents (i) 55,000 options exercisable at \$1.46 per share with a vesting commencement date of March 3, 2010 and (ii) 22,500 options exercisable at \$4.77 per share, with a vesting commencement date of January 1, 2011.
- (5) Represents (i) 35,000 options exercisable at \$1.46 per share with a vesting commencement date of March 3, 2010, (ii) 30,000 options exercisable at \$4.77 per share with a vesting commencement date



of January 1, 2011 and (iii) 5,000 options at \$4.77 per share with a vesting commencement date of December 9, 2010.

- (6) Represents (i) 50,000 options exercisable at \$1.46 per share with a vesting commencement date of March 3, 2010, (ii) 50,000 options exercisable at \$1.46 per share that are fully vested, (iii) 5,000 options exercisable at \$4.77 per share with a vesting commencement date of December 9, 2010 and (iv) 25,000 options exercisable at \$4.77 per share with a vesting commencement date of January 1, 2011.

In December 2009, the Board of Directors adopted our non-employee director compensation policy, pursuant to which non-employee directors are compensated for their services on our Board. This policy was revised by our Board of Directors in October 2010. The Non-Employee Directors Stock Award Plan will supersede the policy described above effective upon closing of the initial public offering. Under the current policy, for service on the Board of Directors each non-employee director receives an initial option grant of 25,000 shares of the company's common stock, of which 20% vests on the first anniversary of the director's election or appointment and the remainder vests on a monthly basis over the subsequent four years. Additionally, each non-employee director receives, during the term of his or her service on the Board of Directors, an annual option grant of 15,000 shares, plus 7,500 shares for service as chair of the Audit, Compensation or Nominating and Corporate Governance Committee, or as Lead Independent Director. In addition, a director receives 5,000 shares for service as a member of (but not as chair of) the Audit, Compensation and/or Nominating and Corporate Governance Committee. For example, a director serving as chair of the Audit Committee and as a member of the Compensation Committee and the Nominating and Corporate Governance Committee would receive, immediately following the date of our annual meeting of stockholders, an annual grant of 32,500 shares (i.e., 15,000 + 7,500 + 5,000 + 5,000). The annual option grants vest as to 50% of the shares one year after the date of grant and the remainder over the succeeding twelve months.

Historically, we have not provided cash compensation to any directors for serving on our Board of Directors or committees of our Board of Directors. Commencing with the closing of the initial public offering, the Company will pay annual cash retainers to directors (other than executive officers) as follows:

All Directors (other than executive officers)	\$ 50,000
Lead Independent Director	\$ 15,000
Audit Committee Chair	\$ 20,000
Other Audit Committee Members	\$ 13,500
Compensation Committee Chair	\$ 14,000
Other Compensation Committee Members	\$ 7,500
Nominating and Corporate Governance Committee Chair	\$ 7,500
Other Nominating and Corporate Governance Committee Members	\$ 5,000

Payments for service as lead director, committee chair or committee member are in addition to payment for service as a director. Payments will be made quarterly beginning on the first day of the quarter following closing of the initial public offering.

We have reimbursed and will continue to reimburse our non-employee directors for their reasonable expenses incurred in attending meetings of our Board of Directors and committees of our Board of Directors.

No cash compensation was paid to directors in 2010.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since our inception to which we have been a party, in which the amount involved in the transaction exceeds \$120,000, and in which any of our directors, executive officers or to our knowledge, beneficial owners of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under the "Executive and Director Compensation" section of this prospectus. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

### Preferred Stock Financings

On August 29, 2000, we entered into a Series A Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 420,000 shares of Series A preferred stock on August 29, 2000 at a purchase price of \$2.50 per share, for aggregate consideration of \$1.1 million.

On September 26, 2001, we entered into a Series AA Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 1,224,967 shares of Series AA preferred stock at a purchase price of \$1.80 per share, for aggregate consideration of \$2.2 million.

On January 21, 2002, we entered into a Series AAA Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 377,410 shares of Series AAA preferred stock at a purchase price of \$2.25 per share, for aggregate consideration of \$850,000.

Between October 7, 2002 and December 12, 2003, we entered into Series B Preferred Stock Purchase Agreements pursuant to which we issued and sold to investors an aggregate of 2,191,193 shares of Series B preferred stock at a purchase price of \$2.50 per share, for aggregate consideration of \$5.5 million.

Between February 8, 2008 and December 17, 2009, we entered into Series C Preferred Stock Purchase Agreements pursuant to which we issued and sold to investors an aggregate of 6,000,000 shares of Series C preferred stock at a purchase price of \$5.00 per share, for aggregate consideration of \$30.0 million.

On July 17, 2009, we entered into a Series D Preferred Stock Purchase Agreement pursuant to which we issued and sold to one investor 1,500,000 shares of Series D preferred stock at a purchase price of \$5.00 per share, for aggregate consideration of \$7.5 million.

Between December 1, 2010 and December 13, 2010, we issued and sold to investors an aggregate of 248,320 shares of our Series E preferred stock, for aggregate consideration of \$7.8 million.

The participants in these preferred stock financings included the following directors, officers and holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the number of shares issued to these related parties in these financings. Upon completion of this offering, each share of Series A preferred stock will convert into 1.389 shares of our Common Stock; each share of Series AA, AAA, B, C and D preferred stock will convert into one share of our Common Stock; and each share of Series E preferred stock will convert into the number of shares of Common Stock obtained by dividing \$31.25 by the Series E conversion price. The Series E conversion price is currently \$6.25. If the Company closes this offering on or before September 1, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of the Company's Common Stock are sold to the public in this offering and (B) 0.85 (as adjusted appropriately

to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with this offering):

Name	Shares of Series A Convertible Preferred Stock	Shares of Series AA Convertible Preferred Stock	Shares of Series AAA Convertible Preferred Stock	Shares of Series B Convertible Preferred Stock	Shares of Series C Convertible Preferred Stock	Shares of Series D Convertible Preferred Stock	Shares of Series E Convertible Preferred Stock
<b>5% or Greater Stockholders</b>							
Stine Seed Farm Inc.(1)	—	—	—	1,760,000	1,000,000	1,500,000	160,000
<b>Executive Officers and Directors</b>							
Sarah Alexander, M.D. F.A.C.P.	—	—	11,112	—	1,000	—	—
David J. Lundquist	—	27,780(2)	—	19,999(2)	20,000(2)	—	—
Nicholas N. Vahanian, M.D.	40,000	—	—	—	—	—	—
Joseph Saluri	—	—	—	—	15,000	—	—

(1) On October 8, 2010, Midwest Oilseeds transferred all of its shares of the Company's stock to Stine Seed Farm Inc.

(2) These shares belong to the David Lundquist Revocable Trust.

## Agreements With Our Stockholders

We have entered into an investor rights agreement with holders of our convertible preferred stock and warrants to purchase shares of our common stock. The investor rights agreement contains a right of first refusal provision that provides that we shall not make certain issuances of our securities unless we first offer such securities to certain holders of preferred stock in accordance with the terms of the investor rights agreement. The right of first refusal provision of the investor rights agreement does not apply to and will terminate upon the closing of this offering. The investor rights agreement also provides that holders of preferred stock and warrants to purchase common stock have the right to (a) demand that we file a registration statement, subject to certain limitations, and (b) request that their shares be covered by a registration statement that we are otherwise filing. See the "Description of Capital Stock — Registration Rights" section of this prospectus for a further discussion of these registration rights.

We have also entered into a right of first refusal and co-sale agreement with holders of convertible preferred stock and certain other stockholders. This agreement provides the holders of preferred stock a right of purchase and of co-sale in respect of sales of securities by certain holders of common stock. These rights of purchase and co-sale will terminate upon the closing of this offering.

We have also entered into a voting agreement with our equity holders that contains agreements with respect to the election of our Board of Directors and its composition. The voting agreement will terminate upon the closing of this offering.

Each of the transactions noted above were entered into prior to our adoption of a written related party transaction policy, which is described below.

## BPS Preferred Stock Financings

Between December 30, 2005 and February 28, 2006, BPS entered into Series A Preferred Stock Purchase Agreements pursuant to which BPS issued and sold to investors an aggregate of 1,444,721 shares of its Series A preferred stock at a purchase price of \$1.75 per share, for aggregate consideration of \$2.5 million.

Between December 22, 2009 and September 7, 2010, BPS entered into Series B Preferred Stock Purchase Agreements pursuant to which BPS issued and sold to investors an aggregate of 555,930 shares of its Series B preferred stock at a purchase price of \$1.75 per share, for aggregate consideration of \$973,000.

**Acquisition of BioProtection Systems Corporation**

On January 7, 2011, we acquired all of the minority interest in our majority-owned subsidiary, BPS, by merging a newly-formed subsidiary of ours with BPS, with BPS as the surviving corporation. In connection with this transaction, we will issue up to an aggregate of 276,304 shares of our Series E preferred stock to the former holders of BPS Series B common stock, Series A preferred stock and Series B preferred stock (other than the Company). 221,066 of the shares of our Series E preferred stock were issued to the holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of our Series E preferred stock were held back to satisfy any indemnity obligations under the merger agreement. If there are no indemnity obligations payable under the merger agreement, those shares will be issued to the former holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock. As a result of this transaction, BPS became a wholly-owned subsidiary of the Company and our note was converted into Series B preferred stock of BPS. All options to purchase shares of BPS stock became options to purchase a total of 106,347 shares of our common stock.

In this transaction, shares of our Series E preferred stock were issued to our officers and directors as follows:

<b>Name</b>	<b>Shares of Series E Preferred Stock Issued at Closing of the Merger</b>	<b>Shares of Series E Preferred Stock Potentially Issuable in the Future</b>
Charles J. Link, Jr., M.D.	41,568	10,392
Nicholas N. Vahanian, M.D.	11,085	2,771
Thomas A. Raffin, M.D.	1,386	346
Ernest J. Talarico, III	1,386	346

In addition, the following directors and officers of NewLink who are also directors or officers of BPS exchanged their BPS stock options for options to acquire NewLink common stock as follows:

<b>Name</b>	<b>Options to Acquire BPS Series B Common Stock</b>	<b>Options to Acquire NewLink Common Stock</b>
Charles J. Link, Jr., M.D.	20,000	5,385
Nicholas N. Vahanian, M.D.	20,000	5,385
Thomas A. Raffin, M.D.	50,000	13,462
Ernest J. Talarico, III	45,000	12,116

The acquisition of BPS was recommended by a special committee of our Board of Directors consisting of Dr. Alexander and Messrs. Lundquist and Saluri, none of whom served as directors of BPS. Dr. Alexander and Mr. Saluri did not own any shares or options in BPS. The David Lundquist Revocable Trust owned shares of Series A Preferred Stock in BPS.

## **Executive Compensation and Employment Arrangements**

Please see the "Executive and Director Compensation" section of this prospectus for information on compensation arrangements with our executive officers, including option grants and agreements with executive officers.

## **Director Compensation**

Please see the "Executive and Director Compensation — Non-Employee Director Compensation" section of this prospectus for information on compensation arrangements for our directors generally.

## **Other Transactions**

We have made loans to certain of our executive officers. For a description of these loans, see the "Executive and Director Compensation — Indebtedness of Management and Related Agreements" section of this prospectus.

## **Policies and Procedures for Related Person Transactions**

Our Board of Directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which we are a participant, the amount involved exceeds \$120,000 and one of our executive officers, directors, director nominees or 5% stockholders (or their immediate family members), each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to the Audit Committee of our Board of Directors. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by the Audit Committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the Audit Committee will review, and, in its discretion, may ratify the related person transaction. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the Audit Committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unaffiliated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The Audit Committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent, with our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our Board of Directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity (whether or not the person is also a director of such entity), that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction or (c) the amount involved in the transaction equals less than the greater of \$200,000 or 5% of the annual consolidated gross revenues of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our charter or by-laws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the Compensation Committee in the manner specified in its charter.

## PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of December 31, 2010 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage of shares beneficially owned before the offering shown in the table is based upon 23,718,351 shares of common stock outstanding as of December 31, 2010, after giving effect to (i) the issuance of 221,066 shares of our Series E preferred stock in connection with our acquisition of the minority interest in BPS and (ii) the conversion of all of our convertible preferred stock into 16,375,568 shares of common stock, which will occur automatically immediately prior to the closing of this offering. The 23,718,351 shares of common stock outstanding as of December 31, 2010 does not include the conversion of 55,238 shares of our Series E preferred stock that were held back to satisfy any indemnification obligations in connection with our acquisition of the minority interest in BPS. The information relating to numbers and percentages of shares beneficially owned after the offering gives effect to the issuance of shares of common stock in this offering, assuming the initial public offering price in this offering is \$ \_\_\_\_\_ per share, the midpoint of the range set forth on the cover page of this prospectus, and assuming that this offering is closed on \_\_\_\_\_, 2011.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before March 1, 2011, which is 60 days after December 31, 2010. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010.

<u>Name of Beneficial Owner</u>	<u>Shares Beneficially Owned Before Offering</u>		<u>Shares Beneficially Owned After Offering</u>	
	<u>Number</u>	<u>Percentage</u>	<u>Number</u>	<u>Percentage</u>
<b>5% Stockholders:</b>				
Stine Seed Farm, Inc**	5,435,000(1)	22.9%		
<b>Named Executive Officers and Directors:</b>				
Charles J. Link, Jr. M.D.	4,266,629(2)	17.0%		
Nicholas N. Vahanian, M.D.	1,355,962(3)	5.5%		
Thomas A. Raffin, M.D.	234,597(4)	1.0%		
Kenneth Lynn	166,856(5)	*		
Ernest J. Talarico, III	210,751(6)	*		
David Lundquist	156,954(7)	*		
Gordon H. Link, Jr.	144,383(8)	*		
W. Jay Ramsey M.D., Ph.D.	92,000(9)	*		
Sarah Alexander, M.D., F.A.C.P.	48,778(10)	*		
Joseph Saluri	15,000	*		
All current directors and executive officers as a group (11 persons)	6,691,910(11)	24.9%		

\* Represents beneficial ownership of less than 1%.

\*\* Address: 22555 Laredo Trail, Adel, Iowa 50003, Attn: Jerald L Reichling

- (1) Includes 160,000 shares of NewLink Series E preferred stock. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.
- (2) Includes 1,437,289 shares Dr. Charles Link has the right to acquire through the exercise of stock options within 60 days of December 31, 2010. Includes 51,960 shares of NewLink Series E preferred stock to be issued in connection with our acquisition of BPS in exchange for 1,500,000 shares of BPS Series B common stock currently held by Dr. Link. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.
- (3) Includes 111,000 shares held by Christina Marie Vahanian, and 979,126 shares Dr. Vahanian has the right to acquire through the exercise of stock options within 60 days of December 31, 2010. Includes 13,856 shares of NewLink Series E preferred stock to be issued in connection with our acquisition of BPS in exchange for 400,000 shares of BPS Series B common stock currently held by Dr. Vahanian. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.
- (4) Includes 125,937 shares Dr. Raffin has the right to acquire through the exercise of stock options within 60 days of December 31, 2010. Includes 1,732 shares of NewLink Series E preferred stock to be issued in connection with our acquisition of BPS in exchange for 50,000 shares of BPS Series B common stock currently held by Mr. Raffin. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price



per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

- (5) Includes 166,856 shares Mr. Lynn has the right to acquire through the exercise of stock options within 60 days of December 31, 2010.
- (6) Includes 177,091 shares Mr. Talarico has the right to acquire through the exercise of stock options within 60 days of December 31, 2010. Includes 1,732 shares of NewLink Series E preferred stock to be issued in connection with our acquisition of BPS in exchange for 50,000 shares of BPS Series B common stock currently held by Mr. Talarico. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.
- (7) Includes 116,954 shares held by David Lundquist Revocable Trust, dated November 19, 2002, David J. Lundquist, Trustee, and 40,000 shares Mr. Lundquist has the right to acquire through the exercise of stock options within 60 days of December 31, 2010. Includes 5,257 shares of NewLink Series E preferred stock to be issued in connection with our acquisition of BPS in exchange for 58,000 shares of BPS Series A preferred stock currently held in the David Lundquist Revocable Trust. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.
- (8) Includes 144,383 shares Mr. Gordon Link has the right to acquire through the exercise of stock options within 60 days of December 31, 2010.
- (9) Includes 42,000 shares Dr. Ramsey has the right to acquire through the exercise of stock options within 60 days of December 31, 2010.
- (10) Includes 36,666 shares Dr. Alexander has the right to acquire through the exercise of stock options within 60 days of December 31, 2010.
- (11) Includes 3,149,348 shares issuable upon exercise of stock options by all executive officers and directors exercisable within 60 days of December 31, 2010. See notes (2) through (10) above.

## DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws, each to be in effect upon the completion of this offering. We have filed copies of these documents with the Securities and Exchange Commission, or SEC, as exhibits to our registration statement of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering. Upon the closing of this offering and the filing of the amended and restated certificate of incorporation, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.01 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.01 per share, all of which preferred stock will be undesignated.

As of December 31, 2010, we had issued and outstanding:

- 7,618,973 shares of our common stock held by 105 stockholders of record;
- 420,000 shares of our Series A preferred stock held by nine stockholders of record that are convertible into an aggregate of 583,333 shares of our common stock;
- 1,217,175 shares of our Series AA preferred stock held by 32 stockholders of record are convertible into shares of our common stock on a one-for-one basis;
- 377,410 shares of our Series AAA preferred stock held by 18 stockholders of record that are convertible into shares of our common stock on a one-for-one basis; and
- 2,191,193 shares of our Series B preferred stock held by 18 stockholders of record that are convertible into shares of our common stock on a one-for-one basis.
- 1,883,337 shares of our Series BB preferred stock held by 92 stockholders of record that are convertible into shares of our common stock on a one-for-one basis;
- 6,000,000 shares of our Series C preferred stock held by 150 stockholders of record that are convertible into shares of our common stock on a one-for-one basis; and
- 1,500,000 shares of our Series D preferred stock held by one stockholder of record that are convertible into shares of our common stock on a one-for-one basis.
- 248,320 shares of our Series E preferred stock held by 38 stockholders of record that are convertible into the number of shares of our common stock obtained by dividing \$31.25 by the Series E conversion price. The Series E conversion price is currently \$6.25. If we close this offering on or before September 1, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of common stock are sold to the public in this offering and (B) 0.85 (as adjusted appropriately to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with this offering).

As of December 31, 2010, we also had outstanding options to purchase 6,370,322 shares of our common stock at a weighted-average exercise price of \$1.34 per share.

On January 7, 2011, we acquired all of the minority interest in BPS. We will issue up to 276,304 shares of our Series E preferred stock as consideration for this acquisition.

Upon the closing of this offering, all of the outstanding shares of our preferred stock will automatically convert into a total of 16,375,568 shares of our common stock. No warrants to purchase shares of common stock remain outstanding as of December 31, 2010.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual

number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

## **Common Stock**

*Voting Rights.* Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our Board of Directors out of legally available funds.

*Liquidation.* In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

*Rights and Preferences.* Holders of common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

*Fully paid and Nonassessable.* All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

## **Preferred Stock**

Upon the closing of this offering, all outstanding shares of preferred stock will have been automatically converted into shares of common stock. Following this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock.

Under the amended and restated certificate of incorporation, our Board of Directors will have the authority, without further action by the stockholders, to issue up to \_\_\_\_\_ shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

## **Registration Rights**

Under an amended and restated investor rights agreement, following the completion of this offering, the holders of an aggregate of \_\_\_\_\_ shares of common stock, or their transferees, will have the right to require us to register their shares with the SEC so that those shares may be publicly

resold, or to include their shares in any registration statement we file, subject to specified exemptions, conditions and limitations.

Beginning twelve months after the closing of this offering, subject to specified limitations, these stockholders may require that we register all or part of these securities for sale under the Securities Act on two occasions. In addition, these stockholders may from time to time make demand for registrations on Form S-3, a short form registration statement, when we are eligible to use this form.

If we register any of our common stock, either for our own account or for the account of other security holders, these stockholders are entitled to notice of the registration and to include their shares of common stock in the registration.

Other than in a demand registration, with specified exceptions, a holder's right to include shares in a registration is subject to the right of the underwriters to limit the number of shares included in the offering. All fees, costs and expenses of any demand registrations and any registrations on Form S-3 will be paid by us, and all selling expenses, including underwriting discounts and commissions, will be paid by the holders of the securities being registered.

#### **Delaware Anti-takeover Law and Certain Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws**

*Delaware law.* We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for this purpose shares owned by persons who are directors and also officers and shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

*Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws.* Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock.

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our Board of Directors to issue up to \_\_\_\_\_ shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected subject to any limitation imposed by law, by the holders of at least 66<sup>2</sup>/<sub>3</sub>% of the voting power of our then outstanding capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our Board of Directors into three classes with staggered, three-year terms;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose;
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66<sup>2</sup>/<sub>3</sub>% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be BNY Mellon Shareowner Services.

#### **NASDAQ Global Market**

We have applied to have our common stock listed on the NASDAQ Global Market under the symbol "NLNK".

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Market sales of shares of our common stock after this offering and from time to time, and the availability of shares for future sale, may reduce the market price of our common stock. Sales of substantial amounts of our common stock, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to obtain capital, especially through an offering of equity securities.

Based on the number of shares of common stock outstanding as of October 31, 2010, upon completion of this offering, \_\_\_\_\_ shares of common stock will be outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of options prior to the completion of this offering. All of the shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, unless held by our affiliates as that term is defined under Rule 144 under the Securities Act. The remaining \_\_\_\_\_ shares of common stock outstanding upon the closing of this offering are restricted securities as defined under Rule 144 of the Securities Act. Restricted securities may be sold in the U.S. public market only if registered or if they qualify for an exemption from registration, including by reason of Rule 144 or 701 under the Securities Act, which rules are summarized below. These remaining shares will generally become available for sale in the public market as follows:

- restricted shares will be eligible for immediate sale upon the completion of this offering;
- approximately \_\_\_\_\_ restricted shares will be eligible for sale in the public market 90 days after the date of this prospectus, subject to the volume, manner of sale and other limitations under Rule 144 and Rule 701; and
- approximately \_\_\_\_\_ restricted shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, which date may be extended in specified circumstances, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Additionally, of the 6,370,322 shares of common stock issuable upon exercise of options outstanding as of December 31, 2010, approximately 3,154,138 shares will be vested and eligible for sale 180 days after the date of this prospectus.

### Rule 144

In general, under Rule 144 under the Securities Act of 1933, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock to be sold for at least six months, would be entitled to sell an unlimited number of shares of our common stock, provided current public information about us is available. In addition, under Rule 144, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares of our common stock to be sold for at least one year, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; and

- the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below under "Underwriting" and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

### **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with some of the restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares under Rule 701. However, all of the Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" and will become eligible for sale at the expiration of the restrictions set forth in those agreements.

### **Lock-up Agreements**

We, along with our directors, executive officers and substantially all of our other stockholders, optionholders and warrant holders, have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, we or they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of common stock, subject to specified exceptions. Wells Fargo Securities, LLC and Cowen and Company, LLC may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs and is publicly announced; or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period.

In this case, the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release of the material news or the occurrence of the material event.

The lock-up agreements signed by our securityholders generally permit them, among other customary exceptions, to make bona fide gifts to their immediate family, to transfer securities to trusts for their or their immediate family's benefit and, if the securityholder is a partnership, limited liability company or corporation, to transfer securities to its partners, members or stockholders. However, the recipients of these transfers must agree to be bound by the lock-up agreement for the remainder of the lock-up period.

## **Registration Rights**

Upon the closing of this offering, the holders of an aggregate of \_\_\_\_\_ shares of our common stock will have the right to require us to register their shares for resale under the Securities Act, beginning six months after the date of this prospectus. Registration of these shares for resale under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of such registration. Any sales of securities by these stockholders could adversely affect the trading price of our common stock. These registration rights are described in more detail under the caption "Description of Capital Stock — Registration Rights."

## **Equity Incentive Plans**

As of December 31, 2010, options to purchase an aggregate of 6,370,322 shares of our common stock were outstanding, of which 3,154,138 were vested and exercisable. Substantially all of the shares issuable upon the exercise of options are subject to the terms of the lock-up agreements with the underwriters. On October 29, 2010, 1,500,000 additional shares of common stock were added to the shares reserved for future issuance under our 2009 plan. This amount will be increased pursuant to an "evergreen provision" on January 1 of each year, from 2012 to (and including) 2019, in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year. However, our Board of Directors will have the authority to designate a lesser number of shares by which the share reserve will be increased.

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our 2000 Equity Incentive Plan, 2009 Equity Incentive Plan, 2010 Non-Employee Directors' Stock Award Plan and 2010 Employee Stock Purchase Plan. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.



**CERTAIN U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO  
NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following is a summary of the U.S. federal income and estate tax consequences to a non-U.S. holder (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income and estate tax consequences and does not address any tax consequences arising under any state, local or foreign tax laws or under other U.S. federal tax laws (such as gift tax laws). This discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), U.S. Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service (the "IRS"), all as in effect on the date of this offering. These authorities are subject to change, possibly retroactively, resulting in tax consequences different from those discussed below. No rulings have been or will be sought from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a different position concerning the tax consequences of a non-U.S. holder's purchase, ownership or disposition of our common stock or that any such position would not be sustained by a court.

This discussion is limited to non-U.S. holders who purchase our common stock in this offering and who hold shares of our common stock as "capital assets" within the meaning of Code Section 1221 (generally, property held for investment). This discussion does not address all U.S. federal income tax or estate tax consequences that may be relevant to a non-U.S. holder in light of the holder's particular circumstances or to holders subject to special rules under the U.S. federal income tax laws, such as banks, financial institutions, U.S. expatriates, insurance companies, regulated investment companies, real estate investment trusts, "controlled foreign corporations," "passive foreign investment companies," dealers in securities or currencies, traders in securities, partnerships or other pass-through entities (or investors in such entities), persons subject to the alternative minimum tax, tax-exempt organizations and persons holding our common stock as part of a "straddle," "hedge," "conversion transaction" or other integrated transaction.

**WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR OWN TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING GIFT TAX LAWS), AND ANY APPLICABLE TAX TREATIES.**

For U.S. federal income tax purposes, a "non-U.S. holder" is a beneficial owner of our common stock who is an individual, corporation, estate or trust for U.S. federal income tax purposes and who is not treated for U.S. federal income tax purposes as:

- an individual who is a citizen or resident of the United States;
- an entity treated as a corporation for U.S. federal income tax purposes that is created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a U.S. court is able to exercise primary supervision over its administration and one or more U.S. persons have authority to control all its substantial decisions or (ii) the trust was in existence on August 20, 1996, was treated as a U.S. person prior to that date, and validly elected to continue to be so treated.

A modified definition of non-U.S. holder applies for U.S. federal estate tax purposes.

If any entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and the activities of the

partnership. Partnerships and their partners should consult their tax advisors as to the tax consequences to them of the purchase, ownership and disposition of our common stock.

This discussion assumes that a non-U.S. holder will not hold our common stock in a manner that would subject the non-U.S. holder to the newly-enacted withholding tax discussed below under "New legislation relating to foreign accounts."

### **Distributions on our Common Stock**

Payments on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a non-U.S. holder's adjusted tax basis in the common stock (determined on a share-by-share basis), but not below zero. Any remaining excess will be treated as capital gain from the sale of property as described below under " — Gain on Disposition of our common stock."

Dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the holder's conduct of a U.S. trade or business generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or a lower rate specified by an applicable tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying the holder's qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, who then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, but which qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their own tax advisors regarding their possible entitlement to benefits under a relevant tax treaty.

If dividends paid on our common stock are effectively connected with a non-U.S. holder's U.S. trade or business, the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI or IRS Form W-8BEN, as applicable (or an applicable successor form) prior to the payment of the dividends.

Any dividends paid on our common stock that are effectively connected with a non-U.S. holder's U.S. trade or business generally will be subject to U.S. federal income tax on a net income basis in the same manner as if the holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of its effectively connected earnings and profits for the taxable year. Non-U.S. holders should consult their own tax advisors regarding any applicable tax treaties that may provide for different rules.

### **Gain on Disposition of our Common Stock**

Subject to the discussion below regarding backup withholding, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States;

- the non-U.S. holder is an individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest by reason of our status as a U.S. real property holding corporation ("USRPHC") at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock (the "applicable period").

Unless an applicable tax treaty provides otherwise, gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis in the same manner as if the holder were a resident of the United States. Non-U.S. holders that are foreign corporations also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of their effectively connected earnings and profits. Non-U.S. holders should consult any applicable tax treaties that may provide for different rules.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or a lower rate specified by an applicable tax treaty), but may be offset by U.S. source capital losses, provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests, there can be no assurance that we are not currently or will not become a USRPHC in the future. In the event we are or become a USRPHC, as long as our common stock is regularly traded on an established securities market, our common stock will constitute a U.S. real property interest only with respect to a non-U.S. holder that actually or constructively holds more than 5% of our common stock at some time during the applicable period. Any taxable gain generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax will not apply.

### **Information Reporting and Backup Withholding**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock paid to such holder and the amount, if any, of tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

Backup withholding, currently at a rate of 28% (and scheduled to increase to 31% in 2011), generally will not apply to payments of dividends to a non-U.S. holder of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification as to its non-U.S. status (typically, by providing a valid IRS Form W-8BEN or W-8ECI) or an exemption is otherwise established.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through a non-U.S. office of a broker will not be subject to information reporting or backup withholding, except that information reporting (but generally not backup withholding) may apply to those payments if the broker does not have documentary evidence that the beneficial owner is a non-U.S. holder, an exemption is not otherwise established, and the broker is:

- a U.S. person;
- a controlled foreign corporation for U.S. federal income tax purposes;

- a foreign person 50% or more of whose gross income is effectively connected with a U.S. trade or business for a specified three-year period; or
- a foreign partnership if at any time during its tax year (1) one or more of its partners are U.S. persons who hold in the aggregate more than 50% of the income or capital interest in the partnership or (2) it is engaged in the conduct of a U.S. trade or business.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through the U.S. office of a broker generally will be subject to information reporting and backup withholding unless the non-U.S. holder certifies as to its non-U.S. status (such as by providing a valid IRS Form W-8BEN or W-8ECI) or otherwise establishes an exemption from information reporting and backup withholding.

Backup withholding is not an additional tax. Taxpayers may use amounts withheld as a credit against their U.S. federal income tax liability or may claim a refund if they timely provide certain information to the IRS.

### **New Legislation Relating to Foreign Accounts**

Newly enacted legislation may impose withholding taxes on certain types of payments made to or through "foreign financial institutions" and certain other non-U.S. entities after December 31, 2012. The legislation imposes a 30% withholding tax on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign financial institution (whether holding stock for its own account or on behalf of its account holders/investors) unless the foreign financial institution enters into an agreement with the U.S. Treasury to among other things, undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. In addition, the legislation imposes a 30% withholding tax on the same types of payments to a foreign non-financial entity unless the entity certifies that it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner and satisfies certain other requirements. Prospective investors should consult their own tax advisors regarding this legislation.

### **Estate Tax**

Common stock owned or treated as owned by an individual who is not a citizen or resident of the United States (as specifically defined for U.S. federal estate tax purposes) at the time of death is considered a U.S. situs asset includible in the individual's gross estate for U.S. federal estate tax purposes and therefore may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise. The United States federal estate tax was automatically repealed effective January 1, 2010, for the estates of decedents dying in the year 2010. Accordingly, at present, there is no United States federal estate tax. However, Congress could pass a law reinstating the estate tax that has retroactive effect. In addition, unless Congress acts to make the current repeal permanent, the estate tax will be reinstated with respect to decedents who die after December 31, 2010. In view of the continuing uncertainty regarding the federal estate tax law, prospective investors are urged to consult their tax advisors regarding the U.S. federal estate tax considerations of acquiring, holding, and disposing of common stock. The test for whether an individual is a resident of the United States for federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be "non-U.S. holders" for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

## UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, we have agreed to sell to the underwriters named below, and the underwriters, for whom Wells Fargo Securities, LLC and Cowen and Company, LLC are acting as joint-book running managers and representatives, have severally agreed to purchase, the respective numbers of shares of common stock appearing opposite their names below:

<u>Underwriter</u>	<u>Number of Shares</u>
Wells Fargo Securities, LLC	
Cowen and Company, LLC	
Robert W. Baird & Co. Incorporated	
Canaccord Genuity Inc.	
Needham & Company, LLC	
Total	

All of the shares to be purchased by the underwriters will be purchased from us.

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer and to reject orders in whole or in part.

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock offered by this prospectus if any are purchased, other than those shares covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

### Over-Allotment Option

We have granted a 30-day option to the underwriters to purchase up to a total of \_\_\_\_\_ additional shares of our common stock from us at the initial public offering price per share less the underwriting discounts and commissions per share, as set forth on the cover page of this prospectus, and less any dividends or distributions declared, paid or payable on the shares that the underwriters have agreed to purchase from us but that are not payable on such additional shares, to cover over-allotment, if any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the prior table.

### Discounts and Commissions

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus and to certain dealers at that price less a concession of not more than \$ \_\_\_\_\_ per share, of which up to \$ \_\_\_\_\_ per share may be reallocated to other dealers. After the initial offering, the public offering price, concession and reallocation to dealers may be changed.

The following table summarizes the underwriting discounts and commissions and the proceeds, before expenses, payable to us, both on a per share basis and in total, assuming either no exercise or full exercise by the underwriters of their overallotment option:

		<u>Total</u>	
	<u>Per Share</u>	<u>Without</u>	<u>With Option</u>
		<u>Option</u>	<u>With Option</u>
Public offering price			
Underwriting discounts and commissions			
Proceeds, before expenses, to us			

We estimate that the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately \$ .

#### **Indemnification of Underwriters**

The underwriting agreement provides that we will indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in respect of those liabilities.

#### **Lock-Up Agreements**

We, all of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering, and the holders of all of our warrants and substantially all of our options outstanding prior to this offering, have agreed, subject to certain exceptions, that, without the prior written consent of Wells Fargo Securities, LLC and Cowen and Company, LLC, we and they will not, during the period beginning on and including the date of this prospectus through and including the date that is the 180th day after the date of this prospectus, directly or indirectly:

- issue (in the case of us), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;
- in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock; or
- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock,

whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. Moreover, if:

- during the last 17 days of the lock-up period, we issue an earnings release or material news or a material event relating to us occurs; or
- prior to the expiration of the lock-up period, we announce that we will release earnings results or become aware that material news on a material event relating to us will occur during the 16-day period beginning on the last day of the lock-up period,

the restrictions described in the immediately preceding sentence will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of

the material news or material event, as the case may be, unless Wells Fargo Securities, LLC and Cowen and Company, LLC waive, in writing, that extension.

Wells Fargo Securities, LLC and Cowen and Company, LLC may, in their sole discretion and at any time or from time to time, without notice, release all or any portion of the shares or other securities subject to the lock-up agreements. Any determination to release any shares or other securities subject to the lock-up agreements would be based on a number of factors at the time of determination, which may include the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares or other securities proposed to be sold or otherwise transferred and the timing, purpose and terms of the proposed sale or other transfer.

### **NASDAQ Global Market Listing**

We have applied to have our common stock listed on the NASDAQ Global Market under the symbol "NLNK."

### **Stabilization**

In order to facilitate this offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the market price of our common stock. Specifically, the underwriters may sell more shares of common stock than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares of common stock available for purchase by the underwriters under the over-allotment option. The underwriters may close out a covered short sale by exercising the over-allotment option or purchasing common stock in the open market. In determining the source of common stock to close out a covered short sale, the underwriters may consider, among other things, the market price of common stock compared to the price payable under the over-allotment option. The underwriters may also sell shares of common stock in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after the date of pricing of this offering that could adversely affect investors who purchase in this offering.

As an additional means of facilitating this offering, the underwriters may bid for, and purchase, common stock in the open market to stabilize the price of our common stock, so long as stabilizing bids do not exceed a specified maximum. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing common stock in this offering if the underwriting syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock.

The foregoing transactions, if commenced, may raise or maintain the market price of our common stock above independent market levels or prevent or retard a decline in the market price of the common stock.

The foregoing transactions, if commenced, may be effected on the Nasdaq Global Market or otherwise. Neither we nor any of the underwriters makes any representation that the underwriters will engage in any of these transactions and these transactions, if commenced, may be discontinued at any time without notice. Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of the effect that the transactions described above, if commenced, may have on the market price of our common stock.

## **Discretionary Accounts**

The underwriters have informed us that they do not intend to confirm sales to accounts over which they exercise discretionary authority in excess of 5% of the total number of shares of common stock offered by them.

## **Pricing of this Offering**

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for our common stock was determined between us and the representative of the underwriters. The factors considered in determining the initial public offering price included:

- prevailing market conditions;
- our results of operations and financial condition;
- financial and operating information and market valuations with respect to other companies that we and the representative of the underwriters believe to be comparable or similar to us;
- the present state of our development; and
- our future prospects.

An active trading market for our common stock may not develop. It is possible that the market price of our common stock after this offering will be less than the initial public offering price. In addition, the estimated initial public offering price range appearing on the cover of this preliminary prospectus is subject to change as a result of market conditions or other factors.

## **Relationships**

The underwriters and/or their respective affiliates may in the future provide various financial advisory, investment banking, commercial banking and other financial services to us, for which they may receive compensation.

## **Sales Outside the United States**

No action has been or will be taken in any jurisdiction (except in the United States) that would permit a public offering of the common stock, or the possession, circulation or distribution of this prospectus or any other material relating to us or the common stock in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither of this prospectus nor any other offering material or advertisements in connection with the common stock may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

Each of the underwriters may arrange to sell common stock offered by this prospectus in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so. In that regard, Wells Fargo Securities, LLC may arrange to sell shares in certain jurisdictions through an affiliate, Wells Fargo Securities International Limited, or WFSIL. WFSIL is a wholly-owned indirect subsidiary of Wells Fargo & Company and an affiliate of Wells Fargo Securities, LLC. WFSIL is a U.K. incorporated investment firm regulated by the Financial Services Authority. Wells Fargo Securities is the trade name for certain corporate and investment banking services of Wells Fargo & Company and its affiliates, including Wells Fargo Securities, LLC and WFSIL.

## ***European Economic Area***

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus (the "Shares") may not be



made in that Relevant Member State except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives of the underwriters; or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of Shares shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

### **United Kingdom**

This prospectus and any other material in relation to the shares described herein is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospective Directive ("qualified investors") that also (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, (ii) who fall within Article 49(2)(a) to (d) of the Order or (iii) to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons"). The shares are only available to, and any invitation, offer or agreement to purchase or otherwise acquire such shares will be engaged in only with, relevant persons. This offering memorandum and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

The distribution of this prospectus in the United Kingdom to anyone not falling within the above categories is not permitted and may contravene the Financial Services and Markets Act of 2000. No person falling outside those categories should treat this prospectus as constituting a promotion to him, or act on it for any purposes whatever. Recipients of this prospectus are advised that we, the underwriters and any other person that communicates this prospectus are not, as a result solely of communicating this prospectus, acting for or advising them and are not responsible for providing recipients of this prospectus with the protections which would be given to those who are clients of any aforementioned entities that is subject to the Financial Services Authority Rules.

### **France**

The prospectus supplement and the accompanying prospectus (including any amendment, supplement or replacement thereto) have not been approved either by the *Autorité des marchés financiers* or by the competent authority of another State that is a contracting party to the Agreement

on the European Economic Area and notified to the *Autorité des marchés financiers*; no security has been offered or sold and will be offered or sold, directly or indirectly, to the public in France within the meaning of Article L. 411-1 of the French *Code Monétaire et Financier* except to permitted investors, or Permitted Investors, consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (*investisseurs qualifiés*) acting for their own account and/or a limited circle of investors (*cercle restreint d'investisseurs*) acting for their own account, with "qualified investors" and "limited circle of investors" having the meaning ascribed to them in Articles L. 411-2, D. 411-1, D. 411-2, D. 411-4, D. 744-1, D. 754-1 and D. 764-1 of the French *Code Monétaire et Financier*; none of this prospectus supplement and the accompanying Prospectus or any other materials related to the offer or information contained therein relating to our securities has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any securities acquired by any Permitted Investors may be made only as provided by Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French *Code Monétaire et Financier* and applicable regulations thereunder.

#### **Notice to the Residents of Germany**

This document has not been prepared in accordance with the requirements for a securities or sales prospectus under the German Securities Prospectus Act (*Wertpapierprospektgesetz*), the German Sales Prospectus Act (*Verkaufsprospektgesetz*), or the German Investment Act (*Investmentgesetz*). Neither the German Federal Financial Services Supervisory Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht — BaFin*) nor any other German authority has been notified of the intention to distribute the securities in Germany. Consequently, the securities may not be distributed in Germany by way of public offering, public advertisement or in any similar manner AND THIS DOCUMENT AND ANY OTHER DOCUMENT RELATING TO THE OFFERING, AS WELL AS INFORMATION OR STATEMENTS CONTAINED THEREIN, MAY NOT BE SUPPLIED TO THE PUBLIC IN GERMANY OR USED IN CONNECTION WITH ANY OFFER FOR SUBSCRIPTION OF THE SECURITIES TO THE PUBLIC IN GERMANY OR ANY OTHER MEANS OF PUBLIC MARKETING. The securities are being offered and sold in Germany only to qualified investors which are referred to in Section 3, paragraph 2 no. 1, in connection with Section 2, no. 6, of the German Securities Prospectus Act. This document is strictly for use of the person who has received it. It may not be forwarded to other persons or published in Germany.

#### **Switzerland**

This document does not constitute a prospectus within the meaning of Art. 652a of the Swiss Code of Obligations. The shares of common stock may not be sold directly or indirectly in or into Switzerland except in a manner which will not result in a public offering within the meaning of the Swiss Code of Obligations. Neither this document nor any other offering materials relating to the shares of common stock may be distributed, published or otherwise made available in Switzerland except in a manner which will not constitute a public offer of the shares of common stock in Switzerland.

## LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Broomfield, Colorado. The underwriters are being represented by Cahill Gordon & Reindel LLP, New York, New York.

## EXPERTS

The consolidated financial statements of NewLink Genetics Corporation and subsidiary (a development stage enterprise) as of December 31, 2010 and 2009, and for each of the years in the three-year period ended December 31, 2010, and for the period from June 4, 1999 (inception), through December 31, 2010, have been included herein in reliance upon the report of KPMG LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2010, financial statements refers to the adoption of new guidance on the presentation and disclosure of noncontrolling interests.

The common stock valuations as of December 31, 2007, 2008 and 2009, March 31, 2010, June 30, 2010, September 30, 2010 and December 31, 2010 have been included herein in reliance upon reports of the Mentor Group, Inc., an independent valuation specialist, and upon the authority of said firm as valuation experts.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to NewLink Genetics Inc. and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at [www.linkp.com](http://www.linkp.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors

NewLink Genetics Corporation and Subsidiary:

We have audited the accompanying consolidated balance sheets of NewLink Genetics Corporation and subsidiary (a development stage enterprise) (the Company) as of December 31, 2009 and 2010, and the related consolidated statements of operations, equity (deficit), and cash flows for each of the years in the three year period ended December 31, 2010 and for the period from June 4, 1999 (inception) through December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NewLink Genetics Corporation and subsidiary (a development stage enterprise) as of December 31, 2009 and 2010, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2010, and for the period from June 4, 1999 (inception) through December 31, 2010, in conformity with U.S. generally accepted accounting principles.

As discussed in note 2 to the consolidated financial statements, the Company has adopted guidance on the presentation and disclosure of noncontrolling interests as of January 1, 2009.

/s/ KPMG LLP

February 25, 2011  
Des Moines, Iowa

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Balance Sheets**  
**(In thousands, except share and per share data)**

	<b>December 31,</b>	
	<b>2009</b>	<b>2010</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,217	\$ 10,572
Certificates of deposit	1,992	2,269
Prepaid expenses	110	1,020
State research and development credit receivable	170	230
Interest receivable	68	8
Other receivables	1,341	604
<b>Total current assets</b>	<b>18,898</b>	<b>14,703</b>
Leasehold improvements and equipment:		
Leasehold improvements	2,293	3,804
Computer equipment	430	691
Lab equipment	1,765	3,165
<b>Total leasehold improvements and equipment</b>	<b>4,488</b>	<b>7,660</b>
Less accumulated depreciation and amortization	(1,569)	(2,224)
<b>Leasehold improvements and equipment, net</b>	<b>2,919</b>	<b>5,436</b>
Notes receivable from related parties	850	—
<b>Total assets</b>	<b>\$ 22,667</b>	<b>\$ 20,139</b>

See accompanying notes to consolidated financial statements.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Balance Sheets**  
**(In thousands, except share and per share data)**

	December 31,		Pro forma Equity at December 31, 2010 (Note 2)
	2009	2010	
<b>Liabilities and Equity</b>			
Current liabilities:			
Accounts payable	\$ 1,080	\$ 552	
Accrued expenses	1,176	1,554	
Deferred rent	947	951	
Obligations under capital leases	35	116	
Current portion of long term debt	—	91	
Deposits on restricted shares	3	1	
Total current liabilities	<u>3,241</u>	<u>3,265</u>	
Long term liabilities:			
Notes payable to Iowa Department of Economic Development	6,000	6,000	
Notes payable to Iowa State University Research Park	—	642	
Notes payable to City of Ames	—	300	
Obligations under capital leases	78	145	
Total long-term liabilities	<u>6,078</u>	<u>7,087</u>	
Total liabilities	<u>9,319</u>	<u>10,352</u>	
Redeemable preferred stock, \$0.01 par value:			
Authorized shares — 14,327,777 at December 31, 2009 and 15,327,777 at December 31, 2010; issued and outstanding shares — 13,200,436 at December 31, 2009, 13,417,435 at December 31, 2010 and 13,693,739 at December 31, 2010 pro forma; liquidation preference of \$54,136 at December 31, 2009, \$61,782 at December 31, 2010 and \$70,417 at December 31, 2010 pro forma	54,134	61,745	70,380
Equity:			
Blank check preferred stock, \$0.01 par value: Authorized shares — 1,388,889 at December 31, 2009 and 2010 and December 31, 2010 pro forma; issued and outstanding shares — 0 at December 31, 2009 and 2010 and December 31, 2010 pro forma	—	—	—
Series A preferred stock, \$0.01 par value: Authorized shares — 450,000 at December 31, 2009 and 2010 and December 31, 2010 pro forma; issued and outstanding shares — 420,000 at December 31, 2009 and 2010 and December 31, 2010 pro forma; liquidation preference — \$1,050,000 at December 31, 2009 and 2010 and December 31, 2010 pro forma	1,030	1,030	1,030
Common stock, \$0.01 par value: Authorized shares — 32,000,000 at December 31, 2010 and 38,833,334 at December 31, 2010 and December 31, 2010 pro forma; issued and outstanding shares — 6,671,401 at December 31, 2009 and 7,618,973 at December 31, 2010 and December 31, 2010 pro forma	67	76	76
Additional paid-in capital	2,765	6,713	1,021
Notes receivable for common stock	(38)	(13)	(13)
Deficit accumulated during the development stage	(46,962)	(62,707)	(62,707)
Total NewLink Genetics shareholders' (deficit) equity	(43,138)	(54,901)	(60,593)
Equity attributable to noncontrolling interests	2,352	2,943	—
Total (deficit) equity	<u>(40,786)</u>	<u>(51,958)</u>	<u>\$ (60,593)</u>
<b>Commitments</b>			
Total liabilities and deficit	<u>\$ 22,667</u>	<u>\$ 20,139</u>	

See accompanying notes to consolidated financial statements.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Operations**  
**(In thousands, except share and per share data)**

	<u>Year Ended December 31,</u>			<b>Cumulative from</b>
	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>June 4, 1999</b>
				<b>(inception)</b>
				<b>through</b>
				<b>December 31,</b>
				<b>2010</b>
Grant revenue	\$ 633	\$ 934	\$ 2,079	\$ 3,845
Operating expenses:				
Research and development	6,517	7,636	13,249	48,259
General and administrative	3,531	3,115	5,023	21,277
Total operating expenses	<u>10,048</u>	<u>10,751</u>	<u>18,272</u>	<u>69,536</u>
Loss from operations	(9,415)	(9,817)	(16,193)	(65,691)
Other income and expense:				
Miscellaneous income	42	19	71	353
Forgiveness of debt	—	—	—	449
Interest income	213	132	75	1,742
Interest expense	(2)	(9)	(47)	(101)
Other income (expense), net	<u>253</u>	<u>142</u>	<u>99</u>	<u>2,443</u>
Net loss	<u>(9,162)</u>	<u>(9,675)</u>	<u>(16,094)</u>	<u>(63,248)</u>
Less net loss attributable to noncontrolling interest	—	233	349	582
Net loss attributable to NewLink	<u>\$ (9,162)</u>	<u>\$ (9,442)</u>	<u>\$ (15,745)</u>	<u>\$ (62,666)</u>
Net loss attributable to common stockholders	<u>\$ (9,162)</u>	<u>\$ (9,442)</u>	<u>\$ (15,745)</u>	
Net loss per share, basic and diluted	<u>\$ (1.40)</u>	<u>\$ (1.42)</u>	<u>\$ (2.24)</u>	
Weighted-average shares outstanding, basic and diluted	<u>6,541,520</u>	<u>6,635,986</u>	<u>7,039,895</u>	
Pro forma net loss per share, basic and diluted (unaudited) (note 2)			<u>(2.24)</u>	
Weighted-average pro forma shares outstanding, basic and diluted (unaudited) (note 2)			<u>7,039,895</u>	

See accompanying notes to consolidated financial statements.



**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Equity (Deficit)**  
(In thousands, except share and per share data)

	Common Stock					Treasury Stock	Deficit Accumulated During the Development Stage	Total NewLink Genetics Shareholders' Equity	Non-Controlling Interest	Total Equity (Deficit)
	Preferred Stock Series A	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Notes Receivable For Common Stock					
Balance at June 4, 1999	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Initial stock issuance (November 11, 1999)	—	4,000,000	40	—	(13)	—	—	27	—	27
Net loss	—	—	—	—	—	—	(64)	(64)	—	(64)
Balance at December 31, 1999	—	4,000,000	40	—	(13)	—	(64)	(37)	—	(37)
Loan payment	—	—	—	—	13	—	—	13	—	13
Common stock issuance (April 18, 2000)	—	1,389,200	12	125	(92)	—	—	45	—	45
Common stock issuance (June 13, 2000)	—	53,000	1	13	(12)	—	—	2	—	2
Issuance of 420,000 shares of Series A preferred stock (net of offering costs) (August 29, 2000)	989	—	—	—	—	—	—	989	—	989
Net loss	—	—	—	—	—	—	(236)	(236)	—	(236)
Balance at December 31, 2000	989	5,442,200	53	138	(104)	—	(300)	776	—	776
Repurchase of common stock and settlement of notes receivable (January 29, 2001)	—	(276,793)	—	—	18	(33)	—	(15)	—	(15)
Issuance of common stock (August 2, 2001)	—	200,000	2	48	—	—	—	50	—	50
Deemed dividend due to sale of Series AA preferred shares (September 26, 2001) (note 3)	41	—	—	—	—	—	(41)	—	—	—
Net loss	—	—	—	—	—	—	(1,448)	(1,448)	—	(1,448)
Balance at December 31, 2001	1,030	5,365,407	55	186	(86)	(33)	(1,789)	(637)	—	(637)
Receipt of payment on note receivable (April 5 and October 5, 2002)	—	—	—	—	2	—	—	2	—	2
Issuance of common stock from exercise of stock options (July 26, 2002)	—	50,000	1	12	—	—	—	13	—	13
Receipt of payment on note receivable (September 4, 2002)	—	—	—	—	31	—	—	31	—	31
Issuance of dividend paid in common stock (October 18, 2002)	—	44,097	1	(1)	—	—	—	—	—	—
Issuance of stock options to nonemployees	—	—	—	14	—	—	—	14	—	14
Accretion of redemption feature of preferred stock	—	—	—	(6)	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(2,253)	(2,253)	—	(2,253)
Balance at December 31, 2002	1,030	5,459,504	57	205	(53)	(33)	(4,042)	(2,836)	—	(2,836)
Issuance of common stock for compensation (March 20, 2003)	—	20,000	1	45	—	—	—	46	—	46
Receipt of payment on note receivable (January 1, April 4, July 9, and September 29, 2003)	—	—	—	—	7	—	—	7	—	7
Issuance of common stock from exercise of warrants (various dates through March 2003)	—	494,628	4	1,108	—	—	—	1,112	—	1,112
Issuance of dividend paid in common stock	—	44,097	1	(1)	—	—	—	—	—	—
Issuance of stock options	—	—	—	15	—	—	—	15	—	15
Accretion of redemption feature of preferred stock	—	—	—	(5)	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(2,979)	(2,979)	—	(2,979)
Balance at December 31, 2003	1,030	6,018,229	63	1,367	(46)	(33)	(7,021)	(4,640)	—	(4,640)
Receipt of payment on note receivable (February 25, 2004 and July 15, 2004)	—	—	—	—	5	—	—	5	—	5
Issuance of stock options	—	—	—	57	—	—	—	57	—	57
Accretion of redemption feature of preferred stock	—	—	—	(5)	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(3,669)	(3,669)	—	(3,669)
Balance at December 31, 2004	\$ 1,030	6,018,229	\$ 63	\$ 1,419	\$ (41)	\$ (33)	\$ (10,690)	\$ (8,252)	\$ —	\$ (8,252)

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Equity (Deficit) — (Continued)**  
**(In thousands, except share and per share data)**

	Preferred Stock Series A	Common Stock				Notes Receivable For Common Stock	Treasury Stock	Deficit Accumulated During the Development Stage	Total NewLink Genetics Shareholders' Equity	Non- Controlling Interest	Total Equity (Deficit)
		Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital							
Balance at December 31, 2004 (brought forward)	\$ 1,030	6,018,229	\$ 63	\$ 1,419	\$ (41)	\$ (33)	\$ (10,690)	\$ (8,252)	\$ —	\$ (8,252)	
Receipt of payment on note receivable	—	—	—	—	1	—	—	1	—	1	
Issuance of stock options	—	—	—	2	—	—	—	2	—	2	
Issuance of dividend paid in common stock (September 23, 2005)	—	88,190	1	(1)	—	—	—	—	—	—	
Issuance of common stock for OncoRx acquisition (June 21, 2005)	—	130,102	1	353	—	—	—	354	—	354	
Issuance of common stock to consultants (April 4 and June 1, 2005)	—	18,787	—	51	—	—	—	51	—	51	
Issuance of 593,247 shares of Series BB preferred stock (net of offering costs of \$36,114) (January and February 2005)	—	—	—	—	—	—	—	—	—	—	
Accretion of redemption feature of preferred stock	—	—	—	(82)	—	—	—	(82)	—	(82)	
Issuance of subsidiary preferred stock	—	—	—	—	—	—	—	—	2,278	2,278	
Net loss	—	—	—	—	—	—	(4,770)	(4,770)	—	(4,770)	
Balance at December 31, 2005	1,030	6,255,308	65	1,742	(40)	(33)	(15,460)	(12,696)	2,278	(10,418)	
Stock compensation	—	—	—	22	—	—	—	22	—	22	
Issuance of common stock for OncoRx acquisition (March 22, 2006)	—	130,102	1	129	—	—	—	130	—	130	
Issuance of dividend paid in common stock (September 25, 2006)	—	44,091	1	(1)	—	—	—	—	—	—	
Issuance of subsidiary preferred stock	—	—	—	—	—	—	—	—	250	250	
Issuance of subsidiary common stock, net of deposits	—	—	—	—	—	—	—	—	7	7	
Accretion of redemption feature of preferred stock	—	—	—	(4)	—	—	—	(4)	—	(4)	
Net loss	—	—	—	—	—	—	(5,318)	(5,318)	—	(5,318)	
Balance at December 31, 2006	1,030	6,429,501	67	1,888	(40)	(33)	(20,778)	(17,866)	2,535	(15,331)	
Stock compensation	—	—	—	56	—	—	—	56	—	56	
Exercise of stock options	—	32,500	—	12	—	—	—	12	—	12	
Receipt of payment on note receivable	—	—	—	—	2	—	—	2	—	2	
Issuance of common stock for license milestone (August 2, 2007)	—	25,000	—	—	—	—	—	—	—	—	
Issuance of dividend paid in common stock	—	44,091	1	(1)	—	—	—	—	—	—	
Retire treasury stock	—	—	(3)	(30)	—	33	—	—	—	—	
Issuance of subsidiary common stock, net of deposits	—	—	—	—	—	—	—	—	8	8	
Net loss	—	—	—	—	—	—	(7,580)	(7,580)	—	(7,580)	
Balance at December 31, 2007	1,030	6,531,092	65	1,925	(38)	—	(28,358)	(25,376)	2,543	(22,833)	
Stock compensation	—	—	—	142	—	—	—	142	—	142	
Exercise of stock options	—	32,125	—	19	—	—	—	19	—	19	
Issuance of common stock for license milestone (September 8, 2008)	—	5,000	—	5	—	—	—	5	—	5	
Issuance of dividend paid in common stock	—	44,099	1	(1)	—	—	—	—	—	—	
Issuance of subsidiary common stock, net of deposits	—	—	—	—	—	—	—	—	(1)	(1)	
Net loss	—	—	—	—	—	—	(9,162)	(9,162)	—	(9,162)	
Balance at December 31, 2008	\$ 1,030	6,612,316	\$ 66	\$ 2,090	\$ (38)	\$ —	\$ (37,520)	\$ (34,372)	\$ 2,542	\$ (31,830)	

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Equity (Deficit) — (Continued)**  
**(In thousands, except share and per share data)**

	Preferred Stock Series A	Common Stock				Notes Receivable For Common Stock	Treasury Stock	Deficit Accumulated During the Development Stage	Total NewLink Genetics Shareholders' Equity	Non- Controlling Interest	Total Equity (Deficit)
		Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital							
Balance at December 31, 2008 (brought forward)	\$ 1,030	6,612,316	\$ 66	\$ 2,090	\$ (38)	\$ —	\$ (37,520)	\$ (34,372)	\$ 2,542	\$ (31,830)	
Stock compensation	—	—	—	661	—	—	—	661	—	661	
Exercise of stock options	—	14,990	—	15	—	—	—	15	—	15	
Issuance of dividend paid in common stock	—	44,095	1	(1)	—	—	—	—	—	—	
Issuance of subsidiary common stock net of deposits	—	—	—	—	—	—	—	—	3	3	
Issuance of 30,000 shares of subsidiary Series B preferred stock (November 16, 2009)	—	—	—	—	—	—	—	—	40	40	
Net loss	—	—	—	—	—	—	(9,442)	(9,442)	(233)	(9,675)	
Balance at December 31, 2009	1,030	6,671,401	67	2,765	(38)	—	(46,962)	(43,138)	2,352	(40,786)	
Stock compensation	—	—	—	1,206	—	—	—	1,206	—	1,206	
Exercise of stock options	—	297,303	3	79	—	—	—	82	—	82	
Exercise of warrants for common stock	—	375,000	3	1,997	—	—	—	2,000	—	2,000	
Receipt of payment and forgiveness of note receivable	—	—	—	—	25	—	—	25	121	146	
Issuance of common stock for OncoRX acquisition (July 29, 2010)	—	364,285	3	816	—	—	—	819	—	819	
Issuance of common stock for license termination (September 3, 2010)	—	50,000	1	112	—	—	—	113	—	113	
Issuance of dividend paid in common stock	—	44,095	1	(1)	—	—	—	—	—	—	
Accretion of redemption feature of preferred stock	—	—	—	(2)	—	—	—	(2)	—	(2)	
Conversion of preferred stock to common stock	—	31,321	—	114	—	—	—	114	—	114	
Repurchase and retirement of common stock (December 20, 2010)	—	(214,432)	(2)	(373)	—	—	—	(375)	(94)	(469)	
Issuance of subsidiary common stock net of deposits	—	—	—	—	—	—	—	—	2	2	
Issuance of 555,930 shares of subsidiary Series B Preferred Stock (September 7, 2010)	—	—	—	—	—	—	—	—	911	911	
Net loss	—	—	—	—	—	—	(15,745)	(15,745)	(349)	(16,094)	
Balance at December 31, 2010	\$ 1,030	7,618,973	\$ 76	\$ 6,713	\$ (13)	\$ —	\$ (62,707)	\$ (54,901)	\$ 2,943	\$ (51,958)	

See accompanying notes to consolidated financial statements.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Cash Flows**  
**(In thousands, except share and per share data)**

	<u>Year Ended December 31,</u>			<b>Cumulative from June 4, 1999 (inception) through December 31, 2010</b>
	<b>2008</b>	<b>2009</b>	<b>2010</b>	
<b>Cash Flows From Development Activities</b>				
Net loss	\$ (9,162)	\$ (9,675)	\$ (16,094)	\$ (63,248)
Adjustments to reconcile net loss to net cash used in development activities:				
Share-based compensation	141	661	1,206	2,270
Depreciation and amortization	294	303	655	2,274
In-process research and development expenses — OncoRx	5	—	819	1,428
Issuance of common stock for license termination	—	—	113	113
Forgiveness of debt	—	—	—	(449)
Forgiveness of notes receivable from related parties	—	—	350	350
Changes in operating assets and liabilities:				
Prepaid expenses	(38)	(60)	(910)	(1,020)
State research and development credit receivable	(272)	379	(60)	(230)
Interest due on notes receivable	(25)	(23)	60	(8)
Other receivables	—	(1,341)	737	(604)
Accounts payable	(361)	(271)	(528)	(197)
Accrued expenses and deferred rent	533	887	382	2,505
Net cash used in development activities	<u>(8,885)</u>	<u>(9,140)</u>	<u>(13,270)</u>	<u>(56,816)</u>
<b>Cash Flows From Investing Activities</b>				
Purchase of investments	(1,850)	(142)	(277)	(8,800)
Sale of investments	—	—	—	6,531
Notes receivable from related parties	(850)	—	500	500
Purchase of equipment	(427)	(1,403)	(2,932)	(6,488)
Cash paid for OncoRx	—	—	—	(120)
Net cash provided by (used in) investing activities	<u>(3,127)</u>	<u>(1,545)</u>	<u>(2,709)</u>	<u>(9,227)</u>
<b>Cash Flows From Financing Activities</b>				
Cash received from noncontrolling interest investment	—	40	911	3,479
Issuance of common stock	—	—	—	192
Issuance of common stock from exercise of stock options	19	15	82	140
Issuance of common stock from exercise of warrants	—	—	2,000	3,113
Repurchase of common stock	—	—	(468)	(501)
Repayments (advances) of notes receivable for common stock	—	—	25	(13)
Proceeds (repurchases) from subsidiary common stock option exercise and notes receivable	(4)	—	121	141
Proceeds from preferred stock (including deposits)	2,039	19,580	7,723	62,743
Transfer (to) from restricted cash	15,880	—	—	—
Proceeds from notes payable	—	—	1,100	7,759
Principal payments on debt	—	—	(67)	(277)
Payments under capital lease obligations	(4)	(9)	(93)	(161)
Net cash provided by financing activities	<u>17,930</u>	<u>19,626</u>	<u>11,334</u>	<u>76,615</u>
Net (decrease) increase in cash and cash equivalents	<u>5,918</u>	<u>8,941</u>	<u>(4,645)</u>	<u>10,572</u>
Cash and cash equivalents at beginning of period	358	6,276	15,217	—
Cash and cash equivalents at end of period	<u>\$ 6,276</u>	<u>\$ 15,217</u>	<u>\$ 10,572</u>	<u>\$ 10,572</u>
Supplemental disclosure of cash flows information:				
Cash paid for interest	\$ 2	\$ 9	\$ 44	\$ 62
Noncash financing and investing activities:				
Accretion on redeemable preferred stock	—	—	2	105
Purchased leasehold improvements and equipment in accounts payable	—	749	—	769
Common stock issued to acquire goods or services	5	—	932	1,654
Issuance of common stock dividend to Series AA preferred shareholders	1	1	1	5
Assets acquired under capital lease	12	114	282	462

See accompanying notes to consolidated financial statements.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Notes to Consolidated Financial Statements**

**1. Description of Business and Development Stage Activities**

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed for the purpose of developing treatments for cancer and other diseases. NewLink initiated operations in April of 2000, which primarily consist of research and development.

In 2005, NewLink created a wholly owned subsidiary, BioProtection Systems Corporation (BPS). NewLink contributed certain licensing agreements and other intangible assets for BPS to create vaccines against potential biological terror threats. During 2006, BPS granted options to the founders of NewLink and employees and consultants of BPS to acquire shares of BPS common stock. A portion of these options were exercised during 2008 and 2009, which diluted NewLink's ownership. At December 31, 2009, NewLink owned 72% of BPS and on an as-if-converted-to-common-stock basis, NewLink's ownership of BPS would be 63%. At December 31, 2010, NewLink owned 71% of BPS and on an as-if-converted-to-common-stock basis, NewLink's ownership of BPS would be 64%.

On January 7, 2011, NewLink acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of NewLink with BPS, with BPS as the surviving corporation. In connection with this transaction, NewLink will issue up to an aggregate of 276,304 shares of NewLink's Series E preferred stock with a fair value of \$8.6 million to the former holders of BPS Series B common stock, Series A preferred stock and Series B preferred stock (other than NewLink). 221,066 of the shares of NewLink's Series E preferred stock were issued to the holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of NewLink's Series E preferred stock were held back to satisfy any indemnity obligations under the merger agreement. If there are no indemnity obligations payable under the merger agreement by June 30, 2011, those shares will be issued to the former holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock. As a result of this transaction, BPS became a wholly-owned subsidiary of NewLink.

NewLink and its subsidiary (the Company) are development stage enterprises and are devoting substantially all of their efforts toward research and development.

The Company has never earned revenue from sales of its drugs under development. The Company has, from June 4, 1999 (inception) through December 31, 2010 generated a cumulative deficit of \$62.7 million. The accompanying financial statements for the year ended December 31, 2010 have been prepared assuming the Company will continue as a going concern. The Company anticipates that its existing capital resources will be adequate to satisfy its liquidity requirements through December 31, 2010. If available liquidity is not sufficient to meet the Company's operating obligations as they come due, management's plans include pursuing alternative funding arrangements or reducing expenditures as necessary to meet the Company's cash requirements through December 31, 2010. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity.

The Company's Board of Directors has approved the filing of a registration statement on Form S-1 with respect to a proposed initial public offering (IPO) of its common stock. There is no assurance that additional financing will be consummated or obtained in sufficient amounts or on acceptable terms to meet the Company's needs.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Notes to Consolidated Financial Statements — (Continued)**

**2. Significant Accounting Policies**

**(a) Use of Estimates**

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**(b) Principles of Consolidation**

The consolidated financial statements include the financial statements of NewLink and its majority-owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

**(c) Cash and Cash Equivalents**

For the purposes of the consolidated statements of cash flows, the Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash equivalents of \$10.6 million and \$15.2 million at December 31, 2010 and December 31, 2009, respectively, consist of money market accounts. Cash received for deposits on sales of equity securities is classified as restricted cash until the shares are issued. No cash is restricted at December 31, 2010 and December 31, 2009.

**(d) Certificates of Deposit**

Certificates of deposit have original maturities of greater than three months. Certificates of deposit are classified as held-to-maturity with due dates through 2011 and are presented at amortized cost, which approximates fair value.

**(e) Prepaid Expenses**

Prepaid Expenses includes costs directly attributable to the Company's offering of its equity securities. In accordance with FASB Accounting Standards Codification (ASC) 340-10, *Other Assets and Deferred Costs*, these costs are deferred and capitalized as part of prepaid expenses. Costs attributable to the equity offerings will be charged against the proceeds of the offering once completed.

**(f) Leasehold Improvements and Equipment**

Leasehold improvements and equipment are stated at cost. Equipment under capital leases is stated at the present value of minimum lease payments.

Depreciation on all leasehold improvements and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years and lab equipment has useful lives of three to seven years.

During 2009, the Company added leasehold improvements to a new facility under an operating lease. As part of the lease, the lessor approved a tenant improvement allowance of \$943,000 for improvements made to the facility. This amount was receivable from the lessor at December 31, 2009 and recorded in other receivables. The receivable was subsequently collected from lessor in January 2010. The offsetting amount is recorded as deferred rent on the financial statements and will reduce rent

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Notes to Consolidated Financial Statements — (Continued)**

expense over the remaining term of the lease. The Company incurred costs in excess of the tenant improvement allowance during 2009.

***(g) Impairment of Long-Lived Assets***

Long-lived assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future net undiscounted cash flows expected to be generated by the asset group, primarily relating to proceeds for selling the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

***(h) Revenue Recognition***

The Company receives payments from government entities under its grants and contracts with the National Institute of Health and the Department of Defense. These agreements provide the Company cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. Revenues are recognized in the period during which the related costs are incurred, provided that the conditions under which the cost reimbursement was provided have been met and we have only perfunctory obligations outstanding. During the years ended December 31, 2010, 2009, 2008, and since inception, the Company has earned \$2.1 million, \$934,000, \$633,000 and \$3.8 million in grant revenue, respectively.

***(i) Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses***

The Company estimates its accrued expenses through a process of reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed and estimating the level of service performed and the associated cost incurred for the service that may not be invoiced from the provider. The estimates of accrued expenses as of each balance sheet date are based on facts and circumstances known at that time. Such estimates are periodically confirmed with the service providers to verify accuracy.

The Company bases its expenses related to clinical trials on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on behalf of the Company. The Company does not expect its estimates to be materially different from amounts actually incurred.

***(j) Pro Forma Stockholders' Equity***

In October 2010, the Company's Board of Directors authorized the filing of a registration statement with the Securities and Exchange Commission (SEC) to sell shares of its common stock to the public in an IPO. The Company filed an initial S-1 registration statement with the SEC on December 21, 2010. Pro forma stockholders' equity includes the issuance of 276,304 shares of Series E preferred stock in connection with our acquisition of the minority interest in our majority owned subsidiary, BPS, which occurred on January 7, 2011.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Notes to Consolidated Financial Statements — (Continued)**

**(k) Research and Development**

Research and development costs are expensed as incurred. Certain research and development expenses are refundable from the state of Iowa without regard to income. State research and development credits of \$230,000, \$170,000, \$272,000, and \$1.6 million at December 31, 2010, 2009, and 2008, and since inception through December 31, 2010, respectively, are reflected as a reduction of research and development expenses on the accompanying consolidated statements of operations.

The Company records expenses related to research and development as a separate caption in the financial statements. During 2010, the Company identified errors related to the classification of certain research and development expenses in the statements of operations. As a result, the Company's historical research and development expenses and general and administrative expenses were misstated. In accordance with the SEC's Staff Accounting Bulletin (SAB) No. 99, Materiality, and SAB No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, management evaluated the materiality of the errors from qualitative and quantitative perspectives and concluded that the errors were immaterial to the Company's financial statements to the prior period. Consequently, the Company has revised its historical presentation of research and development and general and administrative expenses for the years ended December 31, 2009 and 2008 to be consistent with the December 31, 2010 presentation. The errors also had an impact on the cumulative balances from inception as of December 31, 2010. The errors did not have any impact on total equity as of December 31, 2009 or operating loss, net loss, earnings per share or cash flows for the years ended December 31, 2009 and 2008.

The following table represents a summary of the effects of the immaterial error correction on the consolidated statements of operations for the years ended December 31, 2009 and 2008 (in thousands):

	2008		2009	
	Research and Development	General and Administrative	Research and Development	General and Administrative
As previously reported	\$ 5,451	\$ 4,598	\$ 5,559	\$ 5,192
Adjustment	1,066	(1,066)	2,077	(2,077)
As adjusted	<u>\$ 6,517</u>	<u>\$ 3,531</u>	<u>\$ 7,636</u>	<u>\$ 3,115</u>

**(l) Patents**

The Company generally applies for patent protection on processes and products. Patent application costs are expensed as incurred as a component of research and development expense, as recoverability of such expenditures is uncertain.

**(m) Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operating results in the period that includes the enactment date.



**NewLink Genetics Corporation and Subsidiary**  
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**Notes to Consolidated Financial Statements — (Continued)**

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. As of December 31, 2010 and 2009, the Company has not recognized any uncertain tax positions.

**(n) Stock Option Valuation**

The Company is required to estimate the grant-date fair value of stock options issued to employees and recognize this cost over the period these awards vest. The Company estimates the fair value of each option granted using the Black-Scholes option pricing model. Generally, the Company has issued employee awards with a graded vesting schedule that vest over time. For these awards, the Company records compensation cost on a straight-line basis over the vesting period for the entire award.

The Company has issued awards to nonemployee consultants and advisors. All grants to nonemployees are valued using the same fair value method that the Company uses for grants to employees. The compensation cost recognized on these awards is determined on the later of the vesting of the award or completion of services by the nonemployee.

Following is a description of the inputs for the Black-Scholes model:

*Exercise Price*

The Company's stock options are granted with an exercise price as determined by the Board of Directors.

*Expected Term (in Years)*

The expected term of a stock option is the period of time for which the option is expected to be outstanding. The Company has a large number of options outstanding and has no secondary market. Therefore, the Company used the simplified method under current SEC guidance to estimate the expected term. The simplified method uses the midpoint between the fully vested date and the forfeiture date as the expected term for the employee and nonemployee director grants. For nonemployee grants, the contractual life of the option is used.

*Risk-Free Interest Rate*

The Company uses the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

*Expected Dividend Yield*

The expected dividend yield for all of the Company's stock option grants is 0%, as the Company has not declared a cash dividend since inception and has no plans to declare a dividend.

*Expected Volatility*

Since the Company is a privately held firm, the estimated future expected volatility for each stock option valuation utilizes volatility rates of similar publicly traded companies considered to be in the same peer group.

**NewLink Genetics Corporation and Subsidiary**  
**(A Development Stage Enterprise)**  
**Notes to Consolidated Financial Statements — (Continued)**

*Forfeitures*

The share-based compensation expense has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of the Company's option plan, which the Company expects to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock-based award over its vesting period will only be for those shares that actually vest.

**(o) Noncontrolling Interest**

The Company has consolidated 100% of the assets, liabilities, and income from subsidiaries for which the Company has a majority voting interest. The Company has recorded a noncontrolling interest in subsidiaries on the consolidated balance sheets and noncontrolling interest in net loss of subsidiaries on the consolidated statements of operations representing the noncontrolling interest's equity and their proportionate share of net loss.

In December 2007, the Financial Accounting Standards Board (FASB) issued new authoritative guidance on the presentation and disclosures of noncontrolling interests in consolidated financial statements to improve the relevance, comparability, and transparency. The Company adopted the authoritative guidance on noncontrolling interests on January 1, 2009. As a result of the adoption, the Company now allocates a portion of the loss from its subsidiary to the noncontrolling interest. This creates a deficit balance from operations, which was not allowed under previous accounting literature. The amount allocated to the noncontrolling interest was \$349,000 and \$233,000 during the years ended December 31, 2010 and 2009, respectively. Had the Company continued to apply previous accounting literature, the loss for December 31, 2010 and December 31, 2009 would be \$16.1 million and \$9.7 million, respectively, as none of the loss would be allocated to the noncontrolling interest as it would create a deficit balance. The noncontrolling interest was eliminated on January 7, 2011. See note 19.

**(p) Segments**

The Company operates in one segment. NewLink and its majority-owned subsidiary BPS conduct research and development activities based from facilities located in Ames, Iowa. The Ames location also includes corporate headquarters for NewLink and BPS. The companies conduct preclinical and clinical research in the biopharmaceutical industry. Management uses cash flow as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

**(q) Financial Instruments and Concentrations of Credit Risk**

The fair values of cash and cash equivalents, certificates of deposit, prepaid expenses, receivables, accounts payable, and accrued liabilities, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and certificates of deposit. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high quality securities such as money market funds. The fair value of notes payable and capital lease obligations was \$6.0 million, \$6.1 million, and \$7.3 million as of December 31, 2008 and 2009, and December 31, 2010, respectively.

**NewLink Genetics Corporation and Subsidiary**  
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**Notes to Consolidated Financial Statements — (Continued)**

**(r) Recent Accounting Pronouncements**

In April 2009, FASB issued guidance that expands the fair value disclosures required for financial instruments to interim reporting periods for publicly traded companies, including disclosure of the significant assumptions used to estimate the fair value of financial instruments. We adopted this guidance effective June 30, 2010. The adoption did not impact our financial position or results of operations.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The amended guidance requires disclosure of transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy, including the reasons and the timing of the transfers and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of the assets and liabilities measured under Level 3 of the fair value measurement hierarchy. The Company adopted the new disclosure requirements on January 1, 2010, except for the requirement concerning gross presentation of Level 3 activity, which is effective for fiscal years beginning after December 15, 2010. The adoption of the Level 1 and Level 2 disclosure guidance did not have an impact on the Company's consolidated financial position or results of operations.

In recent exposure drafts, the International Accounting Standards Board (IASB) and the FASB proposed a new approach to the accounting for leases. From a lessee's perspective, the exposure drafts propose to abolish the distinction between operating and finance/capital leases. In its place, a right-of-use model would be used. This proposal, as currently written, would require the lessee to recognize an asset for its right to use the underlying leased asset and a liability for its obligation to make lease payments. This would lead to an increase in assets and liabilities for leases currently classified as an operating lease and could also lead to a change in timing as to when the expense is recognized. This exposure draft is not yet finalized.

**3. Acquisition of OncoRx Corporation**

On June 21, 2005, NewLink acquired all of the outstanding shares of OncoRx Corporation (OncoRx) in order to gain access to certain small molecule technologies. NewLink provided the following consideration to the OncoRx shareholders:

- 780,611 shares of NewLink common stock payable in four installments. The first installment was 130,102 shares at closing. The second, third, and fourth installments result in the delivery of 130,102, 260,204, and 260,203 shares, respectively, conditional upon the achievement of certain development milestones as described in the purchase agreement.
- Cash consideration of \$120,000 at closing.

During 2005, the cash and first installment of shares noted above were delivered to OncoRx. During 2006, NewLink issued the second installment of 130,102 shares of common stock with a fair value of \$130,000. All cash and stock consideration paid to the OncoRx shareholders has been recorded as research and development expense at fair value when delivered as there is no alternative use for the acquired research and development activities. There were no other assets or liabilities of OncoRx at the date of acquisition. Upon the achievement of the development milestones, the Company will record the fair value of the third and fourth installments of common stock issued as research and development expense.

On July 29, 2010, the Company entered into an amendment of the stock purchase agreement with OncoRx to reduce the remaining shares payable under the third and fourth installments by accelerating

**NewLink Genetics Corporation and Subsidiary**  
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**Notes to Consolidated Financial Statements — (Continued)**

the payment of such installments to the effective date of the amendment. In consideration for the accelerated stock payment, the Company received a 30% discount on the remaining shares payable, reducing total shares payable under the agreement by 156,122 shares. A total of 364,285 shares were issued with total fair value of \$819,000. Through this acquisition, the Company acquired technology related to its IDO pathway inhibitor product candidates, subject to a licensing agreement with the Lankenau Institute for Medical Research.

#### 4. Notes Receivable for Common Stock

Notes receivable for common stock at December 31, 2010 and 2009 were \$13,000 and \$38,000, respectively. The notes were issued in connection with the sale of common stock to officers of the Company and, accordingly, are shown as a reduction of shareholders' equity (deficit). All of the notes are secured by the common stock and are guaranteed by the officer's personal assets. The outstanding notes for NewLink common stock were due in April 2005 and were subsequently extended for an additional five years through April 2010. Subsequent to April 2010, a decision was made to forgive a portion of these notes, subject to Board approval. All of the notes for NewLink common stock bear interest at rates from 5.00% to 6.71%, payable annually in arrears. Effective as of July 2, 2010, \$25,000 of the notes and accrued interest of \$10,000 were forgiven and a bonus of \$12,000 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options to purchase Company common stock were modified to increase the aggregate exercise price by an amount equal to the amount of the forgiveness plus the bonus paid.

#### 5. Leases

##### (a) Capital Leases

The following is an analysis of the leased property under capital leases by major class (in thousands):

<u>Class of property</u>	<u>Asset balances at December 31</u>	
	<u>2009</u>	<u>2010</u>
Lab equipment	\$ 126	\$ 409
Leasehold improvements	27	27
Total property under capital leases	153	436
Less accumulated depreciation and amortization	72	67
Capital leased assets, net	<u>\$ 81</u>	<u>\$ 369</u>

The depreciation and amortization reflected above has been recorded as depreciation and amortization expense in these consolidated financial statements.

**NewLink Genetics Corporation and Subsidiary**  
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**Notes to Consolidated Financial Statements — (Continued)**

The following is a schedule by years of the future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of December 31, 2010 (in thousands):

<b>Year ending December 31:</b>	
2011	\$ 135
2012	114
2013	40
Total minimum lease payments	289
Less amount representing interest	28
Present value of net minimum lease payments	<u>\$ 261</u>

The present value of net minimum lease payments as of December 31, 2009 is reflected in the balance sheet as current and long-term obligations under capital leases of \$35,000 and \$78,000, respectively. The present value of net minimum lease payments as of December 31, 2010 is reflected in the balance sheet as current and long-term obligations under capital leases of \$116,000 and \$145,000, respectively.

**(b) Operating Leases**

The Company has noncancelable facilities operating leases that expired at various times between February 2009 and June 2009, which are now being leased on a month-to-month basis. In addition, the Company entered into a new lease for additional space in October 2009 expiring in 2015. Under the terms of the lease, the Company has the option to extend the lease for three additional five-year periods upon the same terms as the base lease. The Company also leases laboratory space from one of its licensors. Lease expense is recognized on a straight-line basis. Rental expense for operating leases during the years ended December 31, 2010, 2009, 2008 and since inception through December 31, 2010 was \$601,000 \$482,000, \$294,000, and \$2.4 million respectively.

Future minimum lease payments under the noncancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2010 are as follows (in thousands):

<b>Year ending December 31:</b>	
2011	\$ 266
2012	269
2013	271
2014	271
2015	23
	<u>\$ 1,100</u>

**6. Long-Term Debt**

*March 2005 Iowa Department of Economic Development Loan*

In March 2005, the Company entered into a \$6.0 million forgivable loan agreement with the Iowa Department of Economic Development (IDED). Under the agreement, in the absence of default, there will be no principal or interest payments due until the completion date for the project, which is March 18, 2012, under the current one-year extension granted by the IDED. The project is to provide assistance to the Company for research and product development activities at its Iowa State University Research Park facility. The project calls for the creation of 315 positions and retention of 35 positions

**NewLink Genetics Corporation and Subsidiary**  
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**Notes to Consolidated Financial Statements — (Continued)**

with total project expenditures of \$189.9 million for clinical trials, research and development activities, building construction, equipment purchases, and other working capital needs.

If, as of March 18, 2012, which is the current project completion date under the agreement, the IDEED determines the Company has fulfilled all the job creation and maintenance terms and project expenditure requirements of the loan agreement, the loan will be forgiven. However, on the project completion date the Company will be required to repay the greater of approximately \$17,000 for each of the 350 jobs it fails to create and maintain as of that date or a percentage of the \$6.0 million advanced under the agreement equal to the percentage of any shortfall in its obligation to expend \$189.9 million of project expenditures. Five years following the project completion date, the Company will be required to repay approximately \$17,000 for each of the 350 jobs the IDEED determines it fails to maintain as of that date. In the event of default, including failure to repay any amounts under the loan when due, the Company will be required to repay the note including 6% interest per annum beginning at the date of default.

The Company has not currently fulfilled the requirements for loan forgiveness under this agreement. Absent an amendment granted by the IDEED, the Company would have to repay up to \$4.7 million on or after March 18, 2012. There is no guarantee that the IDEED will agree to further extend the completion date under the agreement. If the amounts under the loan become due in March 2012, it would likely have a material adverse effect on the Company's cash position.

Under the agreement, the Company is obligated to pay a minimum of 0.25% royalties on all gross revenues of its products with a cumulative maximum royalty amount due of \$3.2 million. Royalties the Company pays will first offset amounts the Company is required to repay for amounts of the loan not forgiven and then go toward reducing the total cumulative royalty to be paid. The Company is also obligated to maintain its business in the State of Iowa while amounts remain outstanding under the loan. Substantially all of the Company's assets are pledged against this loan and the Company is required to submit audited financial statements within 90 days of year-end. The Company has failed to meet this covenant each year and has obtained a waiver from the IDEED each year.

The original project completion date for the project was March 18, 2010 and was initially extended to March 18, 2011 and currently to March 18, 2012 by amendments to the agreement approved by the IDEED.

*2009 Iowa State University Research Park Loan*

In 2009, the Company executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of \$800,000. The note represents amounts owed by the Company to ISURP for certain improvements that were made to facilities the Company leases from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including the Company's uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. No amounts were outstanding under this note as of December 31, 2009. The balance outstanding at December 31, 2010 is \$733,000.

*March 2010 City of Ames Forgivable Loan*

In March 2010, the Company entered into a \$400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provides the Company

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Notes to Consolidated Financial Statements — (Continued)**

with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015.

The project calls for the Company to create or retain at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and to create or maintain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for the Company to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, the Company has fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, the Company has failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, the Company will be required to repay approximately \$3,100 per job not created or retained following the respective date. As of December 31, 2010, \$300,000 of the total \$400,000 forgivable loan was advanced to the Company with the final \$100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, the Company will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

**7. Common Stock**

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the NewLink stockholders. Subject to preferences applicable to outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the NewLink Board of Directors.

NewLink and its major investors have a right of first refusal with respect to certain sales of shares by existing stockholders. NewLink's major investors have a right of first refusal to acquire certain equity securities issued by NewLink. These rights expire with an IPO.

In the event of liquidation, dissolution, or winding up of NewLink, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities subject to prior distribution rights of the preferred stock.

On January 7, 2011, the Shareholders approved an amendment to NewLink's Restated Certificate of Incorporation granting the Board of Directors authority to approve a reverse split of shares of issued and outstanding common stock between 1.5-for-1 and 3.0-for-1.

**8. Subsidiary Common Stock and Common Stock Preferences**

Subject to preferences applicable to outstanding preferred stock, the holders of BPS common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the BPS Board of Directors. BPS has issued two classes of common stock: Series A common stock and Series B common stock. All shares of Series A common stock are held by NewLink. The holders of BPS Series A and Series B common stock are entitled to one vote per share on all BPS matters to be voted upon by BPS's stockholders.

In the event of any liquidation, dissolution, or winding up of BPS, whether voluntary or involuntary, the holders of Series A common stock will be entitled to receive \$0.10 per share, plus any declared and unpaid dividends out of the assets of BPS available for distribution, before any payment of any amount to holders of the Series B common stock. In the event of liquidation, dissolution, or winding up of BPS, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities subject to prior distribution rights of the preferred stock.

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On January 7, 2011, NewLink acquired all of the outstanding shares of Series B common stock. See note 19.

**9. Preferred Stock**

NewLink's Amended and Restated Certificate of Incorporation authorizes the issuance of 17,166,666 shares of preferred stock, \$0.01 par value. The NewLink Board of Directors has the authority to issue the preferred stock in one or more series and to fix the voting power and such designations, preferences, and rights subject to approval of outstanding preferred series shareholders. The following is a summary of all preferred stock issued by NewLink and outstanding at December 31, 2010 and 2009:

<b>as of December 31, 2010</b>					
<b>(in thousands, except share and per share data)</b>					
	<b>Issue Price per Share</b>	<b>Shares Authorized</b>	<b>Issued and Outstanding Shares</b>	<b>Liquidation Preference</b>	<b>Carrying Value</b>
Series A	\$ 2.50	450,000	420,000	\$ 1,050	\$ 1,030
Series AA	1.80	1,250,000	1,217,175	2,191	2,191
Series AAA	2.25	377,777	377,410	849	849
Series B	2.50	3,200,000	2,191,193	5,478	5,478
Series BB	4.25	2,000,000	1,883,337	8,004	8,004
Series C	5.00	6,000,000	6,000,000	30,000	30,000
Series D	5.00	1,500,000	1,500,000	7,500	7,500
Series E	31.25	1,000,000	248,320	7,760	7,723
Blank Check Preferred	—	1,388,889	—	—	—
Total			<u>13,837,435</u>	<u>\$ 62,832</u>	<u>\$ 62,775</u>

<b>as of December 31, 2009</b>					
<b>(in thousands, except share and per share data)</b>					
	<b>Issue Price per Share</b>	<b>Shares Authorized</b>	<b>Issued and Outstanding Shares</b>	<b>Liquidation Preference</b>	<b>Carrying Value</b>
Series A	\$ 2.50	450,000	420,000	\$ 1,050	\$ 1,030
Series AA	1.80	1,250,000	1,224,967	2,205	2,205
Series AAA	2.25	377,777	377,410	849	847
Series B	2.50	3,200,000	2,191,193	5,478	5,478
Series BB	4.25	2,000,000	1,906,866	8,104	8,104
Series C	5.00	6,000,000	6,000,000	30,000	30,000
Series D	5.00	1,500,000	1,500,000	7,500	7,500
Blank Check Preferred	—	1,388,889	—	—	—
Total			<u>13,620,436</u>	<u>\$ 55,186</u>	<u>\$ 55,164</u>



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Between December 1, 2010 and December 13, 2010, the Company issued and sold to investors an aggregate of 248,320 shares of Series E preferred stock at a purchase price of \$31.25 per share, for aggregate consideration of \$7.8 million. The related offering costs of \$37,000 were charged as an offset to the proceeds. The carrying value of the Series E preferred stock will be accreted to the liquidation amount by the date the shares are available to be redeemed. Each share of NewLink Series E preferred stock will convert into the number of shares of NewLink Common Stock obtained by dividing \$31.25 by the NewLink Series E conversion price. The NewLink Series E conversion price is currently \$6.25. If NewLink closes an IPO on or before September 1, 2011, the NewLink Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of NewLink's Common Stock are sold to the public in the IPO and (B) 0.85 (as adjusted appropriately to reflect any changes to the NewLink Series E conversion price occurring prior to any such adjustment occurring in connection with an IPO).

On July 17, 2009, NewLink issued 1,500,000 shares of Series D convertible preferred stock at \$5.00 per share for net proceeds of \$7.5 million. The related offering costs were not significant and were charged to expense. NewLink also issued warrants to purchase 375,000 shares of common stock at \$7.20 per share in conjunction with the issuance of Series D shares. On October 21, 2010, a stockholder exercised the warrant for 375,000 shares of common stock at an aggregate purchase price of \$2.0 million. The exercise price of the warrant was reduced from \$7.20 per share to \$5.33 per share in 2010 in exchange for the holder's agreement to exercise the warrant at that time.

During 2009, NewLink collected \$12.1 million for the sale of 2,413,379 shares of NewLink Series C preferred stock and \$7.5 million for the sale of 1,500,000 shares of NewLink Series D preferred stock.

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Following is a summary of all redeemable preferred stock issuances through December 31, 2010:

	<b>Redeemable Preferred Stock</b>						
	<b>Series AA</b>	<b>Series AAA</b>	<b>Series B</b>	<b>Series BB</b>	<b>Series C</b>	<b>Series D</b>	<b>Series E</b>
Balance at June 4, 1999	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
No activity in 1999	—	—	—	—	—	—	—
Balance at December 31, 1999	—	—	—	—	—	—	—
No activity in 2000	—	—	—	—	—	—	—
Balance at December 31, 2000	—	—	—	—	—	—	—
Issuance of 1,224,967 shares of Series AA preferred stock (net of offering costs) (September 26, 2001)	2,179	—	—	—	—	—	—
Balance at December 31, 2001	2,179	—	—	—	—	—	—
Issuance of 377,410 shares of Series AAA preferred stock (net of offering costs) (January 21, 2002)	—	847	—	—	—	—	—
Accretion of redemption feature of preferred stock	6	—	—	—	—	—	—
Balance at December 31, 2002	2,185	847	—	—	—	—	—
Issuance of 2,191,193 shares of Series B preferred stock (net of offering costs) (February 7, 2003)	—	—	5,436	—	—	—	—
Accretion of redemption feature of preferred stock	6	—	—	—	—	—	—
Balance at December 31, 2003	2,191	847	5,436	—	—	—	—
Issuance of 1,313,619 shares of Series BB preferred stock (net of offering costs and receivables of \$706,005) (December 27, 2004)	—	—	—	4,877	—	—	—
Accretion of redemption feature of preferred stock	5	—	—	—	—	—	—
Balance at December 31, 2004	2,196	847	5,436	4,877	—	—	—
Issuance of 593,247 shares of Series BB preferred stock (net of offering costs of \$36,114) (January and February 2005)	—	—	—	3,192	—	—	—
Accretion of redemption feature of preferred stock	5	—	42	35	—	—	—
Balance at December 31, 2005	2,201	847	5,478	8,104	—	—	—
Accretion of redemption feature of preferred stock	4	—	—	—	—	—	—
Balance at December 31, 2006	2,205	847	5,478	8,104	—	—	—
No activity in 2007	—	—	—	—	—	—	—
Balance at December 31, 2007	2,205	847	5,478	8,104	—	—	—
Issuance of 3,586,621 shares of Series C preferred stock (net of offering costs of \$13,530) (February through October 2008)	—	—	—	—	17,920	—	—
Balance at December 31, 2008	2,205	847	5,478	8,104	17,920	—	—
Issuance of 2,413,379 shares of Series C preferred stock (July through October 2009)	—	—	—	—	12,080	—	—
Issuance of 1,500,000 shares of Series D preferred stock (July 17, 2009)	—	—	—	—	—	7,500	—
Balance at December 31, 2009	2,205	847	5,478	8,104	30,000	7,500	—
Issuance of 248,320 shares of Series E preferred stock (net of offering costs) (December 1 through December 13, 2010)	—	—	—	—	—	—	7,723
Accretion of redemption feature of preferred stock	—	2	—	—	—	—	—
Conversion of preferred stock to common stock	(14)	—	—	(100)	—	—	—
Balance at December 31, 2010	<u>\$ 2,191</u>	<u>\$ 849</u>	<u>\$ 5,478</u>	<u>\$ 8,004</u>	<u>\$ 30,000</u>	<u>\$ 7,500</u>	<u>\$ 7,723</u>

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Prior to the acquisition by NewLink of the minority interest in BPS described in note 19, BPS had authority to issue stand-alone preferred stock to outside investors as discussed in note 11. The following is a summary of all preferred stock issued by BPS and outstanding at December 31, 2010:

<u>Original issue</u>	<u>Date(s) issued</u>	<u>Shares issued</u>	<u>Offering price</u>
Series A	January-February 2006	1,444,721	\$1.75
Series B	2009-2010	2,341,644	\$1.40-\$1.75

## 10. Preferred Stock Preferences

Following is a summary of the preferences relating to the various series of NewLink preferred stock:

### (a) Voting Rights

The Series A, AA, AAA, B, BB, C, D and E (collectively, the Series Preferred) vote on an as-if-converted-to-common-stock basis (one vote per share, except for Series A, which receives 1.389 votes per share pursuant to the conversion rights discussed below). Any action taken by the Board of Directors or others that would impact the holders of Series AA, B, BB, C, D or E shares must be approved by a majority of the outstanding shares held by Series AA, B, BB, C, D or E shareholders.

### (b) Dividend Rights

Series A, AAA, B, BB, C, D and E stockholders, in preference to holders of common stock, are entitled to receive a noncumulative cash dividend of 8% of the original issue price per annum, payable only when, as, and if declared by the Board of Directors.

Series AA stockholders, in preference to holders of common stock, are entitled to receive a cumulative stock dividend of 0.036 shares of common stock for each outstanding share of Series AA. The dividend is paid at least annually. Dividends shall accrue monthly, and unpaid dividends shall be paid upon conversion of the Series AA to common stock. A total of 14,683 and 14,683 shares of common stock are accrued for dividends on the Series AA stock as of December 31, 2010 and 2009, respectively.

### (c) Conversion Rights

The Series Preferred will automatically convert into common stock immediately upon the closing of an IPO of common stock, pursuant to an effective registration statement filed by NewLink under the Securities Act of 1933 that generates aggregate gross proceeds of not less than \$20.0 million in aggregate. The Series Preferred may also convert to common stock upon a vote of action by a majority of the holders of the Series Preferred voting together as a single class on an as-if converted basis, or at the option of the holders. Persons holding 20% of NewLink's common stock on an as-if converted basis can request NewLink file a registration statement.

Each share of Series A preferred stock will convert into 1.389 shares of NewLink Common Stock; each share of Series AA, AAA, B, C and D preferred stock will convert into one share of NewLink Common Stock; and each share of Series E preferred stock will convert into the number of shares of NewLink Common Stock obtained by dividing \$31.25 by the Series E conversion price. The Series E conversion price is currently \$6.25. If the Company closes an IPO on or before September 1, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of NewLink's Common Stock are sold to the public in the IPO and (B) 0.85 (as adjust appropriately to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with the IPO). The Series Preferred are subject to weighted average

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ratchet antidilutive protection if NewLink issues shares at a price below the offering price for each series. In addition, these securities are subject to proportional adjustments for stock splits, stock dividends, recapitalizations, and other distributions of common stock of NewLink.

**(d) Liquidation Preferences**

In the event of any liquidation, dissolution, or winding up of NewLink, whether voluntary or involuntary, the holders of Series C, Series D and Series E will be entitled to receive \$5.00 per share, \$5.00 per share and \$31.25 per share, respectively, plus any declared and unpaid dividends out of the assets of NewLink available for distribution before any payment of any amount to holders of the Series A, AA, AAA, B, BB (collectively, the Junior Preferred), or holders of common stock. If the assets available for distribution are insufficient to pay the holders of Series C, Series D and Series E preferred stock, then such holders will share ratably in any distribution of the assets of NewLink in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After payment of the full liquidation to the Series C, Series D and Series E holders, the holders of the Junior Preferred will be entitled to receive \$2.50, \$1.80, \$2.25, \$2.50, \$4.25, respectively, per share plus any declared and unpaid dividends out of the assets of NewLink available for distribution before any payment of any amount to holders of NewLink common stock. If the assets available for distribution are insufficient to pay the holders of Junior Preferred, then such holders will share ratably in any distribution of the assets of NewLink in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After the payment of the full liquidation preference of the Series Preferred, the assets of NewLink legally available for distribution, if any, shall be distributed ratably to the holders of the common stock and Series Preferred on an as-if-converted-to-common-stock basis until such time as the holders of Series A, AA, AAA, and B have received an aggregate amount equal to three times the original issue price (\$28,704,210 at December 31, 2010 and \$28,746,287 at December 31, 2009), the holders of the Series BB have received an aggregate amount equal to two times the original issue price (\$16,008,365 at December 31, 2010 and \$16,208,361 at December 31, 2009). Thereafter, the remaining assets of NewLink legally available for distribution, if any, shall be distributed ratably to the holders of the common stock.

**(e) Additional Preferences**

**Redemption**

If a majority of the outstanding shares of Series AA, B, BB, C, D and E vote to have NewLink redeem its stock, it must do so in three equal installments beginning on September 30, 2014, provided that NewLink receives 60 days' notice. Redemption price shall equal original sale price plus any declared and unpaid dividends on Series Preferred. NewLink is required on or prior to the redemption date to deposit the funds in trust with a bank or trust company.

**Warrants**

Warrants to purchase 375,000 shares of common stock at \$7.20 per share were issued to Series D Preferred stockholders in conjunction with the purchase of NewLink preferred stock in July of 2009. The warrants were exercised on October 21, 2010, at an aggregate purchase price of \$2.0 million. The exercise price of the warrant was reduced in exchange for the holder's agreement to exercise the warrant at that time. NewLink computed the fair value of the warrants at issuance using the Black-Scholes model and determined the fair value of the warrants was *de minimis*.

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**Right of First Refusal**

NewLink's major investors have a right of first refusal to acquire certain equity securities issued by NewLink. These rights expire with an IPO.

**Registration Rights**

Under an amended and restated investor rights agreement, following an IPO, certain holders of NewLink common stock will have the right to require NewLink to register their shares with the SEC so that those shares may be publicly resold, or to include those shares in any registration statement NewLink files, subject to specified exemptions, conditions and limitations.

**11. Subsidiary Preferred Stock Preferences**

During 2009 and 2010, BPS issued 555,930 shares of Series B preferred stock at \$1.75 per share for an aggregate consideration of \$970,000. In December 2010, in connection with the merger of BPS with NewLink, BPS issued 1,785,714 shares of Series B preferred stock to NewLink at \$1.40 per share for an aggregate consideration of \$2.5 million.

During 2006, BPS issued 1,444,721 shares of Series A preferred stock. All deposits received prior to issuance of the shares were considered restricted until the shares of Series A preferred stock were issued. In July 2009, shareholders authorized the issuance of an additional 3,055,279 shares of BPS Series B preferred stock. Prior to the acquisition, BPS's amended Certificate of Incorporation authorized the issuance of 4,500,000 shares of preferred stock at \$0.01 par value. The Board of Directors of BPS has the authority to issue the preferred stock in one or more series and to fix the voting power and such designations, preferences, and rights subject to approval of outstanding preferred series shareholders. The following preferences are in place related to the BPS Series A and B preferred stock:

**(a) Voting Rights**

The BPS Series A and B preferred stock vote on an as-if-converted-to-common-stock basis (one vote per share). Any action taken by the Board of Directors of BPS or others that would impact the holders of BPS Series A and B preferred stock must be approved by a majority of the outstanding shares held by BPS Series A and B shareholders.

**(b) Conversion Rights**

The BPS Series A and B preferred stock will automatically convert into BPS common stock immediately upon the closing of an IPO of BPS common stock, pursuant to an effective registration statement filed by BPS under the Securities Act of 1933 that generates aggregate gross proceeds of not less than \$4.00 per common share and \$10.0 million in aggregate. BPS Series A and B preferred stock may automatically convert upon a vote of action by the class or at the option of the holder.

**(c) Liquidation Preferences**

In the event of any liquidation, dissolution, or winding up of BPS, whether voluntary or involuntary, the holders of BPS Series B preferred stock will be entitled to receive \$1.75 per share, plus any declared and unpaid dividends out of the assets of BPS available for distribution before any payment of any amount to holders of BPS Series A preferred stock or BPS common stock. If the assets available for distribution are insufficient to pay the holders of BPS Series B preferred stock, then such holders will share ratably in any distribution of the assets of BPS in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

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After payment of the full liquidation to the holders of Series B preferred stock, the holders of Series A preferred stock will be entitled to receive \$1.75 per share, plus any declared and unpaid dividends out of the assets of BPS available for distribution before any payment of any amount to holders of BPS common stock. If the assets available for distribution are insufficient to pay the holders of Series A preferred stock, then such holders will share ratably in any distribution of the assets of BPS in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After payment of the full liquidation to the holders of Series A and B preferred stock, the holders of the Series A common stock will be entitled to receive \$0.10 per share (\$700,000 at December 31, 2010 and 2009) out of the assets of BPS available for distribution before any payment of any amount to holders of the Series B common stock. If the assets available for distribution are insufficient to pay the holders of Series A common stock, then such holders will share ratably in any distribution of the assets of BPS in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After the payment of the full liquidation preference of the Series A and B preferred stock and Series A common stock, the assets of BPS legally available for distribution, if any, shall be distributed ratably to the holders of the Series A common stock and Series A and B preferred stock on an as-if-converted-to-common-stock basis until such time as the holders of Series A preferred stock have received an aggregate amount equal to two times the original issue price (\$5.1 million at December 31, 2010 and 2009) and the holders of Series B preferred stock have received an aggregate amount equal to one and one-half times the original issue price (\$6.1 million at December 31, 2010 and \$1.5 million at December 31, 2009). Thereafter, the remaining assets of BPS legally available for distribution, if any, shall be distributed ratably to the holders of the Series A and B common stock.

***(d) Registration Rights.***

Prior to the acquisition by NewLink of the minority interest in BPS, under an amended and restated investor rights agreement, following an IPO, certain holders of BPS common stock had the right to require BPS to register their shares with the SEC so that those shares could be publicly resold, or to include those shares in any registration statement BPS filed, subject to specified exemptions, conditions and limitations.

**12. Common Stock Equity Incentive Plan**

In April 2000, the stockholders approved NewLink's 2000 Equity Incentive Plan (the "2000 Plan"), and in July 2009, the stockholders approved NewLink's 2009 Equity Incentive Plan (the "2009 Plan"). Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan are effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, NewLink may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

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Awards under the 2009 Plan, as amended, may be made to officers, employees, Board of Directors, advisors, and consultants to NewLink. As of December 31, 2010 and 2009, an aggregate of 6,885,000 and 5,505,500 shares of common stock, respectively, were reserved for issuance under the 2009 Plan. In May 2010, stockholders authorized an increase of 2,600,000 shares of common stock available for issuance under the plan. On January 7, 2011, stockholders authorized an increase of 1,500,000 shares of common stock available for issuance under the 2009 Plan.

On October 29, 2010, the Company adopted an Employee Stock Purchase Plan and a Director Stock Option Plan and reserved 950,000 shares of common stock for issuance under the plans. These plans are inactive until the Company completes a successful IPO.

**Stock Options**

The fair value of the awards shall be determined by the Board of Directors in good faith until such time as NewLink's common stock is traded on an established exchange at which time the fair value will be the quoted market price as listed on the public exchange. The estimated fair value of the common stock has been determined by management with the assistance of a third-party appraisal report and an evaluation of milestones achieved. Under provisions of the 2009 Plan, if Incentive Stock Options (ISO) are granted to a 10% stockholder in NewLink, the exercise price shall not be less than 110% of the common stock's fair market value on the date of grant.

In 2008, all options were granted at an exercise price of \$1.00 per share. Additionally, during 2008, NewLink revised the exercise price for 364,000 options under the Plan. The options were previously issued with exercise prices of \$1.75, \$2.00, or \$3.40 per share and were modified to an exercise price of \$1.00 per share. The result of this change was an increase in compensation expense of \$0 and \$34,000 for the years ending December 31, 2010 and 2009, respectively. In January 2009, options were issued at an exercise price of \$1.00 per share. In March 2010, options were issued at an exercise price of \$1.41 per share for grants dated in December 2009, which were subject to pricing based on finalizing NewLink's valuation as of December 31, 2009. In June 2010, options were issued at an exercise price of \$1.46 per share for grants dated in December 2009 and March 2010, which were subject to pricing based on finalizing NewLink's valuation as of March 31, 2010. In October 2010, options were issued at an exercise price of \$1.91 per share for grants dated in June 2010, which were subject to pricing based on finalizing NewLink's valuation as of June 30, 2010.

The life of the options is 10 years under the 2009 Plan unless an ISO is granted to a stockholder who owns more than 10% of NewLink's outstanding stock, in which case the life may not exceed five years.

The NewLink Board of Directors determines the vesting period for each stock option award. Generally, stock options awarded to date under the 2009 Plan vest 20% or 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 months, though some options have effective vesting periods that begin prior to the date of grant. In such cases, compensation expense is recognized for the vested portion of the award upon grant. The stock options may include provisions for early exercise of options. If any shares acquired are unvested, they are subject to repurchase at NewLink's discretion until they become vested.

Share-based employee compensation expense for the years ended December 31, 2010, 2009, 2008, and since inception was \$1,187,000, \$641,108, \$103,198, and \$2.0 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to a related tax benefit of \$0. As of December 31, 2010, the total compensation cost related to nonvested option awards not yet recognized was \$3.0 million and the weighted average period over which it is expected to be recognized was 1.9 years. As of December 31,

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2009, the total compensation cost related to nonvested option awards not yet recognized was \$667,000 and the weighted average period over which it is expected to be recognized was 1.8 years.

The following table summarizes stock option activity for the year ended December 31, 2010:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	3,748,500	\$ 0.92	
Options granted	2,725,250	1.38	
Options exercised	(259,428)	0.32	
Options forfeited	(55,500)	1.00	
Options expired	—	—	
Outstanding at end of period	<u>6,158,822</u>	<u>\$ 1.27</u>	8.2
Options exercisable at end of period	<u>3,135,888</u>	<u>\$ 1.18</u>	7.7

The following table summarizes stock option activity for the year ended December 31, 2009:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	1,545,500	\$ 0.79	
Options granted	2,267,000	1.00	
Options exercised	(52,865)	0.28	
Options forfeited	(11,135)	1.00	
Options expired	—	—	
Outstanding at end of period	<u>3,748,500</u>	<u>\$ 0.92</u>	8.1
Options exercisable at end of period	<u>2,208,241</u>	<u>\$ 0.87</u>	7.5

The following table summarizes options that were granted during the years ended December 31, 2010 and 2009, and the assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Year Ended	
	2009	2010
Number of options granted	2,267,500	2,725,250
Risk-free interest rate	1.6%	2.3%-3.5%
Expected dividend yield	—	—
Expected volatility	44.7%	57.4%-62.5%
Expected term (in years)	7.5	5.0-7.5
Weighted average grant-date fair value per share	\$0.49	\$1.38

The intrinsic value of options exercised during the year ended December 31, 2010 was \$82,000. The fair value of awards vested during the year ended December 31, 2010 was \$3.7 million.



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Although NewLink does not have a formal policy regarding the source of shares issued upon exercise of stock options, these shares were generally issued from treasury stock. As all treasury shares were retired in 2007, NewLink expects shares issued upon future stock option exercises to be new shares.

During the years ended December 31, 2010, 2009 and 2008, and since inception 305,000, 0, 251,000, and 897,000 stock options were granted to nonemployees, respectively. As a result of the issuance of these options, \$124,000, \$63,000, \$29,000, and \$408,000 of expense was recorded in the years ended 2010, 2009 and 2008, and since inception, respectively.

**13. Subsidiary Common Stock Equity Incentive Plan**

In September 2006, the BPS stockholders approved BPS's 2006 Equity Incentive Plan (the "BPS Plan"). Under the provisions of the BPS Plan, prior to the merger described in note 19, BPS could have granted the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the BPS Plan, as amended, could have been made to officers, employees, Board of Directors, advisors, and consultants to BPS. During 2007, BPS authorized up to 3,000,000 shares of BPS's common stock to be awarded under the BPS Plan. During 2008, BPS authorized an increase in the number of shares of BPS's common stock available under the BPS Plan to 3,253,341. During 2009, BPS authorized an increase in the number of shares of BPS's common stock available under the BPS Plan to 3,453,341.

**Stock Options**

The fair value of the awards was determined by the BPS Board of Directors in good faith. The estimated fair value of the common stock was determined by management based on BPS milestones achieved, which provided additional value and the issuance price of preferred stock, discounted for preference items for the Series A and B Preferred, sold to third-party investors. Under provisions of the BPS Plan, if ISOs were granted to a 10% stockholder in BPS, the exercise price could not be less than 110% of the BPS common stock's fair market value on the date of grant. All stock options granted in 2010 had an exercise price of \$0.25 per share. All stock options granted in 2009 had an exercise price of \$0.10 per share.

The life of the options is 10 years under the BPS Plan unless an ISO is granted to a stockholder who owns more than 10% of BPS's outstanding stock, in which case the life may not exceed five years.

The BPS Board of Directors determined the vesting period for each stock option award. Generally, stock options awarded to date under the BPS Plan vest 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 24 to 48 months.

Share-based employee compensation expense for the years ended December 31, 2010, 2009, 2008, and since inception was \$20,000, \$19,000, \$35,000, and \$126,000, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to a related tax benefit of \$0. As of December 31, 2010, the total compensation cost related to nonvested option awards not yet recognized was \$17,000 and the weighted average period over which it is expected to be recognized was 1.7 years. As of December 31, 2009, the total

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compensation cost related to nonvested option awards not yet recognized was \$15,000 and the weighted average period over which it is expected to be recognized was 2.4 years.

The following table summarizes stock option activity for the year ended December 31, 2010:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	227,500	\$ 0.10	
Options granted	169,000	0.25	
Options exercised	—	—	
Options forfeited	(2,500)	0.10	
Options expired	—	—	
Outstanding at end of period	<u>394,000</u>	<u>\$ 0.16</u>	<u>8.4</u>
Options exercisable at end of period	216,033	\$ 0.18	8.4

The following table summarizes stock option activity for the year ended December 31, 2009:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	40,000	\$ 0.09	
Option granted	189,000	0.10	
Options exercised	—	—	
Options forfeited	(1,500)	0.10	
Options expired	—	—	
Outstanding at end of period	<u>227,500</u>	<u>\$ 0.10</u>	<u>8.9</u>
Options exercisable at end of period	56,025	\$ 0.09	8.9

The fair value of awards vested during the year ended December 31, 2010 was \$247,000. The fair value of awards vested during the year ended December 31, 2009 was \$70,446.

The following table summarizes options that were granted during the years ended December 31, 2010 and 2009 and the assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Year Ended	
	2009	2010
Number of options granted	189,000	169,000
Risk-free interest rate	1.6%-2.3%	1.3%-1.9%
Expected dividend yield	—	—
Expected volatility	62.5%-64.2%	61.7%-63.2%
Expected term (in years)	7.5	5.5-7.5
Weighted average grant date fair value per share	\$0.06-0.07	\$0.14

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BPS common stock bonuses during the years ended December 31, 2010, 2009, 2008, and from inception totaled 0, 0, 1,200, and 58,343 shares, respectively. To date, there have been no issues of rights to acquire restricted common stock.

During the years ended December 31, 2010, 2009, 2008, and since inception, 155,000, 30,000, 0, and 355,000 in stock options were granted to nonemployees, respectively. As a result of the issuance of these options, \$2,000, \$3,000, \$2,000, and \$10,000 of expense was recorded in the years ended December 31, 2010, 2009, 2008, and since inception, respectively.

#### 14. Income Taxes

The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at December 31, 2010 and 2009 are presented below (in thousands):

	<b>Year Ended</b>	
	<b>2009</b>	<b>2010</b>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 9,786	\$ 13,042
Federal research credits	1,888	2,101
Gross deferred tax assets	11,674	15,143
Less valuation allowance	(11,581)	(15,017)
Net deferred tax assets	93	126
<b>Deferred tax liability:</b>		
Equipment	(93)	(126)
Total net deferred tax assets	\$ —	\$ —

The valuation allowance for deferred tax assets as of December 31, 2010 and 2009 was \$15.0 million and \$11.6 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2010 and 2009 was an increase of \$3.4 million and \$1.6 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of December 31, 2010 and 2009, due to the uncertainty of future recoverability.

Federal operating loss carryforwards as of December 31, 2010 for approximately \$62.1 million and federal research credit carryforwards of approximately \$2.1 million expire at various dates from 2020 through 2030. Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research audits) to offset any future taxable income if the corporation experiences a cumulative ownership change of more than 50%, as interpreted by the Internal Revenue Service, or IRS, over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

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Based on a preliminary analysis, we believe that, from its inception through December 31, 2009, NewLink experienced Section 382 ownership changes in September 2001 and March 2003. These two ownership changes limit NewLink's ability to utilize its federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the 2003 ownership change. In addition, the net operating loss carryforwards (and certain other tax attributes) of NewLink's subsidiary may be limited by Sections 382 and 383 as a result of a prior ownership change of the subsidiary.

Additional analysis will be required to determine whether changes in the Company's ownership since December 31, 2009 and/or changes in the Company's ownership that will result from this offering have caused or will cause another ownership change to occur, and the conclusions will depend on the terms of the IPO and other information that may not be available to us until after the IPO has occurred. Any such change could result in significant limitations on all of the Company's net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred and does not occur as a result of the IPO, additional ownership changes may occur in the future as a result of events over which the Company will have little or no control, including purchases and sales of the Company's equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of the Company's stock or certain changes in the ownership of any of the Company's 5% stockholders.

The Company incurred no income tax expense for the years ended December 31, 2010, 2009 and 2008, or since inception. Income tax expense differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

## 15. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per common share (in thousands, except per share data):

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2009</b>	<b>2010</b>
<b>Historical net loss per share</b>			
Numerator			
Net loss attributable to common stockholders	\$ (9,162)	\$ (9,442)	\$ (15,745)
Denominator			
Weighted-average common shares outstanding	6,542	6,636	7,040
Denominator for basic and diluted net loss per share	6,542	6,636	7,040
Basic and diluted net loss per share	\$ (1.40)	\$ (1.42)	\$ (2.24)

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The numerator was not adjusted for the stock dividend paid on the Series AA preferred stock as the impact is not material. Potentially dilutive securities not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common equivalent shares):

	<b>As of December 31,</b>		
	<b>2008</b>	<b>2009</b>	<b>2010</b>
Preferred stock(1)	9,870,390	13,783,769	14,994,048
Common stock warrants	—	375,000	—
Common stock options	1,545,500	3,748,500	6,158,822
	<u>11,415,890</u>	<u>17,907,269</u>	<u>21,152,870</u>

(1) 2010 amount is estimated for the current Series E conversion.

## 16. Licensing Agreements

The Company is subject to a number of licensing agreements with respect to certain of the technologies that underlie its intellectual property. Unless otherwise noted, these agreements typically provide that the Company has exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to the Company meeting its financial and other contractual obligations under the agreements. The Company expenses all payments made under the following agreements in the period the payments occurred. For additional information regarding how the Company records payments under these agreements, see note 2(k) above. Certain of the key licensing agreements include the following:

*Central Iowa Health Systems.* The Company is a party to a license agreement, or the CIHS Agreement, dated August 2, 2001, with the Central Iowa Health System, or CIHS. The CIHS Agreement grants the Company an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information and know-how relating to the Company's HyperAcute immunotherapy technology. In partial consideration of the license under the CIHS Agreement, the Company entered into a stock purchase agreement with CIHS, under which the Company issued to CIHS shares of its common stock and granted CIHS certain rights related to ownership of such shares.

In addition, the Company must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If the Company commercializes a licensed product, it also has the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments the Company must make to third parties. If the Company grants a sublicense under the licenses granted by CIHS, it must pay to CIHS a percentage of certain consideration paid by the sublicensee to the Company. Under the CIHS Agreement, the Company must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets.

Unless terminated earlier, the CIHS Agreement shall remain in effect until the expiration of all of the Company's royalty obligations under the agreement. The Company may terminate the agreement, or specific patents covered by the agreement, on written notice to CIHS or for CIHS' uncured material breach of the agreement. CIHS has the right to terminate for the Company's uncured material breach of

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**Notes to Consolidated Financial Statements — (Continued)**

the agreement after written notice. Upon termination of the agreement the Company may sell its existing inventory of licensed products for a period of three months after such termination.

*Drexel University.* The Company is party to a license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel. The Drexel Agreement grants the Company, and its affiliates, an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on alpha-galactosyl epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease.

In consideration of the Company's license under the Drexel Agreement, it has paid and is obligated to continue to pay specified license fees, potential milestone payments in an aggregate amount up to approximately \$1 million for each licensed product, annual license maintenance fees, reimbursement of patent prosecution costs, and royalty payments as a low single-digit percentage of "net sales" of any licensed product that is commercialized, subject to minimum royalty payments. Royalty rates vary depending on the type of licensed product, the territory where it is sold and whether the licensed product is combined with other technologies. In addition, if the Company grants a sublicense under the license granted by Drexel, it must pay Drexel a percentage of the consideration paid by the sublicensee to the Company. In accordance with a development plan included in the Drexel Agreement, the Company is obligated to use commercially reasonable efforts to develop and market products covered by the license as soon as practicable.

Unless terminated earlier, the Drexel Agreement shall remain in effect until the expiration or abandonment of all the licensed Drexel patents. The Company may terminate the Drexel Agreement on written notice to Drexel. Drexel has the right to terminate for the uncured breach of the Company's obligations under the agreement or for certain other reasons. If the Drexel Agreement terminates the Company may, in certain circumstances, sell any remaining inventory of licensed products for a period of six months after termination.

*Lankenau Institute for Medical Research — IDO-1.* The Company is a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants the Company an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, import, sell and offer for sale products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics.

In consideration of the license grant, the Company is obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if the Company grants a sublicense under the IDO-1 Agreement, it must to pay to LIMR a percentage of the consideration received by the Company from the sublicensee. Under the IDO-1 Agreement, the Company is obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines.

Unless terminated earlier, the IDO-1 Agreement shall remain in effect until the expiration of the last licensed LIMR patents. LIMR may terminate the agreement for the Company's failure to achieve specified milestones, failure to make payments due, bankruptcy or similar proceedings. Upon

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termination of the agreement, the Company may sell its current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement.

*Medical College of Georgia.* The Company is a party to a License Agreement dated September 13, 2005, or the MCGRI Agreement, with Medical College of Georgia Research Institute, or MCGRI, which was amended on April 27, 2006 and February 13, 2007. The MCGRI Agreement grants the Company, including its affiliates, an exclusive, worldwide license, under specified MCGRI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

In consideration of such license grant, the Company is obligated to pay to MCGRI specified license fees (including issuing shares of its common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if the Company grants a sublicense under the license granted by MCGRI, it must pay to MCGRI a percentage of the consideration it receives from the sublicensee. Under the agreement, the Company is obligated to make certain investments toward the further development of licensed products within specified time periods.

Unless terminated earlier, the MCGRI Agreement will remain in effect until the expiration of the last licensed MCGRI patents. MCGRI may terminate this agreement for the Company's uncured material breach, bankruptcy or similar proceedings. The Company may terminate this agreement for the uncured material breach of MCGRI. For a period of one year following the termination of the agreement, the Company may sell its licensed products that are fully manufactured and part of its normal inventory at the date of termination.

*University of British Columbia.* The Company is a party to a license agreement dated February 1, 2007, or the UBC License, with the University of British Columbia, or UBC. The UBC License grants the Company an exclusive, worldwide license, under specified UBC patent rights relating to IDO-1 inhibitors and related technology, to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology. In addition, the UBC License grants the Company an option to obtain an exclusive, worldwide license to new IDO-1 inhibitors related technology developed during the term of the agreement.

In consideration of the license grant, the Company must pay to UBC specified license fees, annual payment and license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately \$1.8 million per licensed product, and royalties in a range of 10% or less of net revenue of the licensed product if a licensed product is commercialized, which royalty rate varies depending on the type of license product and field of use. In addition, if the Company grants a sublicense under the licenses granted by UBC, it may be required to pay to UBC a percentage of certain consideration it receives from the sublicensee. The Company is obligated to use its commercially reasonable efforts to develop and market the licensed products, and to achieve certain specific development milestones by agreed-upon deadlines.

Unless terminated earlier, the UBC License will remain in effect for 20 years or until the expiration of the last licensed UBC patents, whichever is later. UBC may terminate this agreement for the Company's uncured material breach, bankruptcy or similar proceedings. The Company may terminate this agreement for the uncured material breach of UBC. Upon termination of the agreement, the Company may not sell any inventory of the licensed product without the prior written consent of UBC.

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**Notes to Consolidated Financial Statements — (Continued)**

*LIMR — IDO-2.* The Company is a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants the Company an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target Indoleamine 2,3 Dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses.

In consideration of the license grant, the Company has paid to LIMR an upfront license fee and annual license maintenance fees, and is obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately \$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for the Company's royalty payments to third parties. In addition, if the Company grants a sublicense under the licenses granted by LIMR, it must pay to LIMR a percentage of the consideration paid by the sublicensee to the Company. Under the LIMR IDO-2 Agreement, the Company has agreed to use its commercially reasonable efforts to develop and exploit products covered by the license.

Unless terminated earlier, the LIMR IDO-2 Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. The Company may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for the Company's uncured material breach, failure to pay, or bankruptcy or similar proceedings. Upon termination of the agreement, The Company may sell its current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement.

*2009 LIMR Exclusive License Agreement.* The Company is a party to a license agreement, or the 2009 LIMR Agreement, dated April 23, 2009 with LIMR. The 2009 LIMR Agreement grants the Company an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. In consideration of such license grant, the Company is obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately \$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for the Company's royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if the Company grants a sublicense under the licenses granted by LIMR, it must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Unless terminated earlier, the LIMR IDO Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. The Company may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for the Company's uncured material breach, failure to pay, or bankruptcy or similar proceedings. Upon termination of the agreement, the Company may sell its current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement.

*Bresagen Patent License Agreement.* The Company is a party to a license agreement, or the Bresagen Agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants the Company a non-exclusive, non-sublicensable license to specified Bresagen patent rights for use in testing microbial and cancer vaccines. In consideration of such license grant, the Company is obligated to pay Bresagen an up front license fee and an annual license fee.



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**Notes to Consolidated Financial Statements — (Continued)**

Unless terminated earlier, the Bresagen Agreement shall continue for an initial period of eight years, which may be extended an additional five years upon agreement of the parties. Either party may terminate the Agreement at any time by agreement in writing, each party not to unreasonably withhold its consent for termination. Bresagen has the right to terminate for the Company's uncured breach, insolvency, change of control without consent or similar proceedings. Upon termination of the agreement, all of the Company's rights under the license are terminated.

During 2010, the Company issued 50,000 shares to Reconstitute, LLC as consideration for terminating a licensing agreement and for performance of certain provisions of the license agreement prior to termination. The fair value of the shares issued was approximately \$113,000.

**17. Employee Benefit Plans**

The Company sponsors a 401(k) plan, which includes a defined contribution feature. The Company contributed \$137,000, \$90,000, \$120,000, and \$508,000 for the years ended December 31, 2010, 2009, 2008, and since inception, respectively.

On October 29, 2010, the Company approved employment agreements for certain executives that provide for the payment of 24, 12 or 6 months of base salary upon termination of the executive in certain circumstances and group health insurance premiums plus accrued obligations. The agreements include provisions to accelerate the vesting of stock options subject to certain events including those related to a change in control.

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**Notes to Consolidated Financial Statements — (Continued)**

**18. Related-Party Transactions**

As of December 31, 2009, the Company was owed \$850,000 in various notes receivable and \$25,000 in notes receivable for common stock by its executive management team. The notes carried interest rates ranging from 2.42% to 6.00% and matured within the next 16 months. On May 7, 2010, the Board of Directors voted to forgive notes receivable and related outstanding interest from two officers. The remaining balances were repaid. Bonuses of \$192,236 were paid to cover the resulting tax liabilities for these individuals. To offset the forgiveness, outstanding options held by the officers to purchase common stock were modified to increase the aggregate exercise price by \$592,406 on July 1, 2010.

Certain purchasing activities are outsourced to a company owned by an immediate family member of the Company's controller. Total purchases through this related party were \$40,000, \$30,000, \$78,000, and \$270,000 for the years ended December 31, 2010, 2009, 2008, and since inception, respectively. The Company paid fees to this related party for consulting services of approximately \$0, \$0, \$0, and \$7,000 for the years ended December 31, 2010, 2009, 2008, and since inception, respectively.

**19. Subsequent Events**

Events that occurred subsequent to December 31, 2010 have been evaluated by management through the filing date of this registration statement for appropriate accounting and disclosure.

On January 7, 2011, stockholders approved an increase of 1,500,000 shares of common stock available for issuance under NewLink's 2009 Equity Incentive Plan (the "2009 Plan"). As of January 7, 2011, an aggregate of 8,385,000 shares of common stock were reserved for issuance under the 2009 Plan.

On January 7, 2011, NewLink acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of NewLink's with BPS, with BPS as the surviving corporation. In connection with this transaction, NewLink will issue up to an aggregate of 276,304 shares of NewLink's Series E preferred stock with a value of \$8.6 million to the former holders of BPS Series B common stock, Series A preferred stock and Series B preferred stock (other than NewLink). 221,066 of the shares of NewLink's Series E preferred stock were issued to the holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of NewLink's Series E preferred stock were held back to satisfy any indemnity obligations under the merger agreement. If there are no indemnity obligations payable under the merger agreement, those shares will be issued to the former holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock. As a result of this transaction, BPS became a wholly-owned subsidiary of NewLink. All options to purchase shares of BPS common stock became options to purchase NewLink's common stock. As part of the merger agreement, each outstanding BPS option was converted into the right to receive the number of NewLink options equal to the product of (A) the number of shares of BPS common stock subject to such BPS option multiplied by (B) a fraction, the numerator of which is \$1.0825 and the denominator of which is \$4.02, which was the fair market value of one share of NewLink common stock on September 30, 2010. As part of the merger agreement each outstanding BPS option was converted into the right to receive that number of NewLink options equal to the product of (A) the number of shares of BPS common stock subject to such BPS option multiplied by (B) a fraction, the numerator of which is \$1.0825 and the denominator of which is \$4.02, which was the fair market value of one share of NewLink common stock as of September 30, 2010. The exchange of options will be accounted for as a modification of an equity-classified award. The Series E preferred stock was issued with similar price and terms as the shares sold to third-parties in December 2010. See Note 9 and 10. As NewLink and BPS are under common control, the acquisition is treated as an equity transaction. The net assets of BPS had a book value of \$2.9 million. The remaining amount paid of \$5.7 million was recorded as a reduction of additional paid-in capital. No gain or loss was recorded as a result of this transaction.

Shares



**Common Stock**

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PRELIMINARY PROSPECTUS

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, 2011

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**Wells Fargo Securities**

**Cowen and Company**

**Baird**

**Canaccord Genuity**

**Needham & Company, LLC**

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Until \_\_\_\_\_, 2011, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to unsold allotments or subscriptions.

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other expenses of issuance and distribution.**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the listing fee for the NASDAQ Global Market.

	<b>Amount Paid or to be Paid</b>
SEC registration fee	\$ 6,150
FINRA filing fee	9,125
The NASDAQ Global Market listing fee	25,000
Blue sky qualification fees and expenses	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	<u>\$ *</u>

\* to be provided by amendment

**Item 14. Indemnification of directors and officers.**

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective upon the completion of this offering,

provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the Board of Directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of NewLink or any of its affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

We have entered into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

<u>Exhibit Document</u>	<u>Number</u>
Form of Underwriting Agreement	1.1
Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering	3.2
Form of Amended and Restated Bylaws to be effective upon completion of this offering	3.4
Form of Indemnity Agreement	10.50

**Item 15. Recent sales of unregistered securities.**

The following list sets forth information regarding all securities sold by us in the three years preceding the filing of this Registration Statement:

- (1) Between February 8, 2008 and December 17, 2009, in connection with our Series C preferred stock financing, we issued and sold an aggregate of 6,000,000 shares of Series C preferred stock to 142 accredited investors at 33 closings, at a purchase price of \$5.00 per share, for aggregate consideration of \$30.0 million. Upon completion of this offering, these shares will convert into 6,000,000 shares of common stock.
- (2) On July 17, 2009, in connection with our Series D preferred stock financing, we issued and sold an aggregate of 1,500,000 shares of Series D preferred stock to one accredited investor at one closing, at a purchase price of \$5.00 per share, for aggregate consideration of \$7.5 million. Upon completion of this offering, these shares will convert into 1,500,000 shares of common stock.
- (3) Between December 1, 2010 and December 13, 2010, in connection with our Series E preferred stock financing, we issued and sold an aggregate of 248,320 shares of Series E preferred stock to 39 accredited investors at two closings, at a purchase price of \$31.25 per share, for aggregate consideration of \$7.8 million. Upon completion of this offering, these shares will convert into 1,241,600 shares of common stock.
- (4) On July 17, 2009, we issued a warrant to Midwest Oilseeds, Inc. to purchase an aggregate of 375,000 shares of our common stock, with an initial exercise price of \$7.20 per share. On October 7, 2010, this warrant was amended and on October 21, 2010 the warrant was exercised for 375,000 shares of common stock at an aggregate exercise price of \$2.0 million.
- (5) From October 30, 2000 to August 6, 2008, we granted stock options under our 2000 Equity Incentive Plan to purchase 1,697,152 shares of common stock (net of expirations and cancellations) to our employees, directors and consultants, having exercise prices ranging from \$0.25 to \$3.40 per share. Of these, options to purchase 475,080 shares of common stock have been exercised through December 31, 2010, for aggregate consideration of \$141,543, at exercise prices ranging from \$0.25 to \$1.75 per share. In addition, we granted stock awards for 38,787 shares of our common stock in exchange for services rendered.
- (6) From May 13, 2009 to December 9, 2010, we granted stock options under our 2009 Equity Incentive Plan to purchase 5,203,250 shares of common stock (net of expirations and cancellations) to our employees, directors and consultants, having exercise prices ranging from \$1.00 to \$3.41 per share. Of these, none of the options to purchase shares of common stock have been exercised through December 31, 2010.
- (7) From May 13, 2009 to December 4, 2009, we granted stock options under our 2009 Equity Incentive Plan to purchase 2,438,275 shares of common stock (net of expirations and cancellations) to Dr. Charles Link, having exercise prices ranging from \$1.00 to \$2.00 per

share. Of these, none of the options to purchase shares of common stock have been exercised through December 31, 2010.

- (8) On September 3, 2010, we issued 50,000 shares of our common stock to Reconstitute, LLC, pursuant to the terms of a Termination Agreement by which we terminated a license agreement with Reconstitute. The stock was issued in consideration of Reconstitute's performance of certain provisions of the license agreement prior to termination and Reconstitute's agreement to terminate the license agreement.
- (9) On July 29, 2010, we issued 364,285 shares of our common stock to nine accredited investors pursuant to the July 21, 2005 purchase agreement with the shareholders of OncoRx Corporation. This issuance was the third and final installment of shares payable under the July 21, 2005 purchase agreement.

The offers, sales and issuances of the securities described in paragraphs (1), (2), (3), (4), (7), (8) and (9) were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

The offers, sales and issuances of the securities described in paragraphs (5) and (6) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2000 Equity Incentive Plan or 2009 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

## Item 16. Exhibits and Financial Statement Schedules

### EXHIBIT INDEX

Exhibit Number	Description
1.1#	Form of Underwriting Agreement
3.1(1)	Restated Certificate of Incorporation filed on November 23, 2010
3.2#	Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering
3.3(1)	Bylaws, as currently in effect
3.4#	Form of Amended and Restated Bylaws to be effective upon completion of this offering
4.1#	Form of the Registrant's Common Stock Certificate
4.2(1)	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4
5.1#	Opinion of Cooley LLP
10.1#	Form of Lock-up Agreement
10.2†(1)	2000 Equity Incentive Plan
10.3†(1)	Form of Stock Option Agreement under 2000 Equity Incentive Plan
10.4†(1)	Form of Stock Option Grant Notice under 2000 Equity Incentive Plan
10.5†(1)	Form of Stock Bonus Agreement under 2000 Equity Incentive Plan
10.6†(1)	Amended and Restated 2009 Equity Incentive Plan
10.7†(1)	Form of Stock Option Agreement under 2009 Equity Incentive Plan

<b>Exhibit Number</b>	<b>Description</b>
10.8†(1)	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan
10.9†(1)	2010 Employee Stock Purchase Plan
10.10†(1)	2010 Non-Employee Directors' Stock Award Plan
10.11†#	Form of Indemnity Agreement by and between Registrant and its directors and executive officers
10.12†(1)	Employment Agreement, dated as of December 6, 2010, by and between Registrant and Charles J. Link, Jr.
10.13†(1)	Employment Agreement, dated as of November 22, 2010, by and between Registrant and Nicholas N. Vahanian
10.14†(1)	Employment Agreement, dated as of June 26, 2008, by and between Registrant and Gordon H. Link, Jr.
10.15†(1)	Employment Agreement, dated as of November 22, 2010, by and between Registrant and Gordon H. Link, Jr.
10.16†(1)	Employment Agreement, dated as of November 22, 2010, by and between Registrant and Kenneth Lynn
10.17†(1)	Employment Agreement, dated as of November 22, 2010, by and between Registrant and W. Jay Ramsey
10.18†(1)	Form of Employee Proprietary Information and Inventions Agreement
10.19†	Promissory Note dated May 2, 2008 by and between the Registrant and Charles Link
10.20†	Promissory Note dated April 18, 2000 by and between the Registrant and Nicholas Vahanian
10.21†	Promissory Note dated August 20, 2008 by and between the Registrant and Nicholas Vahanian
10.22†	Promissory Note dated July 2008 by and between the Registrant and Gordon Link
10.23†	Amendment Agreement dated July 1, 2010 by and between Registrant and Charles Link
10.24†	Amendment Agreement dated July 1, 2010 by and between Registrant and Nicholas Vahanian
10.25†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Charles Link
10.26†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Nicholas Vahanian
10.27†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Gordon Link
10.28†	Acknowledgment Agreement dated November 24, 2010 by and between BioProtection Systems Corporation and Charles Link
10.29†	Acknowledgment Agreement dated November 23, 2010 by and between BioProtection Systems Corporation and Nicholas Vahanian
10.30*(1)	License Agreement dated July 7, 2005 by and between Registrant and Lankenau Institute for Medical Research
10.31*(1)	First Amendment to License Agreement dated May 22, 2006 by and between Registrant and Lankenau Institute for Medical Research
10.32*(1)	Second Amendment to License Agreement September 11, 2007 by and between Registrant and Lankenau Institute for Medical Research
10.33*(1)	Exclusive License Agreement executed December 21, 2007 by and between Registrant and Lankenau Institute for Medical Research
10.34*(1)	Exclusive License Agreement effective April 23, 2009 by and between Registrant and Lankenau Institute for Medical Research
10.35*(1)	License Agreement dated February 27, 2007 by and between Registrant and University of British Columbia



<b>Exhibit Number</b>	<b>Description</b>
10.36*(1)	License Agreement dated October 13, 2004 by and between Registrant and Drexel University
10.37*	License Agreement dated August 2, 2001 by and between Registrant and Central Iowa Health System
10.38*	Letter of Intent for Cooperative Research and Development Agreement (CRADA #2166) dated May 7, 2007 by and between Registrant and National Cancer Institute
10.39*(1)	Amendment No. 1 to Letter of Intent for CRADA #2166 dated January 17, 2008 by and between Registrant and National Cancer Institute
10.40*(1)	Amendment No. 2 to Letter of Intent for CRADA #2166 dated July 7, 2008 by and between Registrant and National Cancer Institute
10.41*(1)	Amendment No. 3 to Letter of Intent for CRADA #2166 dated March 24, 2009 by and between Registrant and National Cancer Institute
10.42*(1)	Amendment No. 4 to Letter of Intent for CRADA #2166 dated October 28, 2009 by and between Registrant and National Cancer Institute
10.43*(1)	Amendment No. 5 to Letter of Intent for CRADA #2166 dated December 16, 2009 by and between Registrant and National Cancer Institute
10.44*(1)	Amendment No. 6 to Letter of Intent for CRADA #2166 dated June 29, 2010 by and between Registrant and National Cancer Institute
10.45*	Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and National Cancer Institute
10.46*(1)	License Agreement dated September 13, 2005 by and between Registrant and Medical College of Georgia Research Institute, Inc.
10.47*(1)	First Amendment to License Agreement dated April 27, 2006 by and between Registrant and Medical College of Georgia Research Institute, Inc.
10.48*(1)	Second Amendment to License Agreement dated April 27, 2006 by and between Registrant and Medical College of Georgia Research Institute, Inc.
10.49*(1)	Third Amendment to License Agreement dated February 13, 2007 by and between Registrant and Medical College of Georgia Research Institute, Inc.
10.50*(1)	Patent License Agreement dated March 1, 2006 by and between Registrant and Bresagen Xenograft Marketing Ltd.
10.51(1)	Lease dated September 1, 2000 by and between Registrant and Iowa State University Research Park Corporation
10.52(1)	Sublease Agreement effective February 1, 2001 by and between Registrant and Iowa State Innovation System
10.53(1)	Memorandum of Agreement dated December 6, 2005 by and between Registrant and Iowa State University Research Park Corporation
10.54(1)	Memorandum of Agreement dated April 13, 2006 by and between Registrant and Iowa State University Research Park Corporation
10.55(1)	Memorandum of Agreement dated February 20, 2008 by and between Registrant and Iowa State University Research Park Corporation
10.56(1)	Memorandum of Agreement dated May 1, 2009 by and between Registrant and Iowa State University Research Park Corporation
10.57(1)	Memorandum of Agreement dated March 24, 2010 by and between Registrant and Iowa State University Research Park Corporation
10.58(1)	Lease dated September 30, 2009 by and between Registrant and Iowa State University Research Park Corporation
10.59(1)	Promissory Note executed in 2009 by and between Registrant and Iowa State University Research Park Corporation
10.60(1)	Forgivable Loan Agreement dated March 10, 2010 by and between Registrant and City of Ames, Iowa

<b>Exhibit Number</b>	<b>Description</b>
10.61(1)	Iowa Values Fund Agreement dated March 18, 2005 by and between Registrant and Iowa Department of Economic Development
10.62(1)	Contract Amendment dated August 19, 2010 between Registrant and Iowa Department of Economic Development
10.63(1)	Master Contract dated December 29, 2005 by and between Registrant and Iowa Department of Economic Development
10.64(1)	Contract Amendment dated April 21, 2009 between Registrant and Iowa Department of Economic Development
10.65(1)	Contract Amendment dated August 19, 2010 between Registrant and Iowa Department of Economic Development
10.66*(1)	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and BioProtection Systems Corporation
10.67*(1)	Sole License Agreement executed May 4, 2010 by and between Her Majesty the Queen in Right of Canada and BioProtection Systems Corporation
10.68	Contract No. W911NF-08-C-0044 dated May 5, 2008 by and between BioProtection Systems Corporation and the United States Department of Defense
10.69	Amendment to Contract No. W911NF-08-C-0044 dated February 12, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense
10.70*	Contract No. HDTRA1-09-C-0014 dated September 25, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense
10.71	Contract No. W911NF-09-C-0072 dated July 31, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense
10.72	Amendment to Contract No. W911NF-09-C-0072 dated April 21, 2010 by and between BioProtection Systems Corporation and the United States Department of Defense
10.73	Grant Number 5U01AI066327-05 issued August 26, 2009 by and between BioProtection Systems Corporation and the National Institutes of Health
10.74	Grant Number 1R43AI084350-01A1 issued April 6, 2010 by and between BioProtection Systems Corporation and the National Institutes of Health
10.75	Agreement and Plan of Merger dated December 1, 2010 by and between the Registrant, BPS Merger Sub, Inc., BioProtection Systems Corporation and BPS Stockholder Representative, LLC
10.76	Certificate of Merger of BPS Merger Sub, Inc. into BioProtection Systems Corporation filed on January 7, 2011
21.1(1)	Subsidiary Information
23.1	Consent of KPMG LLP, independent registered public accounting firm
23.2	Consent of the Mentor Group, Inc., valuation specialist
23.3#	Consent of Cooley LLP (included in Exhibit 5.1)
24.1(1)	Power of Attorney

(1) Filed with the Registrant's Registration Statement on Form S-1 on December 21, 2010

# To be filed by amendment

† Indicates management contract or compensatory plan

\* Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**(b) Financial statement schedule.**

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ames, State of Iowa, on February 28, 2011.

NEWLINK GENETICS CORPORATION

By: /s/ CHARLES J. LINK, JR.

\_\_\_\_\_  
Charles J. Link, Jr.  
*Chief Executive Officer, Chairman of the Board*

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ CHARLES J. LINK, JR.</u> Charles J. Link, Jr.	Chief Executive Officer, Chairman of the Board and Director ( <i>Principal Executive Officer</i> )	February 28, 2011
<u>/s/ GORDON H. LINK, JR.</u> Gordon H. Link, Jr.	Chief Financial Officer and Secretary ( <i>Principal Financial and Accounting Officer</i> )	February 28, 2011
<u>*</u> Thomas A. Raffin	Director	February 28, 2011
<u>*</u> Ernest J. Talarico, III	Director	February 28, 2011
<u>*</u> David J. Lundquist	Director	February 28, 2011
<u>*</u> Sarah Alexander	Director	February 28, 2011
<u>*</u> Joseph Saluri	Director	February 28, 2011

\*By:

/s/ GORDON H. LINK, JR.

Gordon H. Link, Jr.,  
*Attorney-in-Fact*



**PROMISSORY NOTE**

U.S. \$225,000.00

Ames, Iowa

May 2, 2008

FOR VALUE RECEIVED, the undersigned, Charles J. Link (LINK), whose address is 14137 South Shore Drive, Clive, IA 50325, promises to pay, without set off, deduction or counterclaim of any kind or nature to NewLink Genetics Corporation (NEWLINK), whose address is 2901 South Loop Drive, Suite 3900, Ames, IA 50010, as Payee, or Holder, at the address of Payee or Holder listed in this Note, the principal sum of two-hundred and twenty-five thousand Dollars (\$225,000.00).

The unpaid principal of this promissory note shall bear simple interest at the rate of six percent (6.00%) per annum. Interest shall be calculated based on the principal balance outstanding as may be adjusted from time to time. Interest on the unpaid balance of this Note shall accrue monthly but shall not be due and payable until such time as when the principal balance of this Note becomes due and payable. The principal balance of this Promissory Note shall be due and payable on May 1, 2009. There shall be no penalty for early repayment of all or any part of the principal.

LINK and all endorsers now or in the future becoming parties to this promissory note jointly and severally waive presentment and demand for payment, notice of dishonor, protest, and notice of protest of this promissory note.

LINK agrees to pay all costs and expenses of collection incurred by Payee or Holder of this promissory note, in or out of Court, including without limitation, Court related costs and expenses and reasonable attorneys' fees and disbursements (including such costs, fees, and disbursements incurred on appeal of any litigation). No extension of time for payment of this note payable and no alteration, amendment, or waiver of any provision of this note payable shall release, discharge, modify, change, or affect the liability of LINK under this promissory note.

No delay by Payee or Holder in enforcing any covenant or right under this line of credit shall be deemed a waiver of any covenant or right, and no waiver by Payee or Holder of any particular provision of this promissory note shall be deemed a waiver of any other provision or a continuing waiver of any particular provision, and except as so expressly waived in writing, all provisions shall continue in full force and effect.

This PROMISSORY NOTE shall be construed and enforced according to the laws of the State of Iowa.

Whenever used in this PROMISSORY NOTE, the terms "Holder", "LINK", "NEWLINK", and "Payee" shall be construed in the singular or plurals as the context may require.

Charles J. Link

NewLink Genetics Corporation

/s/ Charles J. Link

/s/ Carl Langren

Charles J. LinkCarl Langren, Controller

## PROMISSORY NOTE

\$31,500.00

April 18, 2000

**FOR VALUE RECEIVED**, the undersigned hereby unconditionally promises to pay to the order of NewLink Genetics Corporation a Delaware corporation (the "Company"), at Iowa State University Research Park, 2901 South Loop Drive, Suite 3500, Ames, Iowa, 50010, or at such other place as the holder hereof may designate in writing, in lawful money of the United States of America and in immediately available funds, the principal sum of Thirty-one thousand and five hundred Dollars (\$31,500.00) together with interest accrued from the date hereof on the unpaid principal at the rate of 6.71% per annum, or the maximum rate permissible by law (which under the laws of the State of Iowa shall be deemed to be the laws relating to permissible rates of interest on commercial loans), whichever is less, as follows:

**Principal Repayment.** The outstanding principal amount hereunder shall be due and payable in full on April 18, 2005

**Interest Payments.** Interest shall be payable annually in arrears and shall be calculated on the basis of a 360-day year for the actual number of days elapsed

*provided, however*, that in the event that the undersigned's employment by or association with the Company is terminated for any reason prior to payment in full of this Note, this Note shall be accelerated and all remaining unpaid principal and interest shall become due and payable immediately after such termination.

If the undersigned fails to pay any of the principal and accrued interest when due, the Company, at its sole option, shall have the right to accelerate this Note, in which event the entire principal balance and all accrued interest shall become immediately due and payable, and immediately collectible by the Company pursuant to applicable law.

This Note may be prepaid at any time without penalty. All money paid toward the satisfaction of this Note shall be applied first to the payment of interest as required hereunder and then to the retirement of the principal.

The full amount of this Note is secured by a pledge of shares of Common Stock of the Company, and is subject to all of the terms and provisions of the Founder Stock Purchase Agreement and the Pledge Agreement, each of even date herewith between the undersigned and the Company.

The undersigned hereby represents and agrees that the amounts due under this Note are not consumer debt, and are not incurred primarily for personal, family or household purposes, but are for business and commercial purposes only.

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The undersigned hereby waives presentment, protest and notice of protest, demand for payment, notice of dishonor and all other notices or demands in connection with the delivery, acceptance, performance, default or endorsement of this Note.

The holder hereof shall be entitled to recover, and the undersigned agrees to pay when incurred, all costs and expenses of collection of this Note, including without limitation, reasonable attorneys' fees.

This Note shall be governed by, and construed, enforced and interpreted in accordance with, the laws of the State of Iowa, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

Signed /s/ Nicholas N. Vahanian

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**PROMISSORY NOTE**

U.S. \$125,000.00

Ames, Iowa

August 20, 2008

FOR VALUE RECEIVED, the undersigned, Nicholas N. Vahanian (VAHANIAN), whose address is 9654 NW 47<sup>th</sup> Court, Polk City, IA 50266, promises to pay, without set off, deduction or counterclaim of any kind or nature to NewLink Genetics Corporation (NEWLINK), whose address is 2901 South Loop Drive, Suite 3900, Ames, IA 50010, as Payee, or Holder, at the address of Payee or Holder listed in this Note, the principal sum of one-hundred and twenty-five thousand Dollars (\$125,000.00).

The unpaid principal of this promissory note shall bear simple interest at the rate of six percent (6.00%) per annum. Interest shall be calculated based on the principal balance outstanding as may be adjusted from time to time. Interest on the unpaid balance of this Note shall accrue monthly but shall not be due and payable until such time as when the principal balance of this Note becomes due and payable. The principal balance of this Promissory Note shall be due and payable on March 1, 2009. There shall be no penalty for early repayment of all or any part of the principal.

VAHANIAN and all endorsers now or in the future becoming parties to this promissory note jointly and severally waive presentment and demand for payment, notice of dishonor, protest, and notice of protest of this promissory note.

VAHANIAN agrees to pay all costs and expenses of collection incurred by Payee or Holder of this promissory note, in or out of Court, including without limitation, Court related costs and expenses and reasonable attorneys' fees and disbursements (including such costs, fees, and disbursements incurred on appeal of any litigation). No extension of time for payment of this note payable and no alteration, amendment, or waiver of any provision of this note payable shall release, discharge, modify, change, or affect the liability of VAHANIAN under this promissory note.

No delay by Payee or Holder in enforcing any covenant or right under this line of credit shall be deemed a waiver of any covenant or right, and no waiver by Payee or Holder of any particular provision of this promissory note shall be deemed a waiver of any other provision or a continuing waiver of any particular provision, and except as so expressly waived in writing, all provisions shall continue in full force and effect.

This PROMISSORY NOTE shall be construed and enforced according to the laws of the State of Iowa.

Whenever used in this PROMISSORY NOTE, the terms "Holder", "VAHANIAN", "NEWLINK", and "Payee" shall be construed in the singular or plurals as the context may require.

Nicholas N. Vahanian

NewLink Genetics Corporation

/s/ Nicholas N. Vahanian

Nicholas N. Vahanian

/s/ Gordon Lnk

Gordon Link, Chief Financial Officer





PROMISSORY NOTE

\$ 500,000.00

July , 2008

FOR VALUE RECEIVED, the undersigned, each as principal, jointly and severally, promise(s) to pay to the order of NewLink Genetics Corporation at 2901 South Loop Drive, Suite #3900, Ames , Iowa, the sum of Five Hundred Thousand and 0/100 DOLLARS with interest thereon from July , 2008, payable as provided below at the rate of 2.42 (the current AFR)per cent per annum until payment hereof as follows:

All principal and accrued interest shall be due and payable upon the earlier of eighteen months from the date of this Promissory Note or upon the sale of the undersigned debtors' Colorado home located at , Colorado.

This Promissory Note shall be secured by a first mortgage given upon the property described as Lot 29 in Otter Creek Golf Course Plat 1, an Official Plat, now included in and forming a part of the City of Ankeny, Polk County, Iowa.

Interest shall first be deducted from the payment and any balance shall be applied on principal.

Principal and interest not paid when due shall draw interest at the rate of 12 % per annum. Upon default in payment of any interest, or any installment of principal, the whole amount then unpaid shall become immediately due and payable at the option of the holder without notice. The undersigned, in case of suit on this note, agrees to pay attorney's fees.

Makers, endorsers and sureties waive demand of payment, notice of non-payment, protest and notice. Sureties, endorsers and guarantors agree to all of the provisions of this note, and consent that the time or times of payment of all or any part hereof may be extended after maturity, from time to time, without notice.

**Important. Read Before Signing: The terms of this Agreement should be read carefully because only those terms in writing are enforceable. No other terms or oral promises not contained in this written contract may be legally enforced. You may change the terms of this Agreement only by another written agreement. Borrower acknowledges the receipt of a copy of this document at the time it was signed.**

Address: 1407 NE 47<sup>th</sup> St.  
ANKENY, IA 50021

/s/ Gordon Link  
Gordon H. Link, Jr.

Phone: 303-513-3039

/s/ Dawn Link  
Dawn J. Link

Caveat: This form not to be used for a Consumer Credit Transaction.

AMENDMENT AGREEMENT

This amendment agreement (this "Agreement"), by and among NewLink Genetics Corporation, a Delaware corporation (the "Company"), and Dr. Charles J. Link, Jr. (the "Optionholder"), is entered into as of July 1, 2010 (the "Effective Date").

RECITALS:

- A. Pursuant to a Stock Option Grant Notice ("Grant Notice") and Stock Option Agreement (the "Option Agreement"), the Company granted the Optionholder an option under its 2000 Equity Incentive Plan to purchase shares of the Company's common stock at an exercise price of \$1.00 per share (the "Option").
- B. The Optionholder currently has a loan from the Company (the "Loan") and the Company wishes to forgive of the principal and interest on Loan (the "Loan Forgiveness").
- C. In exchange for the Loan Forgiveness, the Company and the Optionholder wish to amend the Grant Notice to increase the exercise price of 555,396 shares subject to the Option from \$1.00 per share to \$2.00 a share.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Company and the Optionholder agree as follows:

- 1. The Grant Notice is amended to increase the exercise price of 555,396 shares subject to the Option from \$1.00 per share to \$2.00 a share (the "Repriced Options").
- 2. The Optionholder must exercise all of the Repriced Options before the Optionholder may exercise any other options to purchase the Company's Common Stock at a lower per share price.
- 3. This Agreement constitutes an amendment to the Grant Notice. The terms and provisions of the Grant Notice and Option Agreement and all other documents and instruments relating and pertaining to the Grant Notice and Option Agreement continue in full force and effect, as amended hereby. In the event of any conflict between the provisions of the Grant Notice and Option Agreement and the provisions of this Agreement, the provisions of this Agreement will control.
- 4. This Amendment shall be governed by and construed under the laws of the State of Delaware in all respects as such laws are applied to agreements among Delaware residents entered into and to be performed entirely within Delaware.
- 5. This Agreement may be executed in any number of counterparts, each of which shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

OPTIONHOLDER:

/s/ Charles J. Link  
DR. CHARLES J. LINK, JR.

AMENDMENT AGREEMENT SIGNATURE PAGE

Executed as of the Effective Date.

COMPANY:

NEWLINK GENETICS CORPORATION

By: /s/ Nicholas N. Vahanian  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

AMENDMENT AGREEMENT SIGNATURE PAGE

**STOCK OPTION GRANT NOTICE  
2009 EQUITY INCENTIVE PLAN**

NewLink Genetics Corporation (the "**Company**"), pursuant to its 2009 Equity Incentive Plan (the "**Plan**"), hereby grants to Optionholder an option to purchase the number of shares of the Company's Common Stock set forth below. This option is subject to all of the terms and conditions as set forth herein and in the Option Agreement, the Plan, and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety.

Optionholder:	Charles J. Link, Jr.
Date of Grant:	January 21, 2009
Vesting Commencement Date:	June 1, 2007
Number of Shares Subject to Option:	555,396
Exercise Price (Per Share):	\$2.00
Total Exercise Price:	\$1,110,792.00
Expiration Date:	January 20, 2019

**Type of Grant:**                     Incentive Stock Option(1)                     Nonstatutory Stock Option

**Exercise Schedule:**             Same as Vesting Schedule                     Early Exercise Permitted

**Vesting Schedule:**            1/5<sup>th</sup> of the shares vest one year after the vesting commencement date. 1/60<sup>th</sup> of the shares vest monthly thereafter over the next four years.

**Payment:**                        By one or a combination of the following items (described in the Option Agreement):

- By cash or check
- Pursuant to a Regulation T Program if the Shares are publicly traded
- By delivery of already-owned shares if the Shares are publicly traded

**Additional Terms/Acknowledgements:** The undersigned Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding the acquisition of stock in the Company and supersede all prior oral and written agreements on that subject with the exception of (i) options previously granted and delivered to Optionholder under the Plan, and (ii) the following agreements only:

**OTHER AGREEMENTS:**

**NEWLINK GENETICS CORPORATION**

By: /s/ Nicholas N. Vahanian  
Signature

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**OPTIONHOLDER:**

/s/ Charles Link  
Signature

Date: 9/27/10

**ATTACHMENTS:** Option Agreement, 2009 Equity Incentive Plan and Notice of Exercise

(1) If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than \$100,000 in value (measured by exercise price) in any calendar year. Any excess over \$100,000 is a Nonstatutory Stock Option.

**NEWLINK GENETICS CORPORATION  
STOCK OPTION GRANT NOTICE  
2009 EQUITY INCENTIVE PLAN**

NewLink Genetics Corporation (the "**Company**"), pursuant to its 2009 Equity Incentive Plan (the "**Plan**"), hereby grants to Optionholder an option to purchase the number of shares of the Company's Common Stock set forth below. This option is subject to all of the terms and conditions as set forth herein and in the Option Agreement, the Plan, and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety.

Optionholder:	Charles J. Link, Jr.
Date of Grant:	January 21, 2009
Vesting Commencement Date:	June 1, 2007
Number of Shares Subject to Option:	982,879
Exercise Price (Per Share):	\$1.00
Total Exercise Price:	\$982,879.00
Expiration Date:	January 20, 2019

**Type of Grant:**                     Incentive Stock Option(1)                     Nonstatutory Stock Option

**Exercise Schedule:**             Same as Vesting Schedule                     Early Exercise Permitted

**Vesting Schedule:**            1/5<sup>th</sup> of the shares vest one year after the vesting commencement date. 1/60<sup>th</sup> of the shares vest monthly thereafter over the

next four years.

**Payment:** By one or a combination of the following items (described in the Option Agreement):

- By cash or check
- Pursuant to a Regulation T Program if the Shares are publicly traded
- By delivery of already-owned shares if the Shares are publicly traded

**Additional Terms/Acknowledgements:** The undersigned Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding the acquisition of stock in the Company and supersede all prior oral and written agreements on that subject with the exception of (i) options previously granted and delivered to Optionholder under the Plan, and (ii) the following agreements only:

**OTHER AGREEMENTS:**

\_\_\_\_\_  
\_\_\_\_\_

**NEWLINK GENETICS CORPORATION**

**OPTIONHOLDER:**

By: /s/ Nicholas N. Vahanian  
Signature

/s/ Charles Link  
Signature

Title: COO

Date: 9/27/10

Date: 9/27/10

**ATTACHMENTS:** Option Agreement, 2009 Equity Incentive Plan and Notice of Exercise

\_\_\_\_\_

(1) If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than \$100,000 in value (measured by exercise price) in any calendar year. Any excess over \$100,000 is a Nonstatutory Stock Option.

\_\_\_\_\_

AMENDMENT AGREEMENT

This amendment agreement (this "Agreement"), by and among NewLink Genetics Corporation, a Delaware corporation (the "Company"), and Dr. Nicholas Vahanian (the "Optionholder"), is entered into as of July 1, 2010 (the "Effective Date").

RECITALS:

- A. Pursuant to a Stock Option Grant Notice ("Grant Notice") and Stock Option Agreement (the "Option Agreement"), the Company granted the Optionholder an option under its 2000 Equity Incentive Plan to purchase shares of the Company's common stock at an exercise price of \$1.00 per share (the "Option").
- B. The Optionholder currently has a loan from the Company (the "Loan") and the Company wishes to forgive of the principal and interest on Loan (the "Loan Forgiveness").
- C. In exchange for the Loan Forgiveness, the Company and the Optionholder wish to amend the Grant Notice to increase the exercise price of 37,010 shares subject to the Option from \$1.00 per share to \$2.00 a share.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Company and the Optionholder agree as follows:

- 1. The Grant Notice is amended to increase the exercise price of 37,010 shares subject to the Option from \$1.00 per share to \$2.00 a share (the "Repriced Options").
- 2. The Optionholder must exercise all of the Repriced Options before the Optionholder may exercise any other options to purchase the Company's Common Stock at a lower per share price.
- 3. This Agreement constitutes an amendment to the Grant Notice. The terms and provisions of the Grant Notice and Option Agreement and all other documents and instruments relating and pertaining to the Grant Notice and Option Agreement continue in full force and effect, as amended hereby. In the event of any conflict between the provisions of the Grant Notice and Option Agreement and the provisions of this Agreement, the provisions of this Agreement will control.
- 4. This Amendment shall be governed by and construed under the laws of the State of Delaware in all respects as such laws are applied to agreements among Delaware residents entered into and to be performed entirely within Delaware.
- 5. This Agreement may be executed in any number of counterparts, each of which shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

OPTIONHOLDER:

/s/ Nicholas N. Vahanian  
DR. NICHOLAS VAHANIAN

AMENDMENT AGREEMENT SIGNATURE PAGE

Executed as of the Effective Date.

COMPANY:

NEWLINK GENETICS CORPORATION

By: /s/ Charles Link  
Name: Charles Link  
Title: CEO

AMENDMENT AGREEMENT SIGNATURE PAGE



the next four years.

**Payment:** By one or a combination of the following items (described in the Option Agreement):

- By cash or check
- Pursuant to a Regulation T Program if the Shares are publicly traded
- By delivery of already-owned shares if the Shares are publicly traded

**Additional Terms/Acknowledgements:** The undersigned Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding the acquisition of stock in the Company and supersede all prior oral and written agreements on that subject with the exception of (i) options previously granted and delivered to Optionholder under the Plan, and (ii) the following agreements only:

**OTHER AGREEMENTS:**

\_\_\_\_\_

\_\_\_\_\_

**NEWLINK GENETICS CORPORATION**

**OPTIONHOLDER:**

By: /s/ Charles Link  
Signature

/s/ Nicholas N. Vahanian  
Signature

Title: CEO

Date: 9/27/10

Date: 9/27/10

**ATTACHMENTS:** Option Agreement, 2009 Equity Incentive Plan and Notice of Exercise

(1) If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than \$100,000 in value (measured by exercise price) in any calendar year. Any excess over \$100,000 is a Nonstatutory Stock Option.

\_\_\_\_\_

The undersigned executive and NewLink Genetics Corporation (the "Company") hereby acknowledge and agree that the description below is true and correct in all respects.

On May 2, 2008, Dr. Charles Link borrowed \$225,000.00 from the Company, at an interest rate of 6% per annum, with all accrued interest and principal due May 1, 2009. On January 22, 2009, the Company granted Dr. Link a bonus of \$78,149.43, of which \$78,149.43 was applied to the principal due on the loan and \$0 was applied to the interest. On April 24, 2009, Dr. Link repaid the remainder of the loan with a \$159,230.23 payment, of which \$146,851.00 was applied to the principal and \$12,379.23 was applied to the interest.

On April 24, 2009, Dr. Link borrowed \$350,000.00 from the Company, at an interest rate of 6% per annum, with all accrued interest and principal due May 1, 2011. On May 7, 2010, the principal on the loan plus accrued interest of \$25,169.86 was forgiven, effective as of July 2, 2010, and an additional bonus of \$180,226.00 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options to purchase 555,396 shares of the Company's common stock held by Dr. Link were modified to increase the aggregate exercise price from \$1.00 per share to \$2.00 per share (an amount equal to the amount of the forgiveness plus the bonus paid), and Dr. Link agreed to exercise the higher priced options prior to exercising any lower priced options to purchase the Company's common stock.

**EXECUTIVE**

**NEWLINK GENETICS CORPORATION**

/s/ Charles Link \_\_\_\_\_  
Charles Link  
Date: 11/24/10 \_\_\_\_\_

/s/ Gordon Link \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_





The undersigned executive and NewLink Genetics Corporation (the "Company") hereby acknowledge and agree that the description below is true and correct in all respects.

On, April 18, 2000, Dr. Nicholas Vahanian borrowed \$31,500.00 from the Company, at an interest rate of 6.71% per annum, with all accrued interest and principal due April 18, 2005. On December 31, 2003, Dr. Vahanian made a \$6,500.00 payment on the loan, of which \$6,500.00 was applied to the principal and \$0 was applied to the interest. On April 18, 2005, the Company extended the loan to April 18, 2010 at an interest rate of 6.7% per annum. On July 1, 2010, the principal on the loan plus accrued interest of \$10,000 was forgiven, effective as of July 2, 2010, and a bonus of an additional \$12,010 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options to purchase 37,010 shares of the Company's common stock held by Dr. Vahanian were modified to increase the aggregate exercise price from \$1.00 per share to \$2.00 per share (an amount equal to the amount of the forgiveness plus the bonus paid), and Dr. Vahanian agreed to exercise the higher priced options prior to exercising any lower priced options to purchase the Company's common stock.

On August 20, 2008, Dr. Vahanian borrowed \$125,000 from the Company, at an interest rate of 6% per annum, with all accrued interest and principal due March 1, 2009. On January 22, 2009, the Company granted Dr. Vahanian a bonus of \$55,037.08, of which \$55,037.08 was applied to the principal due on the loan and \$0 was applied to the interest. On April 24, 2009, Dr. Vahanian repaid the remainder of the loan with a \$74,335.60 payment, of which \$69,962.92 was applied to the principal and \$4,372.68 was applied to the interest.

**EXECUTIVE**

**NEWLINK GENETICS CORPORATION**

/s/ Nicholas Vahanian  
\_\_\_\_\_  
Nicholas Vahanian  
  
Date: 11/23/10  
\_\_\_\_\_

/s/ Gordon Link  
\_\_\_\_\_  
Print Name: Gordon Link  
Title: CFO  
Date: 11/24/2010  
\_\_\_\_\_



The undersigned executive and NewLink Genetics Corporation (the "**Company**") hereby acknowledge and agree that the description below is true and correct in all respects.

On July 28, 2008, Gordon Link borrowed \$500,000.00 from the Company, at an interest rate of 2.42% per annum, with all accrued interest and principal due January 28, 2010 (18 months from the date of issuance). All principal and interest not paid by January 28, 2010 accrued interest at a rate of 12% per annum.

On January 1, 2010, the Company agreed to extend the loan to June 30, 2010 at the IRS minimum interest rate, adjusted on a monthly basis. On January 21, 2010, the Company granted Mr. Link a bonus of \$34,751.85, of which \$34,751.85 was applied to the principal due on the loan and \$0 was applied to the interest. On April 14, 2010, Mr. Link made a \$65,248.00 payment on the loan, of which \$65,248.00 was applied to the principal and \$0 was applied to the interest. On May 11, 2010, Mr. Link repaid the remainder of the loan with a \$400,000.00 payment, of which \$400,000.00 was applied to the principal and \$0 was applied to the interest. On May 10, 2010, the Company forgave \$10,052.34 of interest due on the loan.

**EXECUTIVE**

**NEWLINK GENETICS CORPORATION**

/s/ Gordon Link  
\_\_\_\_\_  
Gordon Link

/s/ Charles Link  
\_\_\_\_\_  
Print Name: \_\_\_\_\_

Date: 11/24/10  
\_\_\_\_\_

Title: \_\_\_\_\_  
Date: \_\_\_\_\_  
\_\_\_\_\_

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The undersigned executive and BioProtection Systems Corporation (the “*Company*”) hereby acknowledge and agree that the description below is true and correct in all respects.

In 2006, Dr. Charles Link borrowed \$75,000.00 from the Company, at an interest rate of 5.01% per annum. On March 3, 2010 and May 11, 2010, the Company forgave a total of \$30,000.00 of the principal amount of the loan plus \$13,517.00 of interest accrued on the loan. On March 3, 2010, the Company paid Dr. Link a cash bonus of \$15,000.00 to cover the resulting tax liability. On October 31, 2010, the Company paid Dr. Link a bonus of \$50,000.00 gross, of which \$33,775.00 was net and was applied to the principal due on the loan and \$0 was applied to the interest. On November 17, 2010, Dr. Link repaid the remainder of the loan with a \$12,466.52 payment, of which \$11,225.00 was applied to the principal and \$1,241.52 was applied to the interest.

**EXECUTIVE**

**BIOPROTECTION SYSTEMS CORPORATION**

/s/ Charles Link \_\_\_\_\_  
Charles Link  
Date: 11/24/10 \_\_\_\_\_

/s/ Gordon Link \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

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The undersigned executive and BioProtection Systems Corporation (the “*Company*”) hereby acknowledge and agree that the description below is true and correct in all respects.

In 2006, Dr. Nicholas Vahanian borrowed \$20,000.00 from the Company, at an interest rate of 5.01% per annum. On March 3, 2010 and May 11, 2010, the Company forgave a total of \$8,000.00 of the principal amount of the loan plus \$3,604.00 of interest accrued on the loan and paid Dr. Vahanian a cash bonus of \$15,000.00, a portion of which was used to cover the resulting tax liability. On October 31, 2010, Dr. Vahanian repaid the remainder of the loan with a \$12,303.07 payment, of which \$12,000.00 was applied to the principal and \$303.07 was applied to the interest.

**EXECUTIVE**

/s/ Nicholas Vahanian  
Nicholas Vahanian  
  
Date: 11/23/10

**BIOPROTECTION SYSTEMS CORPORATION**

/s/ Gordon Link  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

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**LICENSE AGREEMENT BETWEEN CENTRAL IOWA HEALTH SYSTEM  
AND NEWLINK GENETICS CORPORATION**

**THIS LICENSE AGREEMENT** (the “Agreement”), by and between **CENTRAL IOWA HEALTH SYSTEM**, a not-for-profit corporation, organized and existing under the laws of the state of Iowa (“CIHS”), and **NEWLINK GENETICS CORPORATION**, a Delaware corporation, having a principal place of business at 2901 S. Loop Drive, Ames, Iowa, 50010 (“NEWLINK”) is effective as of the 2<sup>nd</sup> day of August, 2001 (the “Effective Date”). CIHS and NEWLINK are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

**RECITALS**

**WHEREAS**, CIHS owns one hundred percent (100%) interest in the Human Gene Therapy Research Institute located in Des Moines, Iowa (“HGTRI”);

**WHEREAS**, CIHS owns the Inventions, Licensed Patents and Licensed Technology (as hereinafter defined); and

**WHEREAS**, CIHS has the right to grant, and NEWLINK desires to acquire, licenses to make use and sell certain products utilizing the Licensed Patents and Licensed Technology, and to grant sublicenses upon the terms and conditions hereinafter set forth;

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows:

**1. DEFINITIONS**

**1.0 “Active Component”** shall mean an ingredient in a Combination Product, which is biologically active and can be used for either therapeutic or preventative purposes, but does not include diluents, vehicles, adjuvants, or any other ingredients which does not have any, or which has only incidental, therapeutic or preventative properties when present alone.

**1.1 “Affiliate”** shall mean an entity which controls, is controlled by, or is under common control with, a party. For this purpose, “control” means the possession of the power to direct or cause the direction of the management and the policies of an entity, whether through ownership directly or indirectly of fifty percent (50%) or more of the stock entitled to vote, or where control of fifty percent (50%) or more of such rights is not permitted in the country where such entity exists, the maximum permitted in such country.

**1.2 “Commercially Reasonable Efforts”** shall mean the application of efforts and resources consistent with industry standards for a product of similar market and profit potential. Commercially Reasonable Efforts requires that a Party promptly assign responsibility for such matter to specific employee(s) who are held accountable for the progress of such project.

**1.3 “Control”** shall mean the ability to grant a license, sublicense, or access as

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provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

**1.4 “Invention”** shall mean any invention covered by one or more Valid Claims within the Licensed Patents.

**1.5 “Field of Use”** shall mean the diagnosis, prevention, treatment and mitigation of diseases and conditions in humans, animals, and plants.

**1.6 “Licensed Patents”** shall mean (a) the patents and patent applications listed in Exhibit A, and (b) all provisionals, divisionals, substitutions, and continuations of the patents and patent applications in Section 1.6(a), as well as any claim in a continuation-in-part patent or application that would be entitled to claim priority to the filing date of one or more of the patents or patent applications in Section 1.6(a), and (c) the patent applications from which the patents listed on Exhibit A issued, excluding those claims within such patent applications that do not cover the inventions claimed in the patents and patent applications listed in Exhibit A, and (d) all reissues, re-examinations, and extensions of any of the preceding patents or of patents issuing on the preceding patent applications, and all foreign counterparts thereof.

**1.7 “Licensed Product(s)”** shall mean any product useful in the Field of Use, (a) the manufacture, use or sale of which is covered in whole or in part by one or more Valid Claims within the Licensed Patents or (b) that incorporates any Licensed Technology.

**1.8 “Licensed Technology”** shall mean all proprietary information, know-how, biological, chemical or physical materials, procedures, methods, prototypes, designs, technical data, reports, and pre-clinical data owned or Controlled by HGTRI before and as of the Effective Date that are necessary for NEWLINK to exercise and practice all Valid Claims of the Licensed Patents pursuant to this Agreement, as designated by mutual agreement of the Parties and listed or attached in written format in Exhibit B, after the earlier of (a) NEWLINK’s completion of its review of the records and documents at HGTRI relating to such Licensed Technology or (b) six (6) months after the Effective Date. It is understood that NEWLINK’s review of such records and documents at HGTRI shall be during such times and subject to such restrictions (including, but not limited to, confidentiality obligations) as the Parties mutually agree. “Licensed Technology” does not include Licensed Patents.

**1.9 “Net Sales”** shall mean the total amount (in United States dollars) invoiced for sales of the Licensed Product, by NEWLINK, its Affiliates, or Sublicensees to unrelated Third Parties in bona fide arm’s length transactions, less the following deductions, in each case related specifically to the Licensed Product in question and actually allowed and taken and not otherwise recovered by or reimbursed to NEWLINK, its Affiliates, or Sublicensees: (a) trade, cash and quantity discounts; (b) taxes on sales (such as sales or use taxes) to the extent added to the sales price and set forth separately as such in the total amount invoiced; (c) freight, insurance and other transportation charges to the extent added to the sales price and set forth separately as such in the total amount invoiced; and (d) amounts repaid or credited by reason of rejections, defects or returns or because of the retroactive price reductions, chargebacks, or rebates under any government programs.

Phase III clinical trials, respectively, in each case as prescribed by the U.S. Food and Drug Administration or a corresponding foreign entity.

**1.11 "Regulatory Approval"** shall mean (a) in the United States, approval by the FDA of an NDA or equivalent application (such as a BLA or PMA) and satisfaction of any related applicable FDA registration and notification requirements (if any); and (b) in any country other than the United States, approval by regulatory authorities having jurisdiction over such country of a single application or set of applications comparable to an NDA and satisfaction of any related applicable regulatory and notification requirements, if any, together with any other approval necessary to make and sell Products commercially in such country.

**1.12 "Sublicensee"** shall mean any Third Party (a) to whom NEWLINK or its Affiliates has granted a license or sublicense under the Licensed Patents to develop, make, have made, import, use, sell, offer for sale, or otherwise exploit a Licensed Product in the Field of Use within the Territory; or (b) to whom NEWLINK or its Affiliates has granted a right to distribute a Licensed Product in the Field of Use in the Territory pursuant to an agreement between NEWLINK and such Third Party; provided that such Third Party has the responsibility for marketing and/or promoting the Licensed Products within the territory in which such distribution rights are granted. For the avoidance of doubt, wholesalers and retailers who do not take such marketing and/or promotion responsibility shall not be Sublicensees.

**1.13 "Term"** shall have the meaning set forth in Section 8.0.

**1.14 "Territory"** shall mean worldwide.

**1.15 "Third Party(ies)"** shall mean any entity other than CIHS, HGTRI or NEWLINK.

**1.16 "Valid Claim"** shall mean either (a) a claim of an issued and unexpired patent included within the Licensed Patents which has not been held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal; or (b) a claim of a pending patent application included within the Licensed Patents, which claim has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application. Notwithstanding the foregoing, if a claim of a pending patent application has not issued as a claim of an issued patent within seven (7) years from the date from which such claim takes priority, such pending claim shall not be a Valid Claim for purposes of the Agreement, unless and until the patent is issued including such claim.

## 2. GRANT

**2.0 License Grant.** Subject to the reservation of rights set forth in Section 2.1 below, CIHS hereby grants to NEWLINK, upon the terms and conditions herein specified, an exclusive royalty-bearing license, including the right to grant sublicenses, under the Licensed Patents and Licensed Technology to develop, make, have made, use, sell, offer for sale, and import Licensed Products in the Territory and in the Field of Use only.

**2.1 Reservation of Rights.** The grant in Section 2.0 shall be subject to and non-exclusive with respect to:

(a) The right of CIHS to practice the inventions claimed in the Licensed Patents and to use the Licensed Technology for its own non-commercial bona fide research.

(b) The right of CIHS to license nonexclusively other academic or research institutions to practice the inventions claimed in the Licensed Patents and to use the Licensed Technology for non-commercial research purposes.

(c) The right of CIHS to publish any information included in the Licensed Technology and Licensed Patents provided that NEWLINK shall have the right to review such information prior to publication. CIHS shall provide NEWLINK with a copy of the proposed publication at least thirty (30) days prior to submission of such proposed publication to the publisher. NEWLINK will provide comments, if any, within thirty (30) days of receipt of such proposed publication. If NEWLINK determines that such proposed publication contains Confidential Information of NEWLINK, then NEWLINK may notify CIHS in writing, prior to the expiration of the thirty (30) day period, specifying the information that NEWLINK considers its Confidential Information, and may request that such Confidential Information be deleted from the proposed publication. If NEWLINK determines that the proposed publication contains subject matter for which intellectual property protection should be sought, then NEWLINK may so notify CIHS in writing prior to the expiration of the thirty (30) day period and CIHS shall then delay publication of such information for up to a maximum of sixty (60) days from receipt of such notice solely to enable NEWLINK to file Patent Applications or seek other forms of intellectual property protection as deemed necessary by NEWLINK.

**2.2 Government Rights.** This Agreement is subject to all terms and conditions of Title 35 United States Code Sections 200 through 204, including, without limitation, an obligation that Licensed Products sold or produced in the United States be "manufactured substantially in the United States," and NEWLINK agrees to take all reasonable action necessary on its part as licensee to enable CIHS to satisfy its obligation thereunder, relating to the Licensed Technology and the inventions claimed in the Licensed Patents.

**2.3 Due Diligence.**

(a) NEWLINK agrees to [\*], (2) obtain, at a minimum, the[\*] for NEWLINK (or its Affiliates, and its Sublicensees) to [\*] in [\*] in which [\*] are projected to provide [\*] NEWLINK, its Affiliates and Sublicensees, and (3) following receipt of the [\*] in [\*] during the Term of this Agreement. As used herein, "[\*]" shall include but is not limited to, [\*].

(i) As part of its Commercially Reasonable Efforts, NEWLINK shall deliver to CIHS, within ninety (90) days of the Effective Date, a [\*] the [\*] to [\*] the [\*] and [\*] of [\*] and [\*] and [\*] for the [\*] of [\*] of the [\*]. Every half year thereafter, on or before January 1 and June 1 of each calendar year, NEWLINK shall provide CIHS with an [\*] showing the [\*] commencing upon such half yearly date.

(ii) Within thirty (30) days after January 1 of each year, NEWLINK shall make a written annual progress report (“Progress Report”) to CIHS covering the preceding calendar year ending December 31 and detailing the progress of NEWLINK toward commercial use of the Licensed Products. Such report shall include, at a minimum, information sufficient to enable CIHS to satisfy reporting requirements of the U.S. Government and for CIHS to ascertain

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progress by NEWLINK toward meeting the diligence requirements of this Section 2.3.

(iii) The sole purpose of the [\*] and Progress Reports shall be for informational purposes and to enable the Parties to discuss in good faith NEWLINK’s compliance with its obligation to use Commercially Reasonable Efforts as set forth in this Section 2.3. The reporting obligations of NEWLINK under Sections 2.3(a)(i) and 2.3(a)(ii) shall expire upon the commencement of NEWLINK’s reporting obligations under Section 2.3(b).

(b) Commencing ninety (90) days after commercial launch of a Licensed Product in a country and within sixty (60) days after December 31 of each calendar year thereafter, NEWLINK shall provide written annual reports to CIHS which shall include but not be limited to: reports of progress on research and development, Regulatory Approvals received for Licensed Products, manufacturing, sublicensing, marketing and sales activities by NEWLINK, its Affiliates or Sublicensees during the preceding twelve (12) months, as well as, plans of such activities for the coming year. NEWLINK shall also deliver to CIHS a copy of its annual report to stockholders, promptly following the availability of such report.

(c) Without limiting the foregoing, NEWLINK shall have the specific obligation to achieve the following diligence milestones:

(i) Within [\*] after the Effective Date, either (a) NEWLINK will have expended [\*] for research and development related to the Inventions; or (b) NEWLINK will have raised [\*] in equity capital;

(ii) Within [\*] after the Effective Date, either (a) NEWLINK or its Sublicensee will have developed a Licensed Product through [\*] or (b) NEWLINK will have expended [\*] for research and development related to the Inventions; or (c) NEWLINK will have raised an aggregate of [\*] in equity capital, including the equity capital amount set forth in subsection (i) above;

(iii) Within [\*] years after the Effective Date, either (a) NEWLINK or its Sublicensee will have commenced [\*] on a Licensed Product; or (b) NEWLINK will have expended [\*] for research and development related to the Invention; or (c) NEWLINK will have raised an aggregate of [\*] in equity capital, including the equity capital amounts of subsections (i) and (ii) above;

(d) In addition, NEWLINK shall use Commercially Reasonable Efforts to negotiate appropriate sponsored research programs with researchers at CIHS in connection with the development of Licensed Products or other product opportunities in the Field of Use, as funds become available to NEWLINK for basic research. Funds provided by NEWLINK for such sponsored research programs may be used to satisfy the diligence milestones set forth in Section 2.3(c).

(e) NEWLINK shall use Commercially Reasonable Efforts to grant sublicenses for the development and commercialization of Licensed Products within the Field of Use that are not otherwise being diligently developed or commercialized by NEWLINK, its Affiliates or Sublicensees; provided however, that in no event shall NEWLINK be obligated to grant to any Third Party a sublicense if such Third Party is a [\*] or [\*], or if the grant of such sublicense would reasonably have an adverse effect on NEWLINK’s, its Affiliate’s or

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Sublicensee’s development or commercialization of Licensed Products in the field of [\*]. CIHS recognizes that NEWLINK will initially focus its development efforts on a few products of strategic importance, and agrees that NEWLINK’s Commercially Reasonable Efforts hereunder will be evaluated in view of NEWLINK’s available resources and financing stage.

#### **2.4 Failure to Meet Due Diligence Requirements.**

(a) In the event that NEWLINK fails to meet the diligence milestones of Section 2.3(c)(i), the Parties shall in good faith review for a period of thirty (30) days whether NEWLINK has materially satisfied its diligence obligations under this Agreement. If CIHS, in good faith, reasonably concludes that NEWLINK has failed in this respect, it shall so notify NEWLINK in writing and NEWLINK shall then have six (6) months to cure such failure. In the event that NEWLINK fails to meet the diligence milestones of Sections 2.3(c)(ii) or 2.3(c)(iii), the Parties shall in good faith review for a period of thirty (30) days whether NEWLINK has materially satisfied such diligence obligation under this Agreement. If CIHS, in good faith, concludes that NEWLINK has failed in this respect, it shall so notify NEWLINK in writing and NEWLINK shall then have three (3) months to cure such failure. In each case, if NEWLINK fails to cure its failure to meet the appropriate milestone within the applicable cure period, CIHS shall have the right, at its option, to either terminate, or convert to non-exclusive, the license granted under Section 2.0 of this Agreement.

(b) In addition to Section 2.4(a), if CIHS determines in its reasonable good faith judgement that NEWLINK has failed to (i) use Commercially Reasonable Efforts to develop or commercialize the Licensed Products in a particular field within the Field of Use, and/or (ii) use

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Commercially Reasonable Efforts to grant sublicenses for the development and commercialization of Licensed Products within the Field of Use that are not otherwise being diligently developed or commercialized by NEWLINK, its Affiliates or Sublicensees, pursuant to Section 2.3(e), then CIHS shall so notify NEWLINK in writing, and following such notice, the Parties shall in good faith review for a period of thirty (30) days whether NEWLINK has materially satisfied such diligence obligations. If CIHS, in good faith, reasonably concludes that NEWLINK has failed in this respect, it shall so notify NEWLINK in writing and NEWLINK shall then have six (6) months to cure such failure. If NEWLINK fails to cure such failure within the applicable cure period, CIHS shall have the right, at its option, to either terminate, or convert to non-exclusive, the license granted under Section 2.0 of this Agreement with respect to such particular field.

## 2.5 Sublicenses.

(a) **General.** The license granted to NEWLINK under Section 2.0 of this Agreement shall include the right to grant sublicenses. Any sublicenses granted by NEWLINK under this Agreement shall be subordinate to the terms and conditions of this Agreement. NEWLINK shall promptly notify CIHS of the identity and address of each Sublicensee with whom it concludes a sublicense agreement and agrees to provide to CIHS a redacted copy of each such sublicense agreement sufficient in scope to ensure compliance with the terms of this Agreement.

(b) **Assignment of Sublicenses.** Upon request by a Sublicensee, and at CIHS's discretion, a sublicense granted by NEWLINK under the Licensed Patents and Licensed Technology shall remain in effect and be assigned to CIHS in the event this Agreement terminates, but only to the extent such sublicense is consistent with the terms of this Agreement and is not in breach thereof.

## 3. ROYALTIES AND MILESTONES

3.0 **License Issue Fee.** In partial consideration of the licenses granted under Section 2.0, NEWLINK shall enter into a stock purchase agreement with the Stoddard Cancer Research Institute (a d.b.a. of CIHS) in the form attached hereto as Exhibit C (the "Stock Purchase Agreement") concurrently with the execution of this Agreement, which Stock Purchase Agreement shall be consistent with the terms set forth in subsections (a) and (b), as follows:

(a) NEWLINK shall issue, [\*] to the Stoddard Cancer Research Institute, [\*] shares of NEWLINK's common stock (the "Shares"); and

(b) In addition, the Stock Purchase Agreement shall provide that CIHS shall have the following rights with respect to such Shares:

(i) The right to [\*];

(ii) [\*];

(iii) The right to [\*] [\*] in [\*], to [\*]; and

(iv) [\*] no later than [\*] following an [\*].

3.1 **Patent Fees and Expenses.** Additionally, NEWLINK shall reimburse CIHS for

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any out-of-pocket patent fees and expenses incurred by CIHS for filing, prosecuting and maintaining the Licensed Patents [\*], subject to the following: (a) if NEWLINK fails or elects not to pay any such patent fees or expenses with respect to a patent or patent application within thirty (30) days after an invoice therefor from CIHS, NEWLINK's rights and licenses granted to NEWLINK hereunder with respect to such patent or patent application shall immediately terminate and such patent application or patent shall no longer be included in Licensed Patents; and (b) if NEWLINK disputes its obligation to pay any out-of-pocket patent fees and expenses invoiced by CIHS pursuant to Section 3.1, then the Parties shall for thirty (30) days in good faith attempt to resolve the dispute, provided that NEWLINK shall not thereby be relieved of its obligations to make timely payment of any and all undisputed amounts when due to CIHS.

3.2 **Royalties.** Subject to the terms and conditions of this Agreement, commencing on the Effective Date of this Agreement, NEWLINK shall pay CIHS royalties on Net Sales of Licensed Products by NEWLINK, its Affiliates and Sublicensees on a country-by-country and Licensed Product-by-Licensed Product basis as follows:

(a) In countries where the manufacture, use, sale, offer for sale, or import of Licensed Products would, but for the grant of the license under the Agreement, infringe a Valid Claim of the Licensed Patents, NEWLINK shall pay to CIHS a royalty on Net Sales of Licensed Products in such countries at a rate equal to [\*] of annual Net Sales of Licensed Products. In the event that the manufacture, sale or use of any Licensed Product is not covered by a Valid Claim within the Licensed Patents in a country, then NEWLINK shall pay to CIHS a royalty with respect to Net Sales in such country of such Licensed Products by NEWLINK, its Affiliates and Sublicensees at a rate equal to [\*].

(b) The royalty obligations of NEWLINK shall expire on a country-by-country and Licensed Product-by-Licensed Product basis upon the later of (i) the expiration of the last to expire Valid Claim within the Licensed Patents covering the Licensed Product in a country (such expiration to occur only after expiration of extensions of any nature to such patents which may be obtained under applicable statutes or regulations in the respective countries of the Territory, such as the Drug Price Competition and Patent Term Restoration Act of 1984 in the U.S.A., and similar patent extension laws in other countries), or (ii) until [\*] following the first commercial sale of a Licensed Product in a country. Following expiration of the royalty obligations for each Licensed Product in each country, NEWLINK shall retain a fully-paid, [\*] license under the Licensed Technology to make, have made, use, sell, offer for sale, and import such Licensed Products in such country.

(c) **Combination Products.** Sales of any products that contain one or more Licensed Products and one or more Active Component(s) that is not a Licensed Product ("Combination Product") shall be determined as follows. Net Sales shall first be calculated in accordance with the definition of Net Sales set forth in Section 1.10, and then multiplied by the fraction, A/A + B, where A is the invoiced sales price charged for the Licensed Products included in such Combination Product and B is the invoiced sales price charged for the other Active Component(s) included in the Combination Product. If there are no separate sales of such Active Component(s), Net Sales of the Combination Product shall first be determined in accordance with the



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Product nor the other Active Component(s) included in such Combination Product are sold separately, then Net Sales of the Combination Product shall be first determined in accordance with the definition of Net Sales set forth in Section 1.10, as adjusted by a mechanism to be agreed upon by the Parties in good faith based upon the respective fair market values of such Licensed Product and such Active Component(s). The cost in each case shall be determined in accordance with generally accepted accounting principles of the United States.

(d) Notwithstanding the foregoing, in no event shall the royalties owed to CIHS on a given Licensed Product under Section 3.2(a) be less than [\*] of Net Sales (as defined in Section 1.10) in the case of Licensed Products covered by a Valid Claim, or less than [\*] of Net Sales (as defined in Section 1.10) in the case of Licensed Products not covered by a Valid Claim.

**3.3 Minimum Royalties.** Following the First Commercial Launch of Licensed Product, NEWLINK shall pay to CIHS a minimum annual royalty as follows: Prior to December 31 of the calendar year in which the first Licensed Product is Commercially Launched, NEWLINK shall pay to CIHS [\*] (“Initial Payment”). A second payment of [\*] shall be due on the first anniversary of the Initial Payment. Prior to each of the second and third anniversaries of the Initial Payment, NEWLINK shall pay CIHS [\*], and prior to the fourth and fifth anniversaries of the Initial Payment, NEWLINK shall pay CIHS [\*]. Any royalties resulting from Net Sales of Licensed Products in a given year may be credited against the minimum royalty due for that year. For purposes of this Section 3.3, “First Commercial Launch” or “Commercially Launched” shall mean, with respect to each Licensed Product in each country, the first bona fide commercial sale of a Licensed Product in a country by or under authority of NewLink, its Affiliates or Sublicensees, including without limitation, any offer for sale or sale made by NewLink, its Affiliates or Sublicensees to a Third Party pursuant to a written agreement.

**3.4 Sublicensing Fee.** In addition to the amounts owed by NewLink to CIHS pursuant to Section 3.0, 3.1, 3.2, and 3.3 above, if NEWLINK grants a sublicense of its rights hereunder to a Third Party, NEWLINK agrees to pay to CIHS a sublicensing fee of [\*] of any [\*] and other consideration (other than [\*] or [\*] on [\*], and [\*] within [\*] of [\*]) (collectively, the “Sublicensing Fee”) received by NEWLINK from each Sublicensee in consideration for the grant of a sublicense of the Licensed Patents or development of a Licensed Product.

**3.5 Third Party Royalties.** NEWLINK shall be responsible for all Third Party payments and/or licenses of Third Party technology necessary to practice the Licensed Patents and Licensed Technology to make, use or sell Licensed Products (“Necessary Rights”). In the event that NEWLINK pays royalties to Third Parties pursuant to a written agreement under which it obtains Necessary Rights for a particular Licensed Product in a particular country(ies) (each a “Third Party Agreement”), NEWLINK may offset, on a Licensed Product-by-Licensed Product and country-by-country basis, up to [\*] of the royalties due under such Third Party Agreements against royalties which are due CIHS hereunder for such Licensed Product in such country(ies), in each case, in such calendar year. Notwithstanding the foregoing, the royalty due to CIHS as set forth in Section 3.2 in each calendar quarter for any Licensed Product shall not be reduced to less than [\*] of that (or, i.e., [\*] of Net Sales for Licensed Products covered by a Valid Claim in such country, and [\*] of Net Sales for Licensed Products not covered by a Valid Claim in such country).

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### 3.6 Schedule and Form of Payment/Taxes.

(a) Following the first commercial sale of a Licensed Product, NEWLINK shall make quarterly written reports to CIHS within thirty (30) days after the end of each calendar quarter, stating in each such report the aggregate Net Sales of Products sold by NEWLINK, its Affiliates and Sublicensees during the calendar quarter. Simultaneously with the delivery of each such report, NEWLINK shall pay to CIHS the total royalties, if any, due to CIHS for the period of such report. If no royalties are due, NEWLINK shall so report. Neither Party shall provide to Third Parties any information contained in reports provided to such Party pursuant to this Section 3.6, except as required by a Party’s agreements with its licensors.

(b) All amounts payable to CIHS hereunder shall be payable in United States dollars. All amounts payable to CIHS hereunder shall be payable in United States dollars in Iowa, or at such other place as CIHS may reasonably designate, provided, however, that if the law of any foreign country prevents any payment payable to CIHS hereunder to be made in Iowa, or otherwise designated by CIHS or prevents any such payment to be made in United States dollars, CIHS agrees to accept such royalty in form and place as permitted, including deposits by NEWLINK in the applicable foreign currency in a local bank or banks in such country designated by NEWLINK. If any currency conversion is required in connection with any payments to CIHS hereunder, such conversion shall be made at the buying rate for the transfer of such other currency as quoted by CITICORP BANK (NEW YORK) on the last business day of the applicable accounting period, in the case of any payment payable with respect to a specified accounting period, or in the case of any other payment, the last business day prior to the date of such payment. All such payments shall be paid in United States dollars, originated from a United States bank located in the United States and made by bank wire transfer in immediately available funds to such account as the receiving party shall designate.

(c) Where required to do so by applicable law or treaty, NEWLINK shall withhold taxes required to be paid to a taxing authority on account of such income to CIHS, and NEWLINK shall furnish CIHS with satisfactory evidence of such withholding and payment in order to permit CIHS to obtain a tax credit or other relief as may be available under the applicable law or treaty.

(d) Any amounts payable to CIHS hereunder that are not paid on the date such payments are due under this Agreement shall accrue interest from the due date until paid, at a rate equal to [\*] per month (or the maximum allowed by law, if less). Said

**3.7 Records.** NEWLINK shall maintain complete and accurate records showing gross sales, deductions and other relevant information sufficient to enable accurate calculation of royalties on a country-by-country and Licensed Product-by-Licensed Product basis and other fees payable hereunder by NEWLINK to CIHS. NEWLINK shall, at CIHS's request and expense, provide certified statements from NEWLINK's auditors, concerning royalties and other fees due pursuant to this Agreement. Once a calendar year, CIHS shall have the right to select a certified public accountant to inspect, on reasonable notice and during regular business hours, the records of NEWLINK to verify NEWLINK's statements and royalty payments due pursuant to this Agreement. Inspections conducted under this Section 3.7 shall be at CIHS's expense, provided, if such an audit correctly uncovers a deficiency in payment of royalties payable by NEWLINK hereunder, NEWLINK shall immediately pay to CIHS such deficient amount, and if the amount of any such deficiency is greater than five percent (5%) of the total amount due during the audited period, NEWLINK shall bear the reasonable out of pocket expenses of such accounting firm to conduct such audit. Records shall be preserved by NEWLINK for five (5) years for inspection by CIHS.

#### **4. PROSECUTION AND MAINTENANCE OF LICENSED PATENTS**

**4.0 Prosecution.** CIHS shall, using patent counsel of its choice, have the initial right to control the preparing, filing, prosecuting and maintaining patent applications and patents within the Licensed Patents. CIHS shall provide NEWLINK a reasonable opportunity to review and comment upon all such filings prior to their submission to patent authorities. If CIHS elects not to pursue any patent application or patent within the Licensed Patents, CIHS shall notify NEWLINK reasonably in advance of any filing deadline or material date and NEWLINK shall have the right, but not the obligation, to assume control of the preparation, filing, protection and maintenance of such patent or patent application, at its expense.

**4.1 Payment of Costs.** NEWLINK shall pay all costs incurred in connection with preparing, filing, prosecuting and maintaining patent applications and patents within the Licensed Patents that accrue on or after January 1, 2000. In the event that NEWLINK decides not to continue to pay costs related to a particular patent/patent application within the Licensed Patents in a particular country, NEWLINK shall timely notify CIHS in writing thereof, and concurrent with such notice, NEWLINK's rights under this Agreement to practice the inventions under such patent/patent application within the Licensed Patents in such country shall immediately terminate.

#### **4.2 Patent Enforcement.**

**(a)** Each Party shall notify the other Party in writing of any alleged or threatened infringement of Licensed Patents of which it becomes aware and which may adversely impact the rights of the Parties hereunder.

**(b)** NEWLINK shall have the first right, but not the obligation, to prosecute any infringement of the Licensed Patents or defend any declaratory judgment with respect to the

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Licensed Patents. If NEWLINK elects to commence an action described above, CIHS may, to the extent permitted by law, elect to join as a party to the action. Any recovery obtained in such an action shall be used first to reimburse costs of NEWLINK, then CIHS, in prosecuting such action (including reasonable attorney's fees). Any remainder of the recovery shall be distributed as follows: [\*]. CIHS shall have the right, but not the obligation, to prosecute any such infringement of the Licensed Patents if NEWLINK does not elect to do so within one hundred eighty (180) days after the Parties become aware of allegedly infringing activities. Any recovery obtained in such an action brought by CIHS under the preceding sentence shall be used first to reimburse costs of CIHS, then NEWLINK, in prosecuting such action (including reasonable attorney's fees). Any remainder of the recovery shall be distributed as follows: [\*].

**4.3 Control of Third Party Enforcement Actions.** During the term of this Agreement, either Party that brings an action to enforce the Licensed Patent shall prosecute such action, at its own expense, utilizing counsel of its choice, subject to reimbursement of costs pursuant to Section 4.2(b). No settlement, consent judgment or other voluntary final disposition of any such suit may be entered into without the written consent of the other Party, which consent shall not unreasonably be withheld.

**4.4 Cooperation.** In any suit to enforce and/or defend the Licensed Patent pursuant to this Agreement, the Party not in control of such suit shall, at the request and expense of the controlling Party, cooperate in all respects and, to the extent reasonably possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like. Any out-of-pocket costs incurred by the Party not in control of such suit shall be promptly reimbursed by the Party controlling such suit, subject to reimbursement pursuant to Section 4.2(b).

**4.5 Activities for Licensed Products Infringing Rights of Third Parties.** Each Party shall promptly notify the other if any legal proceedings are commenced or threatened against either Party alleging that the manufacture, use, sale or possession of the Licensed Product infringes a Third Party's patent or other intellectual property rights. In such event, the Parties shall meet to discuss the course of action to be taken with respect to an enforcement action with respect to such infringement or misappropriation.

#### **5. MARKINGS**

**5.1 Product Markings.** NEWLINK shall mark all Licensed Products (or their containers or labels) made, sold, or otherwise disposed of by NEWLINK, its Affiliates or Sublicensees, under the license granted in this Agreement, in accordance with all applicable United States and foreign statutes pertaining to the marking of products with patent pending, patent number(s), copyrights, or other intellectual property notices and legends required to maintain the intellectual property rights licensed in this Agreement.

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#### **6. CONFIDENTIALITY**

**6.0 Confidential Information.** Except as expressly provided herein, the Parties agree that, for the term of this Agreement and for five (5) years thereafter, the receiving Party shall not publish or otherwise disclose and shall not use for any purpose any Confidential Information furnished to it by the other Party hereto pursuant to this Agreement. For purposes of this Agreement, "Confidential Information" shall mean all nonpublic technical and/or business information (whether patentable or copyrightable), including without limitation, inventions, unpublished and draft patent applications and any

information contained therein, formulae, trade secrets, processes, laboratory notebooks, reports, technical data and technology, that is owned or possessed by the disclosing Party and furnished or otherwise made available to the receiving Party either (a) between January 1, 1999 and the Effective Date (“Pre-Agreement Period”) or (b) after the Effective Date, provided that such information is either (i) disclosed in writing and marked “Confidential,” or in a similar manner, to indicate its confidential nature, or (ii) if disclosed orally, is confirmed in writing as confidential within forty-five (45) days following such disclosure. Notwithstanding the foregoing, the Parties understand and agree that the marking and reduction to writing requirements of subsections (i) and (ii) above shall not apply to Confidential Information disclosed during the Pre-Agreement Period.

**6.1 Confidential Information Exclusions.** Notwithstanding the provisions of Section 6.0, the obligation of confidentiality shall not apply to information that the receiving Party can demonstrate:

- (a) is now in the public domain or which becomes generally available to the public through no fault of the receiving Party; or
- (b) is already known to, or in the possession of, the receiving Party prior to disclosure by the disclosing party as can be demonstrated by documentary evidence; or
- (c) is disclosed on a non-confidential basis from a Third Party having the right to make such a disclosure; or
- (d) is independently developed by the receiving Party (without the use of any Confidential Information) as can be demonstrated by competent documentary evidence.

**6.2 Permitted Usage.** Notwithstanding the provisions of Section 6.0 above, the receiving Party may use or disclose Confidential Information of the disclosing Party to the extent necessary to exercise the rights granted to it hereunder (provided it uses reasonable efforts to protect such information commensurate with the efforts used to protect its own information) in prosecuting or defending litigation, complying with applicable governmental regulations and/or submitting information to tax or other governmental authorities; provided that if the receiving Party is required by law to make any public disclosures of Confidential Information of the disclosing Party, to the extent it may legally do so, it will give reasonable advance notice to the disclosing Party of such disclosure and will use its reasonable efforts to secure confidential treatment of Confidential Information prior to its disclosure (whether through protective orders or otherwise).

## 7. WARRANTIES AND INDEMNITIES

### 7.0 Representations and Warranties.

(a) NEWLINK hereby represents and warrants that (i) it has the authority and right to enter into and perform this Agreement, and has taken all necessary corporate or other action and obtained all necessary approvals to do so, and (ii) its execution, delivery and performance of this Agreement does not and will not conflict with any other agreement to which it is or becomes a party or by which it is or becomes bound.

(b) CIHS hereby represents and warrants that to the best of its knowledge as of the Effective Date, all rights, interest, and title in and to the Invention has been properly assigned by all inventors thereof to HGTRI.

**7.1** CIHS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT USE OF A LICENSED PRODUCT OR A PRODUCT MADE USING A LICENSED PROCESS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OF THIRD PARTIES.

### 7.2 Indemnities.

(a) NEWLINK agrees to indemnify, hold harmless and defend CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents from and against all losses, liabilities, damages, costs and expenses (including without limitation, reasonable attorney’s fees and other expenses of litigation) (“Liabilities”) arising from any claims, demands, actions or other proceedings (“Claims”) by any and all Third Parties for [\*] arising out of (i) [\*], under this Agreement and (ii) [\*]; provided however, that NEWLINK shall not be obligated to indemnify, hold harmless and defend CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents from and against any Liabilities arising from any Claims arising out of the [\*] of CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents.

(b) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, WHATSOEVER, WHETHER GROUNDED IN TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, CONTRACT OR OTHERWISE. CIHS SHALL NOT HAVE [\*] WITH RESPECT TO LICENSED PRODUCT(S).

(c) NEWLINK shall at all times comply, through insurance or self-insurance, with all statutory workers’ compensation and employers’ liability requirements covering any and all employees with respect to activities performed under this Agreement.

**7.3 Insurance.** In addition to the foregoing, NEWLINK shall maintain during the term of this Agreement, Comprehensive General Liability Insurance, including Products Liability Insurance, with reputable and financially secure insurance carrier(s) to cover the indemnity granted in Section 7.2. NEWLINK shall maintain an insurance policy that provides minimum limits of liability as follows: beginning on the Effective Date to the commencement of the first clinical trial of any Licensed Product, the minimum limit shall be two million dollars (\$2,000,000); beginning on the commencement of the first clinical trial of any Licensed Product to the commencement of the first Phase III clinical trial of any Licensed Product, the minimum limit shall increase to ten million dollars (\$10,000,000); and beginning on the first Phase III clinical trial of any Licensed Product to the termination or expiration of this Agreement, the minimum limit shall increase to twenty million dollars (\$20,000,000). Such insurance shall include CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents as additional insureds. Such insurance shall be written to cover claims incurred, discovered, manifested, or made during or

after the expiration of this Agreement and should be placed with carriers with ratings of at least A- as rated by A.M. Best. Within fifteen (15) days of the Effective Date of this Agreement, NEWLINK shall furnish a Certificate of Insurance evidencing primary coverage and additional insured requirements and requiring thirty (30) days prior notice of cancellation or material change to CIHS. NEWLINK shall advise CIHS, in writing, that it maintains excess liability coverage (following form) over primary insurance for at least the minimum limit set forth above. All such insurance of NEWLINK shall be primary coverage.

## 8. TERM AND TERMINATION

**8.0 Term.** Unless previously terminated as herein provided, the term of this Agreement shall commence upon the Effective Date and expire on the date when NEWLINK has no further royalty obligations hereunder.

### 8.1 Termination.

(a) This Agreement may be terminated prior to its expiration under Section 8.0 under the following circumstances:

(i) If a Party commits material breach of this Agreement, the non-breaching Party at its option, may terminate this Agreement by giving the breaching Party written notice of its election to terminate as of a stated date, not less than forty-five (45) days from the date of the notice. Such notice shall state the nature of the defaults claimed by the non-breaching Party. The breaching Party may, during such forty-five (45) day period, or such longer period as may be specified in such notice, correct any default stated in such notice and if such default is corrected, this Agreement shall continue in full force and effect as if such notice had not been given.

(ii) This Agreement may be terminated by NEWLINK, at will, at any time upon not less than sixty (60) days prior written notice to CIHS.

(b) NEWLINK may terminate its license with respect to a specific patent or patent application within the Licensed Patents, at will, at any time upon not less than ninety (90) days prior written notice to CIHS. In such event, the specified patent application or patent shall no

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longer be a Licensed Patent and NEWLINK shall retain an exclusive license to the remaining patents and patent applications within the Licensed Patents.

### 8.2 Effect of Termination.

(a) **Accrued Obligations.** Termination of this Agreement for any reason shall not release either Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

(b) **Termination of Agreement.** In the event of any early termination of this Agreement, whether by CIHS pursuant to Section 2.4(a) due to NEWLINK's failure to meet one or more of its diligence obligations, or by CIHS pursuant to Section 8.1(a)(i) due to NEWLINK's material breach, or by NEWLINK pursuant to Section 8.1(a)(ii), in each case:

(i) NEWLINK, its Affiliates and Sublicensees shall immediately cease all development and commercialization of Licensed Products, and all practice or use of the Licensed Patents and Licensed Technology; provided, however, that NEWLINK, its Affiliates, Sublicensees and distributors shall have the right to sell or otherwise distribute Licensed Products in their inventories or otherwise in their control as of such termination of this Agreement for a period not to exceed three (3) months from such termination.

(ii) NEWLINK shall return, or destroy, at CIHS's option, all Confidential Information of CIHS, including any copies of any Licensed Technology.

(c) **Termination of a patent within the Licensed Patents.** In the event of any early termination of NEWLINK's license to a particular patent and/or patent application within the Licensed Patents, whether by NEWLINK pursuant to Section 8.1(b), or by CIHS pursuant to Section 4.1, in each case:

(i) NEWLINK, its Affiliates and Sublicensees shall immediately cease all development and commercialization of Licensed Products relating to such patent or patent application, and all practice or use of such patent or patent application; provided, however, that NEWLINK, its Affiliates, Sublicensees and distributors shall have the right to sell or otherwise distribute Licensed Products relating to such patent or patent application that is in their inventories or otherwise in their control as of such termination of this Agreement for a period not to exceed three (3) months from such termination.

(ii) NEWLINK shall return, or destroy, at CIHS's option, all Confidential Information of CIHS, including any copies of any Licensed Technology relating to such patent or patent application, unless such Confidential Information or Licensed Technology also relates to patents or patent applications with respect to which NEWLINK still retains a license under this Agreement.

(d) **Termination of a field within the Field.** In the event of any termination of NEWLINK's license to a particular field within the Field, by CIHS pursuant to Section 2.4(b):

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(i) NEWLINK, its Affiliates and Sublicensees shall immediately cease all development and commercialization of Licensed Products in such field, and all practice or use of Licensed Patents and Licensed Technology in such field; provided, however, that NEWLINK, its Affiliates, Sublicensees and distributors shall have the right to sell or otherwise distribute Licensed Products in such field that is in their inventories or otherwise in their control as of such termination of this Agreement for a period not to exceed three (3) months from such termination.

(ii) NEWLINK shall return, or destroy, at CIHS's option, all Confidential Information of CIHS, including any copies of any Licensed Technology relating to field, unless such Confidential Information or Licensed Technology also relates to Licensed Patents, Licensed Technology or Licensed Products in a field with respect to which NEWLINK retains a license under this Agreement.

**8.3 Survival.** Articles 1, 5, 6, and 9, and Sections 2.5(b), 3.2-3.7, 4.5, 7.1, 7.2, 8.2 and 8.3 of this Agreement shall survive expiration or termination of this Agreement.

## 9. MISCELLANEOUS

**9.0 Notices.** All notices, requests and other communications hereunder shall be in writing and shall be personally delivered, sent by courier, sent by registered or certified mail, return receipt requested, postage prepaid, or sent via facsimile in each case to the respective address specified below, or such other address as may be specified in writing to the other Party hereto:

CIHS:	Central Iowa Health System 1200 Pleasant Street Des Moines, Iowa 50309 Attn: President Fax: 515-241-5994
with copies to:	Wilson Sonsini Goodrich & Rosati Professional Corporation 650 Page Mill Road Palo Alto, California 94304-1050 Attn: Kenneth A. Clark, Esq. Fax: (650) 493-6811
	Iowa Health System 1200 Pleasant Street Des Moines, Iowa 50309 Attn: General Counsel Fax: 515-241-4656
NEWLINK:	NEWLINK Genetics Corporation 2901 S. Loop Drive Ames, Iowa 50010 Attn: Chairman

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Fax: 515-296-5557

with a copy to:	Cooley Godward, L.L.P. 380 Interlocken Crescent Suite 900 Broomfield, CO 80021-8023 Attn: James C. Linfield, Esq. Fax: (650) 493-6811
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Any such notice mailed by registered or certified mail or air express shall be deemed to have been given when mailed, as evidenced by the date on the receipt retained by the sender. Either Party may change the address to which notices to it are to be given by notice as provided herein.

**9.1 Force Majeure.** Neither Party to this Agreement shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of God, fires, earthquakes, strikes and labor disputes, acts of war, civil unrest, or intervention of any governmental authority, provided that the affected Party shall use reasonable efforts to remedy any such delay or failure.

**9.2 Assignments.** Except as provided in this Section 9.2, this Agreement may not be assigned by NEWLINK without the written prior consent of CIHS, which consent shall not be unreasonably withheld, provided that NEWLINK may assign this Agreement without CIHS' prior consent to an Affiliate or in connection with the sale or transfer of all or substantially all the assets of NEWLINK relating to the Agreement. CIHS may assign this Agreement at its discretion.

**9.3 Injunctive Relief.** The Parties acknowledges that the terms hereunder are necessary and reasonable to protect the Parties, and expressly agree that monetary damages may not be a sufficient remedy for any breach of this Agreement, and therefore the breaching Party will not oppose the non-breaching Party's requests for injunctive relief as a remedy for any such breach. In addition, the Parties agrees that they shall be entitled to seek temporary and permanent injunctive relief against any threatened violation of the terms of this Agreement or the continuation of any such violation in any court of competent jurisdiction, without the necessity of proving actual damages or the posting of any bond. For avoidance of doubt, any such equitable remedies shall be cumulative and not exclusive and are in addition to any other remedies, which either Party may have under this Agreement or applicable law.

**9.4 Severability.** In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall remain in full force and effect without said provision. In such event, the parties shall in good faith negotiate an amendment providing a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement.



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Inventions and know how

1. [\*]

2. [\*]

3. [\*]

4. [\*]

5. [\*]

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**EXHIBIT "C"**

Stock Purchase Agreement with the Stoddard Cancer Research Institute

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**NEWLINK GENETICS CORPORATION**

**STOCK PURCHASE AGREEMENT**

This Stock Purchase Agreement (the "Agreement") is made this 2<sup>nd</sup> day of August, 2001, between Newlink Genetics Corporation, a Delaware corporation (the "Company"), and Stoddard Cancer Research Institute, a d.b.a. of Central Iowa Health System, an Iowa non-profit corporation, (the "Purchaser").

1. Sale of Stock. The Company hereby agrees to sell to the Purchaser and the Purchaser hereby agrees to purchase an aggregate of [\*] shares of the Company's Common Stock (the "Shares").

2. Payment of Purchase Price. The purchase price for the Shares shall be deemed paid by Purchaser's grant of licenses to the Company pursuant to Section 2.0 of the License Agreement dated August 2, 2001 between Purchaser and the Company.

3. Representations and Warranties of the Company. The Company represents and warrants to the Purchaser as follows:

(a) Organization and Standing. The Company is a corporation duly organized and validly existing under, and by virtue of, the laws of the State of Delaware and is in good standing under such laws. The Company has requisite corporate power and authority to own and operate its properties and assets, and to carry on its business as presently conducted. The Company is duly qualified to do business as a foreign corporation in each jurisdiction in which the failure to be so qualified will have a material adverse affect on the Company's business.

(b) Corporate Power; Authorization. The Company has all requisite legal and corporate power and authority to execute and deliver this Agreement and to issue the Common Stock sold under this Agreement. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization, execution, delivery and performance of this Agreement and the performance of all of the Company's obligations under this Agreement has been taken. The Shares, when issued in compliance with the provisions of this Agreement will be validly issued, fully paid and nonassessable.

(c) Capitalization. The authorized capital stock of the Company consists or will, upon the execution of the Agreement, consist of 12,000,000 shares of Common Stock and 3,000,000 shares of Preferred Stock, 1,600,000 of which is designated Series A Preferred Stock. Immediately prior to the execution of this Agreement, 5,198,200 shares of Common Stock and 420,000 shares of Series A Preferred Stock will be issued and outstanding. No other shares of capital stock will be outstanding. All of the issued and outstanding shares of Common Stock and Series A Preferred Stock are duly authorized, validly issued, fully paid and nonassessable, and were issued in compliance with applicable federal and state securities laws. Except for (i) the conversion privileges of the Series A Preferred Stock, (ii) 188,000 shares of Common Stock subject to issued options issued under the Company's 2000 Equity Incentive Plan, and (iii) 1,500,000 shares of Common Stock reserved for future issuance pursuant to the Company's Equity Incentive Plan and (iv) the rights provided in the Company's Investors' Rights Agreement, there are no other outstanding shares of capital stock or outstanding rights of first refusal, preemptive rights or other rights, options, warrants, conversion rights, or other

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agreements either directly or indirectly for the purchase or acquisition from the Company of any shares of its capital stock.

4. Representations and Warranties of the Purchaser. Purchaser represents and warrants to the Company as follows:

(a) Restricted Securities. Purchaser is aware that the Shares to be issued to Purchaser by the Company pursuant to this Agreement have not been registered under the Securities Act of 1933, as amended (the "Act"), and that the Shares are deemed to constitute "restricted securities" under Rule 144 promulgated under the Act.

(b) Accredited Investor. Purchaser is an accredited investor within the meaning of Regulation D prescribed by the Securities and Exchange Commission pursuant to the Act.

(c) Investment Experience. By virtue of such Purchaser's experience in evaluating and investing in private placement transactions of securities in companies similar to the Company, Purchaser has sufficient knowledge and experience in business and financial matters to evaluate the Company, its proposed activities and is capable of evaluating the merits and risks of such Purchaser's investment in the Company, Purchaser has the capacity to protect such Purchaser's own interests in connection with the purchase of the Shares by virtue of the business or financial expertise of any professional advisors to Purchaser who are unaffiliated with and who are not compensated by the Company or any of its affiliates, directly or indirectly. Purchaser has the ability to accept the high risk and lack of liquidity inherent in this type of investment.

(d) Investment Intent. Purchaser is acquiring the Securities for investment for such Purchaser's own account and not with a view to, or for resale in connection with, any distribution thereof. Purchaser understands that the Securities have not been registered under the Act by reason of a specific exemption from the registration provisions of the Act that depends upon, among other things, the bona fide nature of the investment intent as expressed herein.

(e) Rule 144. Purchaser understands that the exemption from registration under Rule 144 will not be available for at least two years from the date of receipt of the Shares unless at least one year from the date of receipt (i) a public trading market then exists for the Common Stock of the Company, (ii) adequate information concerning the Company is then available to the public, and (iii) other terms and conditions of Rule 144 are complied with; and that any sale of the Shares may be made only in limited amounts in accordance with such terms and conditions and that after ninety days after the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Shares may be resold by persons other than affiliates in reliance on Rule 144 without compliance with paragraphs (c), (d), (e) and (h) thereof, and by affiliates without compliance with paragraph (d) thereof.

(f) Knowledge of Company, Company Information. Purchaser is familiar with the Company, the nature of its business, its financial prospects and the merits and risks of an investment in the Company, and has the capacity to protect its own interests. Purchaser has had an opportunity to discuss the Company's business, management and financial affairs with directors, officers and management of the Company. Purchaser has also had the opportunity to ask questions of, and receive answers from, the Company and its management regarding the terms and conditions of this investment.

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(g) Additional Capital. Purchaser understands that the Company may need to raise additional financing to support expansion, develop new or enhanced applications and services, respond to competitive pressures, acquire complementary business or technologies or take advantage of unanticipated opportunities. Purchaser understands that the Company may need to raise additional funds by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Purchaser understands that such financing may be dilutive to existing stockholders.

5. [\*].



(a) [\*] The Company hereby [\*], on the terms set forth in this Section 5, [\*] to [\*] or [\*] of [\*] of the [\*] which the [\*] to [\*] to [\*] and [\*]. The Purchaser may [\*] on the [\*] and [\*] the [\*] to [\*]. For the purposes of [\*] of the [\*] is a [\*] the [\*] is the [\*] of [\*] and the [\*] is the [\*] of the [\*] of [\*] of or [\*] of, as the case may be, [\*] or [\*] to the [\*] of the [\*].

(b) [\*] of the [\*] or [\*] and [\*] or [\*] to [\*] and [\*] of [\*] or [\*] into [\*] that [\*] does [\*] to a [\*] or [\*] or [\*] to [\*] or [\*] of the [\*] to [\*] or [\*] by the [\*] of the [\*] to [\*] to [\*] by the [\*] of the [\*] or [\*] or [\*] or [\*] from [\*] or [\*] or [\*] by the [\*] of the [\*] of [\*] in [\*] with [\*] or [\*] by the [\*] and [\*] the [\*] and other [\*] or [\*] or [\*] or [\*].

(c) [\*] In the event [\*] to [\*] of [\*], it [\*] to the [\*] of its [\*] the [\*] of [\*] the [\*] the [\*] to [\*] the [\*] the [\*] of the [\*] and [\*] to the [\*] of [\*] of [\*] to [\*]. The [\*] from the [\*] of the [\*] to [\*] of [\*] of the [\*] for the [\*] and [\*] the [\*] in the [\*] to the [\*] the [\*] of [\*] to be [\*] and [\*] for [\*] to the [\*] if [\*] or in [\*] the [\*] of the [\*] in the [\*]

(d) [\*] The [\*] be [\*] the [\*] to [\*] any [\*] or [\*] of [\*] to any [\*] or [\*] or [\*] of the [\*].

(e) [\*] The [\*] under this Section 5 [\*] the [\*] of the [\*] to [\*] by the [\*]

6. [\*]

(a) [\*] If the [\*] to [\*] of [\*] for [\*] or [\*] of [\*] other [\*] to [\*] or [\*] to [\*] to [\*] or [\*] on [\*] or [\*] the [\*] to be [\*] the [\*] of the [\*] the [\*] the [\*] and [\*] and [\*] the [\*] of [\*] in [\*] the [\*] of [\*] the [\*] in [\*].

(b) [\*] If the [\*] for [\*] the [\*] is for [\*] the [\*] to [\*] be [\*] the [\*] in [\*] and the [\*] of [\*] in the [\*] to [\*] in [\*] with the [\*] or [\*] by the [\*]. Notwithstanding any other provision of this Section, if the [\*] that [\*] on the [\*] of [\*] to be [\*] and [\*] may [\*] of the [\*] with the [\*] that may be [\*] in the [\*] and [\*] the [\*] and all other [\*] to have [\*] in [\*] in [\*] as nearly as [\*], to the [\*] of [\*] which they [\*] to be [\*] in [\*].

(c) [\*] of the [\*] of [\*] for the [\*] shall be [\*] by the [\*] to the [\*] of [\*] and [\*] of the [\*] in the [\*] by [\*] which [\*] by the [\*] and [\*] on the [\*] of the [\*].

(d) [\*] The [\*] under this Section 6 [\*] to a [\*] of [\*] to [\*] or [\*]. ‘

(e) [\*] The [\*] under this Section 6 [\*] as to the [\*] or a [\*] when [\*] is [\*] under this Agreement [\*] in [\*]

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7. Financial Information. The Company will provide the Purchaser with reports and provide access for Purchaser as set forth below.

(a) As soon as practicable after the end of each fiscal year, and in any event within one hundred twenty (120) days thereafter, consolidated balance sheets of the Company and its subsidiaries, if any, as of the end of such fiscal year, and unaudited consolidated statements of income and consolidated statements of changes in financial position of the Company and its subsidiaries, if any, for such year, prepared in accordance with generally accepted accounting principles and setting forth in each case in comparative form the figures for the previous fiscal year (or, at the election of the Company, setting forth in comparative form the budgeted figures for the fiscal year then reported), all in reasonable detail.

(b) As soon as practicable after the end of each quarter, and in any event within sixty (60) days after each quarterly accounting period, an unaudited quarterly report including a balance sheet, profit and loss statement and cash flow analysis (prepared in accordance with generally accepted accounting principles other than for accompanying notes and subject to changes resulting from year-end audit adjustments).

(c) The Company shall permit each Purchaser, at such Purchaser's expense, to visit and inspect the Company's properties, to examine its books of account and records and to discuss the Company's affairs, finances and accounts with its officers, all at such reasonable times as may be requested by the Investor.

(d) Anything in Section 7(c) to the contrary notwithstanding, the Purchaser or transferee of the Purchaser by reason of this Agreement shall not have access to any trade secrets or classified information of the Company. The Purchaser hereby agrees to hold in confidence and trust and not to misuse or disclose any confidential information provided pursuant to Section 7(c) and any transferee of must agree, in writing, to the same. The Company shall not be required to comply with this Section 7(c) in respect of the Purchaser or transferee of the Purchaser whom the Company reasonably determines to be a competitor or an officer, employee, director or greater than 5% shareholder of a competitor or to the extent compliance would result in disclosure of trade secrets.

(e) Termination of Covenants. The covenants set forth in this Section 7 shall terminate and be of no further force or effect upon the closing of the Company's initial underwritten public offering pursuant to an effective registration statement filed by the Company under the Act.

8. Legends. The share certificate evidencing the Shares issued hereunder shall be endorsed with the following legends (in addition to any legend required under applicable state securities laws):

(a) THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISPOSITION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL SATISFACTORY

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TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.

(b) THE SHARES OF STOCK REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS PURSUANT TO THE COMPANY'S BYLAWS. SUCH BYLAW, AMONG OTHER THINGS, RESTRICTS CERTAIN RIGHTS WITH RESPECT TO THE SALE AND TRANSFER OF THE SHARES AND OTHERWISE ENCUMBERS THE SHARES REPRESENTED HEREBY. COPIES OF THE BYLAWS MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE COMPANY.

(c) Any legend required to be placed thereon by the Delaware Commissioner of Corporations or any other applicable state securities laws.

9. Restrictions on Transfer.

(a) Without in any way limiting the foregoing, Purchaser further agrees that Purchaser shall in no event make any disposition of all or any portion of the Shares which Purchaser is being issued unless and until: (i) there is then in effect a registration statement under the Act covering such proposed disposition and such disposition is made in accordance with said registration statement; or (ii) (A) The transferee has agreed in writing to be bound by the terms of this Agreement, (B) Purchaser shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and (C) if reasonably requested by the Company, Purchaser shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration of the Shares under the Act. In addition, Purchaser agrees that any such disposition shall be made in accordance with the provisions of the Company's Bylaws, provided however that the Company hereby waives any right of first refusal pursuant to Article XIV of the Company's Bylaws with respect to any transfer of the Shares by Purchaser to any parent corporation or entity, subsidiary or affiliate of Purchaser.

(b) The Company shall not be required (i) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in the Section 9(a) or (ii) to treat as owner of such Shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such Shares shall have been so transferred.

(c) Purchaser hereby agrees that for a period of not less than 180 days following the effective date of the first registration statement of the Company covering Common Stock (or other securities) to be sold on its behalf in an underwritten public offering, Purchaser shall not, to the extent requested by the Company or any underwriter, sell or otherwise transfer or dispose of (other than to donees who agree to be similarly bound) any Common Stock of the Company held by Purchaser at any time during such period except Common Stock included in such registration.

(d) In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Common Stock held by Purchaser (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

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10. Adjustment for Stock Split. All references to the number of Shares and the purchase price of the Shares in this Agreement shall be appropriately adjusted to reflect any stock split, stock dividend or other change in the Shares which may be made by the Company after the date of this Agreement.

11. Tax Consequences. The Purchaser has reviewed with the Purchaser's own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. The Purchaser is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Purchaser understands that the Purchaser (and not the Company) shall be responsible for the Purchaser's own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

12. General Provisions.

(a) This Agreement shall be governed by the laws of the State of Delaware. This Agreement represents the entire agreement between the parties with respect to the purchase of Common Stock by the Purchaser and may only be modified, amended or waived in writing signed by both parties.

(b) Any notice, demand or request required or permitted to be given by either the Company or the Purchaser pursuant to the terms of this Agreement shall be in writing and shall be deemed given when delivered personally or deposited in the U.S. Mail, First Class with postage prepaid, and addressed to the parties at the addresses of the parties set forth at the end of this Agreement or such other address as a party may request by notifying the other in writing.

(c) Except as otherwise provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors and assigns of the parties, hereto.

(d) Either party's failure to enforce any provision or provisions of this Agreement shall not in any way be construed as a waiver of any such provision or provisions, nor prevent that party thereafter from enforcing each and every other provision of this Agreement. The rights granted both parties herein are cumulative and shall not constitute a waiver of either party's right to assert all other legal remedies available to it under the circumstances.

(e) The Purchaser agrees upon request to execute any further documents or instruments necessary or desirable to carry out the purposes or intent of this Agreement.

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IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the day and year first set forth above.

**COMPANY**

NEWLINK GENETICS CORPORATION  
a Delaware corporation

**PURCHASER**

STODDARD CANCER RESEARCH INST.  
a d.b.a. of Central Iowa Health System

/s/Charles Link, Jr.  
(Signature)

Charles Link, Jr.  
(Print Name)

Chairman  
(Title)

2901 S. Loop Drive  
(Address)

Ames, IA 50010  
(City, State Zip)

/s/ Eric Crowell  
(Signature)

Eric Crowell  
(Print Name)

President  
(Include Title if signing on behalf of an entity)

1200 Pleasant St.  
(Address)

Des Moines, IA 50309  
(City, State Zip)



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health  
 National Cancer Institute  
 Technology Transfer Center  
 Executive Plaza South, Room 450  
 6120 Executive Blvd, MSC 7182  
 Bethesda MD 20892-7182  
 (301) 496-0477  
 (301) 402-2117 Fax

May 7, 2007

Dr. Charles Link  
 NewLink Genetics Corporation  
 Suite 3900  
 2901 South Loop Drive  
 Ames, IA 50010 USA

Re: Letter of Intent for a Cooperative Research and Development Agreement #02166  
 NCI Principal Investigators: Drs. Sherry S. Ansher, Lee Jia and Howard Streicher Collaborator Investigators: Drs. Charles Link and Nicholas Vahanian  
 Title: Preclinical and Clinical Development of [\*]

Dear Dr. Link:

It is my understanding that a cooperative research and development project between the parties referenced below is being considered. Accordingly, until the formal Cooperative Research and Development Agreement (CRADA) is reviewed by the CRADA Subcommittee and approved by the Director, National Cancer Institute (NCI), this Letter is offered to permit the joint research to commence. However, in the case of human clinical trials which are a part of the subject CRADA, the parties agree that all such trials which may begin prior to the execution of the formal CRADA shall be preceded by the appropriate regulatory approvals (U.S. Food and Drug Administration IND approval or international equivalents thereof).

It is acknowledged by the parties below that cooperative research pursuant to the Research Plan, attached as Appendix A, will be conducted informally by the NCI Principal Investigators and Collaborator pending formal approval of the CRADA. It is further acknowledged that patentable inventions may be made by NCI employees and employees of the Collaborator. Pursuant to its authority under the Federal Technology Transfer Act of 1986, as amended, NCI agrees that should this CRADA be approved, it will have retroactive effect to the date that the last party has executed this Letter for any inventions that may be made under this Research Plan. NCI further agrees that should this CRADA be approved it will have retroactive effect to the date that the last party has executed this Letter for confidentiality obligations specified in the NIH Model CRADA. The Model CRADA for Extramural-PHS Clinical Research (2005) provisions for the protection of proprietary information are incorporated in this Letter by reference and are considered controlling during the period of informal joint research. These provisions include, but are not limited to Articles 2.0 and 8. The Model CRADA for Extramural-PHS Clinical Research

(2005) is attached as Appendix B and the CTEP Exceptions or Modifications to this CRADA (6/27/06) is attached as Appendix C.

You understand, however, that this Letter is not a commitment on the part of either party to enter into a CRADA. Further, this Letter is effective for a term not to exceed six (6) months. The six month term may be extended, provided the CRADA is under active negotiation and the collaborative research is continuing. Assuming that the necessary approvals are forthcoming, we look forward to a successful collaboration.

Sincerely,

/s/ Kathleen Carroll for  
 \_\_\_\_\_  
 Karen Maurey, M.S.  
 Chief, Technology Transfer Center, NCI

**AGREED AND ACCEPTED:****National Cancer Institute**

/s/Anna D. Barker  
 \_\_\_\_\_  
 Anna D. Barker, Ph.D.  
 Deputy Director

05/14/07

Date

**NewLink Genetics Corporation**

/s/ Charles Link  
 \_\_\_\_\_

05/23/07

Date

**Appendix A**

**Letter of Intent Research Plan**

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**APPENDIX A: LETTER OF INTENT RESEARCH PLAN**

**Pre-Clinical and Clinical Development of [\*]**

**National Cancer Institute (NCI) Investigators:**

Dr. Sherry Ansher  
Dr. Lee Jia  
Dr. Howard Streicher

**NewLink Genetics Corporation Investigators:**

Dr. Charles Link  
Dr. Nicholas Vahanian

**Term of Proposed CRADA:**

Four (4) years from the date of CRADA execution

**1. RESEARCH GOALS OF PROPOSED CRADA**

The overall goal of this proposed CRADA is to collaborate with NewLink Genetics Corporation (hereafter NewLink) on the pre-clinical and clinical development of [\*] (also known as [\*], or Investigational Agent) for the treatment of [\*] and other [\*].

The Division of Cancer Treatment and Diagnosis (DCTD), NCI and NewLink will both provide resources and expertise for the pre-clinical development of [\*] and will work together towards the successful clinical development of [\*] as a safe and effective novel pharmaceutical compound. The DCTD will provide expertise in designing, implementing and monitoring [\*] clinical trials through its intramural and extramural clinical trials network. Additionally, the DCTD will work jointly with NewLink to obtain all the necessary regulatory approval by the U.S. Food and Drug Administration (FDA) for [\*] as [\*]. NewLink will provide expertise in the development, formulation and production of [\*]. The Parties will work together in the design, implementation and monitoring of the clinical trials planned under this CRADA as well as all regulatory aspects and New Drug Application (N DA) filings as necessary for marketing approval for [\*] as [\*].

**2. SCIENTIFIC BACKGROUND**

[\*]

[\*]

[\*]

**3. PRE-CLINICAL DEVELOPMENT OF [\*]**

[\*]

The following sections summarize the pre-clinical studies conducted by the NCI prior to this CRADA Letter of Intent.

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[\*]

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[\*]

#### 4. BACKGROUND OF THE COLLABORATOR

NewLink is a biopharmaceutical company applying innovative techniques in cancer biology to produce new diagnostic and therapeutic agents for cancer patients. NewLink is privately held and was incorporated in June 1999. The core of NewLink is a Cancer Vaccine Development Division that exists to accelerate the deployment of oncology pharmaceuticals, including HyperAcute™ Vaccines, into clinical testing and commercialization. NewLink has recently acquired a worldwide, exclusive license to patents covering therapeutic uses of [\*] as [\*] for [\*], and [\*] undertakes the development [\*].[\*] is envisioned as [\*] and as [\*] for use in [\*] for the purpose of [\*] of the [\*]. NewLink expects to start [\*] **clinical trials in** [\*] ([\*]), subject to the filing of one or more NewLink-sponsored INDs to support such studies.

#### 5. DETAILED DESCRIPTION OF THE RESEARCH PLAN

The Division of Cancer Treatment and Diagnosis (DCTD), NCI and NewLink are interested in the evaluation of [\*] in a pre-clinical and clinical development program that includes [\*] and other [\*]. The pre-clinical work will include IND-directed toxicology studies and formulation studies. In addition, [\*] may conduct pre-clinical research aimed at enhancing the understanding of the mechanism of action of [\*] and its targets and optimizing its clinical development program. NCI's work may also include such activities as the development of assays to detect target modulation, biomarker studies, and pharmacodynamic analyses performed in conjunction with the DCTD-sponsored clinical studies. DCTD will sponsor [\*] clinical trials that will help determine the [\*] of [\*]. DCTD and NewLink are also interested in evaluating [\*] in [\*] or [\*] such as [\*] in clinical trials.

#### 6. RESPECTIVE CONTRIBUTIONS OF THE PARTIES

##### A. Joint Responsibilities

##### 1. Steering Committee and Communication Plan

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A Steering Committee will be employed by the Parties to exchange information and data and to discuss and to plan the proposed and ongoing clinical research. The Steering Committee shall be composed of the CRADA Principal Investigators from NCI and NewLink. In addition, other NCI and NewLink staff with expertise in toxicology, pharmacology, pharmaceutical development, project management and other disciplines as pertinent to the current development stage of the Investigational Agent at the time of a meeting may participate in the meetings of the Steering Committee. Both Parties shall report regularly to the Steering Committee on the progress of the clinical research and development efforts covered by this CRADA, will review the current progress, and will make any required decisions. The routes of communication, format of written minutes, etc. will be determined at the Steering Committee meetings and will be driven by the needs of the project. The Parties have been meeting regularly prior to the execution of this CRADA Letter of Intent, and will continue to do so.

The Steering Committee will function under the oversight of Co-Chairs, one from NCI and one from the Collaborator. NCI's Steering Committee Co-Chair will be appointed by the DCTD Division Director and report to the DCTD Division Director or his or her designee. Steering Committee meeting minutes summarizing all key decisions and issues under discussion will be provided to all the Steering Committee members and to the DCTD Division Director within [\*] of each meeting. Steering Committee decisions will be made [\*].

2. DCTD's preclinical and ancillary studies shall be conducted [\*], as per [\*].
3. The DCTD and NewLink will explore the clinical utility of [\*] for [\*]. As [\*] are identified, it will be important to develop [\*] and [\*] and to [\*] and [\*] with [\*] for these [\*].[\*] studies may be important in diseases where [\*] and where there is a [\*] following [\*].
4. Both Parties shall collaborate in the collection and analysis of data generated under the Research Plan.
5. Both Parties will work closely together to ensure that the pre-clinical and clinical studies move forward expeditiously.
6. Subject to the obligations of the Parties to maintain the data under this CRADA as confidential and proprietary, the Parties may publicly disclose the results of their research under the circumstances set forth in the model CRADA.
7. When pre-clinical studies and/or a CRADA clinical protocol involves either [\*] or involves [\*], the NCI, NewLink [\*] will jointly determine a reasonable and appropriate mechanism for intellectual property and data access and sharing prior to initiation of the pre-clinical studies and/or the clinical trial.
8. For activities conducted pursuant to this CRADA in the United States of America, both Parties agree to comply with all appropriate DHHS regulations relating to Human Subjects Use, all U.S. Department of Agriculture regulations, and all Public Health Service policies relating to the use and care of laboratory animals. For

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activities conducted pursuant to this CRADA outside of the United States of America, both Parties shall conduct such in accordance with GLPs and all applicable rules, regulations and statutes, both local and national, governing such activity in that country.

9. The Parties acknowledge that [\*] means any [\*] that is either readily usable as a [\*] or is [\*] that will be useful to [\*] in developing [\*] (rather than useful [\*] or [\*]). A [\*] may simultaneously be a [\*] and be the essence of a [\*], or [\*] (or an integral component of such [\*]). For the purposes of this CRADA, [\*] shall include, but not be limited to, a [\*]. If NewLink elects to request [\*] that is a [\*], such [\*]

will ensure, as appropriate for the circumstances, that (a) the [\*] will undertake to make the [\*] on a [\*] to [\*] for [\*] under [\*], such [\*], or (b) [\*] the right to make the [\*] on a [\*] to [\*] for [\*] purposes under [\*].

## B. NewLink Responsibilities

1. Following execution of the CRADA, [\*] will provide [\*] funding for pre-clinical studies including the IND-directed toxicity studies and formulation studies which will be conducted by [\*]. The exact amount of funding and the payment schedule will be agreed upon and addressed in an Appendix B to the executed CRADA.
2. Following CRADA execution, [\*] will be responsible for the [\*] cost of GMP-grade [\*] in current [\*] inventories manufactured to support pre-clinical studies, NCI-sponsored [\*] clinical trials, and NewLink-sponsored [\*] clinical trials. The exact amount of funding and the payment schedule will be agreed upon and addressed in an Appendix B to the executed CRADA.

If additional formulated [\*] is required for clinical studies under this CRADA Research Plan, [\*] will be responsible for the provision and costs of such extra supply of formulated and acceptably labeled [\*]. [\*] may elect to produce bulk [\*] and formulated [\*] through contractors other than established [\*] contractors in order to obtain the most competitive pricing. [\*] will then be responsible for subsequent payment of such contractors, and [\*] will have no obligations with respect to such contractors. If [\*] elects to perform any portion of this CRADA Research Plan through a contractor or consultant, [\*] shall incorporate into such contracts all provisions necessary to ensure that the work of the contractor or consultant is governed by the terms of the CRADA, including, but not limited to, a provision for the assignment of inventions of the contractor or consultant to [\*]; such inventions shall be deemed [\*] of [\*]. In addition, [\*] will ensure that any contractor or consultant is obligated to maintain [\*] Confidential Information regarding [\*] manufacturing and formulation in confidence at least to the extent provided for by the terms of the CRADA.

Following the use of [\*] supplies of [\*], [\*] will provide [\*] to [\*] for use by [\*] in [\*] studies, studies designed to [\*], and other studies relevant to the development of [\*] as provided in the Research Plan.

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3. NewLink will prepare and submit to the FDA an Investigational New Drug Application (IND) for NewLink sponsored clinical studies of [\*], which will cross-reference the DCTD IND.
  4. NewLink agrees to permit DCTD to supply formulated [\*] for all clinical trials set forth in this CRADA. This includes:
    - Provision of appropriately packaged and labeled [\*] for all NCI-sponsored clinical studies;
    - Supply of [\*] for compassionate use, as described in the NCI Investigator Handbook; and
    - Supply of [\*] for, and any resources necessary for the management of, Group C distribution, as described in the NCI Investigator Handbook. Group C distribution shall be initiated if such action is justified by clinical results and is feasible based on adequate [\*] supply, such that NewLink's NDA efforts are not negatively impacted.

NewLink agrees to supply [\*], or to provide unformulated analytical grade [\*] or metabolites, if available, to DCTD for DCTD to provide to DCTD intramural and extramural investigators for the development of analytical assays or ancillary correlative studies conducted in conjunction with DCTD-approved protocols. NewLink also agrees to provide [\*] for distribution for pre-clinical studies designed to [\*]. These will include pre-clinical studies designed to support clinical trials in [\*]; pre-clinical [\*] studies to provide data in support of a clinical trial; and other pertinent requests.

5. Upon CRADA execution, NewLink will provide resources for data collection and management, beyond that normally carried out by the DCTD as set forth in the CRADA for CTEP-sponsored studies, if NewLink desires such data collection and management. This would include the collection of the data required to submit an NDA to the FDA.
6. Upon CRADA execution, NewLink may provide funds for partial support of the DCTD-sponsored clinical trials and IND.
7. Upon CRADA execution, NewLink will provide funds for travel by DCTD staff to attend meetings sponsored by NewLink concerning [\*] clinical trials, such funds not to exceed [\*] per year of the term of the CRADA.
8. NewLink intends and will use reasonable efforts to prepare and submit an NDA to the FDA expeditiously when justified by clinical studies, with the object of obtaining pharmaceutical regulatory approval for the commercial marketing of [\*].
9. NewLink may sponsor its own clinical trials using [\*]. Such Collaborator-sponsored trials are outside the scope of this CRADA. For these clinical trials, NewLink will maintain possession and control of the clinical trial results. NewLink will permit

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DCTD to review and use the results for DCTD-sponsored clinical trials which are under the CRADA.

10. NewLink will update DCTD on the progress of its preclinical studies of [\*] to help ensure optimal experimental designs and avoid duplication.

## C. NCI Responsibilities

I. Division of Cancer Treatment and Diagnosis, NCI

1. DCTD will develop and implement its preclinical/pharmacodynamic program for [\*]. DCTD also may conduct [\*] studies to [\*]. DCTD will update Collaborator regarding progress and findings to help ensure optimal experimental designs and avoid duplication.
2. DCTD will conduct [\*] studies in [\*], and [\*] studies using existing supplies of [1MT]. As stated in B(l) above, upon execution of the CRADA, NewLink will be responsible for partial costs associated with such studies.
3. DCTD will provide GMP-grade [\*] for [\*] clinical studies, initial [\*] clinical studies, and [\*] clinical trials. As stated in [\*], upon execution of the CRADA, [\*] will be responsible for the costs associated with the drug production for such clinical studies.
4. The DCTD, as sponsor, will prepare and submit to the FDA an IND for [\*] for NCI-sponsored clinical studies. DCTD will permit NewLink to participate in DCTD's IND preparation process.
5. The DCTD will collaborate solely with NewLink for [\*] development, and will assist NewLink in all aspects of the regulatory approval process, so long as NewLink is pursuing clinical development of [\*].
6. To the extent permitted by law, the DCTD will maintain the DCTD-sponsored IND, including protocols and other supporting information relative to [\*] as [\*] in DCTD's possession and control, as proprietary and confidential, and make it available exclusively to NewLink. The DCTD will permit NewLink to review, cross-reference and use the IND in conducting clinical trials and in fulfilling all of the requirements necessary for obtaining FDA approval to market [\*] as [\*].
7. To the extent permitted by law, the DCTD will maintain the clinical data, results and raw data from all new studies developed under this proposed CRADA in its possession and control, as proprietary and confidential, and make them available exclusively to NewLink for use in obtaining approval for the commercial marketing of [\*] as [\*], so long as NewLink is pursuing commercial development for [\*].
8. The DCTD will solicit protocol Letters of Intent (LOI) from the investigators in the DCTD's clinical trials network as appropriate.

The Protocol Review Committee (PRC), of the DCTD, will:

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- Evaluate the rationale of each LOI received at the DCTD;
- Review the LOIs for study design, including dose, schedule and comparison groups, if relevant, in order to address any pertinent scientific questions;
- Examine the characteristics of the patient population to be studied;
- Assess the feasibility of the projected accrual, including the ability of each investigator to accrue the appropriate patient population in a timely manner;
- Review competing studies of the investigator in the specified disease(s);
- Provide investigator(s) with consensus review(s) of the PRC's evaluation to be used to revise the protocol;
- Provide a copy of the consensus review to NewLink. All CTEP approved clinical LOIs will be sent by NCI to NewLink. NewLink will provide NCI with its approval or disapproval within [\*] of receiving the CTEP approved clinical LOIs. Only LOIs that have been approved by both the PRC and NewLink will lead to the submission of full study protocols.

The protocols received from investigators in response to the fully approved LOIs will be reviewed and evaluated by the PRC and by NewLink. The PRC will:

- Evaluate each protocol from agent, disease, statistical and regulatory perspectives in order to ensure that the study design that was approved by the PRC at the LOI stage is carried out.
  - Provide each clinical research protocol received by DCTD to NewLink for review and comment approximately [\*] before it is reviewed by the PRC of CTEP. Comments from NewLink received by CTEP before the PRC meeting will be discussed by the PRC, will be given due consideration, and will be incorporated into the protocol, absent good cause. Comments from either NewLink or the CTEP staff that are agreed upon in the PRC meeting will be formatted as a consensus review, which is returned to the investigator for necessary and/or suggested changes before the protocol can be given final approval and submitted to the FDA. In addition, the PRC will review any correlative laboratory studies, solicited from investigators, to address cellular pharmacological and/or pharmacokinetics questions as necessary.
9. The DCTD will evaluate each of the active studies as they progress to ensure that the appropriate questions are being addressed and to ensure that the studies are modified as required based on the developing data. The DCTD will utilize its existing procedures and mechanisms to follow the clinical studies to ensure that all studies meet the pertinent FDA regulations.

II. Experimental Immunology Branch, Center for Cancer Research, NCI

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[\*] studies such as [\*] in [\*] will be conducted in the Experimental Immunology Branch under the direction of [\*].



7. Intellectual Property of the Parties:

NCI Patents and Patent Applications: [\*]

NewLink has obtained a worldwide, exclusive license to the following patents covering [\*] for [\*] from the University of Georgia.

[\*]

[\*]

[\*]

[\*]

[\*]

[\*]

[\*]

[\*]

[\*]

[\*]

In addition, a number of patent applications corresponding to the above patent applications and patents have been filed in countries other than the U.S.

Appendix B

NIH Model CRADA for Extramural-PHS Clinical Research (version 2005)

PUBLIC HEALTH SERVICE

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT  
FOR EXTRAMURAL-PHS CLINICAL RESEARCH

This Agreement is based on the model Cooperative Research and Development Agreement (“CRADA”) adopted by the U.S. Public Health Service (“PHS”) Technology Transfer Policy Board for use by components of the National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), and the Food and Drug Administration (“FDA”), which are agencies of the PHS within the Department of Health and Human Services (“HHS”).

This Cover Page identifies the Parties to this CRADA:

The U.S. Department of Health and Human Services, as represented by  
[Insert the full name of the ICD]  
an Institute, Center, or Division (hereinafter referred to as the “ICD”) of the  
[INSERT as appropriate: NIH, CDC, or FDA]

and

[Insert Collaborator’s official name],  
hereinafter referred to as the “Collaborator”,  
having offices at [Insert Collaborator’s address],  
created and operating under the laws of [Insert State of Incorporation].

This CRADA between ICD and Collaborator will be effective when signed by the Parties, which are identified on both the Cover Page and the Signature Page (page 22). The official contacts for the Parties are identified on the Contacts Information Page (page 23). Publicly available information regarding this CRADA appears on the Summary Page (page 24). The research and development activities that will be undertaken by ICD, ICD's contractors or grantees, and Collaborator in the course of this CRADA are detailed in the Research Plan, attached as Appendix A. The staffing, funding, and materials contributions of the Parties are set forth in Appendix B. Any changes to the model CRADA are set forth in Appendix C.

## Article 2. Definitions

The terms listed in this Article will carry the meanings indicated throughout the CRADA. To the extent a definition of a term as provided in this Article is inconsistent with a corresponding definition in the applicable sections of either the United States Code (U.S.C.) or the Code of Federal Regulations (C.F.R.), the definition in the U.S.C. or C.F.R. will control.

“Adverse Drug Experience” or “ADE” means an Adverse Event associated with the use of the Test Article, that is, an event where there is a reasonable possibility that the Test Article may have caused the event (a relationship between the Test Article and the event cannot be ruled out), in accordance with the definitions of 21 C.F.R. Part 310, 305, or 312, or other applicable regulations.

“Adverse Event” or “AE” means any untoward medical occurrence in a Human Subject administered Test Article. An AE does not necessarily have a causal relationship with the Test Article, that is, it can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the Test Article, whether or not it is related to it. See FDA Good Clinical Practice Guideline (International Conference on Harmonisation (ICH) E6: “Good Clinical Practice: Consolidated Guidance, 62 Federal Register 25, 691 (1997)).

“Affiliate” means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of the CRADA. For this purpose, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.

“Annual Report” means the report of progress of an IND-associated investigation that the Sponsor must submit to the FDA within sixty (60) days of the anniversary of the effective date of the IND (pursuant to 21 C.F.R. § 312.33).

“Background Invention” means an Invention conceived and first actually reduced to practice before the Effective Date.

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“Clinical Data in ICD’s Possession and Control” means all Raw Data that ICD employees create directly; and all copies of Raw Data and Summary Data that ICD obtains from Clinical Investigators or contractors performing CRADA activities.

“Clinical Investigator” means, in accordance with 21 C.F.R. § 312.3, an individual who actually conducts a clinical investigation, that is, who directs the administration or dispensation of Test Article to a subject, and who assumes responsibility for studying Human Subjects, for recording and ensuring the integrity of research data, and for protecting the welfare and safety of Human Subjects.

“Clinical Research Site(s)” means the site(s) at which the Protocol(s) described in the Research Plan will be performed.

“Collaborator Materials” means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by Collaborator and used in the performance of the Research Plan. The term “Collaborator Materials” does not include “Test Article” (defined below).

“Confidential Information” means confidential scientific, business, financial information, or Identifiable Private Information provided that Confidential Information does not include:

- (a) information that is publicly known or that is available from public sources;
- (b) information that has been made available by its owner to others without a confidentiality obligation;
- (c) information that is already known by the receiving Party, or information that is independently created or compiled by the receiving Party without reference to or use of the provided information; or
- (d) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan.

“Cooperative Research and Development Agreement” or “CRADA” means this Agreement, entered into pursuant to the Federal Technology Transfer Act of 1986, as amended (15 U.S.C. §§ 3710a et seq.), and Executive Order 12591 of April 10, 1987.

“CRADA Data” means information developed by or on behalf of the Parties in the performance of the Research Plan, excluding Raw Data.

“CRADA Materials” means all tangible materials first produced in the performance of the Research Plan other than CRADA Data.

“CRADA Principal Investigator(s)” or “CRADA PI(s)” means the person(s) designated by the Parties who will be responsible for the scientific and technical conduct of the Research Plan.

“CRADA Subject Invention” means any Invention of either or both Parties, conceived or first actually reduced to practice in the performance of the Research Plan.

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“Drug Master File” or “DMF” is described in 21 C.F.R. Part 314.420. A DMF is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

“Effective Date” means the date of the last signature of the Parties executing this Agreement.

“Government” means the Government of the United States of America.

“Human Subject” means, in accordance with the definition in 45 C.F.R. § 46.102(f), a living individual about whom an investigator conducting research obtains:

- (a) data through intervention or interaction with the individual; or
- (b) Identifiable Private Information.

“ICD Materials” means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by ICD and used in the performance of the Research Plan.

“IND” means an “Investigational New Drug Application,” filed in accordance with 21 C.F.R. Part 312 under which clinical investigation of an experimental drug or biologic (Test Article) is performed in Human Subjects in the United States or intended to support a United States licensing action.

“Identifiable Private Information” or “IPI” about a Human Subject means private information from which the identity of the subject is or may readily be ascertained. Regulations defining and governing this information include 45 C.F.R. Part 46 and 21 C.F.R. Part 50.

“Institutional Review Board” or “IRB” means, in accordance with 45 C.F.R. Part 46, 21 C.F.R. part 56, and other applicable regulations, an independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of the Human Subjects involved in a study.

“Invention” means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act, 7 U.S.C. §§ 2321 et seq.

“Investigator’s Brochure” means, in accordance with the definition in 21 C.F.R. § 312.23(a)(5), a document containing information about the Test Article, including animal screening, preclinical toxicology, and detailed pharmaceutical data, including a description of possible risks and side effects to be anticipated on the basis of prior experience with the drug or related drugs, and precautions, such as additional monitoring, to be taken as part of the investigational use of the drug.

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“Patent Application” means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office (“U.S.P.T.O.”) or the corresponding patent-issuing authority of another nation.

“Patent” means any issued United States patent, any international counterpart(s), and any corresponding grant(s) by a non-U.S. government in place of a patent.

“Placebo” means an inactive substance identical in appearance to the material being tested that is used to distinguish between drug action and suggestive effect of the material under study.

“Protocol” means the formal, detailed description of a study to be performed as provided for in the Research Plan. It describes the objective(s), design, methodology, statistical considerations, and organization of a trial. For the purposes of this CRADA, the term, Protocol, for clinical research involving Human Subjects, includes any and all associated documents, including informed consent forms, to be provided to Human Subjects and potential participants in the study.

“Raw Data” means the primary quantitative and empirical data first collected from experiments and clinical trials conducted within the scope of this CRADA.

“Research Plan” means the statement in Appendix A of the respective research and development commitments of the Parties. The Research Plan should describe the provisions for sponsoring the IND, clinical and safety monitoring, and data management.

“Sponsor” means, in accordance with the definition in 21 C.F.R. § 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing clinical trials with Test Articles, and is sometimes referred to as the IND holder.

“Steering Committee” means the research and development team whose composition and responsibilities with regard to the research performed under this CRADA are described in Appendix A.

“Summary Data” means any extract or summary of the Raw Data, generated either by or, on behalf of, ICD or by, or on behalf of, Collaborator. Summary Data may include extracts or summaries that incorporate IPI.

“Test Article” means, in accordance with 21 C.F.R. § 50.3(j), any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act that is intended for administration to humans or animals, including a drug or biologic as identified in the Research Plan and Appendix B, that is used within the scope of the Research Plan. The Test Article may also be referred to as Investigational Agent, Study Material, or Study Product.

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### Article 3. Cooperative Research and Development

**3.1 Performance of Research and Development.** The research and development activities to be carried out under this CRADA will be performed by the Parties identified on the Cover Page, as well as ICD's contractors or grantees as described in the Research Plan. However, ICD's contractors or grantees are not Parties to the CRADA, and this CRADA does not grant to Collaborator any rights to Inventions made by ICD's contractors or grantees. The CRADA PIs will be responsible for coordinating the scientific and technical conduct of this project on behalf of their employers. Any Collaborator employees who will work at ICD facilities will be required to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.

**3.2 Research Plan.** The Parties recognize that the Research Plan describes the collaborative research and development activities they will undertake and that interim research goals set forth in the Research Plan are good faith guidelines. Should events occur that require modification of these goals, then by mutual agreement the Parties can modify them through an amendment, according to Paragraph 13.6.

**3.3 Use and Disposition of Collaborator Materials and ICD Materials.** The Parties agree to use Collaborator Materials and ICD Materials only in accordance with the Research Plan and Protocol(s), not to transfer these materials to third parties except in accordance with the Research Plan and Protocol(s) or as approved by the owning or providing Party, and, upon expiration or termination of the CRADA, to dispose of these materials as directed by the owning or providing Party.

**3.4 Third-Party Rights in Collaborator's CRADA Subject Inventions.** If Collaborator has received (or will receive) support of any kind from a third party in exchange for rights in any of Collaborator's CRADA Subject Inventions, Collaborator agrees to ensure that its obligations to the third party are both consistent with Articles 6 through 8 and subordinate to Article 7 of this CRADA.

**3.5 Disclosures to ICD.** Prior to execution of this CRADA, Collaborator agrees to disclose to ICD all instances in which outstanding royalties are due under a PHS license agreement and in which Collaborator had a PHS license terminated in accordance with 37 C.F.R. § 404.10. These disclosures will be treated as Confidential Information upon request by Collaborator in accordance with Paragraphs 2.4, 8.3, and 8.4.

**3.6 Clinical Investigator Responsibilities.** The Clinical Investigator will be required to submit, or to arrange for submission of, each Protocol associated with this CRADA to all appropriate IRBs, and for ensuring that the IRBs are notified of the role of Collaborator in the research. In addition to the Protocol all associated documents, including informational documents and advertisements, must be reviewed and approved by the appropriate IRB(s) before starting the research at each Clinical Research Site. The research will be done in strict accordance with the Protocol(s) and no substantive changes in a finalized Protocol will be made unless mutually agreed upon, in writing, by the Parties. Research will not commence (or will continue unchanged, if already in progress) until each substantive change to a Protocol, including

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those required by either the FDA or the IRB, has been integrated in a way acceptable to the Parties, submitted to the FDA (if applicable) and approved by the appropriate IRBs.

#### **3.7 Investigational Applications.**

**3.7.1** If an IND is required either ICD or Collaborator, as indicated in the Research Plan, will submit an IND and all Clinical Investigators must have completed registration documents on file (1572 forms).

**3.7.2** If ICD elects to file its own IND, Collaborator agrees to provide ICD background data and information necessary to support the IND. Collaborator further agrees to provide a letter of cross-reference to all pertinent regulatory filings sponsored by Collaborator. Collaborator's employees will be reasonably available to respond to inquiries from the FDA regarding information and data contained in the Collaborator's IND, DMF, other filings, or other information and data provided to ICD by the Collaborator pursuant to this Article 3. If ICD has provided information or data to assist Collaborator in its IND filing, ICD will provide a letter of cross reference to its IND and respond to inquiries related to information provided by ICD, as applicable.

**3.7.3** If Collaborator supplies Confidential Information to ICD in support of an IND filed by ICD, this information will be protected in accordance with the corresponding confidentiality provisions of Article 8.

**3.7.4** Collaborator may sponsor its own clinical trials and hold its own IND for studies performed outside the scope of this CRADA. These studies, however, should not adversely affect the ability to accomplish the goal of the Research Plan, for example, by competing for the same study population. All data from those clinical trials are proprietary to Collaborator for purposes of this CRADA.

**3.8 Test Article Information and Supply.** Collaborator agrees to provide ICD without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade Test Article (and, as required by the Protocol(s), Placebo) to complete the clinical trial(s) agreed to and approved under this CRADA. Collaborator will provide a Certificate of Analysis to ICD for each lot of the Test Article provided.

**3.9 Test Article Delivery and Usage.** Collaborator will ship the Test Article and, if required, Placebo to ICD or its designee in containers marked in accordance with 21 C.F.R. § 312.6. ICD agrees that the Clinical Investigators will keep appropriate records and take reasonable steps to ensure that the Test Article is used in accordance with the Protocol(s) and applicable FDA regulations. In addition, ICD agrees that the Test Article (and all Confidential Information supplied by Collaborator relating to the Test Article) will be used solely for the conduct of the CRADA research and development activities. Furthermore, ICD agrees that no analysis or modification of the Test Article will be performed without Collaborator's prior written consent. At the completion of the Research Plan, any unused quantity of Test Article will be returned to Collaborator or disposed as directed by Collaborator. Pharmacy contacts at ICD or its designee will be determined by ICD and communicated to Collaborator.

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### 3.10 Monitoring.

- 3.10.1 The Sponsor or its designee will be primarily responsible for monitoring clinical sites and for assuring the quality of all clinical data, unless otherwise stated in the Research Plan. Monitoring will comply with FDA Good Clinical Practice (International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guidance; 62 Federal Register 25, 691 (1997)). The other Party may also perform quality assurance oversight. The monitor will communicate significant Protocol violations and submit documentation of monitoring outcomes on Protocol insufficiencies to the other Party in a timely manner.
- 3.10.2 Subject to the restrictions in Article 8 concerning IPI, and with reasonable advance notice and at reasonable times, ICD will permit Collaborator or its designee(s) access to clinical site(s) to monitor the conduct of the research, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with FDA Good Clinical Practice and the Protocol(s).

3.11 FDA Meetings/Communications. All meetings with the FDA concerning any clinical trial within the scope of the Research Plan will be discussed by Collaborator and ICD in advance. Each Party reserves the right to take part in setting the agenda for, to attend, and to participate in these meetings. The Sponsor will provide the other Party with copies of FDA meeting minutes, all transmittal letters for IND submissions, IND safety reports, formal questions and responses that have been submitted to the FDA, Annual Reports, and official FDA correspondence, pertaining either to the INDs under this CRADA or to the Clinical Investigators on Protocols performed in accordance with the Research Plan, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law.

### Article 4. Reports

4.1 Interim Research and Development Reports. The CRADA PIs should exchange information regularly, in writing. This exchange may be accomplished through meeting minutes, detailed correspondence, circulation of draft manuscripts, Steering Committee reports, copies of Annual Reports and any other reports updating the progress of the CRADA research. However, the Parties must exchange updated Investigator's Brochure, formulation and preclinical data, and toxicology findings, as they become available.

4.2 Final Research and Development Reports. The Parties will exchange final reports of their results within six (6) months after the expiration or termination of this CRADA. These reports will set forth the technical progress made; any publications arising from the research; and the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications.

4.3 Fiscal Reports. If Collaborator has agreed to provide funding to ICD under this CRADA and upon the request of Collaborator, then concurrent with the exchange of final research and development reports according to Paragraph 4.2, ICD will submit to Collaborator a statement of all costs incurred by ICD for the CRADA. If the CRADA has been terminated, ICD will specify any costs incurred before the date of termination for which ICD has not received funds from

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Collaborator, as well as for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned Collaborator property, for which Collaborator will be responsible.

4.4 Safety Reports. In accordance with FDA requirements, the Sponsor will establish and maintain records and submit safety reports to the FDA, as required by 21 C.F.R. § 312.32 and 21 C.F.R. 812.150(b)(1), or other applicable regulations. In the conduct of research under this CRADA, the Parties will comply with specific ICD guidelines and policies for reporting ADEs and AEs, as well as procedures specified in the Protocol(s). The Sponsor must provide the other Party with copies of all Safety Reports concurrently with their submission to the FDA, and with any other information affecting the safety of Human Subjects in research conducted under this CRADA.

4.5 Annual Reports. The Sponsor will provide the other Party a copy of the Annual Report concurrently with the submission of the Annual Report to the FDA. Annual Reports will be kept confidential in accordance with Article 8,

### Article 5. Staffing, Financial, and Materials Obligations

5.1 ICD and Collaborator Contributions. The contributions of any staff, funds, materials, and equipment by the Parties are set forth in Appendix B. The Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a(d)(1) prohibits ICD from providing funds to Collaborator for any research and development activities under this CRADA.

5.2 ICD Staffing. No ICD employees will devote 100% of their effort or time to the research and development activities under this CRADA. ICD will not use funds provided by Collaborator under this CRADA for ICD personnel to pay the salary of any permanent ICD employee. Although personnel hired by ICD using CRADA funds will focus principally on CRADA research and development activities, Collaborator acknowledges that these personnel may nonetheless make contributions to other research and development activities, and the activities will be outside the scope of this CRADA.

5.3 Collaborator Funding. Collaborator acknowledges that Government funds received by Collaborator from an agency of the Department of Health and Human Services may not be used to fund ICD under this CRADA. If Collaborator has agreed to provide funds to ICD then the payment schedule appears in Appendix B and Collaborator will make payments according to that schedule. If Collaborator fails to make any scheduled payment, ICD will not be obligated to perform any of the research and development activities specified herein or to take any other action required by this CRADA until the funds are received. ICD will use these funds exclusively for the purposes of this CRADA. Each Party will maintain separate and distinct current accounts, records, and other evidence supporting its financial obligations under this CRADA and, upon written request, will provide the other Party a Fiscal Report according to Paragraph 4.3, which delineates all payments made and all obligated expenses, along with the Final Research Report described in Paragraph 4.2.

5.4 Capital Equipment. Collaborator's commitment, if any, to provide ICD with capital equipment to enable the research and development activities under the Research Plan appears in

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Appendix B. If Collaborator transfers to ICD the capital equipment or provides funds for ICD to purchase it, then ICD will own the equipment. If Collaborator loans capital equipment to ICD for use during the CRADA, Collaborator will be responsible for paying all costs and fees associated with the transport, installation, maintenance, repair, removal, or disposal of the equipment, and ICD will not be liable for any damage to the equipment.

## Article 6. Intellectual Property

6.1 Ownership of CRADA Subject Inventions, CRADA Data, and CRADA Materials. Subject to the Government license described in Paragraph 7.5, the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.2, the producing Party will retain sole ownership of and title to all CRADA Subject Inventions, all copies of CRADA Data, and all CRADA Materials produced solely by its employee(s). The Parties will own jointly all CRADA Subject Inventions invented jointly and all CRADA Materials developed jointly. A PHS contractor's or grantee's rights in data it generates will not be affected by this CRADA.

6.2 Reporting. The Parties will promptly report to each other in writing each CRADA Subject Invention reported by their respective personnel, and any Patent Applications filed thereon, resulting from the research and development activities conducted under this CRADA. Each Party will report all CRADA Subject Inventions to the other Party in sufficient detail to determine inventorship, which will be determined in accordance with U.S. patent law. These reports will be treated as Confidential Information in accordance with Article 8. Formal reports will be made by and to the Patenting and Licensing Offices identified on the Contacts Information Page herein.

6.3 Filing of Patent Applications. Each Party will make timely decisions regarding the filing of Patent Applications on the CRADA Subject Inventions made solely by its employee(s), and will notify the other Party in advance of filing. Collaborator will have the first opportunity to file a Patent Application on joint CRADA Subject Inventions and will notify PHS of its decision within sixty (60) days of an Invention being reported or at least thirty (30) days before any patent filing deadline, whichever occurs sooner. If Collaborator fails to notify PHS of its decision within that time period or notifies PHS of its decision not to file a Patent Application, then PHS has the right to file a Patent Application on the joint CRADA Subject Invention. Neither Party will be obligated to file a Patent Application. Collaborator will place the following statement in any Patent Application it files on a CRADA Subject Invention: "This invention was created in the performance of a Cooperative Research and Development Agreement with the [INSERT into Agency's model as appropriate: National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention], an Agency of the Department of Health and Human Services. The Government of the United States has certain rights in this invention." If either Party files a Patent Application on a joint CRADA Subject Invention, then the filing Party will include a statement within the Patent Application that clearly identifies the Parties and states that the joint CRADA Subject Invention was made under this CRADA.

6.4 Patent Expenses. Unless agreed otherwise, the Party filing a Patent Application will pay all preparation and filing expenses, prosecution fees, issuance fees, post issuance fees, patent maintenance fees, annuities, interference expenses, and attorneys' fees for that Patent Application and any resulting Patent(s). If a license to any CRADA Subject Invention is granted

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to Collaborator, then Collaborator will be responsible for all expenses and fees, past and future, in connection with the preparation, filing, prosecution, and maintenance of any Patent Applications and Patents claiming exclusively licensed CRADA Subject Inventions and will be responsible for a pro-rated share, divided equally among all licensees, of those expenses and fees for non-exclusively licensed CRADA Subject Inventions. Collaborator may waive its exclusive option rights at any time, and incur no subsequent financial obligation for those Patent Application(s) or Patent(s).

6.5 Prosecution of Patent Applications. The Party filing a Patent Application will provide the non-filing Party with a copy of any official communication relating to prosecution of the Patent Application within thirty (30) days of transmission of the communication. Each Party will also provide the other Party with the power to inspect and make copies of all documents retained in the applicable Patent Application or Patent file. The Parties agree to consult with each other regarding the prosecution of Patent Applications directed to joint CRADA Subject Inventions. If Collaborator elects to file and prosecute Patent Applications on joint CRADA Subject Inventions, then Collaborator agrees to use the U.S.P.T.O. Customer Number Practice and/or grant PHS a power(s) of attorney (or equivalent) necessary to assure PHS access to its intellectual property rights in these Patent Applications. PHS and Collaborator will cooperate with each other to obtain necessary signatures on Patent Applications, assignments, or other documents.

## Article 7. Licensing

7.1 Background Inventions. Other than as specifically stated in this Article 7, nothing in this CRADA will be construed to grant any rights in one Party's Background Invention(s) to the other Party, except to the extent necessary for the Parties to conduct the research and development activities described in the Research Plan.

7.2 Collaborator's License Option to CRADA Subject Inventions. With respect to Government rights to any CRADA Subject Invention made solely by an ICD employee(s) or made jointly by an ICD employee(s) and a Collaborator employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.

7.3 Exercise of Collaborator's License Option. To exercise the option of Paragraph 7.2 Collaborator must submit a written notice to the PHS Patenting and Licensing Contact identified on the Contacts Information Page (and provide a copy to the ICD Contact for CRADA Notices) within three (3) months after either (i) Collaborator receives written notice from PHS that the Patent Application has been filed or (ii) the date on which

nine (9) months after the exercise of the option. If PHS has not responded in writing to the last proposal by Collaborator within this nine (9) month period, the negotiation period will be extended to expire one (1) month after PHS so responds, during which month Collaborator may accept in writing the final license proposal of PHS. In the absence of Collaborator's exercise of the option, or upon election of a nonexclusive license, PHS will be free to license the CRADA Subject Invention to others. These time periods may be extended at the sole discretion of PHS upon good cause shown in writing by Collaborator.

7.4 Government License in ICD Sole CRADA Subject Inventions and Joint CRADA Subject Inventions. Pursuant to 15 U.S.C. § 3710a(b)(1) (A), for CRADA Subject Inventions owned solely by ICD or jointly by ICD and Collaborator, and licensed pursuant to the option of Paragraph 7.2, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government. In the exercise of this license, the Government will not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered privileged or confidential if it had been obtained from a non-federal party.

7.5 Government License in Collaborator Sole CRADA Subject Inventions. Pursuant to 15 U.S.C. § 3710a(b)(2), for CRADA Subject Inventions made solely by an employee of Collaborator, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

7.6 Third Party License. Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if PHS grants Collaborator an exclusive license to a CRADA Subject Invention made solely by an ICD employee or jointly with a Collaborator employee, the Government will retain the right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the CRADA Subject Invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or, if Collaborator fails to grant a license, to grant a license itself. The exercise of these rights by the Government will only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator; (ii) the action is necessary to meet requirements for public use specified by federal regulations, and such requirements are not reasonably satisfied by Collaborator; or (iii) Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this Paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(2).

7.7 Third-Party Rights In ICD Sole CRADA Subject Inventions. For a CRADA Subject Invention conceived prior to the Effective Date solely by an ICD employee that is first actually reduced to practice after the Effective Date in the performance of the Research Plan, the option offered to Collaborator in Paragraph 7.2 may be restricted if, prior to the Effective Date, PHS had filed a Patent Application and has either offered or granted a license in the CRADA Subject Invention to a third party. Collaborator nonetheless retains the right to apply for a license to a ny

such CRADA Subject Invention in accordance with the terms and procedures of 35 U.S.C. § 209 and 37 C.F.R. Part 404.

7.8 Joint CRADA Subject Inventions Not Exclusively Licensed by Collaborator. If Collaborator does not acquire an exclusive commercialization license in a joint CRADA Subject Invention in all fields of use then, for those fields of use not exclusively licensed to Collaborator, each Party will have the right to use the joint CRADA Subject Invention and to license its use to others, and each Party will cooperate with the other, as necessary, to fulfill international licensing requirements. The Parties may agree to a joint licensing approach for any remaining fields of use.

## Article 8. Rights of Access and Publication

8.1 Right of Access to CRADA Data and CRADA Materials. ICD and Collaborator agree to exchange all CRADA Data and to share all CRADA Materials. If the CRADA is terminated, both Parties agree to provide CRADA Materials in quantities needed to complete the Research Plan. Such provision will occur before the termination date of the CRADA or sooner, if required by the Research Plan. If Collaborator possesses any human biological specimens from clinical trials under the CRADA, the specimens must be handled as described in the Protocol or as otherwise directed by ICD before the termination date of the CRADA.

8.2 Use of CRADA Data and CRADA Materials. The Parties will be free to utilize CRADA Data and CRADA Materials internally for their own purposes, consistent with their obligations under this CRADA. ICD may share CRADA Data or CRADA Materials with any contractors, grantees, or agents it has engaged to conduct the CRADA research and development activities, provided the obligations of this Article 8.2 are simultaneously conveyed. Collaborator may share CRADA Data or CRADA Materials with any contractors, Affiliates, or agents it has engaged to conduct the CRADA research and development activities, provided the obligations of this Article 8.2 are simultaneously conveyed.

### 8.2.1 CRADA Data.

Collaborator and ICD will use reasonable efforts to keep CRADA Data confidential until published or until corresponding Patent Applications are filed. To the extent permitted by law, each Party will have the right to use any and all CRADA Data in and for any regulatory filing by or on behalf of the Party.

### 8.2.2 CRADA Materials.

Collaborator and ICD will use reasonable efforts to keep descriptions of CRADA Materials confidential until published or until corresponding Patent Applications are filed. Collaborator acknowledges that the basic research mission of PHS includes sharing with third parties for further research those research resources made in whole or in part with NIH funding. Consistent with this

Notwithstanding the above, if those joint CRADA Materials are the subject of a pending Patent Application or a Patent, or were created using a patent-pending or patented material or technology, the Parties may agree to restrict distribution or freely distribute them. Either Party may distribute those CRADA Materials made solely by the other Party only upon written consent from that other Party or that other Party's designee.

**8.3 Confidential Information.** Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out the Research Plan, and will place a confidentiality notice on all this information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Party within fifteen (15) days of the disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described in the Research Plan. Either Party may object to the designation of information as Confidential Information by the other Party.

**8.4 Protection of Confidential Information.** Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or federal law or regulation. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.

**8.5 Human Subject Protection.** The research to be conducted under this CRADA involves Human Subjects or human tissues within the meaning of 45 C.F.R. Part 46, and all research to be performed under this CRADA will conform to applicable federal laws and regulations. Additional information is available from the HHS Office for Human Research Protections (<http://www.hhs.gov/ohrp/>).

**8.6 Duration of Confidentiality Obligation.** The obligation to maintain the confidentiality of Confidential Information will expire at the earlier of the date when the information is no longer Confidential Information as defined in Paragraph 2.4 or three (3) years after the expiration or termination date of this CRADA, except for IPI, for which the obligation to maintain confidentiality will extend indefinitely. Collaborator may request an extension to this term when necessary to protect Confidential Information relating to products not yet commercialized.

**8.7 Publication.** The Parties are encouraged to make publicly available the results of their research and development activities. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a CRADA Subject Invention, CRADA Data, or CRADA Materials, the other Party will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that Confidential Information is protected. Either Party may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to file a Patent Application.

**8.8 Clinical Investigators' Research and Development Activities.** Although this CRADA does not grant to Collaborator any rights to Inventions made or Raw Data generated by ICD's contractors or grantees, as they are not parties to this CRADA, ICD agrees that:

**8.8.1** Subject to the other provisions of Article 8 of this CRADA, ICD will maintain, to the extent permitted by law, all Clinical Data in ICD's Possession and Control as Confidential Information, and make them available to Collaborator for its own use and for exclusive use in obtaining regulatory approval for the commercial marketing of Test Article and related CRADA Subject Inventions.

**8.8.2** With regard to Collaborator's Confidential Information, ICD will require the Clinical Investigators to agree to confidentiality provisions at least as restrictive as those provided in this CRADA and to Collaborator's use of data in accordance with Paragraph 8.8.1 for obtaining regulatory approval for marketing Test Article.

**8.8.3** If Collaborator wants access to Raw Data or any other data in the possession of the Clinical Investigators working with Test Article, Collaborator must first contact the CRADA PI. Collaborator will bear any costs associated with Raw Data provided in formats customized for Collaborator.

**8.8.4** Collaborator's right to access Clinical Data in ICD's Possession and Control under Paragraph 8.8 is dependent upon Collaborator's continued development and commercialization of Investigational Agent. If Collaborator fails to continue development or commercialization of Investigational Agent without the transfer of its development efforts to another party within ninety (90) days of discontinuation, ICD has the right to make Clinical Data in ICD's Possession and Control available to a third party.

## **Article 9. Representations and Warranties**

**9.1 Representations of ICD.** ICD hereby represents to Collaborator that:

**9.1.1** ICD has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that ICD's official signing this CRADA has authority to do so.

**9.1.2** To the best of its knowledge and belief, neither ICD nor any of its personnel involved in this CRADA is presently subject to debarment or suspension by any agency of the Government which would directly affect its performance of the CRADA. Should ICD or any



of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, ICD will notify Collaborator within thirty (30) days of receipt of final notice.

**9.2 Representations and Warranties of Collaborator.** Collaborator hereby represents and warrants to ICD that:

**9.2.1** Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that Collaborator's official signing this CRADA has authority to do so.

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**9.2.2** Neither Collaborator nor any of its personnel involved in this CRADA, including Affiliates, agents, and contractors are presently subject to debarment or suspension by any agency of the Government. Should Collaborator or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, Collaborator will notify ICD within thirty (30) days of receipt of final notice.

**9.2.3** Subject to Paragraph 12.3, and if and to the extent Collaborator has agreed to provide funding under Appendix B, Collaborator is financially able to satisfy these obligations in a timely manner.

**9.2.4** The Test Article provided has been produced in accordance with the FDA's current Good Manufacturing Practice set out in 21 C.F.R. §§ 210-211, and ICH QA7, and meets the specifications cited in the Certificate of Analysis and Investigator's Brochure provided.

**Article 10. Expiration and Termination**

**10.1** Expiration. This CRADA will expire on the last date of the term set forth on the Summary Page. In no case will the term of this CRADA extend beyond the term indicated on the Summary Page unless it is extended in writing in accordance with Paragraph 13.6.

**10.2** Termination by Mutual Consent. ICD and Collaborator may terminate this CRADA at any time by mutual written consent.

**10.3** Unilateral Termination. Either ICD or Collaborator may unilaterally terminate this CRADA at any time by providing written notice at least sixty (60) days before the desired termination date. ICD may, at its option, retain funds transferred to ICD before unilateral termination by Collaborator for use in completing the Research Plan. If Collaborator terminates this Agreement before the completion of all approved or active Protocol(s), then Collaborator will supply enough Test Article (and Placebo, if applicable) to complete these Protocol(s) unless termination is for safety concern s.

**10.4** Funding for ICD Personnel. If Collaborator has agreed to provide funding for ICD personnel and this CRADA is mutually or unilaterally terminated by Collaborator before its expiration, then Collaborator agrees that funds for that purpose will be available to ICD for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever occurs sooner. If there are insufficient funds to cover this expense, Collaborator agrees to pay the difference.

**10.5** New Commitments. Neither Party will incur new expenses related to this CRADA after expiration, mutual termination, or a notice of a unilateral termination and will, to the extent feasible, cancel all outstanding commitments and contracts by the termination date. Collaborator acknowledges that ICD will have the authority to retain and expend any funds for up to one (1) year subsequent to the expiration or termination date to cover any unpaid costs obligated during the term of the CRADA in undertaking the research and development activities set forth in the Research Plan.

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**10.6** Collaborator Failure to Continue Development. If Collaborator suspends development of the Test Article without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, Collaborator agrees that ICD may continue developing the Test Article. In that event, the following will apply:

**10.6.1** Collaborator agrees to transfer to ICD all information necessary to enable ICD to contract for the manufacture of the Test Article and, unless abandoned for reasons relating to safety as determined by the data safety monitoring board, to provide the Test Article (and Placebo, if any) in Collaborator's inventory to ICD.

**10.6.2** Further, Collaborator hereby grants to ICD a nonexclusive, irrevocable, world-wide, paid-up license to practice, or have practiced for or on behalf of the Government, any Background Invention that Collaborator may currently have or will obtain on the Test Article, its manufacture, or on any method of using the Test Article for the indication(s) described in the Research Plan, including the right to sublicense to third parties.

**Article 11. Disputes**

**11.1** Settlement. Any dispute arising under this CRADA which is not disposed of by agreement of the CRADA Principal Investigators will be submitted jointly to the signatories of this CRADA. If the signatories, or their designees, are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) will propose a resolution. Nothing in this Paragraph will prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

**11.2** Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article 11, the Parties agree that performance of all obligations will be pursued diligently.

**Article 12. Liability**

12.1 NO WARRANTIES. EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR MATERIAL, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR MATERIAL, OR THAT A TECHNOLOGY UTILIZED BY A PARTY IN THE PERFORMANCE OF THE RESEARCH PLAN DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.

12.2 Indemnification and Liability. Collaborator agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by Collaborator for any purpose of the CRADA Data, CRADA Materials or CRADA Subject Inventions produced in whole or part by ICD employees under this CRADA, unless due to the negligence or willful misconduct of ICD, its employees, or agents. The Government has no statutory authority to indemnify Collaborator. Each Party otherwise will be

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liable for any claims or damages it incurs in connection with this CRADA, except that ICD, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Chapter 171.

12.3 *Force Majeure*. Neither Party will be liable for any unforeseeable event beyond its reasonable control and not caused by its own fault or negligence, which causes the Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. If a *force majeure* event occurs, the Party unable to perform will promptly notify the other Party. It will use its best efforts to resume performance as quickly as possible and will suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

### Article 13. Miscellaneous

13.1 Governing Law. The construction, validity, performance and effect of this CRADA will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this CRADA conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.

13.2 Compliance with Law. ICD and Collaborator agree that they will comply with, and advise any contractors, grantees, or agents they have engaged to conduct the CRADA research and development activities to comply with, all applicable Executive Orders, statutes, and HHS regulations relating to research on human subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56) and relating to the appropriate care and use of laboratory animals (7 U.S.C. §§ 2131 et seq.; 9 C.F.R. Part 1, Subchapter A). ICD and Collaborator will advise any contractors, grantees, or agents they have engaged to conduct clinical trials for this CRADA that they must comply with all applicable federal regulations for the protection of Human Subjects, which may include the Standards for Privacy of Individually Identifiable Health Information set forth in 45 C.F.R. Part 164. Collaborator agrees to ensure that its employees, contractors, and agents who might have access to a “select agent or toxin” (as that term is defined in 42 C.F.R. §§ 73.4-73.5) transferred from ICD is properly licensed to receive the “select agent or toxin.”

13.3 Waivers. None of the provisions of this CRADA will be considered waived by any Party unless a waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, will not be deemed a waiver of any rights of any Party.

13.4 Headings. Titles and headings of the articles and paragraphs of this CRADA are for convenient reference only, do not form a part of this CRADA, and will in no way affect its interpretation.

13.5 Severability. The illegality or invalidity of any provisions of this CRADA will not impair, affect, or invalidate the other provisions of this CRADA.

13.6 Amendments. Minor modifications to the Research Plan may be made by the mutual written consent of the CRADA Principal Investigators. Substantial changes to the CRADA, extensions of the term, or any changes to Appendix C will become effective only upon a written amendment signed by the signatories to this CRADA or by their representatives duly authorized

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to execute an amendment. A change will be considered substantial if it directly expands the range of the potential CRADA Subject Inventions, alters the scope or field of any license option governed by Article 7, or requires a significant increase in the contribution of resources by either Party.

13.7 Assignment. Neither this CRADA nor any rights or obligations of any Party hereunder will be assigned or otherwise transferred by either Party without the prior written consent of the other Party. This CRADA will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

13.8 Notices. All notices pertaining to or required by this CRADA will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, or by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the Contacts Information Page, or to any other address designated in writing by the other Party. Notices will be considered timely if received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Notices regarding the exercise of license options will be made pursuant to Paragraph 7.3. Either Party may change its address by notice given to the other Party in the manner set forth above.

13.9 Independent Contractors. The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party will maintain sole and exclusive control over its personnel and operations.

13.10 Use of Name; Press Releases. By entering into this CRADA, the Government does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this CRADA or to any patent or other intellectual-property license or

agreement that implements this CRADA by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or services. Each Party agrees to provide proposed press releases that reference or rely upon the work under this CRADA to the other Party for review and comment at least five (5) business days before publication. Either Party may disclose the Title and Abstract of the CRADA to the public without the approval of the other Party.

13.11 Reasonable Consent. Whenever a Party's consent or permission is required under this CRADA, its consent or permission will not be unreasonably withheld.

13.12 Export Controls. Collaborator agrees to comply with U.S. export law and regulations. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by ICD, or ICD Materials, or ICD's Confidential Information to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.

13.13 Entire Agreement. This CRADA constitutes the entire agreement between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.

13.14 Survivability. The provisions of Paragraphs 3.3, 3.4, 3.8, 4.2, 4.3, 5.3, 5.4, 6.1-9.2, 10.3-10.6, 11.1, 11.2, 12.1-12.3, 13.1-13.3, 13.7, 13.10 and 13.14 will survive the expiration or early termination of this CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

SIGNATURE PAGE

ACCEPTED AND AGREED

BY EXECUTING THIS AGREEMENT, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR ICD:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Typed Name:  
Title:

FOR COLLABORATOR:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Typed Name:  
Title:

CONTACTS INFORMATION PAGE

CRADA Notices

For ICD:

For Collaborator:

**Patenting and Licensing**

For ICD: For Collaborator (if separate from above):

Division Director, Division of Technology  
Development and Transfer  
NIH Office of Technology Transfer  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804  
Tel: 301-496-7057  
Fax: 301-402-0220

**Delivery of Materials Identified In Appendix B (if any)**

For ICD: For Collaborator:

**ICD Project Officer for Extramural Investigators**

**Name:**  
**Branch:**  
**Address:**  
**Telephone:**

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**SUMMARY PAGE**

*EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,  
RELEASE THIS SUMMARY PAGE TO THE PUBLIC.*

**TITLE OF CRADA:**

**PHS [ICD] Component:**  
**ICD CRADA Principal Investigator:**

**Collaborator:**  
**Collaborator CRADA Principal Investigator:**

**Term of CRADA:** ( ) years from the Effective Date

**ABSTRACT OF THE RESEARCH PLAN:**

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**Appendix C**

**CTEP Exceptions or Modifications to this CRADA (6/26/06)**

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**Appendix C**

**Exceptions or Modifications to this CRADA**

Additions and deletions within Articles of the extramural clinical trial CRADA appear as underline and strikeout, respectively.

“Test Article” means, in accordance with 21 C.F.R. § 50.3(j), any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act that is intended for administration to humans or animals, including a drug or biologic as identified in the Research Plan and Appendix B, that is used within the scope of the Research

Plan. The Test Article may also be referred to as Investigational Agent, Study Material, or Study Product. For this Agreement, Investigational Agent means xxxxxxxxxxxx.

Add the following new sections to the Article 2. Definitions:

“Contract” means a Funding Agreement that is a research and development mechanism that provides that the contractor perform for the benefit of the Government, with an expectation of completion of the stated research goals and the delivery of a report, data, materials or other product. Generally, Contracts are administered under the Federal Acquisition Regulations (FAR) codified at Title 48 C.F.R., Chapter 1 or the Health Services Acquisition Regulations (HSAR) codified at Title 48 C.F.R., Chapter 3.

“Cooperative Agreement” means a Funding Agreement that is a species of a Grant, whereby the funding Federal agency intends to be substantially involved in carrying out the research program.

“CTA” means Clinical Trial Agreement.

“CTEP” means the Cancer Therapy Evaluation Program, DCTD, NCI, a program within NCI which plans, assesses and coordinates all aspects of clinical trials including extramural clinical research programs, internal resources, treatment methods and effectiveness, and compilation and exchange of data.

“DTP” means Developmental Therapeutics Program, DCTD, NCI, the program within the NCI which coordinates preclinical development of agents to be evaluated in DCTD-sponsored clinical trials.

“DCTD” means Division of Cancer Treatment and Diagnosis, NCI.

“FDA” means U.S. Food and Drug Administration.

“Funding Agreement” means a Contract, Grant, or Cooperative Agreement entered into between a Federal agency and another party for the performance of experimental, developmental or research work funded in whole or in part by the Federal Government.

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“Grant” means a Funding Agreement that is an award of financial assistance which may be provided for support of basic research in a specific field of interest to the funding Federal agency.

“Multi-Party Data” means clinical data from clinical studies sponsored by NCI pursuant to CTAs or CRADAs, where such data are collected under protocols involving combinations of investigational agents from more than one CTA or CRADA collaborator.

“Protocol Review Committee” (or “PRC”) means the CTEP/DCTD committee that reviews and approves studies involving NCI investigational agents and/or activities supported by NCI.

### 3.7 Investigational New Drug Applications.

3.7.1 ~~If an IND is required either ICD or Collaborator, DCTD, NCI, as indicated in the Research Plan, will prepare and submit an IND and all Clinical Investigators participating in DCTD-sponsored clinical trials must have completed registration documents on file (1572 forms) with CTEP.~~

3.7.2 ~~If ICD elects to file its own IND, To support the DCTD IND, Collaborator agrees to provide ICD DCTD background data and information necessary to support the IND. Collaborator further agrees to provide a letter of cross-reference to all pertinent regulatory filings including an IND and/or DMF sponsored by Collaborator. Collaborator’s employees will be reasonably available to respond to inquiries from the FDA regarding information and data contained in the Collaborator’s IND, DMF, other filings, or other information and data provided to ICD DCTD by the Collaborator pursuant to this Article 3. If ICD DCTD has provided information or data to assist Collaborator in its IND filing, ICD DCTD will provide a letter of cross reference to its IND and respond to inquiries related to information provided by ICD DCTD, as applicable.~~

3.7.3 If Collaborator supplies Confidential Information to ~~ICD DCTD~~ in support of an IND filed by ~~ICD DCTD~~, this information will be protected in accordance with the corresponding confidentiality provisions of Article 8.

3.7.4 Collaborator may sponsor its own clinical trials and hold its own IND for studies performed outside the scope of this CRADA. These studies, however, should not adversely affect the ability to accomplish the goal of the Research Plan, for example, by competing for the same study population. All data from those clinical trials are proprietary to Collaborator for purposes of this CRADA.

3.7.5 In the event that Canadian institutions are participating on DCTD-sponsored clinical trials, Collaborator will need to assist in the submission of the regulatory documents to the Canadian Health Products and Food Branch to allow for such participation. This may include a letter of cross-reference to an existing Clinical Trials Application (CTA) or a DMF, including supporting documentation on the production of the Investigational Agent. The forms and procedures for preparing Canadian CTAs are available at [http://www.hc-sc.gc.ca/hpfb-dgpsa/index\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/index_e.html).

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3.8 ~~Test Article Investigational Agent~~ Information and Supply. Collaborator agrees to provide ~~ICD DCTD~~ without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade ~~Test Article Investigational Agent~~ (and, as required by the Protocol(s), Placebo) to complete the clinical trial(s) agreed to and approved under this CRADA. Collaborator will provide a Certificate of Analysis to ~~ICD DCTD~~ for each lot of the ~~Test Article Investigational Agent~~ provided. It is

understood that DCTD shall take responsibility for and reasonable steps to maintain appropriate records and assure appropriate supply, handling storage, distribution and usage of these materials in accordance with the terms of this Agreement, the Protocol(s) and any applicable laws and regulations relating thereto.

Collaborator agrees to supply sufficient inventory to ensure adequate and timely supply of Investigational Agent for mutually agreed upon Protocol(s). DCTD will provide updated forecasts of amounts of Investigational Agent anticipated for ongoing and anticipated studies. Collaborator further agrees to provide draft Investigational Agent labels to the NCI Pharmaceutical Management Branch (PMB) for review and agrees to reasonable labeling revisions to comply with DCTD label guidelines. NCI NSC (National Service Center) numbers will be required to be on the label of Investigational Agent for all DCTD-sponsored clinical trials.

Furthermore, Collaborator agrees to provide without charge Investigational Agent or unformulated analytical grade Investigational Agent or metabolites, if available, to DCTD to supply to NCI investigators for the development of mutually agreed upon analytical assays, ancillary correlative studies and pre-clinical studies conducted in conjunction with DCTD-sponsored protocols.

Collaborator agrees to allow Investigational Agent to be distributed to NCI investigators for mutually agreeable preclinical studies designed to enhance the basic understanding and development of Investigational Agent. These will include preclinical studies designed to support clinical trials in pediatric patients; preclinical combination studies to provide data in support of a clinical trial and other pertinent requests. All NCI investigators will sign Material Transfer Agreements (MTAs) that acknowledge the proprietary nature of the Investigational Agent to Collaborator and include intellectual property and publication provisions consistent with those in this Agreement and for clinical trials.

For many investigational agents for which NCI collaborates in development, NCI will undertake non-clinical studies to enhance the understanding of the mechanism of action of the investigational agent and its targets such as, but not limited to, the development of assays to detect target modulation, biomarker studies, and pharmacodynamics in conjunction with the conduct of clinical studies sponsored by DCTD. Collaborator agrees to provide Investigational Agent to DCTD for these non-clinical studies. A general plan for the non-clinical studies of the Investigational Agent will be established by the Steering Committee. Manuscripts and presentations related to non-clinical studies will be handled in accordance with Article 8.7 of this CRADA.

Collaborator agrees to provide to the PMB the Investigator's Brochure (IB) for Investigational Agent and all subsequent revisions/editions. In addition to being filed to the CTEP IND, the IB

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will be on file in the PMB and will be distributed to all investigators participating on a clinical trial using the Investigational Agent. Distribution will be accompanied by a statement about the confidentiality of the document and it is anticipated that distribution will be electronic. All electronic distribution will be done using Adobe Acrobat PDF. Any IB received by the PMB that is not in this format will be converted before distribution. Hard copy IBs should be sent to IB Coordinator, Pharmaceutical Management Branch, CTEP, DCTD, NCI, 6130 Executive Blvd, Room 7149, Rockville, MD 20852. Electronic versions should be emailed to the IB Coordinator at [IBCoordinator@mail.nih.gov](mailto:IBCoordinator@mail.nih.gov).

3.9 ~~Test Article Investigational Agent~~ Delivery and Usage. Collaborator will ship the ~~Test Article Investigational Agent~~ and, if required, Placebo to ~~ICD~~ NCI or its designee in containers marked in accordance with 21 C.F.R. § 312.6. ~~ICD~~ NCI agrees that the Clinical Investigators will keep appropriate records and take reasonable steps to ensure that the ~~Test Article Investigational Agent~~ is used in accordance with the Protocol(s) and applicable FDA regulations. In addition, ~~ICD~~ NCI agrees that the ~~Test Article Investigational Agent~~ (and all Confidential Information supplied by Collaborator relating to the ~~Test Article Investigational Agent~~) will be used solely for the conduct of the CRADA research and development activities. Furthermore, ~~ICD~~ NCI agrees that no analysis or modification of the ~~Test Article Investigational Agent~~ will be performed without Collaborator's prior written consent. At the completion of the Research Plan, any unused quantity of ~~Test Article Investigational Agent~~ will be returned to Collaborator or disposed as directed by Collaborator. ~~Pharmacy contacts at ICD or its designee will be determined by ICD and communicated to Collaborator. The contact person for NCI will be Mr. Charles Hall, Chief, Pharmaceutical Management Branch (Telephone Number 301-496-5725) and the Collaborator contact will be XXXXXX (Telephone Number XXXXX).~~

### 3.10 Monitoring.

3.10.1 ~~The Sponsor or its designee DCTD, NCI will be primarily responsible for monitoring clinical sites and for assuring the quality of all clinical data, unless otherwise stated in the Research Plan. Monitoring will comply with FDA Good Clinical Practice (International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guidance; 62 Federal Register 25, 691 (1997)). The other Party may also perform quality assurance oversight. The monitor will communicate significant Protocol violations and submit documentation of monitoring outcomes on Protocol insufficiencies to the other Party in a timely manner.~~

3.10.2 Subject to the restrictions in Article 8 concerning IPI, and with reasonable advance notice and at reasonable times, ~~ICD~~ DCTD will permit Collaborator or its designee(s) access to clinical site(s) to monitor the conduct of the research, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with FDA Good Clinical Practice and the Protocol(s).

3.11 FDA Meetings/Communications. All formal meetings with the FDA concerning any clinical trial within the scope of the Research Plan will be discussed by Collaborator and ICD in advance. Each Party reserves the right to take part in setting the agenda for, to attend, and to participate in these meetings. The Sponsor will provide the other Party with copies of FDA

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meeting minutes, all transmittal letters for IND submissions, IND safety reports, formal questions and responses that have been submitted to the FDA, Annual Reports, and official FDA correspondence, pertaining either to the INDs under this CRADA or to the Clinical Investigators on Protocols performed in accordance with the Research Plan, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law.

Add a new Article 3.12 as follows:

3.12 Steering Committee and CRADA Research. The Parties agree to establish a Steering Committee comprising at least the CRADA Principal Investigators to conduct and monitor the research of the Investigational Agent in accordance with the CRADA Research Plan. Members of the Steering Committee shall continue to remain employed by their respective employers under their respective terms of employment.

Investigational Agent's development under the CRADA Research Plan shall be a collaborative undertaking by Collaborator and NCI. Details of this development beyond those set forth in the CRADA Research Plan shall be formulated and/or discussed in Steering Committee meeting(s) before implementation of large-scale or resource intensive studies. The clinical development plans formulated by the Steering Committee shall be implemented either intramurally at the NCI or extramurally under NCI-sponsored Funding Agreements.

Additional CRADA information, including Steering Committee meeting reports, Protocol Review Committee records, clinical trial protocols, Institutional Review Board approval information, IND and general regulatory information, and preclinical and clinical data in NCI's possession and control shall remain on file with NCI.

Add a new Article 3.13 as follows:

3.13 Clinical Protocols. Clinical protocol Letters of Intent (LOI) or concepts for each study within the scope of the CRADA Research Plan will be solicited by CTEP from selected intramural and extramural Clinical Investigators. Clinical protocols from each DCTD- and Collaborator-approved LOI or concept will describe in detail the research to be conducted at each center and must be submitted to the Protocol Review Committee (PRC) for review and approval prior to implementation. Each clinical protocol received by NCI will be forwarded electronically to Collaborator for review and comment approximately two weeks before it is reviewed by the PRC. Comments from Collaborator received by CTEP before the PRC meeting will be discussed by the PRC, will be given due consideration, and will be incorporated into the protocol, absent good cause. Comments from either Collaborator or the CTEP staff that are agreed upon in the PRC meeting will be formatted as a consensus review, which is returned to the Clinical Investigator for necessary and/or suggested changes before the protocol can be given final approval and submitted to the FDA. A copy of the final approved protocol will be forwarded to Collaborator within 24 to 48 hours of its submission to the FDA.

4.2 Final Research and Development Reports. The Parties will exchange final reports of their results within six (6) months after the expiration or termination of this CRADA. These reports will set forth the technical progress made; any publications arising from the research; and

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the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications. Abstracts and publications provided to CTEP by investigators and further provided by CTEP to Collaborator will fulfill this final report obligation.

4.4 Safety Reports. ~~In accordance with FDA requirements, the Sponsor will establish and maintain records and submit safety reports to the FDA, as required by 21 C.F.R. § 312.32 and 21 C.F.R. 312.150(b)(1), or other applicable regulations. In the conduct of research under this CRADA, the Parties will comply with specific ICD guidelines and policies for reporting ADEs and AEs, as well as procedures specified in the Protocol(s). The Sponsor must provide the other Party with copies of all Safety Reports concurrently with their submission to the FDA, and with any other information affecting the safety of Human Subjects in research conducted under this CRADA. DCTD shall report all serious and/or unexpected Adverse Events to FDA in accordance with the reporting obligations of 21 CFR 312.32 and will, within 24 to 48 hours of notification to FDA, forward all such reports to Collaborator. All other Adverse Event reports received by DCTD shall be reported to the FDA consistent with 21 CFR 312.32 and 312.33. In the event that Collaborator informs the FDA of any serious and/or unexpected Adverse Events, Collaborator must notify the NCI at the same time by sending the reports to CTEPSupportAE@tech-res.com. NCI will then notify the Clinical Investigator(s) conducting studies under DCTD-sponsored protocols, if appropriate.~~

4.5 Annual Reports. ~~The Sponsor DCTD will provide the other Party Collaborator a copy of the Annual Report concurrently with the submission of the Annual Report to the FDA. Annual Reports will be kept confidential in accordance with Article 8. Collaborator will provide DCTD with a copy of its Annual Report to the FDA if Collaborator is sponsoring studies of Investigational Agent under its own IND.~~

7.2 Collaborator's License Option to CRADA Subject Inventions. With respect to Government rights to any CRADA Subject Invention made solely by an ICD employee(s) or made jointly by an ICD employee(s) and a Collaborator employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive, or co-exclusive, if applicable, or nonexclusive commercialization license. The option to elect a co-exclusive license shall apply when a CRADA Subject Invention is also a CRADA Subject Invention under another CRADA resulting from mutually agreed upon studies as described in Article 8.9 and the field of use of this co-exclusive license shall be to the use of the combination of the Investigational Agent with another agent(s) commensurate with the scope of the Research Plan. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.

7.6 Third Party License. Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if PHS grants Collaborator an exclusive, or co-exclusive, license to a CRADA Subject Invention made solely by an ICD employee or jointly with a Collaborator employee, the Government will retain the

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right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the CRADA Subject Invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or, if Collaborator fails to grant a license, to grant a license itself. The exercise of these rights by the Government will only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by federal regulations, and such requirements are not reasonably satisfied by Collaborator; or (iii) Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this Paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(2).

8.7 Publication. The Parties are encouraged to make publicly available the results of their research and development activities. Before ~~either Party Collaborator or NCI~~ submits a paper or abstract for publication ~~or otherwise intends to publicly disclose information~~ about a CRADA

Subject Invention, CRADA Data, or CRADA Materials, the other Party will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that Confidential Information is protected. Either Party may request in writing that the a proposed publication ~~or other disclosure~~ be delayed for up to thirty (30) additional days as necessary to file a Patent Application. Manuscripts to be submitted for publication by NCI investigators will be sent to NCI's Regulatory Affairs Branch [anshers@mail.nih.gov] for forwarding to Collaborator for review as soon as they are received and in compliance with the timelines outlined above. Abstracts to be presented by NCI investigators will be sent to NCI's Regulatory Affairs Branch [anshers@mail.nih.gov] for forwarding to Collaborator as soon as they are received, preferably no less than three days prior to submission, but prior to presentation or publication, to allow for preservation of U.S. or foreign patent rights.

8.8 **Clinical Investigators' Research and Development Activities.** In pursuing the development of Investigational Agent pursuant to this CRADA, NCI may utilize contractors and extramural investigators that are not NCI employees for part or all of the completion of this Research Plan, which may cover pre-clinical, non-clinical and clinical studies, through Funding Agreements. Participation in DCTD-sponsored clinical trials by these investigators shall be determined after competitive solicitation and review of Protocol Letters of Intent (LOIs) and study protocols by CTEP, NCI. All Funding Agreements for the conduct of extramural clinical trials will include the Intellectual Property Option to Collaborator Terms of Award Addition offering Collaborator first rights of negotiation to extramural inventions (web site: <http://ctep.cancer.gov/industry>). Although this CRADA does not grant to Collaborator any rights to Inventions made or Raw Data generated by ~~ICD's~~ NCI's contractors or grantees, as they are not parties to this CRADA, ~~ICD~~ NCI agrees that:

8.8.1 Subject to the other provisions of Article 8 of this CRADA, ~~ICD~~ NCI will maintain, to the extent permitted by law, all Clinical Data in ~~ICD's~~ NCI's Possession and Control as Confidential Information, and make them available to Collaborator for its own use and for exclusive use in obtaining regulatory approval for the commercial marketing of ~~Test Article Investigational Agent~~ and related CRADA Subject Inventions. Similarly, NCI will also maintain, to the extent permitted by law, all data generated in preclinical and non-clinical studies that are in NCI's possession and control as Confidential

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Information, and make them available to Collaborator for its own use and for exclusive use in obtaining regulatory approval for the commercial marketing of Investigational Agent and related CRADA Subject Inventions. Collaborator will not publish any such data provided under the CRADA without NCI's permission. Accordingly, said data shall not be transferable by Collaborator to any third party, except to Collaborator affiliates and development partners, without the written permission of the NCI. Following NCI's permission, the third party shall enter into a Confidential Disclosure Agreement with the NCI and Collaborator, if requested by NCI, before any data can be transferred.

8.8.2 With regard to Collaborator's Confidential Information, ~~ICD~~ NCI will require the Clinical Investigators to agree to confidentiality provisions at least as restrictive as those provided in this CRADA and to Collaborator's use of data in accordance with Paragraph 8.8.1 for obtaining regulatory approval for marketing ~~Test Article Investigational Agent~~.

8.8.3 If Collaborator wants access to Raw Data or any other data in the possession of the Clinical Investigators working with ~~Test Article Investigational Agent~~ under a Funding Agreement or other agreements, Collaborator must first contact the ~~CRADA PI~~ Regulatory Affairs Branch (RAB), CTEP, NCI [Telephone 301-496-7912; anshers@mail.nih.gov]. Subsequent to authorization by RAB, Collaborator may directly contact the Clinical Investigators. Collaborator will bear any costs associated with Raw Data provided in formats customized for Collaborator, which costs will be paid by Collaborator directly to the Clinical Investigators.

8.8.4 Collaborator's right to access Clinical Data in ~~ICD's~~ NCI's Possession and Control under Paragraph 8.8 is dependent upon Collaborator's continued development and commercialization of Investigational Agent, If Collaborator fails to continue development or commercialization of Investigational Agent without the transfer of its development efforts to another party within ninety (90) days of discontinuation, ~~ICD~~ NCI has the right to make Clinical Data in ~~ICD's~~ NCI's Possession and Control available to a third party.

Add a new Article 8.9 as follows:

8.9 **Multi-Party Data Rights.** For clinical protocol(s) where Investigational Agent is used in combination with another investigational agent supplied to NCI pursuant to a CTA or CRADA between NCI and an entity not a Party to this CRADA [hereinafter referred to as "Third Party"], the access and use of Multi-Party Data by the Collaborator and Third Party shall be co-exclusive as follows:

8.9.1 NCI will provide both Collaborator and Third Party with notice regarding the existence and nature of the agreements governing their collaborations with NIH, the design of the proposed combination protocol(s), and the existence of any obligations that might restrict NCI's participation in the proposed Combination protocols.

8.9.2 Collaborator shall agree to permit use of the Multi-Party Data from these trials by Third Party to the extent necessary to allow Third Party to develop, obtain regulatory approval for, or commercialize its own investigational agent(s). However, this provision

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will not apply unless Third Party also agrees to Collaborator's reciprocal use of Multi-Party Data.

8.9.3 Collaborator and Third Party must agree in writing prior to the commencement of the combination trial(s) that each will use the Multi-Party Data solely for the development, regulatory approval, and commercialization of its own investigational agent(s).

Add a new Article 8.10 as follows:

8.10 **Access, review and receipt of Identifiable Private Information.** Collaborator access to and review of Identifiable Private Information shall be only for on-site quality auditing. Collaborator will receive Identifiable Private Information only if necessary for purposes of satisfying FDA or other health authorities' reporting requirements, and for internal research purposes, directly related to obtaining regulatory approval of Investigational Agent. Collaborator is prohibited from access, review, receipt, or use of such information for other purposes. All IRB approved protocols and informed consent documents related to this research project will clearly describe this



practice. If the Collaborator will have access to Identifiable Private Information, the protocol and the informed consent must clearly state (i) the existence of the Collaborator; (ii) the Collaborator's access to Identifiable Private Information, if any; and (iii) the extent to which confidentiality will be maintained. For clinical protocol(s) involving a third party, the other party's access, review, receipt, or use of Identifiable Private Information shall be subject to the same limitations as described in this Article 8.10.

10.6 **Collaborator Failure to Continue Development.** If Collaborator suspends development of the ~~Test Article~~ Investigational Agent without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, Collaborator agrees that ICD may continue developing the ~~Test Article~~ Investigational Agent. In that event, the following will apply:

10.6.1 Collaborator agrees to transfer to ICD all information necessary to enable ICD to contract for the manufacture of the ~~Test Article~~ Investigational Agent and, unless abandoned for reasons relating to safety as determined by the data safety monitoring board, to provide the ~~Test Article~~ Investigational Agent (and Placebo, if any) in Collaborator's inventory to ICD or arrange for an independent contractor to manufacture and provide Investigational Agent to NCI for two years or until the completion of ongoing mutually agreed to studies.

10.6.2 Further, Collaborator hereby grants to ICD a nonexclusive, irrevocable, world-wide, paid-up license to practice, or have practiced for or on behalf of the Government, any Background Invention that Collaborator may currently have or will obtain on the ~~Test Article~~ Investigational Agent, its manufacture, or on any method of using the ~~Test Article~~ Investigational Agent for the indication(s) described in the Research Plan, including the right to sublicense to third parties.

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13.9 **Independent Contractors.** The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party will maintain sole and exclusive control over its personnel and operations. If Collaborator elects to perform any portion of the Research Plan through a contractor or consultant, Collaborator agrees to incorporate into such contract all provisions necessary to ensure that the work of such contractor or consultants is governed by the terms of the CRADA, including, but not limited to a provision for the assignment of inventions of the contractor or consultant to the Collaborator.

13.12 **Export Controls.** Collaborator agrees to comply with U.S. export law and regulations, including 21 U.S.C. 382 and 21 CFR Part 312.110. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by ICD, or ICD Materials, or ICD's Confidential Information to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.

13.14 **Survivability.** The provisions of Paragraphs [3.3, 3.4, 3.8, 4.2, 4.3, 4.4, 5.3, 5.4, 6.1-9.2, 10.3-10.6, 11.1, 11.2, 12.1-12.3, 13.1-13.3, 13.7, 13.10 and 13.14] will survive the expiration or early termination of this CRADA.

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AMENDMENT #7

To Letter of Intent for Proposed CRADA #2166

“Preclinical and Clinical Development of [\*]”

The purpose of this Amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled “Preclinical and Clinical Development of [\*].” These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this Amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other original is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is extended for six months from November 23, 2010 to, May 23, 2011.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/ Douglas R. Lowy  
Douglas R. Lowy, M.D.  
Deputy Director, NCI

11/26/10  
Date

For NewLink Genetics Corporation:

/s/ Nicholas Vahanian  
Nicholas Vahanian, M.D.  
Chief Operating Officer

1/12/10  
Date

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REPLY TO  
ATTENTION OF

DEPARTMENT OF THE ARMY  
U.S. ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND ACQUISITION  
CENTER  
RESEARCH TRIANGLE PARK DIVISION  
P.O. BOX 12211  
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709-2211

[stamp:] May 8, 2008

AMSRD-ACC-R 70-1t

Subject: Contract No. W911NF-08-C-0044 (Proposal 54590-CH-CB1)

Bio Protection Systems Corporation  
Attn: Mr. Carl Langren  
2901 S. Loop Drive  
Suite 3360  
Ames, IA 50010-8646

Dear Mr. Langren:

Enclosed for your retention is a signed copy of the subject contract.

All correspondence pertaining to the scientific and technical aspects of the contract should be directed to the Government technical monitor specified in the contract. Other correspondence should be directed to Mr. Leroy R. Hardy at (919) 549-4237 or by email @leroy.r.hardy@us.army.mil.

Sincerely,

/s/Leroy R. Hardy Jr.

\_\_\_\_\_  
LEROY R. HARDY JR.  
Contracting Officer

Enclosure

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<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)		RATING		PAGE OF PAGES 1   17	
2. CONTRACT (Proc Inst Ident) NO. W911NF-06-C0044		3. EFFECTIVE DATE 05 May 2008		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 54590CHCBD08141			
5. ISSUED BY US ARMY RDECOM ACQ CTR - W911NF 4300 S. MIAMI BLVD DURHAM NC 27703		CODE W911NF		6. ADMINISTERED BY (If other than Item 5) <b>See Item 5</b>			
7. NAME AND ADDRESS OF CONTRACTOR BIOPROTECTION SYSTEMS CORPORATION 2901 S LOOP DR STE 3360 AMES IA 50010-8646 <i>(No, street, city, county, state and zip code)</i>				8. DELIVERY <input type="checkbox"/> POB ORIGIN <input checked="" type="checkbox"/> OTHER (see below)		9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days	
CODE 47EJ3		FACILITY CODE		10. SUBMIT INVOICES 3 4 copies unless otherwise specified TO THE ADDRESS SHOWN IN:		ITEM <b>Section G</b>	
11. SHIP TO/MARK FOR TRANSPORTATION OFFICE - W38QYT PR PROP BK ACCT DURHAM PO BOX 12211 RESEARCH TRIANGLE PARK NC 27708-2211		CODE W38QYT		12. PAYMENT WILL BE MADE BY DFAS ROCK ISLAND DFAS COLUMBUS DFAS-ROCK ISLAND / JAIBAC ATTN: ROCK ISLAND PO BOX: 182316 COLUMBUS OH 43218-2316		CODE HQ0303	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c) ( ) <input type="checkbox"/> 41 U.S.C. 253(c) ( )				14. ACCOUNTING AND APPROPRIATION DATA <b>See Schedule</b>			
15A. ITEM NO.		15B. SUPPLIES / SERVICES		15C. QUANTITY		15D. UNIT.	
		<b>SEE SCHEDULE</b>				15E. UNIT PRICE	
						15F. AMOUNT	
				<b>15G. TOTAL AMOUNT OF CONTRACT \$69,990.00</b>			
<b>16. TABLE OF CONTENTS</b>							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
<b>PART I - THE SCHEDULE</b>				<b>PART II - CONTRACT CLAUSES</b>			
X	A	SOLICITATION/CONTRACT FORM	1 - 3	X	I	CONTRACT CLAUSES	14 - 16
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4	<b>PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS</b>			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	5	J	LIST OF ATTACHMENTS		
X	D	PACKAGING AND MARKING	6	<b>PART IV - REPRESENTATIONS AND INSTRUCTIONS</b>			
X	E	INSPECTION AND ACCEPTANCE	7	K	REPRESENTATIONS CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	8 - 9	L	INSTRS. CONDS. AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	10 - 11	M	EVALUATION FACTORS FOR AWARD		
X	H	SPECIAL CONTRACT REQUIREMENTS	12 - 13				
<b>CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE</b>							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign (his document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.			
19A. NAME AND TITLE OF SIGNER. (Type or print)				20A. NAME AND TITLE OF CONTRACTING OFFICER LEROY R. HARDY / CONTRACTING OFFICER TEL 919-549-4237 EMAIL: leroy.r.hardy@us.army.mil			
19B. NAME OF CONTRACTOR		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA		20C. DATE SIGNED 05-May -2008	
By: _____ (Signature of person authorized to sign)				By: /s/Leroy R. Harding Jr. (Signature of Contracting Officer)			
NSN 7540-01-152-8069		26-107		STANDARD FORM 26 (REV. 4-85)			
PREVIOUS EDITION UNUSABLE		GPO 1985 O - 469-794		Prescribed by GSA PAR (48 CFR) 53.214(a)			

## SECTION B - Supplies or Services and Prices

### CLIN 0001 (Firm Fixed Price)

#### B.1. This is a Fixed Price Contract.

B.2. **Line Item Description.** In accordance with the terms and conditions of this contract, the Contractor, independently and not as an agent of the Government, shall provide all necessary materials, labor, equipment, and facilities, except as specified herein to be furnished by the Government, and shall do all that which is necessary or incident to the satisfactory and timely performance of Contract Line Item Number(s).

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE	AMOUNT
0001	SCIENTIFIC RESEARCH SERVICES FFP Small Business Innovative Research (SBIR) proposal C081-105-0080, titled "Multiple Indication Adjuvants" sets forth the research to be completed under this contract line item number. The negotiated price of \$69,998.00 shall be disbursed as delineated in the SubCLINs shown below.				

PURCHASE REQUEST NUMBER: 54590CHCBD08141

NET AMT \$ 0.00

ACRN AA \$ 0.00  
CIN: 54590CHCBD081410001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AA		1	Dollars, U.S.	\$11,660.00	\$11,660.00

## FIRST MONTHLY REPORT

Firm Fixed Price

Report due 30 days after the date specified in block 3 of the Standard Form 26. Payments shall be disbursed in accordance with the total amount delineated in each subclin listed herein.

PURCHASE REQUEST NUMBER: 54590CHCBD08141

PROJECT: 54590CHCBD

NET AMT \$ 11,660.00

ACRN AA \$ 11,660.00  
CIN: 54590CHCBD081410001AA

2

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AB		1	Dollars, U.S.	\$11,666.00	\$11,666.00

## SECOND MONTHLY REPORT

Firm Fixed Price

Report due 60 days after the date specified in block 3 of the Standard Form 26. Payments shall be disbursed in accordance with the total amount delineated in each subclin listed herein.

PURCHASE REQUEST NUMBER: 54590CHCBD08141

PROJECT: 54590CHCBD

NET AMT \$ 11,666.00

ACRN AA \$ 11,666.00  
CIN: 54590CHCBD081410001AB

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AC		1	Dollars, U.S.	\$11,666.00	\$11,666.00

## THIRD MONTHLY REPORT

Firm Fixed Price

Report due 90 days after the date specified in block 3 of the Standard Form 26. Payments shall be disbursed in accordance with the total amount delineated in each subclin listed herein.

PURCHASE REQUEST NUMBER: 54590CHCBD08141

PROJECT: 54590CHCBD

NET AMT \$ 11,666.00

ACRN AA \$ 11,666.00  
CIN: 54590CHCBD081410001AC

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AD		1	Dollars, U.S.	\$11,666.00	\$11,666.00

## FOURTH MONTHLY REPORT

Firm Fixed Price

Report due 120 days after the date specified in block 3 of the Standard Form 26. Payments shall be disbursed in accordance with the total amount delineated in each subclin listed herein.

PURCHASE REQUEST NUMBER: 54590CHCBD08141

PROJECT: 54590CHCBD

NET AMT \$ 11,666.00

ACRN AA \$ 11,666.00  
CIN: 54590CHCBD081410001AD

3

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AE		1	Dollars, U.S.	\$11,666.00	\$11,666.00

## FOURTH MONTHLY REPORT

Firm Fixed Price

Report due 150 days after the date specified in block 3 of the Standard Form 26. Payments shall be disbursed in accordance with the total amount delineated in each subclin listed herein.

PURCHASE REQUEST NUMBER: 54590CHCBD08141

NET AMT \$ 11,666.00

ACRN AA \$ 11,666.00  
CIN: 54590CHCBD081410001AE

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AF		1	Dollars, U.S.	\$11,666.00	\$11,666.00

FINAL REPORT

Firm Fixed Price

See Section F.2 for final report due date. Payments shall be disbursed in accordance with the total amount delineated in each subclin listed herein.

PURCHASE REQUEST NUMBER: 54590CHCBD08141

PROJECT: 54590CHCBD

NET AMT \$ 11,666.00

ACRN AA \$ 11,666.00  
CIN: 54590CHCBD081410001AF

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002			Dollars, U.S.	\$29,995.00	\$29,995.00

OPTION SCIENTIFIC RESEARCH SERVICES

FFP

Small Business Innovative Research (SBIR) proposal C081-105-0080, titled "Multiple Indication Adjuvants" sets forth the research to be completed under this contract line item number. The negotiated price of \$29,995,00 shall be disbursed if the option period is exercised,

PURCHASE REQUEST NUMBER: 54590CHCBD08141

PROJECT: 54590CHCBD

NET AMT \$ 29,995.00

4

**SECTION C - Descriptions and Specifications**

C.1. **Proposed Effort.** The FY 08 Small Business Innovative Research (SBIR) Program Phase I proposal C081-105-0080, titled "Multiple Indication Adjuvants", sets forth the research to be performed under this contract and is incorporated by reference into the subject contract. The work to be performed under this contract will be in accordance with the Contractor's proposal and modifications to the contract, if any.

C.2. **Principle Investigator.** The Principle Investigator for this contract is Dr. Ramon Flick. Changes to the PI require prior approval and a modification to the contract.

5

**SECTION D - Packaging and Marking**

D.1. **Packaging (preservation and packing) and marking of deliverable items called for under this contract shall be in accordance with Contractor's best commercial practice to insure safe arrival at destination.**

6

**SECTION E - Inspection and Acceptance****Supplies/services will be inspected/accepted at:**

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0001AA	Destination	Government	Destination	Government
0001AB	Destination	Government	Destination	Government
0001AC	Destination	Government	Destination	Government
0001AD	Destination	Government	Destination	Government
0001AE	Destination	Government	Destination	Government
0001AF	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government

**THE FOLLOWING CONTRACT CLAUSE IS PERTINENT TO THIS SECTION AND HEREBY INCORPORATED BY REFERENCE:**

REF #:	FAR CLAUSE	CLAUSE TITLE AND DATE
1	52.246-9	INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) APR 1984

E.1. The contractor will submit all scientific reports to the office specified in Section F.2. of the contract for inspection and acceptance. Reports shall be prepared in accordance with the SBIR Program Solicitation and in accordance with Sections F.2 of this contract.

**SECTION F - Deliveries or Performance**

CLIN	DATE	QTY	SHIP TO ADDRESS	UIC
0001			TRANSPORTATION OFFICE - W36QYT PR PROP BK ACCT DURHAM PO BOX 12211 RESEARCH TRIANGLE PARK NC 27709-2211 FOB: Destination	W36QYT
0001AA	04 JUN 2008	1	(Same as stated above)	
0001AB	04 JUL 2008	1	(Same as stated above)	
0001AC	03 AUG 2008	1	(Same as stated above)	
0001AD	02 SEP 2008	1	(Same as stated above)	
0001AE	02 OCT 2008	1	(Same as stated above)	
0001AF	01 NOV 2008	1	(Same as stated above)	
0002	N/A	1	(Same as stated above)	N

**NOTICE: THE FOLLOWING CONTRACT CLAUSES PERTINENT TO THIS SECTION ARE HEREBY INCORPORATED BY REFERENCE:**

REF. NO.	FAR CLAUSE NUMBER	CLAUSE TITLE AND DATE
1.	52.242-15	STOP-WORK ORDER (AUG 1989)
2.	52.247-34	F.O.B. DESTINATION (NOV 1991)

F.1. **Period Of Performance:** The research called for by this contract shall be performed during the six month period of performance from the effective date shown in block 3 of the Standard Form 26 or contract cover page.

F.2. **Delivery of Data:** Reports called for by this contract must be delivered as follows:

(a) **Monthly Status Reports** — The reports will be submitted on a monthly basis and will be submitted electronically in PDF format to the following e-mail address: [reports@aro.army.mil](mailto:reports@aro.army.mil). Hard copies will be accepted if electronic submission is not possible. If hard copies are sent, send 2 copies of the Monthly Status Report to the appropriate address below. Reports will identify (1) the name of the contractor, (2) the contract number, (3) the Contract Line Item Number (CLIN) being billed against and (4) the period of performance.

**VIA U.S. MAIL:**

U.S. Army Research Office  
ATTN: Mr. Bill Bratton  
P.O. Box 12211  
Research Triangle Park, NC 27709-2211  
Email: [bill.bratton@us.army.mil](mailto:bill.bratton@us.army.mil)

**VIA OVERNIGHT CARRIER:**

U.S. Army Research Office  
ATTN: Mr. Bill Bratton  
4300 South Miami Blvd.  
Durham, NC 27703-9142  
PH: 919-549-4220

(b) **Final Technical Report** - A Final Technical Report (FTR) shall be submitted electronically in PDF format to the following e-mail address: <http://www.arl.army.mil/main/main/default.cfm?Action=29&Page=218>. Hard copies will be accepted if electronic submission is not possible. If hard copies are sent, send 2 copies to the appropriate address shown above.

The FTR report will be delivered within 30 calendar days after the expiration of the Performance Period (F.1 ) or any extensions thereto. Administrative costs are permitted for the development of this report, but total payment not-to-exceed the total negotiated contract line item amount. The report shall include a completed SF298, "Report Documentation Page" as the first page, identifying the purpose of the work, a brief description of the work, the findings or results, and potential applications of the effort. The SF298 may be published by DoD, and therefore must not contain proprietary or classified information. The balance of the report should indicate in detail the project objectives; work carried out, and results obtained. In completing the SF 298, the following issues need to be addressed:

(1) Block 12a (Distribution/Availability Statement) of the SF 298 in each unclassified final report must contain the following statements (see [www.aro.army.mil/forms](http://www.aro.army.mil/forms)):

- Distribution authorized to U.S. Government Agencies only; contains proprietary information.

(2) Block 13 (Abstract) of the SF 298 must include as the first sentence, "Report developed under SBIR contract W911NF-08-C-0044" for topic "CBD08-105". The abstract must identify the purpose of the work, a brief description of the work performed, results achieved and potential applications of the effort. Since the DoD will publish the abstract, it must not contain proprietary or classified data.

(3) Block 14 (Subject Terms) of the SF298 must include the term "SBIR Report."

(4) DD Form 882, Report of Inventions and Subcontracts. Submit two copies with the Final Technical Report.

**Note:** The final payment is subject to an approved Final Technical Report. The U.S. Army Research Office has the responsibility to submit a copy of the Final Technical Report to the Defense Technical Information Center (DTIC).



## SECTION G - Contract Administration Data

## ACCOUNTING AND APPROPRIATION DATA

AA: 97 0809 0400 2601 018129 8 6N 6N7C 60605502BPM 255Y 8PM54590CHSAPM 8XSAPM 018129

AMOUNT: \$69,990.00

CIN 54590CHCBD081410001AA: \$11,660.00

CIN 54590CHCBD081410001AB: \$11,666.00

CIN 54590CHCBD081410001AC: \$11,666.00

CIN 54590CHCBD081410001AD: \$11,666.00

CIN 54590CHCBD081410001AE: \$11,666.00

CIN 54590CHCBD081410001AF: \$11,666.00

## Note:

1. Final payment should be made upon receipt of the approved Final Technical Report.
2. Contractor costs incurred after the period of performance for the preparation and shipping of the Final Technical Report are allowable if within the contract ceiling amount.

G.1. Contract Administration. Personnel assigned to the office shown in Block #5 of Standard Form 26, Contract Cover Page, will administer this contract.

G.2. Contracting Officer's Technical Representative (COR).

Dr. Jennifer Becker  
 US Army Research Office  
 P.O. Box 12211  
 Research Triangle Park, NC 27709-2211  
 Voice: (919) 549-4224  
 FAX: (919) 549-4310

G.3. Defense Contract Audit Agency (DCAA)

Minneapolis Branch Office — 03541  
 250 Marquette Avenue  
 Suite 525  
 Minneapolis, MN 55401  
 Phone No: 612-343-7750  
 Fax No: 612-343-7774  
 E-mail: dcaa-fao3541@dcaa.mil

G.4. Payment Information and Inquiries.

- a) This manual process shall only be used temporary until be the Army is fully operational on the WAWF system. Once the WAWF system is functional Mr. Bill Bratton will notify all contractors.
- b) The contractor shall submit its payment invoices electronically (preferably with monthly report) to reports@aro.army.mil or bill.bratton@us.army.mil. If this is not possible, you may fax the invoice only to 919-549-4310 to "Attention Mr. Bill Bratton".

c) The contractor shall include the following information on all vouchers:

1. The Contractor shall identify on all vouchers: Name and Address of the Contractor.
2. Invoice Date (The contractor is encouraged to date invoices as close as possible to the date of the mailing or transmission).
3. Contract Number
4. Description of services performed.
5. Name (where applicable), title, telephone number, and mailing address of person to be notified in the event of a defective invoice.
6. Any other pertinent information or documentation required by the contract (verification that a monthly report was submitted).
7. Invoice #
8. Cage Code

d) The ARO Invoice Processing personnel will then obtain the appropriate signatures on the certification form for payments and send them BY FAX to the cognizant DFAS payment office. DFAS customer service is 1-800-756-4571. The DFAS payment office is identified on the face of the SF26.

Note: All invoices must identify the CLIN and sub-CLIN under which payment is being requested. INVOICES, WHICH DO NOT IDENTIFY THE PROPER CLIN(S), WILL BE REJECTED BY THE PAYMENT OFFICE AS IMPROPER. If DFAS discovers one or more errors in the invoice, it

will note the errors on the invoice and fax it to the contractor for revision or execution of required certifications. The contractor may then revise the invoice and fax it back to DFAS for continued processing. The contractor should contact DFAS to verify receipt of the fax. This process is estimated to take thirty days or more.

## SECTION H - Special Contract Requirements

### H.1. Release of Information and Acknowledgment of Sponsorship

- a. Neither the contractor nor any of his employees shall release or publish any news related to this contract without providing a copy to the Contracting Officer Representative (CORI/COTR).
- b. The contractor agrees that in the release of information relating to this contract, such release shall include a statement to the effect that the project or effort depicted was or is sponsored by the U.S. Army Research Office, and that the content of the information does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.
- c. For the purpose of this provision, "information" includes news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association proceedings, symposia, etc.
- d. The contractor further agrees to include this provision in any subcontract awarded as a result of this contract.

### H.2. Research Responsibility

- a. The contractor shall bear responsibility for the conduct of the research specified in the contractor's proposal identified in the contract. The contractor will exercise judgment in obtaining the stated research objectives within the limits of the terms and conditions of the contract; provided, however, that the contractor will obtain the contracting officer's (CO) approval to change the Statement of Work. Consistent with the foregoing the contractor shall conduct the work as set forth in his proposal and accepted by the contract award.
- b. The Contractor shall notify the CO if the principal investigator plans to devote less effort to the project than specified in the proposal and, prior to a change in the PI, the Contractor shall notify the CO and request approval of a replacement.

### H.3. Section K - Representations and Certifications

Section K — Representations and Certifications, and Other Statement of Offerors, as completed by the Contractor in relation to this contract, is hereby incorporated by reference.

### H.4. Option

This contract is renewable, at the option of the Government and may be exercised at any time prior to the end of the time of performance cited in Section F. Should the Government exercise this option, written notification will be provided to the contractor by modification to this contract signed by the Contracting Officer.

### H.5. Contractor Manpower Reporting

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including subcontractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address:  
<https://contractormanpower.army.pentagon.mil>.

The required information includes the following:

1. Contracting Office, Contracting Officer, Contracting Officer's Technical Representative;
2. Contract number, including task and delivery order number;
3. Beginning and ending dates covered by reporting period;
4. Contractor name, address, phone number, e-mail address, identity of contractor employee entering data;
5. Estimated direct labor hours (including sub-contractors);
6. Estimated direct labor dollars paid this reporting period (including sub-contractors);
7. Total payments (including sub-contractors);
8. Predominant Federal Service Code (FSC) reflecting services provided by contractor (and separate predominant FSC for each sub-contractor if different);
9. Estimated data collection cost;

10. Organizational title associated with the Unit Identification Code (UIC) for the Army Requiring Activity (the Army Requiring Activity is responsible for providing the contractor with its UIC for the purposes of reporting this information);
11. Locations where contractor and sub-contractors perform the work (specified by zip code in the United States and nearest city, country, when in an overseas location, using standardized nomenclature provided on website);
12. Presence of deployment or contingency contract language;  
Number of contractor and sub-contractor employees deployed in theater this reporting period (by country). As part of its submission, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. Reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year. Contractors may use a direct XML data transfer to the database server or fill in the fields on the website. The XML direct transfer is a format for transferring files from a contractor's systems to the secure web site without the need for separate data entries for each required data element at the web site. The specific formats for the XML direct transfer may be downloaded from the web site.

SECTION I - Contract Clauses

CLIN 0001 (Firm, Fixed Price)

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): <http://arlininside.arl.mil/offices/procure/library.htm> or <http://farsite.hill.af.mil/VFFARa.htm>

FAR CLAUSE #	TITLE	DATE
FAR 52.202-1	Definitions	(JUL 2004)
FAR 52.203-3	Gratuities	(APR 1984)
FAR 52.203-5	Covenant Against Contingent Fees	(APR 1984)
FAR 52.203-6	Restrictions on Subcontractor Sales to the Government	(SEP 2006)
FAR 52.203-7	Anti-Kickback Procedures	(JUL 1995)
FAR 52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	(JAN 1997)
FAR 52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	(JAN 1997)
FAR 52.203-12	Limitation on Payments to Influence Certain Federal Transactions	(SEP 2007)
FAR 52.204-4	Printed or Copied Double-Sided on Recycled Paper	(AUG 2000)
FAR 52.204-7	Central Contractor Registration	(JUL 2007)
FAR 52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	(SEP 2006)
FAR 52.211-8	Time of Delivery	(JUN 1997)
FAR 52.215-2	Audit & Records-Negotiation Alt II	(JUN 1999) (APR 1998)
FAR 52.215-8	Order of Precedence Uniform Contract Format	(OCT 1997)
FAR 52.215-10	Price Reduction For Defective Cost or Pricing Data	(OCT 1997)
FAR 52.215-12	Subcontractor Cost Or Pricing Data	(OCT 1997)
FAR 52.215-14	Integrity of Unit Prices	(OCT 1997)
FAR 52.215-15	Pension Adjustments and Asset Reversions	(OCT 2004)
FAR 52.215-19	Notification of Ownership Changes	(OCT 1997)
FAR 52.217-9	Option to Extend the Term of the Contract	(MAR 2000)
FAR 52.219-8	Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns	(MAY 2004)
FAR 52.219-14	Limitations on Subcontracting	(DEC 1996)
FAR 52.222-3	Convict Labor	(JUN 2003)
FAR 52.222-26	Equal Opportunity	(MAR 2007)
FAR 52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era	(SEP 2006)
FAR 52.222-36	Affirmative Action for Workers with Disabilities	(JUN 1998)
FAR 52.222-37	Employment Reports on Special Disabled Veterans and Veterans of the Vietnam Era	(SEP 2006)
FAR 52.222-50	Combating Trafficking in Persons	(AUG 2007)
FAR 52.223-6	Drug-Free Workplace	(MAY 2001)
FAR 52.223-14	Toxic Chemical Release Reporting	(AUG 2003)
FAR 52.227-1	Authorization and Consent Alternate I	(DEC 2007) (APR 1984)
FAR 52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	(DEC 2007)
FAR 52.227-11	Patent Rights — Ownership by the Contractor	(DEC 2007)
FAR 52.228-7	Insurance—Liability to Third Persons	(MAR 1996)
FAR 52.229-3	Federal, State, and Local Taxes	(APR 2003)
FAR 52.232-2	Payments under Fixed-Price Research and Development Contracts	(APR 1984)
FAR 52.232-9	Limitation on Withholding of Payments	(APR 1984)
FAR 52.232-17	Interest	(JUN 1996)

FAR CLAUSE #	TITLE	DATE
FAR 52.232-23	Assignment of Claims	(JAN 1986)
FAR 52.232-25	Prompt Payment	(OCT 2003)
FAR 52.232-33	Payment by Electronic Funds Transfer Payment	(OCT 2003)
FAR 52.233-1	Disputes	(JUL 2002)
FAR 52.233-3	Protest After Award	(AUG 1996)
	Alternate I	(JUN 1985)
FAR 52.242-1	Notice of Intent to Disallow Costs	(APR 1984)
FAR 52.242-13	Bankruptcy	(JUL 1995)
FAR 52.243-1	Changes-Fixed Price	(AUG 1987)
	Alternate V	(APR 1984)
FAR 52.244-2	Subcontracts (Fixed Price)	(JUN 2007)
FAR 52.244-5	Competition in Subcontracting	(DEC 1996)
FAR 52.246-23	Limitation of Liability	(FEB 1997)
FAR 52.247-63	Preference for U.S.-Flag Air Carriers	(JUN 2003)
FAR 52.249-1	Termination for Convenience of the Gov (Fixed Price) (Short Form)	(APR 1984)
FAR 52.249-9	Default (Fixed Price Research and Development)	(APR 1984)
FAR 52.253-1	Computer Generated Forms	(JAN 1991)
FAR 52.215-19	Notification of Ownership Changes	(OCT 1997)

**(a) The Contractor shall make the following notifications in writing:**

**(1) When the Contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records, the Contractor shall notify the Administrative Contracting Officer (ACO) within 30 days.**

**(2) The Contractor shall also notify the ACO within 30 days whenever changes to asset valuations or any other cost changes have occurred or are certain to occur as a result of a change in ownership.**

**(b) The Contractor shall —**

**(1) Maintain current, accurate, and complete inventory records of assets and their costs;**

**(2) Provide the ACO or designated representative ready access to the records upon request;**

**(3) Ensure that all individual and grouped assets, their capitalized values, accumulated depreciation or amortization, and remaining useful lives are identified accurately before and after each of the Contractor's ownership changes; and**

**(4) Retain and continue to maintain depreciation and amortization schedules based on the asset records maintained before each Contractor ownership change.**

**(c) The Contractor shall include the substance of this clause in all subcontracts under this contract that meet the applicability requirement of FAR 15.408(k).**

**I.2. DEFENSE ACQUISITION REGULATION SUPPLEMENT (48 CFR CHAPTER 2) CLAUSES:**

DFARS CLAUSE #	TITLE	DATE
DFARS 252.201-7000	Contracting Officer's Representative	(DEC 1991)
DFARS 252.203-7001	Prohibition on Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	(DEC 2004)
DFARS 252.204-7001	Commercial and Government Entity (CAGE) Code Reporting	(AUG 1999)
DFARS 252.204-7003	Control of Government Personnel Work Product	(APR 1992)
DFARS 252.204-7004	Alternate A, Central Contractor Registration	(SEP 2007)
DFARS 252.205-7000	Provision of Information to Cooperative Agreement Holders	(DEC 1991)
DFARS 252.209-7004	Subcontracting with Firms That are Owned or Controlled by the Government of a Terrorist Country	(DEC 2006)
DFARS 252.225-7001	Buy American Act and Balance of Payments Program.	(JUN 2005)
DFARS 252.225-7002	Qualifying Country Sources as Subcontractors.	(APR 2003)
DFARS 252.225-7012	Preference for Certain Domestic Commodities	(MAR 2008)
DFARS 252.225-7016	Restriction on Acquisition of Ball and Roller Bearings.	(MAR 2008)
DEARS 252.227-7016	Rights in Bid or Proposal Information	(JUN 1995)
DFARS 252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	(JUN 1995)
DFARS 252.227-7018	Rights in Noncommercial Technical Data and Computer Software—Small Business Innovation Research (SBIR) Program.	(JUN 1995)
DFARS 252.227-7019	Validation of Asserted Restrictions-Computer Software	(JUN 1995)
DEARS 252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	(JUN 1995)
DFARS 252.227-7030	Technical Data — Withholding of Payment	(MAR 2000)
DFARS 252.227-7037	Validation of Restrictive Markings on Technical Data	(SEP 1999)
DFARS 252.227-7039	Patents — Reporting of Subject Inventions	(APR 1990)
DFARS 252.231-7000	Supplemental Cost Principles	(DEC 1991)
DFARS 252.232-7003	Electronic Submission of Payment Requests	(MAR 2008)



Purchase Card Used As Payment Method:	<input type="checkbox"/>
Letter Contract:	<input type="checkbox"/>
Performance Based Service Acquisition: * FY 2004 and prior; 80% or more specified as performance requirement * FY 2005 and later; 50% or more specified as performance requirement	<input type="checkbox"/>
Contingency Humanitarian Peacekeeping Operation:	Select One
Contract Financing:	Not Applicable
Cost Accounting Standards Clause:	<input type="checkbox"/>
Number Of Actions:	1
Consolidated Contract: (* > \$5 Million)	<input type="checkbox"/>
Legislative Mandates	Principal Place of Performance
Clinger Cohen Act:	<input type="checkbox"/> Principal Place Of Performance Code (State, Location, Country): IA 01855 US
Service Contract Act:	<input type="checkbox"/> Principal Place Of Performance Name: AMES
Walsh-Healey Act:	<input type="checkbox"/> Congressional District Place Of Performance: IOWA 04
Davis Bacon Act:	<input type="checkbox"/> Place Of Performance Zip Code(+4): 50010 - 8646
<b>Product Or Service Information</b>	
Product/Service Code:	AZ11 Description: R&D-OTHER R & D-B RES
Principal NAICS Code:	541712 Description: RESEARCH AND DEVELOPMENT IN THE PHYSICAL
Bundled Contract: (* > \$5 Million)	Not a bundled requirement
System Equipment Code:	000
Country of Product Origin:	US UNITED STATES
Place of Manufacture:	Not Applicable
Use Of Recovered Material:	No Clauses Included
InfoTech Commercial Item Category:	Not IT Products or Services
Claimant Program Code:	S1 Description: SERVICES
Sea Transportation:	No
GFE/GFP Provided Under This Action:	<input type="checkbox"/>
Use Of EPA Designated Products:	Not Required
Description Of Requirement: (4000 characters)	BASIC CONTRACT AWARD
<b>Competition Information</b>	
Extent Competed For Referenced IDV:	
Extent Competed:	Full and Open Competition after exclusion of sources
Solicitation Procedures:	Negotiated Proposal/Quote
Type Of Set Aside:	Small Business Set Aside - Total
Evaluated Preference:	No Preference used
SBIR/STTR:	Small Business Innovation Research Program Phase I Action
Statutory Exception To Fair Opportunity:	Select One
Reason Not Competed:	Select One
Number Of Offers Received:	9 Pre Award FBO Synopsis: <input checked="" type="checkbox"/>
Small Business Competitiveness Demonstration Program:	<input type="checkbox"/> SBA/OFPP Synopsis Waiver Pilot: <input type="checkbox"/>
Commercial Item Test Program:	<input type="checkbox"/> Alternative Advertising: <input type="checkbox"/>

Commercial Item Acquisition Procedures:	<input type="checkbox"/>	A76 Action:	<input type="checkbox"/>
Preference Programs / Other Data			
Contracting Officer's Business Size Selection:	Small Business <input type="button" value="v"/>		
Subcontract Plan:	Plan Not Required <input type="button" value="v"/>		
Price Evaluation Percent Difference:	0 %		
Reason Not Awarded To Small Disadvantaged Business:	No Known SDB Source <input type="button" value="v"/>		
Reason Not Awarded To Small Business:	Select One <input type="button" value="v"/>		



**DEPARTMENT OF THE ARMY**  
**U.S. ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND ACQUISITION**  
**CENTER**  
**RESEARCH TRIANGLE PARK DIVISION**  
**P.O. BOX 12211**  
**RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709-2211**

REPLY TO  
 ATTENTION OF

[stamp:] 14 FEB 2009

AMSRD-ACC-R 70-1t

Subject: Contract No. W911NF-08-C-0044, P00002 (Proposal 54590-CH-CB1)

**Bio Protection Systems Corporation**  
**Attn: Mr. Carl Langren**  
**2901 S. Loop Drive**  
**Suite 3360**  
**Ames, IA 50010-8646**

Dear Mr. Langren:

Enclosed for your retention is a signed copy of the subject contract.

All correspondence pertaining to the scientific and technical aspects of the contract should be directed to the Government technical monitor specified in the contract. Other correspondence should be directed to Mr. Leroy R. Hardy at (919) 549-4237 or by email @ leroy.r.hardy@us.army.mil.

Sincerely,

/s/Leroy R. Hardy Jr.  
 LEROY R. HARDY JR.  
 Contracting Officer

Enclosure

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**

1. CONTRACT ID CODE

PAGE  
 OF  
 PAGES  
 1 3

2. AMENDMENT/MODIFICATION NO. P00002	3. EFFECTIVE DATE 12-Feb-2009	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE	5. PROJECT NO. (If applicable)
6. ISSUED BY US ARMY RDECOM ACQ CTR — W911NF 4300 S. MIAMI BLVD DURHAM NC 27703	CODE W911NF	7. ADMINISTERED BY (If other than Item 6)	CODE

See Item 6

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, County, State and Zip Code)

9A. AMENDMENT OF SOLICITATION NO.

BIOPROTECTION SYSTEMS CORPORATION  
 2901 S LOOP DR STE 3360  
 AMES IA 50010-8646

9B. DATED (SEE ITEM 11)

x 10A. MOD. OF CONTRACT/ORDER NO.  
 W911NF-08-C-0044  
 x 10B. DATED (SEE ITEM 13)  
 05-May-2008

CODE 47EJ3

FACILITY CODE

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer o is extended, o is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:  
 (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
 See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS  
 IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

- A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
- B. THE ABOVE NUMBERED CONTACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF PAR. 43.103(B).
- C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
- D. OTHER (Specify type of modification and authority)
- x FAR 52.243-1 Changes — Fixed Price
- E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)



P-54590-CH-CBD

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)

LEROY R. HARDY JR./CONTRACTING OFFICER  
TEL: 919-549-4237 EMAIL: leroy.r.hardy@us.army.mil

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED

(Signature of person authorized to sign)

BY /s/Leroy R. Hardy Jr.

(Signature of Contracting Officer)

12-Feb-2009

EXCEPTION TO SF 30  
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)  
Prescribed by GSA  
PAR (48 CFR) 53.243

**SECTION SF 30 BLOCK 14 CONTINUATION PAGE**

**SUMMARY OF CHANGES**

The purpose of this modification is to: (1) exercise contract line item number (CLIN) 0002 in accordance with the terms and conditions established in the above noted contract; and (2) fully fund CLIN 0002 in the amount of \$29,995.00. Therefore, the following changes are hereby incorporated:

**SECTION A - SOLICITATION/CONTRACT FORM**

The total cost of this contract was increased by \$29,995.00 from \$69,990.00 to \$99,985.00.

**SECTION B - SUPPLIES OR SERVICES AND PRICES**

CLIN 0002: The word "Option" is hereby deleted in its entirety and CLIN 0002 is exercised and fully funded as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE	AMOUNT
0002	SCIENTIFIC RESEARCH SERVICES CPFF Small Business Innovative Research (SBIR) proposal C081-105-0080, titled "Multiple Indication Adjuvants" sets forth the research to be completed under this contract line item number. The negotiated price of \$29,995.00 shall be disbursed if the option period is exercised. Purchase Request Number: 54590CHCBD08141 Project: 54590CHCBD				
ACRN AB					\$ 0.00
	CIN: 54590CHCBD081410002				

SubCLIN 0002AA is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE \$9,999.00	AMOUNT \$9,999.00
0002AA	FIRST MONTHLY REPORT Firm Fixed Price Report due 30 days after the date specified in block 3 of the Standard Form 26. Purchase Request Number: 54590CHCBD08141-0002 Project: 54590CHCBD				
ACRN AB					\$ 9,999.00
	CIN: 54590CHCBD081410002AA				

SubCLIN 0002AB is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE \$9,998.00	AMOUNT \$9,998.00
0002AB	SECOND MONTHLY REPORT Firm Fixed Price Report due 60 days after the date specified in block 3 of the Standard Form 26. Purchase Request Number: 54590CHCBD08141-0002 Project: 54590CHCBD				
ACRN AB					\$ 9,998.00
	CIN: 54590CHCBD081410002AA				

SubCLIN 0002AC is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE \$9,998.00	AMOUNT \$9,998.00
0002AC					

FINAL TECHNICAL REPORT  
 Firm Fixed Price  
 See Section F for final technical report submittal instructions.

Purchase Request Number: 54590CHCBD08141-0002  
 Project: 54590CHCBD

ACRN AB	\$	9,998.00
CIN: 54590CHCBD081410002AC		

**SECTION E - INSPECTION AND ACCEPTANCE**

The following Acceptance/Inspection Schedule is added for CLIN 0002:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

**SECTION F - DELIVERIES OR PERFORMANCE**

The Delivery Schedule for CLIN 0002 is shown below:

DELIVERY DATE	SHIP TO ADDRESS	UIC
01 MAY 2009	TRANSPORTATION OFFICE - W36QYT PR PROP BK ACCT DURHAM PO BOX 12211 RESEARCH TRIANGLE PARK NC 27709-2211 FOB: Destination	W36QYT

**SECTION G - CONTRACT ADMINISTRATION DATA**

The accounting and appropriation data for CLIN 0002 is delineated below:

ACRN AB:	9780400260186N6N7C60605502BPM255YXR00008 PM54590CHSAPM8XSAPM018129		
SubCLIN 0002AA	54590CHCBD081410002AA	\$	9,999.00
SubCLIN 0002AB	54590CHCBD081410002AB	\$	9,998.00
SubCLIN 0002AC	54590CHCBD081410002AC	\$	9,998.00
		\$	29,995.00

As a result of this modification, the total funded amount for this document was increased by \$29,995.00 from \$69,990.00 to \$99,985.00.

Except as provided herein, all terms and conditions set forth in the above noted contract remains unchanged and in full force and effect.

(End of Summary of Changes)

<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)		RATING		PAGE OF PAGES 1 33	
2. CONTRACT (Proc. Inst. Ident.) NO. HDTRA1-09-C-0014		3. EFFECTIVE DATE 25 Sep 2009		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. SEE SCHEDULE			
3. ISSUED BY DEFENSE THREAT REDUCTION AGENCY/BE-BC 8725 JOHN J. KINGMAN ROAD, MSC 6201 FORT BELVOIR VA 22060-6201		CODE HDTRA1		6. ADMINISTERED BY (If other than Item 5) DCMA TWIN CITIES B.H. WHIPPLE FEDERAL BLDG., RM 1150 FT. SNELLING MN 55111			
7. NAME AND ADDRESS OF CONTRACTOR BIOPROTECTION SYSTEMS CORPORATION 2901 S LOOP DR STE 3360 AMES IA 50010-8646 <i>(Via, street, city, county, state and zip code)</i>				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (see below)			
				9. DISCOUNT FOR PROMPT PAYMENT			
				10. SUBMIT INVOICES 1 ITEM <i>(4 copies unless otherwise specified)</i> TO THE ADDRESS SHOWN IN:			
CODE 47EJ3		FACILITY CODE HDTRA1		12. PAYMENT WILL BE MADE BY DFAS COLUMBUS CENTER DFAS-COWEST ENTITLEMENT OPERATIONS P.O. BOX 182381 COLUMBUS OH 43218-2381			
11. SHIP TO/MARK FOR DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MSC 6201 FORM BELVOIR VA 22060-6201		CODE HDTRA1		14. ACCOUNTING AND APPROPRIATION DATA <b>See Schedule</b>			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c) ( ) <input type="checkbox"/> 41 U.S.C. 253(c) ( )				15A. ITEM NO.			
				15B. SUPPLIES / SERVICES		15F. AMOUNT	
				<b>SEE SCHEDULE</b>			
				15G. TOTAL AMOUNT OF CONTRACT		\$3,707,837.00	
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I – THE SCHEDULE				PART II – CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	15-32
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2-4	PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	5	X	J	LIST OF ATTACHMENTS	33
X	D	PACKAGING AND MARKING	6	PART IV – REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	7		K	REPRESENTATIONS CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	8		L	INSTRS. CONDS. AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	9-13		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	14	CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE			
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT <i>Contractor is required to sign this document and return 1 copies to issuing office.</i> Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. <i>(Attachments are listed herein.)</i>				18. <input type="checkbox"/> AWARD <i>(Contractor is not required to sign this document.)</i> Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.			
19A. NAME AND TITLE OF SIGNER <i>(Type or print)</i> Carl Langren, Chief Financial Officer				20A. NAME AND TITLE OF CONTRACTING OFFICER ALYNNE FAUGHNAN / CONTRACT SPECIALIST TEL _____ EMAIL: alynn.Faughnan@dtra.mil			
19B. NAME OF CONTRACTOR By: <u>/s/ Carl Langren</u> <i>(Signature of person authorized to sign)</i>		19C. DATE SIGNED 9/21/09		20B. UNITED STATES OF AMERICA By: <u>/s/Alynn Faughnan</u> <i>(Signature of Contracting Officer)</i>		20C. DATE SIGNED 9-21-09	

NSN 7540-01-152-8069

26-107

STANDARD FORM 26 (REV. 12/2002)

Previous edition is usable

GPO 1985 O - 489-794

Prescribed by GSA  
PAR (48 CFR) 53.214(a)

**Section B - Supplies or Services and Prices**

**BAA REFERENCE**

This contract is awarded as a result of Solicitation HDTRA1-07-RDINO-BAA, Broad Agency Announcement.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Lot	UNIT PRICE	AMOUNT
0001	Base Period CPFF				\$3,707,837.00
	In accordance with Statement of Work entitled "aGal Adjuvant Technology for Biodefense Agents," dated March 15, 2009 as attachment number one.				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBS080011915				
				ESTIMATED COST	\$ 3,408,767.00

FIXED FEE	\$	299,070.00
TOTAL EST COST + FEE	\$	3,707,837.00

ITEM NO 000101	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT \$0.00
	Base Period Funding				
	CPFF				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBS080011915				
				ESTIMATED COST	\$ 0.00
				FIXED FEE	\$ 0.00
				TOTAL EST COST + FEE	\$ 0.00
	ACRN AA				\$ 1,429,820.00
	CIN: CBS080011915000101				

2

ITEM NO 000102	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT \$0.00
	Base Period Funding				
	CPFF				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBM09001379				
				ESTIMATED COST	\$ 0.00
				FIXED FEE	\$ 0.00
				TOTAL EST COST + FEE	\$ 0.00
	ACRN AB				\$ 2,278,017.00
	CIN: CBM090013719000102				

ITEM NO 0002	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT NSP
	Contract Data Requirements List				
	CPFF				
	CDRLS IAW attachment 1				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBS080011915				
				ESTIMATED COST	\$ 0.00
				FIXED FEE	\$ 0.00
				TOTAL EST COST + FEE	\$ 0.00

See Exhibit A

ITEM NO 0003	SUPPLIES/SERVICES	QUANTITY	UNIT Lot	UNIT PRICE	AMOUNT \$6,891,784.00
OPTION	Option Year One				
	CPFF				
	FOB: Destination				
				ESTIMATED COST	\$ 6,705,742.00
				FIXED FEE	\$ 186,042.00
				TOTAL EST COST + FEE	\$ 6,891,784.00

3

**Section C - Descriptions and Specifications**

**CLAUSES INCORPORATED BY FULL TEXT**

**252.211-9000 Description/Specifications/Work Statement**

The Contractor shall provide the supplies and/or services set forth in Section B, in accordance with the following:

- a. Statement of Work entitled "aGal adjuvant Technology for Biodefense Agents", Dated March 15, 2009, Attachment 1 to the Contract.
- b. Contract Data Requirements List (DD Form 1423), Exhibit A to the Contract.

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**Section D - Packaging and Marking**

**CLAUSES INCORPORATED BY FULL TEXT**

(a) All data contained in Exhibit A, Contract Data Requirements List (CDRL), DD Form 1423 delivered under this contract shall be delivered using best commercial practices to meet the packaging requirements of the carrier and to insure delivery, to the addressees specified on the Data Item Cover Sheet, at destination and in accordance with applicable security requirements.

(b) All data and correspondence submitted to the Contracting Officer shall reference the Contract Number, the CDRL number, and the date submitted. A copy of all correspondence sent to the Contracting Officer's Representative (COR) or Project Manager shall be simultaneously provided to the Contracting Officer.

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## Section E - Inspection and Acceptance

### INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	Destination	Government	Destination	Government
000102	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government

### CLAUSES INCORPORATED BY FULL TEXT

#### 252.246-9000 INSPECTION AND ACCEPTANCE (JUL 2007)

Government inspection and acceptance of data is specified on the Contract Data Requirements List, DD Form 1423. In accordance with FAR 52.246-9, inspection and acceptance for all work performed at any and all times under this contract shall be the responsibility of the:

x Contracting Officer's Representative (COR) or Project Manager (PM). The Wide Area Work Flow (WAWF) Acceptor DoDDAC is located in DTRA 252.201-9000 *Project Manager* or DTRA 252.201-9002 *Contracting Officer's Representative*.

o Administrative Contracting Officer (ACO). The WAWF Acceptor DoDAAC can be found in the "Administered By" block on page 1 of the contract.

(End of Clause)

6

## Section F - Deliveries or Performance

### DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	POP 25-SEP-2009 TO 24-SEP-2011	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1
000101	N/A	N/A	N/A	N/A
000102	N/A	N/A	N/A	N/A
0002	POP 25-SEP-2009 TO 24-SEP-2012	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1
0003	POP 25-SEP-2011 TO 24-SEP-2012	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	HDTRA1

### CLAUSES INCORPORATED BY REFERENCE

52.242-15 Alt I  
52.247-34

Stop-Work Order (Aug 1989) - Alternate I  
F.O.B. Destination

APR 1984  
NOV 1991

7

Section G - Contract Administration Data

ADMINISTRATION

ASSIGNMENT OF CONTRACT ADMINISTRATION SERVICES (CAS)  
FUNCTIONS (AUG 2007)

a. The contract administration functions stated in FAR 42.302(a) are assigned to:  
See Section A, Block 6.

b. Notwithstanding that assignment, in accordance with FAR 42.202(b)(2), the following functions are determined to be best performed by the PCO and are retained by the DTRA Contracting Office:

(1) FAR 42.302(a)(3) Conduct postaward orientation conferences.

(2) FAR 42.302(a)(20) Perform Postaward Security Administration.

(3) FAR 42.302(a)(40) Perform engineering surveillance to assess compliance with contractual terms for schedule, cost, and technical performance in the areas of design, development, and production.

(4) FAR 42.302(a)(51) In accordance with FAR 52.244-2, consent to the placement of subcontracts which have experimental, developmental, or research work as one of its purposes.

(5) Approval or disapproval of the data items listed on Exhibit A, DD Form 1423, Contract Data Requirements List.

(END OF CLAUSE)

ACCOUNTING AND APPROPRIATION DATA

AA: 9780400.2620 1000 B62D 255999 BD27846000 S49012  
AMOUNT: \$1,429,820.00  
CIN CBS080011915000101: \$1,429,820.00

AB: 9790400.2620 1000 B62D 255999 BD29356000 S49012  
AMOUNT: \$2,278,017.00  
CIN CBM090013719000102: \$2,278,017.00

CLAUSES INCORPORATED BY FULL TEXT

252.201-9002 CONTRACTING OFFICER'S REPRESENTATIVE (MAY 2007)

a. The Contracting Officer's Representative (COR) for this contract is:

8

X SEE SEPARATE LETTER  
Defense Threat Reduction Agency/  
8725 John J. Kingman Rd, MS 6201  
Fort Belvoir VA 22060-6201  
Telephone number (703)  
e-mail address @dtra.mil. WAWF Acceptor DoDAAC: HDTRA1

Defense Threat Reduction Agency/  
1680 Texas St SE  
Kirtland AFB NM 87117-5669  
Telephone number (505) -  
e-mail address @abq.dtra.mil.  
WAWF Acceptor DoDAAC: HDTRA2

b. The COR will act as the Contracting Officer's Representative for technical matters providing technical direction and discussion as necessary with respect to the specification/statement of work and monitoring the progress and quality of the Contractor's performance. The COR is NOT an Administrative Contracting Officer (ACO) and does not have the authority to take any action, either directly or indirectly that would change the pricing, quality, quantity, place of performance, delivery schedule, or any other terms and conditions of the contract, or to direct the accomplishment of effort, which goes beyond the scope of the specifications/statement of work in the contract.

c. When, in the opinion of the contractor, the COR requests effort outside the existing scope of the contract, the contractor shall promptly notify the Contracting Officer in writing. No action shall be taken by the contractor under such direction until the Contracting Officer has issued a modification to the contract or has otherwise resolved the issue.

CLAUSES INCORPORATED BY FULL TEXT

In accordance with DFARS 204.7108 *Payment Instructions*, payment shall be made by the numbered payment instruction identified below:

- o (1) *Line item specific: single funding.* If there is only one source of funding for the contract line item (i.e., one ACRN), the payment office will make payment using the ACRN funding of the line item being billed.
- o (2) *Line item specific: sequential ACRN order.* If there is more than one ACRN within a contract line item, the payment office will make payment in sequential ACRN order within the line item, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: Alpha/Alpha; Alpha/Numeric; Numeric/Alpha; and Numeric/Numeric.
- o (3) *Line item specific: contracting officer specified ACRN order.* If there is more than one ACRN within a contract line item, the payment office will make payment within the line item in the sequence

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ACRN order specified by the contracting officer, exhausting all funds in the previous ACRN before paying from the next ACRN.

- x (4) *Line item specific: by fiscal year.* If there is more than one ACRN within a contract line item, the payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from each ACRN within a fiscal year in the same proportion as the amount of funding obligated for each ACRN within the fiscal year.
- o (5) *Line item specific: by cancellation date.* If there is more than one ACRN within a contract line item, the payment office will make payment using the ACRN with the earliest cancellation date first, exhausting all funds in that ACRN before disbursing funds from the next. In the event there is more than one ACRN associated with the same cancellation date, the payment amount shall be disbursed from each ACRN with the same cancellation date in the same proportion as the amount of funding obligated for each ACRN with the same cancellation date.
- o (6) *Line item specific: proration.* If there is more than one ACRN within a contract line item, the payment office will make payment from each ACRN in the same proportion as the amount of funding currently unliquidated for each ACRN.
- o (7) *Contract-wide: sequential ACRN order.* The payment office will make payment in sequential ACRN order within the contract or order, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: alpha/alpha; alpha/numeric; numeric/alpha; and numeric/numeric.
- o (8) *Contract-wide: contracting officer specified ACRN order.* The payment office will make payment in sequential ACRN order within the contract or order, exhausting all funds in the previous ACRN before paying from the next ACRN in the sequence order specified by the contracting officer.
- o (9) *Contract-wide: by fiscal year.* The payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from each ACRN within a fiscal year in the same proportion as the amount of funding obligated for each ACRN within the fiscal year.
- o (10) *Contract-wide: by cancellation date.* The payment office will make payment using the ACRN with the earliest cancellation date first, exhausting all funds in that ACRN before disbursing funds from the next. In the event there is more than one ACRN associated with the same cancellation date, the payment amount shall be disbursed from each ACRN with the same cancellation date in the same proportion as the amount of funding obligated for each ACRN with the same cancellation date.
- o (11) *Contract-wide: proration.* The payment office will make payment from each ACRN within the contract or order in the same proportion as the amount of funding currently unliquidated for each ACRN.
- o (12) *Other.* If none of the standard payment instructions identified in paragraphs (d)(1) through (11) of this section are appropriate, the contracting officer may insert other payment instructions, provided the other payment instructions—
  - (i) Provide a significantly better reflection of how funds will be expended in support of contract performance; and
  - (ii) Are agreed to by the payment office and the contract administration office.

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252.232-9007 PAYMENT INFORMATION IN CENTRAL CONTRACTOR REGISTRATION (CCR) DATABASE

This contract contains FAR clause 52.204-7, Central Contractor Registration. All contractors must be registered in the CCR database prior to award, during performance, and through final payment of any contract, except for awards to foreign vendors for work to be performed outside the United States.

The Contractor is responsible for the accuracy and completeness of the data within the CCR, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. In addition to the contractor's requirement to confirm on an annual basis that its information in the CCR database is accurate and complete, the contractor's information in the CCR database must be updated whenever changes occur to the contractor's remit-to data (e.g., account number, vendor name and address, etc.) and the paying office notified of any changes. The



contractor's failure to maintain accurate information in the CCR database could result in payment delays for which the Government shall not be liable.

**CLAUSES INCORPORATED BY FULL TEXT**

**252.232-9012 WIDE AREA WORK FLOW (WAWF) — RECEIPT AND ACCEPTANCE (RA) INSTRUCTIONS (December 2007)**

(a) As prescribed in DFARS clause 252.232-7003 Electronic Submission of Payment Requests (Jan 2004), Contractors must submit payment requests in electronic form. Paper copies will no longer be accepted or processed for payment unless the conditions of DFARS clause 252.232-7003(c) apply. To facilitate this electronic submission, the Defense Threat Reduction Agency (DTRA) has implemented the DoD sanctioned Wide Area Workflow-Receipt and Acceptance (WAWF-RA) for contractors to submit electronic payment requests and receiving reports. The contractor shall submit electronic payment requests and receiving reports via WAWF-RA. Vendors shall send an email notification to the Contracting Officer Representative (COR), Program/Project Manager or other government acceptance official identified in the contract by clicking on the Send More Email Notification link upon submission of an invoice/cost voucher in WAWF-RA. To access WAWF, go to <https://wawf.eb.mil/>.

**\*\* For questions, contact the DTRA WAWF Team at 703-767-6840 or [wawfhelp@dtra.mil](mailto:wawfhelp@dtra.mil) \*\***

**(b) Definitions:**

**Acceptor:** Contracting Officer's Representative, Program/Project Manager, or other government acceptance official as identified in the contract/order.

**Pay Official:** Defense Finance and Accounting Service (DFAS) payment office identified in the contract/order.

**SHIP To/Service Acceptor DoDAAC:** Acceptor DoDAAC or DCMA DoDAAC (as specified in the contract/order).

**DCAA Auditor DoDAAC:** Needed when invoicing on cost-reimbursable contracts. (Go to [www.dcaa.mil](http://www.dcaa.mil) and click on the appropriate link under the Audit Office Locator to search for your DCAA DoDAAC.)

>>> **For contracts that are administered by the Office of Naval Research (ONR):** <<<  
Enter the ONR DoDAAC in the DCAA Auditor DoDAAC field in WAWF.

**(c) WAWF Contractor Input Information:**

The contractor shall use the following information in creating electronic payment requests in WAWF:

**Invoice Type in WAWF:**

- If billing for Cost Type/Reimbursable contracts (including T&M and LH), select "Cost Voucher"
- If billing for Firm-Fixed Price Materials Only, select "Combo"
- If billing for Firm-Fixed Price Materials and Service, select "Combo"
- If billing for Firm-Fixed Price Services Only, select "2-n-1 (Services Only)"

**For WAWF Routing Information, See Table Below:**

Description	SF 26	SF 33	SF 1449	DD 1155
	Located in Block/Section			
Contract Number	2	2	2	1
Delivery Order	See Individual Order		4	2
CAGE Code	7	15a	17a	9
Pay DoDAAC	12	25	18a	15
Inspection	Section E (except SF 1449, See Entitled): INSPECTION AND ACCEPTANCE			
Acceptance	Section E (except SF 1449, See Entitled): INSPECTION AND ACCEPTANCE			
Issue Date	3	5	3	3
Issue by DoDAAC	5	7	9	6
Admin DoDAAC	6	24	16	7
Ship To / Service Acceptor DoDAAC	6	24	16	7
Ship to Extension	Do Not Fill In			
Services or Supplies	Based on majority of requirement as determined by monetary value			
Final Invoice?	Do not change "N" (no) to "Y" (yes) unless this is the last invoice and the contract is ready for closeout.			

**(d) Final Invoices/Vouchers -Final Payment shall be made in accordance with the Federal Acquisition Regulation (FAR) 52.216-7, entitled "Allowable Cost and Payment."**

**Invoices - Invoice 2-n-1 (Services Only) and Invoice and Receiving Report (Combo)**

Select the "Y" selection from the "Final Invoice?" drop-down box when submitting the final invoice for payment for a contract. Upon successful submission of the final invoice, click on the *Send More Email Notifications* link to send an additional email notification to the Contracting Officer Representative (COR), Program/Project Manager or other government acceptance official identified in the contract.



**Cost Vouchers** - Once the final DCAA audit is complete for cost reimbursable contracts and authorization is received to submit the final cost voucher, select the "Y" selection from the "Final Voucher" drop-down box when submitting the final cost voucher. Upon successful submission of the final cost voucher, click on the *Send More Email Notifications* link to send an additional email notification to the following email address: [finalcostvouchers@dtra.mil](mailto:finalcostvouchers@dtra.mil)

(e) WAWF Training may be accessed online at <http://www.wawftraining.com/>. To practice creating documents in WAWF, visit practice site at <https://wawftraining.eb.mil/>. General DFAS information may be accessed using the DFAS website at <http://www.dod.mil/dfas/>. Payment status information may be accessed using the myInvoice system at <https://myinvoice.csd.disa.mil/> or by calling the DFAS Columbus

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helpdesk at 800-756-4571. (Select Option 1) Your contract number and shipment/invoice number will be required to check status of your payment. Note: For specific invoice related inquiries email: [wawfvendorpay@dtra.mil](mailto:wawfvendorpay@dtra.mil). Vendors shall forward any additional DTRA related WAWF questions to [wawfhelp@dtra.mil](mailto:wawfhelp@dtra.mil).

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## Section H - Special Contract Requirements

### H.1 PATENT RIGHTS RETENTION BY THE CONTRACTOR

In accordance with FAR 52.227-11 (f), reporting on utilization of subject inventions:

The Contractor agrees to submit, periodic reports annually on the utilization of a subject invention or efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees.

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## Section I - Contract Clauses

### CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	JUL 1995
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	SEP 2007
52.203-13	Contractor Code of Business Ethics and Conduct	DEC 2007
52.203-14	Display of Hotline Poster(s)	DEC 2007
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.204-7	Central Contractor Registration	APR 2008
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	SEP 2006
52.215-2	Audit and Records—Negotiation	JUN 1999
52.215-8	Order of Precedence—Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	OCT 1997
52.215-12	Subcontractor Cost or Pricing Data	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.216-7	Allowable Cost And Payment	DEC 2002
52.216-8	Fixed Fee	MAR 1997
52.217-9	Option To Extend The Term Of The Contract	MAR 2000
52.219-8	Utilization of Small Business Concerns	MAY 2004
52.219-28	Post-Award Small Business Program Rerepresentation	JUN 2007
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity For Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	SEPT 2006
52.222-36	Affirmative Action For Workers With Disabilities	JUN 1998
52.222-37	Employment Reports On Special Disabled Veterans, Veterans Of The Vietnam Era, and Other Eligible Veterans	SEPT 2006

52.222-39	Notification of Employee Rights Concerning Payment of Union Dues or Fees	DEC 2004
52.222-50	Combating Trafficking in Persons	AUG 2007
52.223-6	Drug-Free Workplace	MAY 2001
52.223-14	Toxic Chemical Release Reporting	AUG 2003
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-11 Alt II	Patent Rights—Ownership by the Contractor (Dec 2007) — Alternate II	DEC 2007
52.228-7	Insurance—Liability To Third Persons	MAR 1996
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	JUN 1996

52.232-20	Limitation Of Cost	APR 1984
52.232-23 Alt I	Assignment of Claims (Jan 1986) - Alternate I	APR 1984
52.232-25 Alt I	Prompt Payment (Oct 2003) Alternate I	FEB 2002
52.232-33	Payment by Electronic Funds Transfer—Central Contractor Registration	OCT 2003
52.233-1 Alt I	Disputes (Jul 2002) - Alternate I	DEC 1991
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-2 Alt V	Changes—Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
52.244-2	Subcontracts	JUN 2007
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	MAR 2007
52.245-1	Government Property	JUN 2007
52.245-9	Use And Charges	JUN 2007
52.246-9	Inspection Of Research And Development (Short Form)	APR 1984
52.246-25	Limitation Of Liability—Services	FEB 1997
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.251-1	Government Supply Sources	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	JAN 2009
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2004
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	JAN 2009
252.204-7000	Disclosure Of Information	DEC 1991
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A	Central Contractor Registration (52.204-7) Alternate A	SEP 2007
252.204-7009	Requirements Regarding Potential Access to Export-Controlled Items	JUL 2008
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.211-7007	Reporting of Government-Furnished Equipment in the DoD Item Unique Identification (IUID) Registry	NOV 2008
252.215-7000	Pricing Adjustments	DEC 1991
252.215-7002	Cost Estimating System Requirements	DEC 2006
252.215-7004	Excessive Pass-Through Charges	MAY 2008
252.225-7006	Quarterly Reporting of Actual Contract Performance Outside the United States	MAY 2007
252.225-7012	Preference For Certain Domestic Commodities	MAR 2008
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	SEP 2004
252.227-7013	Rights in Technical Data—Noncommercial Items	NOV 1995
252.227-7016	Rights in Bid or Proposal Information	JUN 1995
252.227-7025	Limitations on the Use or Disclosure of Government- Furnished Information Marked with Restrictive Legends	JUN 1995
252.227-7027	Deferred Ordering Of Technical Data Or Computer Software	APR 1988
252.227-7030	Technical Data—Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 1999
252.227-7039	Patents—Reporting Of Subject Inventions	APR 1990
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008

252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7002	Animal Welfare	DEC 1991
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.243-7002	Requests for Equitable Adjustment	MAR 1998

252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	JAN 2007
252.247-7023	Transportation of Supplies by Sea	MAY 2002
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000
252.251-7000	Ordering From Government Supply Sources	NOV 2004

**CLAUSES INCORPORATED BY FULL TEXT**

**52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)**

(a) The Government may extend the term of this contract by written notice to the Contractor on or before the expiration of the contract basic period. The Government will give the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36-Months.

(End of clause)

**52.222-2 PAYMENT FOR OVERTIME PREMIUMS (JUL 1990)**

(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed \$0.00 or the overtime premium is paid for work —

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall—

(1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;

(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;

(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and

(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

\* Insert either “zero” or the dollar amount agreed to during negotiations. The inserted figure does not apply to the exceptions in paragraph (a)

(1) through (a)(4) of the clause.

(End of clause)

**52.249-14 EXCUSABLE DELAYS (APR 1984)**

(a) Except for defaults of subcontractors at any tier, the Contractor shall not be in default because of any failure to perform this contract under its terms if the failure arises from causes beyond the control and without the fault or negligence of the Contractor. Examples of these causes are (1) acts of God or of the public enemy, (2) acts of the Government in either its sovereign or contractual capacity, (3) fires, (4) floods, (5) epidemics, (6) quarantine restrictions, (7) strikes, (8) freight embargoes, and (9) unusually severe weather. In each instance, the failure to perform must be beyond the control and without the fault or negligence of the Contractor. “Default” includes failure to make progress in the work so as to endanger performance.

(b) If the failure to perform is caused by the failure of a subcontractor at any tier to perform or make progress, and if the cause of the failure was beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either, the Contractor shall not be deemed to be in default, unless—

(1) The subcontracted supplies or services were obtainable from other sources;

(2) The Contracting Officer ordered the Contractor in writing to purchase these supplies or services from the other source; and

(3) The Contractor failed to comply reasonably with this order.

(c) Upon request of the Contractor, the Contracting Officer shall ascertain the facts and extent of the failure. If the Contracting Officer determines that any failure to perform results from one or more of the causes above, the delivery schedule shall be revised, subject to the rights of the Government under the termination clause of this contract.

(End of clause)

#### 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://farsite.hill.af.mil/>

(End of clause)

#### 252.201-9003 LIMITATION OF AUTHORITY

No person in the Government, other than a Contracting Officer, has the authority to provide direction to the Contractor, which alters the Contractor's obligations or changes this contract in any way. If any person representing the Government, other than a Contracting Officer, attempts to alter contract obligations, change the contract specifications/statement of work or tells the contractor to perform some effort which the Contractor believes to be outside the scope of this contract, the Contractor shall immediately notify the Procuring Contracting Officer (PCO). Contractor personnel shall not comply with any order or direction which they believe to be outside the scope of this contract unless the order or direction is issued by a Contracting Officer.

#### 252.203-9004 ETIOLOGIC AGENTS — BIOLOGICAL DEFENSE RESEARCH PROGRAM (FEB 2008)

- a. For purpose of this contract etiologic agent—biological defense program is defined as: any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 73, 9 CFR 121, and 7 CFR 331, of the Department of Health and Human Services and Department of Agriculture regulations, respectively, and any agent of biological origin that poses a degree of hazard to those agents and is further identified by the US Army. The contractor shall comply with the following when working with etiologic agents:
  - (1) 29 Code of Federal Regulations 1910, Occupational Health and Safety;
  - (2) US Department of Health and Human Services (DHHS) and US Department of Agriculture, Select Agent Program(s), 42 CFR 73, 9 CFR 121, and 7 CFR 331; and
  - (3) DHHS Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, latest edition.
- b. Etiologic agents shall be packaged, labeled, shipped, and transported in accordance with applicable Federal, State, and local laws and regulations, to include:
  - (1) 42 CFR 72 (Interstate Shipment of Etiologic Agents);
  - (2) 49 CFR 172 and 173 (Department of Transportation);
  - (3) 9 CFR 122 (USDA Restricted Animal Pathogens);
  - (4) International Air Transport Association Dangerous Goods Regulations;
  - (5) The United States Postal Service shall not be used for transportation of BDRP related etiologic agents; and
  - (6) If performance is outside of the United States, any additional procedures required by the nation where the work is to be performed.

#### 252.204-9004 IMPLEMENTATION OF DISCLOSURE OF INFORMATION (JUN 2007)

In accordance with DFARS 252.204-7000 Disclosure of Information, any information to be released shall be submitted at least 45 days before the proposed release date, for security and policy review. Submit one copy to each below:

- (a) Office of Public Affairs, DTRA/DIR/COS/PA, 8725 John J. Kingman Dr, MS 6201, Ft Belvoir VA 22060-6201.
- (b) Contracting Officer
- (c) Program Manager
- (d) Task Order Manager

(End of Clause)

#### 252.209-9002 NON-GOVERNMENT SUPPORT PERSONNEL (JAN 2008)

The following companies may have access to contractor information, technical data or computer software that may be marked as proprietary or otherwise marked with restrictive legends: Suntiva LLC (Formerly C-Systems International Corporation)(contract specialist support); Systems Research and Analysis (SRA, managing JPRAS)and The Tauri Group (Advisory and Assistance Services). Each contract contains organizational conflict of interest provisions and/or includes contractual requirements for non-disclosure of proprietary contractor information or data/software

marked with restrictive legends. The contractor, by submitting a proposal or entering into this contract, is deemed to have consented to the disclosure of its information to Suntiva LLC, SRA, and The Tauri Group under the conditions and limitations described herein.

252.215-9004 KEY PERSONNEL (FEB 2000)

The personnel listed below are considered essential to the work being performed hereunder. Prior to removing, replacing, or diverting any of the specified individuals, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on this Contract. No deviation shall be made by the Contractor without the prior written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing the change, such ratification shall constitute the consent of the Contracting Officer required by this paragraph. The personnel listed below may, with the consent of the contracting parties, be amended from time to time during the course of the Contract to either add or delete personnel as appropriate.

Principal Investigator

252.216-9003 CONSULTANTS (OCT 1998)

Services of consultants shall be at rates and for periods approved in advance by the Contracting Officer. Requests for approval shall be submitted to the Contracting Officer sufficiently in advance of the need to use a consultant under this Contract. The request shall include (a) a copy of the proposed consultant agreement, (b) a brief biography of the consultant, and (c) an indication of the area(s) in which consultant's expertise will be utilized and why it is essential for contract performance. In addition, significant deviations from the dollar amount approved for consultant services, or changes in the

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consultants to be utilized, must likewise be approved in advance upon submission of adequate justification.

252.227-7013 RIGHTS IN TECHNICAL DATA—NONCOMMERCIAL ITEMS. (NOV 1995)

(a) Definitions. As used in this clause:

- (1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.
- (2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.
- (3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.
- (4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.
- (5) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.
- (6) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art. To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.
- (7) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.
  - (i) Private expense determinations should be made at the lowest practicable level.
  - (ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.
- (8) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.
- (9) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.

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- (10) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(11) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

(12) Government purpose rights means the rights to—

(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

(ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes.

(13) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release or disclose such data or authorize the use or reproduction of the data by persons outside the Government if reproduction, release, disclosure, or use is—

(i) Necessary for emergency repair and overhaul; or

(ii) A release or disclosure of technical data (other than detailed manufacturing or process data) to, or use of such data by, a foreign government that is in the interest of the Government and is required for evaluational or informational purposes;

(iii) Subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and

(iv) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.

(14) Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(15) Unlimited rights means rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

(b) Rights in technical data. The Contractor grants or shall obtain for the Government the following royalty free, world-wide, nonexclusive, irrevocable license rights in technical data other than computer software documentation (see the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause of this contract for rights in computer software documentation):

(1) Unlimited rights.

The Government shall have unlimited rights in technical data that are—

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Created exclusively with Government funds in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Contractor or subcontractor without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(ix) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with —

(A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or

(B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has expired.

(2) Government purpose rights.

(i) The Government shall have government purpose rights for a five-year period, or such other period as may be negotiated, in technical data—

(A) That pertain to items, components, or processes developed with mixed funding except when the Government is entitled to unlimited rights in such data as provided in paragraphs (b)(ii) and (b)(iv) through (b)(ix) of this clause; or

(B) Created with mixed funding in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The five-year period, or such other period as may have been negotiated, shall commence upon execution of the contract, subcontract, letter contract (or similar contractual instrument), contract modification, or option exercise that required development of the items, components, or processes or creation of the data described in paragraph (b)(2)(i)(B) of this clause. Upon expiration of the five-year or other negotiated period, the Government shall have unlimited rights in the technical data.

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(iii) The Government shall not release or disclose technical data in which it has government purpose rights unless-

(A) Prior to release or disclosure, the intended recipient is subject to the non-disclosure agreement at 227.7103-7 of the Defense Federal Acquisition Regulation Supplement (DFARS); or

(B) The recipient is a Government contractor receiving access to the data for performance of a Government contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(iv) The Contractor has the exclusive right, including the right to license others, to use technical data in which the Government has obtained government purpose rights under this contract for any commercial purpose during the time period specified in the government purpose rights legend prescribed in paragraph (f)(2) of this clause.

(3) Limited rights.

(i) Except as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause, the Government shall have limited rights in technical data—

(A) Pertaining to items, components, or processes developed exclusively at private expense and marked with the limited rights legend prescribed in paragraph (f) of this clause; or

(B) Created exclusively at private expense in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The Government shall require a recipient of limited rights data for emergency repair or overhaul to destroy the data and all copies in its possession promptly following completion of the emergency repair/overhaul and to notify the Contractor that the data have been destroyed.

(iii) The Contractor, its subcontractors, and suppliers are not required to provide the Government additional rights to use, modify, reproduce, release, perform, display, or disclose technical data furnished to the Government with limited rights. However, if the Government desires to obtain additional rights in technical data in which it has limited rights, the Contractor agrees to promptly enter into negotiations with the Contracting Officer to determine whether there are acceptable terms for transferring such rights. All technical data in which the Contractor has granted the Government additional rights shall be listed or described in a license agreement made part of the contract. The license shall enumerate the additional rights granted the Government in such data.

(4) Specifically negotiated license rights.

The standard license rights granted to the Government under paragraphs (b)(1) through (b)(3) of this clause, including the period during which the Government shall have government purpose rights in technical data, may be modified by mutual agreement to provide such rights as the parties consider appropriate but shall not provide the Government lesser rights than are enumerated in paragraph (a)(13) of this clause. Any rights so negotiated shall be identified in a license agreement made part of this contract.

(5) Prior government rights.

Technical data that will be delivered, furnished, or otherwise provided to the Government under this contract, in which the Government has previously obtained rights shall be delivered, furnished, or provided with the pre-existing rights, unless—

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(i) The parties have agreed otherwise; or

(ii) Any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(6) Release from liability.

The Contractor agrees to release the Government from liability for any release or disclosure of technical data made in accordance with paragraph (a)(13) or (b)(2)(iii) of this clause, in accordance with the terms of a license negotiated under paragraph (b)(4) of this clause, or by others to whom the recipient has released or disclosed the data and to seek relief solely from the party who has improperly used, modified, reproduced, released, performed, displayed, or disclosed Contractor data marked with restrictive legends.

(c) Contractor rights in technical data. All rights not granted to the Government are retained by the Contractor.

(d) Third party copyrighted data. The Contractor shall not, without the written approval of the Contracting Officer, incorporate any copyrighted data in the technical data to be delivered under this contract unless the Contractor is the copyright owner or has obtained for the Government the license rights necessary to perfect a license or licenses in the deliverable data of the appropriate scope set forth in paragraph (b) of this clause, and has affixed a statement of the license or licenses obtained on behalf of the Government and other persons to the data transmittal document.

(e) Identification and delivery of data to be furnished with restrictions on use, release, or disclosure. (1) This paragraph does not apply to restrictions based solely on copyright.

(2) Except as provided in paragraph (e)(3) of this clause, technical data that the Contractor asserts should be furnished to the Government with restrictions on use, release, or disclosure are identified in an attachment to this contract (the Attachment). The Contractor shall not deliver any data with restrictive markings unless the data are listed on the Attachment.

(3) In addition to the assertions made in the Attachment, other assertions may be identified after award when based on new information or inadvertent omissions unless the inadvertent omissions would have materially affected the source selection decision. Such identification and assertion shall be submitted to the Contracting Officer as soon as practicable prior to the scheduled date for delivery of the data, in the following format, and signed by an official authorized to contractually obligate the Contractor: Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data should be restricted—

Technical data to be Furnished With Restrictions \1/	Basis for Assertion \2/	Asserted Rights Category \3/	Name of Person Asserting Restrictions \4/
(LIST)	(LIST)	(LIST)	(LIST)

\1/ If the assertion is applicable to items, components or processes developed at private expense, identify both the data and each such items, component, or process.

\2/ Generally, the development of an item, component, or process at private expense, either exclusively or partially, is the only basis for asserting restrictions on the Government's rights to use, release, or

disclose technical data pertaining to such items, components, or processes. Indicate whether development was exclusively or partially at private expense. If development was not at private expense, enter the specific reason for asserting that the Government's rights should be restricted.

\3/ Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited or government purpose rights under this or a prior contract, or specifically negotiated licenses).

\4/ Corporation, individual, or other person, as appropriate.

Date \_\_\_\_\_

Printed Name and Title \_\_\_\_\_

Signature \_\_\_\_\_

(End of identification and assertion)

(4) When requested by the Contracting Officer, the Contractor shall provide sufficient information to enable the Contracting Officer to evaluate the Contractor's assertions. The Contracting Officer reserves the right to add the Contractor's assertions to the Attachment and validate any listed assertion, at a later date, in accordance with the procedures of the Validation of Restrictive Markings on Technical Data clause of this contract.

(f) Marking requirements. The Contractor, and its subcontractors or suppliers, may only assert restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data to be delivered under this contract by marking the deliverable data subject to restriction. Except as provided in paragraph (f)(5) of this clause, only the following legends are authorized under this contract: the government purpose rights legend at paragraph (f)(2) of this clause; the limited rights legend at paragraph (f)(3) of this clause; or the special license rights legend at paragraph (f)(4) of this clause; and/or a notice of copyright as prescribed under 17 U.S.C. 401 or 402.

(1) General marking instructions. The Contractor, or its subcontractors or suppliers, shall conspicuously and legibly mark the appropriate legend on all technical data that qualify for such markings. The authorized legends shall be placed on the transmittal document or storage container and, for printed material, each page of the printed material containing technical data for which restrictions are asserted. When only portions of a page of printed material are subject to the asserted restrictions, such portions shall be identified by circling, underscoring, with a note, or other appropriate identifier. Technical data transmitted directly from one computer or computer terminal to another shall contain a notice of asserted restrictions. Reproductions of technical data or any portions thereof subject to asserted restrictions shall also reproduce the asserted restrictions.

(2) Government purpose rights markings. Data delivered or otherwise furnished to the Government purpose rights shall be marked as follows:



## Government Purpose Rights

Contract No.

Contractor Name

Contractor Address

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Expiration Date

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(2) of the Rights in Technical Data—Noncommercial Items clause contained in the above identified contract. No restrictions apply after the expiration date shown above. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(3) Limited rights markings. Data delivered or otherwise furnished to the Government with limited rights shall be marked with the following legend:

Limited Rights

Contract No.

Contractor Name

Contractor Address

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(3) of the Rights in Technical Data—Noncommercial Items clause contained in the above identified contract. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings. Any person, other than the Government, who has been provided access to such data must promptly notify the above named Contractor.

(End of legend)

(4) Special license rights markings. (i) Data in which the Government's rights stem from a specifically negotiated license shall be marked with the following legend:

Special License Rights

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these data are restricted by Contract No. (Insert contract number) , License No. (Insert license identifier) . Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(ii) For purposes of this clause, special licenses do not include government purpose license rights acquired under a prior contract (see paragraph (b) (5) of this clause).

(5) Pre-existing data markings. If the terms of a prior contract or license permitted the Contractor to restrict the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data deliverable under this contract, and those restrictions are still applicable, the Contractor may mark such data with the appropriate restrictive legend for which the data qualified under the prior contract or license. The marking procedures in paragraph (f)(1) of this clause shall be followed.

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(g) Contractor procedures and records. Throughout performance of this contract, the Contractor and its subcontractors or suppliers that will deliver technical data with other than unlimited rights, shall—

(1) Have, maintain, and follow written procedures sufficient to assure that restrictive markings are used only when authorized by the terms of this clause; and

(2) Maintain records sufficient to justify the validity of any restrictive markings on technical data delivered under this contract.

(h) Removal of unjustified and nonconforming markings. (1) Unjustified technical data markings. The rights and obligations of the parties regarding the validation of restrictive markings on technical data furnished or to be furnished under this contract are contained in the Validation of Restrictive Markings on Technical Data clause of this contract. Notwithstanding any provision of this contract concerning inspection and acceptance, the Government may ignore or, at the Contractor's expense, correct or strike a marking if, in accordance with the procedures in the Validation of Restrictive Markings on Technical Data clause of this contract, a restrictive marking is determined to be unjustified.

(2) **Nonconforming technical data markings.** A nonconforming marking is a marking placed on technical data delivered or otherwise furnished to the Government under this contract that is not in the format authorized by this contract. Correction of nonconforming markings is not subject to the validation of Restrictive Markings on Technical Data clause of this contract. If the Contracting Officer notifies the Contractor of a nonconforming marking and the Contractor fails to remove or correct such marking within sixty (60) days, the Government may ignore or, at the Contractor's expense, remove or correct any nonconforming marking.

(i) **Relation to patents.** Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.

(j) **Limitation on charges for rights in technical data.** (1) The Contractor shall not charge to this contract any cost, including, but not limited to, license fees, royalties, or similar charges, for rights in technical data to be delivered under this contract when—

(i) The Government has acquired, by any means, the same or greater rights in the data; or

(ii) The data are available to the public without restrictions.

(2) The limitation in paragraph (j)(1) of this clause—

(i) Includes costs charged by a subcontractor or supplier, at any tier, or costs incurred by the Contractor to acquire rights in subcontractor or supplier technical data, if the subcontractor or supplier has been paid for such rights under any other Government contract or under a license conveying the rights to the Government; and

(ii) Does not include the reasonable costs of reproducing, handling, or mailing the documents or other media in which the technical data will be delivered.

(k) **Applicability to subcontractors or suppliers.** (1) The Contractor shall ensure that the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320, 10 U.S.C. 2321, and the identification, assertion, and delivery processes of paragraph (e) of this clause are recognized and protected.

(2) Whenever any technical data for noncommercial items is to be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, and require its subcontractors or suppliers to do so,

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without alteration, except to identify the parties. No other clause shall be used to enlarge or diminish the Government's, the Contractor's, or a higher-tier subcontractor's or supplier's rights in a subcontractor's or supplier's technical data.

(3) Technical data required to be delivered by a subcontractor or supplier shall normally be delivered to the next higher-tier contractor, subcontractor, or supplier. However, when there is a requirement in the prime contract for data which may be submitted with other than unlimited rights by a subcontractor or supplier, then said subcontractor or supplier may fulfill its requirement by submitting such data directly to the Government, rather than through a higher-tier contractor, subcontractor, or supplier.

(4) The Contractor and higher-tier subcontractors or suppliers shall not use their power to award contracts as economic leverage to obtain rights in technical data from their subcontractors or suppliers. (5) In no event shall the Contractor use its obligation to recognize and protect subcontractor or supplier rights in technical data as an excuse for failing to satisfy its contractual obligations to the Government.

(End of clause)

#### 252.227-9000 COMPUTER CODE DEVELOPMENT (OCT 1998)

Computer code development (the writing of a new computer program or the enhancement of an existing program to expand its capabilities) even if not explicitly specified in the Tasks of the SOW, shall be accompanied by a report which will be a brief summary describing the software, associated machine requirements and development and documentation status of each Computer Code for DTRA to determine the applicability of the Computer program to specific research programs.

#### 252.235-9000 SOURCES OF INFORMATION (JULY 2000)

a. The results of the research to be delivered to the Government under this Contract shall embody the most recent reliable information in the field which is available to the Contractor from private and governmental sources, and the Contractor agrees to utilize all sources of such information available to it. In this connection, information in this field which is in the control of DTRA shall, with the consent of the Contracting Officer's Representative (COR) and under such safeguards and procedures as he/she may prescribe, be made available to the Contractor on request. Additionally, the Contractor is encouraged to make use of the resources available through the Defense Threat Reduction Information Analysis Center (DTRIAC), 1680 Texas Street, Southeast, Kirtland AFB, New Mexico 87117.

b. Reasonable assistance in obtaining access to information, or in obtaining permission to use Government or private facilities, will be given to the Contractor by DTRA. Specifically, the Contractor must register with the Defense Technical Information Center, ATTN: DTIC, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218, in accordance with Defense Logistics Agency (DLA) Regulation 4185.10, Certification and Registration for Access to DoD Defense Technical Information. DD Form 1540, the registration form, shall be forwarded to the DTRA Contracting Officer for approval (DFARS 35.010(b)).

(End of clause)

#### 252.227-9000 PROHIBITION OF USE OF LABORATORY ANIMALS (OCT 2008)(DTRA)

No animal studies may be conducted using DOD funds until Animal Care and Use Review Office (ACURO) approval has been granted. Studies involving non human primates, dogs, cats, or marine mammals will require a site visit by a DoD laboratory animal veterinarian. The recipient (including subcontractors) is expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Material Command (MRMC), Animal Care and Use Review Office (ACURO). You must complete the ACURO Animal Use Appendix for Research Involving Animals found at the following web site: <https://mrmc->

[www.army.mil/AnimalAppendix.asp](http://www.army.mil/AnimalAppendix.asp). Please submit the completed ACURO appendix, contact information, the DTRA contract number and a copy of the contract for processing to the email address listed at the ACURO website for processing. You will receive written approval to begin research under the applicable protocol proposed for this award from the US Army MRMC ACURO under separate email to the recipient and Principal Investigator. A copy of this approval will be provided to the Defense Threat Reduction Agency (DTRA) for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

*(End of Clause)*

**252.235-9001 PROHIBITION OF USE OF LABORATORY ANIMALS (OCT 2008)(DTRA)**

No animal studies may be conducted using DOD funds until Animal Care and Use Review Office (ACURO) approval has been granted. Studies involving non human primates, dogs, cats, or marine mammals will require a site visit by a DoD laboratory animal veterinarian. The recipient (including subcontractors) is expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Material Command (MRMC), Animal Care and Use Review Office (ACURO). You must complete the ACURO Animal Use Appendix for Research Involving Animals found at the following web site: <https://mrmc-www.army.mil/AnimalAppendix.asp>. Please submit the completed ACURO appendix, contact information, the DTRA contract number and a copy of the contract for processing to the email address listed at the ACURO website for processing. You will receive written approval to begin research under the applicable protocol proposed for this award from the US Army MRMC ACURO under separate email to the recipient and Principal Investigator. A copy of this approval will be provided to the Defense Threat Reduction Agency (DTRA) for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

**252.242-9000 CONTRACTOR PERFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS) (NOV 2002)**

1. As required by FAR Parts 42 and 15, and DTRA policy for the Contractor Performance Assessment Reporting System (CPARS) and Past Performance Information Retrieval System (PPIRS), formerly known as PPAIS, effective July, 2001, the Government shall complete a CPAR each year of the period of performance of this contract. The contractor will have an opportunity to provide their comments in each CPAR before it is completed. In accordance with DTRA CPARS policy the completed CPARs will be entered into PPIRS, a retrieval system for Government source selection teams to access the CPARS of contractor's performance. The DTRA CPARS and PPIRS policy includes an explanation of the process and procedures that will be utilized under this contract. A copy is available for contractor reference via the DTRALink ([www.dtra.mil](http://www.dtra.mil)) by accessing Acquisition, Doing Business With Us.

2. The CPARs shall occur annually in accordance with the schedule established below:

(i) Initial CPAR: 12 months after contract start date (date performance begins) TBD (by PCO)

(ii) Interim CPAR(s) will be performed annually on the anniversary of the contract start date according to the following schedule: TBD (by PCO)

(iii) A Final CPAR will be completed upon contract termination, transfer of program management/contract management responsibility outside of DTRA, the delivery of the final end item on contract and/or the completion of the performance period.

(iv) An Out-of-Cycle CPAR may be required when there is a significant change in performance that alters the assessment in one or more evaluation area(s). An Out-of-Cycle CPAR is optional and shall be processed in accordance with DTRA CPARS policy referenced in paragraph 1. above.

3. Each CPAR shall only cover the period elapsing from the last annual CPAR. The final CPAR shall not be used to summarize or "roll-up" the contractor's performance under the entire contract. Each annual CPAR and the final CPAR together will comprise a total picture of contractor performance.

4. At the request of the Government, a verbal, informal review of the Contractor's performance may be held 3-6 months before the completion of the Interim or Final Evaluation periods. This review entails discussing any problems or areas of concern regarding the Contractor's performance to date. No written evaluation form or other formal documentation is required for this evaluation. It may be conducted with the Contractor by telephone, teleconference or face-to-face. This is designed to offer the Contractor an opportunity to correct known deficiencies or weaknesses prior to the formal written evaluation.

5. As set forth in DTRA CPARS policy, any disagreements between the Contractor and the Program Manager regarding the CPAR(s) that cannot be resolved shall be reviewed by the designated Reviewing Official prior to completion of the CPAR.

6. Special Requirements for Indefinite Delivery Contracts (IDIQ and Requirements type), CPARs shall be processed (select one)

o for all existing orders (combined) at the time the CPAR is processed

o on an order-by-order basis

o on a grouped order basis

7. The policy and procedures set forth in this clause and DTRA CPARS policy are not subject to "Disputes" as described in FAR Part 33.

**252.245-9000 Government Property (AUG 2009)**

(a) In accordance with FAR 52.245-1(b), Property Management, and FAR 52.245-1(f), Contractor Plans and Systems, the Contractor shall have a system to manage (control, use, preserve, protect, repair and maintain) Government property in its possession.

(b) The Contract Data Requirements Lists (CDRLs) associated with the Property for this Contract are contained in Exhibit "A" and included in Section J of this contract. The spreadsheet required by the CDRL entitled "Master Government Property List (MGPL) will be incorporated in Section J of this contract.

(c) The Contractor shall provide to the Government an updated MGPL according to the CDRL.

(d) The Government Site Visits/Physical Inventory — The DTRA will annually verify the Property in the Possession of the Contractor. The Contactor's Point of Contact shall coordinate with the Program Manager/Contracting Officer Representative or DTRA Accountable Property Officer (APO) on prearranged site visits upon request.

(e) The Contractor shall annually conduct and provide to the DTRA a physical inventory report of ALL Government Property in its possession according to the Master Government Property List (Physical Inventory) CDRL.

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(f) The physical inventory report shall be validated/confirmed via signature by both the Contractor's Property Administrator and the DTRA's Government Representative (i.e. COR, APO, etc.). Inventory discrepancies must be reported immediately to the Contracting Officer, COR/Program Manager and resolved by the DTRA APO.

(g) The Contractor shall provide all CDRL reports to the Government electronically in a spreadsheet using Microsoft Office Excel. Unless otherwise specified, the contractor shall submit all data through the IUID Registry.

(End of Clause)

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**Section J - List of Documents, Exhibits and Other Attachments**

**Exhibit/Attachment Table of Contents**

<b>DOCUMENT TYPE</b>	<b>DESCRIPTION</b>	<b>PAGES</b>	<b>DATE</b>
Exhibit A	CLIN 0002 Exhibit(s)	1	
Attachment 1	Statement of Work	11	15-MAR-2009
Attachment 2	CDRLS	5	15-SEP-2009

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**Statement of Work**  
**03/15/09**

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CONTRACT DATA REQUIREMENTS LIST (2 Data Items)						Form Approved OMB No. 0704-0188			
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the government issuing Contracting Officer for the Contract PR No. listed in Block E.									
A. CONTRACT LINE ITEM NO. 002		B. EXHIBIT A		C. CATEGORY: TDP _____ TM _____ OTHER _____					
D. SYSTEM/ITEM Alphagal Adj Tech for biodefense			E. CONTRACT/PR NO. TBD		F. CONTRACTOR BioProtection Systems Corp				
1. DATA ITEM NO. A004	2. TITLE OF DATA ITEM Expenditure Forecast			3. SUBTITLE Project Spend Plan					
4. AUTHORITY (Data Acquisition Document No.) DU-MGMT-81468			5. CONTRACT REFERENCE N/A		6. REQUIRING OFFICE DIRA-RD-CBM				
7. DD 250 REQ LT	9. DIST STATEMENT REQUIRED NA	10. FREQUENCY See Blk 16		12. DATE OF FIRST SUBMISSION See Blk 16		14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE See Blk. 16	13. DATE OF SUBSEQUENT SUBMISSION See Blk. 16			a. ADDRESSEE		b. COPIES	
						Draft	Final		
						Reg	Repro		
16. REMARKS 1. Submission shall be furnished electronically via e-mail in contractor format. 2. See attached addressee sheet for a listing of e-mail and postal addresses for the individuals listed in Block 14. 3. First submission within 30 days of contract award. Updates to be made annually.						DIRA-RD-CBM	0	1	0
						DIRA-BE-BCR	0	1	0
						15. TOTAL	0	2	0
1. DATA ITEM NO. A005	2. TITLE OF DATA ITEM Patents - Reporting of subject inventions			3. SUBTITLE N/A					
4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711A			5. CONTRACT REFERENCE SOW		6. REQUIRING OFFICE DIRA-RD-CBM				
7. DD 250 REQ LT	9. DIST STATEMENT REQUIRED NA	10. FREQUENCY See Blk. 16		12. DATE OF FIRST SUBMISSION See Blk. 16		14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE See Blk. 16	13. DATE OF SUBSEQUENT SUBMISSION See Blk. 16			a. ADDRESSEE		b. COPIES	
						Draft	Final		
						Reg	Repro		
16. REMARKS 1. See attached addressee sheet for a listing of e-mail and postal addresses for the individuals listed in Block 14. 2. Provide copies of invention disclosures for subject inventions within 2 months of an employee inventor reporting a subject invention to the Contractor. 3. Report all subject inventions on DD Form 882 every 12 months from the date of the contract award. 4. Report all subject inventions on DD Form 882 in a final report.						DIRA-RD-CBM	1	1	0
						DIRA-BE-BCR	0	1	0
						15. TOTAL	1	2	0
G. PREPARED BY /s/William Dowling		H. DATE 9/15/09		I. APPROVED BY /s/William Dowling		J. DATE 9-15-09			

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)						Form Approved OMB No. 0704-0188		
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the government issuing Contracting Officer for the Contract PR No. listed in Block E.								
A. CONTRACT LINE ITEM NO. 002		B. EXHIBIT A		C. CATEGORY: TDP _____ TM _____ OTHER _____				
D. SYSTEM/ITEM Alphagal adi tech for biodefense			E. CONTRACT/PR NO. TBD		F. CONTRACTOR BioProtection Systems Corp			
1. DATA ITEM NO. A006	2. TITLE OF DATA ITEM Regulatory approval and technical data packages			3. SUBTITLE Submission Report (Regulatory Appr. Docs)				
4. AUTHORITY (Data Acquisition Document No.) NA			5. CONTRACT REFERENCE NA		6. REQUIRING OFFICE DIRA-RD-CBM			
7. DD 250 REQ LT	9. DIST STATEMENT REQUIRED NA	10. FREQUENCY See Blk 16		12. DATE OF FIRST SUBMISSION See Blk. 16		14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE See Blk. 16	13. DATE OF SUBSEQUENT SUBMISSION See Blk. 16		a. ADDRESSEE		b. COPIES	
						Draft	Final	
						Reg	Repro	
16. REMARKS 1. Submission shall be furnished electronically via e-mail in contractor format. 2. See attached addressee sheet for a listing of e-mail and postal addresses for the individuals listed in Block 14. 3. The contractor will provide the Government copies of all technical data generated by the company prior to or during the performance of this contract that would be necessary to pursue FDA approval of an investigational new drug, a new drug application, biologics license application or other approval and notify the Government of FDA decisions.					DIRA-RD-CBM	0	1	0
					DIRA-BE-BCR	0	1	0
					15. TOTAL	0	2	0
1. DATA ITEM NO. A007	2. TITLE OF DATA ITEM Miscellaneous data submissions			3. SUBTITLE None				
4. AUTHORITY (Data Acquisition Document No.) N/A			5. CONTRACT REFERENCE N/A		6. REQUIRING OFFICE DIRA-RD-CBM			
7. DD 250 REQ LT	9. DIST STATEMENT REQUIRED NA	10. FREQUENCY 1 time		12. DATE OF FIRST SUBMISSION See Blk. 16		14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE See Blk. 16	13. DATE OF SUBSEQUENT SUBMISSION See Blk. 16		a. ADDRESSEE		b. COPIES	
						Draft	Final	
						Reg	Repro	
16. REMARKS Submission frequencies and dates will be dictated in the SOW tasks. Deliverable shall be compatible electronic media. Contractor format acceptable, unless specifically cited in SOW.					DIRA-RD-CBM	0	1	0
					DIRA-BE-BCR	0	1	0
					15. TOTAL	0	2	0
G. PREPARED BY William Dowling /s/William Dowling			H. DATE 9/15/09	I. APPROVED BY William Dowling /s/William Dowling		J. DATE 9/15/09		

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE





CONTRACT DATA REQUIREMENTS LIST (1 Data Items)						Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503. Please DO NOT RETURN your form to either of these addresses. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.							
A. CONTRACT LINE ITEM NO. 002		B. EXHIBIT A		C. CATEGORY: TDP    TM    OTHER			
D. SYSTEM/ITEM Alphagal adj tech for biodefense			E. CONTRACT/PR NO. TBD		F. CONTRACTOR BioProtection Systems Corporation		
1. DATA ITEM NO. A009	2. TITLE OF DATA ITEM Master Government Property - Physical Inventory			3. SUBTITLE GFP, GFE, GFM, and Contractor Acquired Property)			17. PRICE GROUP
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80441		5. CONTRACT REFERENCE SOW PARA		6. REQUIRING OFFICE DTRA/BE-BL			
7. DO 250 REQ LT	5. DIST STATEMENT REQUIRED N/A	10. FREQUENCY See Block 16	12. DATE OF FIRST SUBMISSION See Block 16	14. DISTRIBUTION			
8. APP CODE A	11. AS OF DATE See Block 16	13. DATE OF SUBSEQUENT SUBMISSION See Block 16	15. TOTAL	a. ADDRESSEE	b. COPIES		
					Draft	Reg	Repro
16. REMARKS  BLOCK 4: This DID is for reference only. The report shall be prepared according to the remarks below. BLOCK 10: Annually BLOCK 11: Award of Contract/Task Order BLOCK 12: 1 Month after Contract/Task Order Award BLOCK 13: Annually  Remarks: The Contractor shall annually perform, record and disclose physical inventory results of all Contractor Acquired Property in the Contractor's possession. This report shall include ALL Government Property/Contractor Acquired Property/Equipment/Material. A final coordinated physical inventory shall be performed upon contract completion or termination and approved by the DTRA Accountable Property Officer.  The physical inventory report shall identify the Contractor's Point of Contact with telephone number and signature and the following data elements at a minimum: Accountable Contract Task Order Number, Original Manufacturer's Name, Description/Commercial Use, Original Manufacturer's Part Number, Model Number, Serial Number, DTRA Asset ID #, Equipment Identification Number, Quantity, Task Order to which equipment is assigned, Work Breakdown Schedule (WBS) Project Number, Item Unique Identifier or equivalent, Project Descriptor, Equipment Location, Data Placed in Service, Condition of Property, Status (active, stored, in-transit or waiting disposal), Government Property Type (Government Furnished Equipment (GFE), Government Furnished Material (GFM), Government Furnished Property (GFP), Contractor Acquired Property (CAP)). Unit Acquisition Cost (From Accounting System) and Remarks.  The physical inventory report shall be documented in writing and validated/confirmed, via signature, by both the Contractor's Property Administrator and the DTRA's Governmental Representative. Inventory discrepancies must be reported immediately to the Contracting Officer, Contracting Officer Representative/Program Manager or DTRA Accountable Property Officer. The report shall contain original signatures with spreadsheet attachments and be delivered electronically in a spreadsheet using Microsoft Office Excel. Abbreviations are not allowed.  Ninety (90) days prior to Contract expiration, the Contractor shall submit a final property identification listing suitable for close-out purposes containing use/disposition recommendations. The report must be reviewed, approved and signed by the DTRA Accountable Property Officer prior to contract close out.				DTRA/BE-BL	1		
				DTRA/BE-BF	1		
				DTRA/BE-BI	1		
				DTRA/BE-BC	1		
				DTRA/COR	1		
				0	5	0	
G. PREPARED BY William Dowling  /s/ William Dowling		H. DATE 09/15/09	I. APPROVED BY William Dowling  /s/ William Dowling		J. DATE 09/15/09		

DD FORM 1423-1, JUN 90 (EG)

PREVIOUS EDITION ARE OBSOLETE

Page 1 of 1 Pages

BE-BC SOP 09-03 Enclosure

<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)		RATING		PAGE OF PAGES 1   10	
2. CONTRACT (Proc Inst Ident) NO. W911NF-09-C0072		3. EFFECTIVE DATE 31 Jul 2009		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 66273GHCBD209265			
5. ISSUED BY CODE US ARMY RDECOM ACQ CTR - W911NF 4300 S. MIAMI BLVD DURHAM NC 27703		W911NF		6. ADMINISTERED BY (If other than Item 3) DCM TWIN CITIES 3001 METRO DR BLOOMINGTON MN 55425-1573		CODE S2401A	
7. NAME AND ADDRESS OF CONTRACTOR (Name, street, city, county, state and zip code) BIOPROTECTION SYSTEMS CORPORATION 2001 S LOOP DR STE 3360 AMES IA 50010-8646				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days	
CODE 47EJ3				FACILITY CODE W911NF		10. SUBMIT INVOICES <input type="checkbox"/> # copies unless otherwise specified TO THE ADDRESS SHOWN IN: Section G	
11. SHIP TO/MARK FOR CODE US ARMY RDECOM ACQ CTR - W911NF DONAVAN LYONS 4300 S. MIAMI BLVD DURHAM NC 27703		W911NF		12. PAYMENT WILL BE MADE BY CODE DFAS COLUMBUS CENTER DFAS-COWEST ENTITLEMENT OPERATIONS PO BOX: 182381 COLUMBUS OH 43216-2381		HQ0339	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c) ( ) <input type="checkbox"/> 41 U.S.C. 253(c) ( )				14. ACCOUNTING AND APPROPRIATION DATA See Schedule			
15A. ITEM NO.		15B. SUPPLIES / SERVICES		15C. QUANTITY		15D. UNIT	
		SEE SCHEDULE				15E. UNIT PRICE	
						15F. AMOUNT	
				15G. TOTAL AMOUNT OF CONTRACT \$630,738.00			
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1 -- 1	I		CONTRACT CLAUSES	
	B	SUPPLIES OR SERVICES AND PRICES/COSTS		PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS			
	C	DESCRIPTION/SPECS/WORK STATEMENT		J		LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
	E	INSPECTION AND ACCEPTANCE		K		REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	F	DELIVERIES OR PERFORMANCE		L		INSTRS., CONDS., AND NOTICES TO OFFERORS	
	G	CONTRACT ADMINISTRATION DATA		M		EVALUATION FACTORS FOR AWARD	
	H	SPECIAL CONTRACT REQUIREMENTS					
CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> AWARD (Contractor is not required to sign this document). Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award constitutes the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.			
19A. NAME AND TITLE OF SIGNER (Type or print) Carl Langren, CFO				20A. NAME OF CONTRACTING OFFICER LEROY R. HARDY JR./CONTRACTING OFFICER TEL: 919-549-4237 EMAIL: leroy.r.hardy@us.army.mil			
19B. NAME OF CONTRACTOR By: /s/ Carl Langren (Signature of person authorized to sign)		19C. DATE SIGNED 7/30/2009		20B. UNITED STATES OF AMERICA By: /s/ Leroy R. Hardy Jr. (Signature of Contracting Officer)		20C. DATE SIGNED 31-Jul-2009	
NSN 7540-01-152-8069 Previous edition is usable		26-107 GPO 1985 O - 469-794		STANDARD FORM 26 (REV. 12/2002) Prescribed by GSA PAR (48 CFR) 53.214(a)			

SECTION B — Supplies or Services and Prices

CLINs 0001 and 0002 (Cost plus Fixed Fee)

B.1 The Contractor, as an independent contractor and not as an agent of the Government, shall, in accordance with the terms and conditions more particularly set forth below, furnish all management, facilities, supplies, personnel, and equipment and shall do all which is necessary or incident to the satisfactory and timely performance of the work as proposed and accepted by the Government.

B.2 It is the intention of the parties that this contract reflects the provisions of FAR 16.306 to constitute a Cost plus Fixed Fee contract as defined therein. The work performed hereunder shall be performed by personnel possessing no less than the level of qualifications proposed by the Contractor and considered by the Government in awarding this contract.

B.3 The final price of this contract shall be the total of all costs determined reimbursable in accordance with the Allowable Cost and Payment Clause, FAR 52.216-7, but not exceeding the estimated cost which is specified above.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE	AMOUNT
0001					\$630,738.00

SCIENTIFIC RESEARCH SERVICES

Cost Plus Fixed

Small Business Innovative Research (SBIR) Phase II proposal titled, "Improved Venezuelan Equine Encephalitis Virus Vaccines" sets forth the research to be completed under this contract line item number.

Purchase Request Number: 56273CHCBD209265

Project: CBD08-105

Estimated Cost	\$	595,036.00
Fixed Fee	\$	35,702.00
<b>Total Est. Cost + Fee</b>	<b>\$</b>	<b>630,738.00</b>

ACRN AA

CIN: 56273CHCBD2092650001 \$ 630,738.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE	AMOUNT
0002	SCIENTIFIC RESEARCH SERVICES				\$119,261.00
Option	Cost Plus Fixed				
	Small Business Innovative Research (SBIR) Phase II proposal titled, "Improved Venezuelan Equine Encephalitis Virus Vaccines" sets forth the research to be completed under this contract line item number.				
	Purchase Request Number: 56273CHCBD209265				
	Project: CBD08-105				
				Estimated Cost	\$ 112,510.00
				Fixed Fee	\$ 6,751.00
				<b>Total Est. Cost + Fee</b>	<b>\$ 119,261.00</b>

SECTION C - Descriptions and Specifications

(Cost plus Fixed Fee)

C.1 The research and services required under Section B shall be performed in accordance with the contractor's Small Business Innovative Research (SBIR) Phase II proposal C081-105-0080 titled, Multiple Indication Adjuvants. The above noted proposal is incorporated herein by reference and a copy is on file at the U.S. Army Research Office.

C.2 In the event of an inconsistency between the provisions of this contract and the Contractor's proposal, the inconsistency shall be resolved by giving precedence in the following order: (a) the contract, (b) other attachments or modifications to the contract, and (c) the technical proposal.

C.3 The named Principle Investigator shall be closely involved and continuously responsible for the conduct of the work. The PI for this project is Dr. Ramon Flick. A change to the PI requires prior approval by the Contracting Officer through a modification to the contract.

SECTION D - Packaging and Marking

Cost Plus Fixed Fee

D.1. Packaging (preservation and packing) and marking of deliverable items called for under this contract shall be in accordance with Contractor's best commercial practice to insure safe arrival at destination.

SECTION E - Inspection and Acceptance

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government

The following contract clause is pertinent to this section and is hereby incorporated by reference:

REF #:	FAR CLAUSE	CLAUSE TITLE AND DATE
1	52.246-9	INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) APR 1984

E.1. The contractor will submit all scientific reports to the office specified in Section F.2 (a) and (b) of the contract for inspection and acceptance. Reports shall be prepared in accordance with the SBIR program solicitation and in accordance with Sections F.2 and F.3 of this contract.

**SECTION F - Deliveries or Performance**

**CLINs 0001 and 0002 (Cost plus Fixed Fee)**

The following contract clauses are hereby incorporated by reference:

Ref #	FAR Clause #	Clause Title	Date
1.	52.242-15 Alternate I	Stop Work Order	(AUG 1989) (AUG 1989)
2.	52.247-34	F.O.B. Destination	(NOV 1991)

**F.1 Performance Period:**

**CLIN 0001:** The research called for during CLIN 0001 shall be performed for a period not to exceed twelve months starting on the effective date of this contract (see block 3 on the Standard Form 26).

**CLIN 0002:** This contract also contains a twelve month option that may be unilaterally exercised by the government (see FAR Clause 52.217-9 located in Section I of the contract). If the Government elects to exercise the option period; the period of performance will start on the effective date of the modification and shall conclude 12 months thereafter.

CLIN	DELIVERY DATE	QTY	SHIP TO ADDRESS
0001	30 JUL 2010	N/A	Transportation Office - W36QYT PR PROP BK ACCT Durham PO Box 12211 Research Triangle Park NC 27709-2211 FOB: Destination
0002	30 JUL 2011	N/A	(Same as above)

**F.2 Delivery of Data: Reports called for by this contract shall be delivered as follows:**

a. **Quarterly Progress Reports** — (1 copy) These reports must be received by the 20<sup>th</sup> day of the month following the end of the preceding quarter. The quarterly reports shall include a completed SF 298 (<http://www.arl.army.mil/main/main/default.cfm?Action=29&Page=218>), "Report Documentation Page". Quarterly reports shall be submitted electronically in PDF format to <https://extranet.aro.army.mil>. Hard copies will be accepted if electronic submission is not possible. If hard copies are sent, send 2 copies to the appropriate address shown below.

**VIA U. S. MAIL:**

U. S. Army Research Office  
ATTN: AMSRL-RO-S  
P. O. Box 12211  
Research Triangle Park, NC 27709-2211

**VIA OVERNIGHT CARRIER:**

U. S. Army Research Office  
ATTN: AMSRL-RO-S  
4300 South Miami Boulevard  
Durham, NC 27703-9142

b. **Final Progress Report** — (3 copies) Submitted within ninety (90) days of the expiration of the performance period specified in F.1 above or any extension thereto. Administrative costs are permitted for the development of the Final Progress Report even if beyond period of performance but total payment not-to-exceed the total negotiated contract line item amount. The Final Progress Report, SF 298, copy of Final Voucher, and DD Form 882 shall be submitted to one of the addresses in F.2.a. above. Distribution for the final report shall be in accordance with the instructions shown in F.2 above.

c. **DD Form 882, Report of Inventions and Subcontracts** (2 copies) - The contractor shall disclose each subject invention to the ARO agency within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor.

**F.3 Reports:** Quarterly reports and a final report are required for each Phase II project. All reports shall include a completed SF 298, "Report Documentation Page" as the first page identifying the purpose of the work, a brief description of the work carried out, the findings or results, and potential applications of the effort. The summary may be published by DoD and therefore must not contain proprietary or classified information. The balance of the report should indicate in detail the project objectives; work carried out, and results obtained. In completing the SF 298, the following issues need to be addressed:

a. Block 12a (Distribution/Availability Statement) of the SF 298 in each **unclassified final report** must contain one of the following statements:

1. Distribution authorized to U.S. Government Agencies only; contains proprietary information.
2. Approved for public release; distribution unlimited.

b. Block 13 (Abstract) of the SF 298 must include as the first sentence, “Report developed under SBIR contract W911NF-09-C-0072 for topic “CBD08-105””. The abstract must identify the purpose of the work, a brief description of the work carried out, the findings or results, and potential applications of the effort. Since the DoD will publish the abstract, it must not contain proprietary or classified data.

c. Block 14 (Subject Terms) of the 298 must include the term “SBIR Report.”

d. The final payment on the contract will not be processed until all deliverables are received.

e. The Army Research Office (ARO) will make primary distribution to the Defense Technical Information Center (DTIC), who secondarily distributes the unclassified and unlimited distribution reports to the National Technical Information Service (NTIS) for sale to the general public. DTIC distributes limited distribution reports according to the limitations imposed by the sponsored agency.

Note: Reporting instructions are further defined in ARO Form 18 found at <http://www.arl.army.mil/main/main/default.cfm?Action=29&Page=218>.

#### F.4 Contractor Manpower Reporting Requirements:

##### Technical Cost Analysis of Contractor Manpower Reporting (CMR) Requirement

Accounting for Contract Services, otherwise known as contractor Manpower Reporting (CMR), is a Department of Defense Business Initiative Council (BIC) sponsored program to obtain better visibility of the contractor service workforce. This reporting requirement applies to all Army contracts. Offerors are instructed to include costs to report CMR data within their cost proposal.

The contractor is required to report contractor manpower information associated with performance of this contract action in support of Army requirements, to the Office, Assistant Secretary of the Army (Manpower and Reserve Affairs), using the secure Army data collection web-site at <https://cmra.army.mil/>.

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## SECTION G - Contract Administration Data

### CLINs 0001 (Cost plus Fixed Fee)

#### Accounting and Appropriation Data:

Funding for CLIN 0001 is added as follows:

ACRN: AA	9780400260186N6N7C60605502BPM255YXR00008PM5627 3CHSAPM8XSAPM018129
AMOUNT :	\$630,738.00
CIN	56273CHCBD2092650001

#### G.1 Delegation of Administrative Functions:

Per FAR Part 42, the Contracting Officer has delegate property administration and certain administrative responsibilities to the Defense Contract Management Agency provided herein.

##### The cognizant DCMA Office

DCMA Twin Cities  
B.H. Whipple Federal Building  
Room 1150  
1 Federal Drive  
Ft. Snelling, MN 55111  
Phone#: 612-605-4100  
DoDAAC: S2401A

#### G.2 Payment of voucher:

Payment vouchers (Standard Form 1034) shall be submitted no more frequently than twice a month through the wide area workflow (WAWF) database in accordance with FAR Clause 52.216-4, Allowable Cost and Payment.

All relevant DoDAAC codes are located in this document, these codes are required when input data into the WAWF database. You can track your payment information on the DFAS website at [www.dod.mil/dfas/contractorpay/myinvoice.html](http://www.dod.mil/dfas/contractorpay/myinvoice.html).

#### G.3 Audit Functions:

Audit functions will be conducted by the following Defense Contract Audit Agency:

Minneapolis Branch Office — 03541  
250 Marquette Avenue  
Suite 525  
Minneapolis, MN 55401-1872  
DoDAAC: HAA240  
Phone No: 612-343-7750  
Email: [dcaa-fao3541@dcaa.mil](mailto:dcaa-fao3541@dcaa.mil)

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Information on the audit process, including submission of vouchers is available from the Defense Contract Audit Agency. The contractor may request a copy of a guide entitled "Information for Contractors" (DCAAP 7641-90), August 1996, from Headquarters, Defense Contract Audit Agency, Operating Administrative Office, 8725 John J. Kingman Road, Suite 2135, Fort Belvoir, VA 22060-6219; Telephone No. (703) 767-1066; Facsimile No. (703) 767-1061; or request by e-mail: \*CMO@hq1.dcaa.mil. To ensure you have the necessary information to process billings and inquire if the DCAA office assigned to this contract has any procedures peculiar to that office, it is advisable you familiarize yourself with the audit process.

G.4 The Contracting Officer's Technical Representative for this project is:

Dr. Jennifer Becker  
US Army Research Office  
P.O. Box 12211  
Research Triangle Park, NC 27709-2211  
Voice: (919) 549-4224

---

SECTION H - Special Contract Requirements

H.1 Release of Information: The Contractor agrees that in the release of information relating to this contract, such release shall include a statement to the effect that the project or effort depicted was or is sponsored by the Defense Advanced Research Projects Agency and U.S. Army Research Office, and that the content of the information does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred. For the purpose of this provision, "information" includes news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association proceedings, symposia, etc. The Contractor further agrees to include this provision in any subcontract awarded as a result of this contract.

H.2 Publications: Publication of results of the research project in appropriate professional journals is encouraged as an important method of recording and reporting scientific information. All information pertaining to this effort shall be submitted to and approved by DARPA prior to public release. One copy of each manuscript submitted for publication shall be forwarded to DARPA and ARO. Following publication, copies of reprints shall be submitted to the ARO in accordance with the reporting instructions in ARO Form 18. The Contracting Officer may request submission of publications to other addressees.

H.3 Research responsibility: The Contractor shall bear responsibility for the conduct of the research specified in the Contractor's proposal identified in the contract. The Contractor will exercise judgment in obtaining the stated research objectives within the limits of the terms and conditions of the contract; provided, however, the Contractor will obtain the Contracting Officer's approval to change the statement of work. Consistent with the foregoing the Contractor shall conduct the work as set forth in his proposal and accepted by the contract award. The Principal Investigator identified in the proposal shall be continuously responsible for the conduct of the research project and shall be closely involved with the research efforts. The Contractor shall advise the Contracting Officer if the Principal Investigator identified in the contract plans to devote less effort to the project than set forth in the proposal. The Contractor shall obtain the Contracting Officer's approval prior to changing the named Principal Investigator.

H.4 Restriction on Printing: The government authorizes the reproduction of reports, data or other written material, if required, provided the material produced does not exceed 5,000 production units of any page, and items consisting of multiple pages do not exceed 25,000 production units in the aggregate. The Contractor shall obtain the express prior written authorization of the Contracting Officer to reproduce material in excess of the quantities cited above.

H.5 Security: If in the conduct of this contract, the Contractor develops information, which in the Contractor's opinion might have an adverse effect on the national security if it were disclosed, the Contractor shall promptly notify the COR and should not disclose the information without the prior concurrence of the COR.

H.6 Export Licenses: The Contractor shall comply with all applicable U.S. export control laws and regulations, including the International Traffic in Arms Regulations (ITAR), 22 CFR parts 120 through 130, and the Export Administration Regulations (EAR), 15 CFR parts 730 through 799, in the performance of this contract. In the absence of available license exemptions/exceptions, the Contractor shall be responsible for obtaining the appropriate licenses or other approvals, if required, for exports of hardware, technical data, and software, or for the provision of technical assistance. The Contractor shall be responsible for obtaining export licenses, if required, before utilizing foreign persons in the performance of this contract, including instances where the work is to be performed on-site at any Government installation (whether within the U.S. or elsewhere), where the foreign person will have access to export-controlled technical data or software. The Contractor shall be responsible for all regulatory record keeping requirements associated with the use of licenses and license exemptions/exceptions.

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H.7 Reimbursement of Travel and Per Diem Costs: The Government will reimburse the Contractor allowable travel costs incurred by the Contractor in performance of the contract in accordance with Far Subpart 31.2. Travel required for tasks assigned under this contract shall be governed in accordance with rules set forth for temporary duty travel in the Department of Defense Joint Travel Regulations, Volume II, for civilian personnel.



**H.8 New Effort Certification:** By execution of this contract, the Contractor certifies that he has not delivered nor is obligated to delivery to the Government under any contract or subcontract the same or substantially the same research that will be performed under this contract.

**H.9 Safety:** When and if applicable, the Contractor is required to comply with the safety provisions and guidelines specified in the following regulations:

- AR 50-6 — Chemical Surety
- AR 385-10 — Army Safety Program
- AR 385-61 — Army Chemical Agent Safety Program
- DA Pam 385-69 — Biological Defense Safety Program
- 42 CFR Part 73 — Select Agents and Toxins

Contractor shall ensure that all subcontractors comply with the aforementioned, where applicable.

**H.10 Human Subjects:** Research at funded organizations using human subjects may not begin until the U.S. Army Surgeon General's Human Subjects Research Review Board (HSRRB) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the U.S. Army Medical Research and Materiel Command, HSRRB, under separate letter to the funded organization and the Principal Investigator. Non-compliance with any part of this provision may result in withholding of funds and/or the termination of the award.

The Principal Investigator will notify the ARO COR and the DARPA Program Manager within 24 hours if any of the following occur: (i) the protocol is suspended, (ii) a death occurs as a consequence of the research protocol, or (iii) a life-threatening, adverse event occurs as a consequence of the research protocol.

By accepting funds under this contract, the Contractor assures that it will comply with applicable provisions of the Common Federal Policy for the Protection of Human Subjects, codified by the Department of Health and Human Services at 45 CFR Part 46 and implemented by the Department of Defense at 32 CFR Part 219.

**H.11 Option:** This contract is renewable, at the option of the Government and may be exercised at any time prior to the end of the time of performance cited in Section F, Subsection F.1. Should the Government exercise this option, written notification will be provided to the contractor by modification to this contract signed by the Contracting Officer.

## SECTION I - Contract Clauses

### FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSES

#### FAR 52.252-2 Clauses Incorporated by Reference (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): <http://arlininside.arl.mil/offices/procure/library.htm> or <http://farsite.hill.af.mil/VFFARa.htm>.

FAR CLAUSE #	TITLE	DATE
FAR 52.202-1	Definitions	(JUL 2004)
FAR 52.203-3	Gratuities	(APR 1984)
FAR 52.203-5	Covenant Against Contingent Fees	(APR 1984)
FAR 52.203-6	Restrictions on Subcontractor Sales to the Government	(SEP 2006)
FAR 52.203-7	Anti-Kickback Procedures	(JUL 1995)
FAR 52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	(JAN 1997)
FAR 52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	(JAN 1997)
FAR 52.203-12	Limitation on Payments to Influence Certain Federal Transactions	(SEP 2007)
FAR 52.204-2	Security Requirements(Alternate 1)	(APR 1984)
FAR 52.204-4	Printed or Copied Double-Sided on Recycled Paper	(AUG 2000)
FAR 52.204-7	Central Contractor Registration	(APR 2008)
FAR 52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	(SEP 2006)
FAR 52.211-8	Time of Delivery (See Section F)	(JUN 1997)
FAR 52.215-2	Audit & Records—Negotiation Alt II	(MAR 2009) (APR 1998)
FAR 52.215-8	Order of Precedence Uniform Contract Format	(OCT 1997)
FAR 52.215-10	Price Reduction For Defective Cost or Pricing Data	(OCT 1997)
FAR 52.215-12	Subcontractor Cost Or Pricing Data	(OCT 1997)
FAR 52.215-14	Integrity of Unit Prices	(OCT 1997)
FAR 52.215-15	Pension Adjustments and Asset Reversions	(OCT 2004)
FAR 52.215-17	Waive of Facilities Capital Cost of Money	(OCT 1997)
FAR 52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	(JUL 2005)
FAR 52.215-19	Notification of Ownership Changes	(OCT 1997)
FAR 52.216-7	Allowable Cost and Payment	(DEC 2002)
FAR 52.216-8	Fixed Fee	(MAR 1997)
FAR 52.217-9	Option to Extend the Term of the Contract	(MAR 2000)
FAR 52.219-8	Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns	(MAY 2004)
FAR 52.222-2	Payment for Overtime Premiums	(JUL 1990)

FAR 52.222-3	Convict Labor	(JUN 2003)
FAR 52.222-21	Prohibition of Segregated Facilities	(FEB 1999)
FAR 52.222-26	Equal Opportunity	(MAY 2007)
FAR 52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	(SEP 2006)
FAR 52.222-36	Affirmative Action for Workers with Disabilities	(JUN 1998)
FAR 52.222-37	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era and Other Eligible Veterans	(SEP 2006)
FAR 52.222-39	Notification of Employee Rights Concerning Payment of Union Dues or Fees	(DEC 2004)
FAR 52.222-50	Combating Trafficking in Persons	(FEB 2009)

FAR CLAUSE #	TITLE	DATE
FAR 52.223-6	Drug-Free Workplace	(MAY 2001)
FAR 52.223-14	Toxic Chemical Release Reporting	(AUG 2003)
FAR 52.225-13	Restriction on Certain Foreign Purchases	(JUN 2008)
FAR 52.227-1	Authorization and Consent	(DEC 2007)
	Alternate I	(APR 1984)
FAR 52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	(DEC 2007)
FAR 52.227-11	Patent Rights — Retention by the Contractor (Short Form)	(DEC 2007)
FAR 52.227-20	Rights in Data-SBIR	(DEC 2007)
FAR 52.228-7	Insurance—Liability to Third Persons	(MAR 1996)
FAR 52.230-3	Disclosure and Consistency of Cost Accounting Practices	(OCT 2008)
FAR 52.230-6	Administration of Cost Accounting Standards	(MAR 2008)
FAR 52.232-9	Limitation on Withholding of Payments	(APR 1984)
FAR 52.232-17	Interest	(OCT 2008)
FAR 52.232-18	Availability of Funds	(APR 1984)
FAR 52.232-20	Limitation of Cost	(APR 1984)
FAR 52.232-22	Limitation of Funds	(APR 1984)
FAR 52.232-23	Assignment of Claims	(JAN 1986)
FAR 52.232-25	Prompt Payment	(OCT 2003)
FAR 52.232-33	Payment by Electronic Funds Transfer Payment	(OCT 2003)
FAR 52.233-1	Disputes	(JUL 2002)
FAR 52.233-3	Protest After Award	(AUG 1996)
	Alternate I	(JUN 1985)
FAR 52.233-4	Applicable Law for Breach of Contract Claim	(OCT 2004)
FAR 52.242-1	Notice of Intent to Disallow Costs	(APR 1984)
FAR 52.242-3	Penalties for Unallowable Costs	(MAY 2001)
FAR 52.242-4	Certification of Final Indirect Costs	(JAN 1997)
FAR 52.242-13	Bankruptcy	(JUL 1995)
FAR 52.242-15	Stop-Work Order	(AUG 1989)
	Alternate I	(APR 1984)
FAR 52.243-2	Changes — Cost Reimbursement	(AUG 1987)
	Alternate I	(APR 1984)
FAR 52.244-2	Subcontracts	(JUN 2007)
	Alternate I	(JUN 2007)
FAR 52.244-5	Competition in Subcontracting	(DEC 1996)
FAR 52.244-6	Subcontracts for Commercial Items	(MAR 2007)
FAR 52.245-1	Government Property	(JUN 2007)
FAR 52.245-9	Use and Charges	(JUN 2007)
FAR 52.246-9	Inspection of Research and Development (Short Form)	(APR 1984)
FAR 52.247-1	Commercial Bill of Lading Notations	(FEB 2006)
FAR 52.247-63	Preference for U.S.-Flag Air Carriers	(JUN 2003)
FAR 52.249-6	Termination (Cost Reimbursement)	(MAY 2004)
FAR 52.249-14	Excusable Delays	(APR 1984)
FAR 52.253-1	Computer Generated Forms	(JAN 1991)
FAR 52.215-19	Notification of Ownership Changes	(OCT 1997)

**(a) The Contractor shall make the following notifications in writing:**

**(1) When the Contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records, the Contractor shall notify the Administrative Contracting Officer (ACO) within 30 days.**

**(2) The Contractor shall also notify the ACO within 30 days whenever changes to asset valuations or any other cost changes have occurred or are certain to occur as a result of a change in ownership.**

**(b) The Contractor shall —**

**(1) Maintain current, accurate, and complete inventory records of assets and their costs;**



(2) Provide the ACO or designated representative ready access to the records upon request;

(3) Ensure that all individual and grouped assets, their capitalized values, accumulated depreciation or amortization, and remaining useful lives are identified accurately before and after each of the Contractor's ownership changes; and

(4) Retain and continue to maintain depreciation and amortization schedules based on the asset records maintained before each Contractor ownership change.

(c) The Contractor shall include the substance of this clause in all subcontracts under this contract that meet the applicability requirement of FAR 15.408(k).

**I.2. DEFENSE ACQUISITION REGULATION SUPPLEMENT (48 CFR CHAPTER 2) CLAUSES:**

<b>DFARS CLAUSE #</b>	<b>TITLE</b>	<b>DATE</b>
DFARS 252.201-7000	Contracting Officer's Representative	(DEC 1991)
DFARS 252.203-7001	Prohibition on Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	(DEC 2008)
DFARS 252.203-7002	Requirement to Inform Employees of Whistleblower Rights	(JAN 2009)
DFARS 252.204-7001	Commercial and Government Entity (CAGE) Code Reporting	(AUG 1999)
DFARS 252.204-7003	Control of Government Personnel Work Product	(APR 1992)
DFARS 252.204-7004	Alternate A, Central Contractor Registration	(SEP 2007)
DFARS 252.204-7006	Billing Instructions	(OCT 2005)
DFARS 252.204-7009	Requirements Regarding Potential Access to Export-Controlled Items	(JUL 2008)
DFARS 252.204-7000	Disclosure of Information	(DEC 1991)
DFARS 252.205-7000	Provision of Information to Cooperative Agreement Holders	(DEC 1991)
DFARS 252.209-7004	Subcontracting with Firms That are Owned or Controlled by the Government of a Terrorist Country	(DEC 2006)
DFARS 252.215-7000	Pricing Adjustment	(DEC 1991)
DFARS 252.215-7002	Cost Estimating System Requirements	(DEC 2006)
DFARS 252.225-7001	Buy American Act and Balance of Payments Program.	(JUN 2005)
DFARS 252.225-7002	Qualifying Country Sources as Subcontractors.	(APR 2003)
DFARS 252.225-7012	Preference for Certain Domestic Commodities	(MAR 2008)
DFARS 252.225-7016	Restriction on Acquisition of Ball and Roller Bearings.	(MAR 2006)
DFARS 252.227-7016	Rights in Bid or Proposal Information	(JUN 1995)
DFARS 252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	(JUN 1995)
DFARS 252.227-7018	Rights in Noncommercial Technical Data and Computer Software— Small Business Innovation Research (SBIR) Program.	(JUN 1995)
DFARS 252.227-7019	Validation of Asserted Restrictions-Computer Software	(JUN 1995)
DFARS 252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	(JUN 1995)
DFARS 252.227-7030	Technical Data — Withholding of Payment	(MAR 2000)
DFARS 252.227-7034	Patents-Subcontracts	(APR 1984)
DFARS 252.227-7037	Validation of Restrictive Markings on Technical Data	(SEP 1999)
DFARS 252.231-7000	Supplemental Cost Principles	(DEC 1991)
DFARS 252.232-7003	Electronic Submission of Payment Requests and Receiving Report	(MAR 2008)
DFARS 252.232-7010	Levies on Contract Payments	(DEC 2006)
DFARS 252.235-7003	Frequency Authorization	(DEC 1991)
DFARS 252.235-7010	Acknowledgment of Support & Disclaimer	(MAY 1995)
DFARS 252.235-7011	Final Scientific or Technical Report	(NOV 2004)
DFARS 252.243-7002	Request For Equitable Adjustment	(MAR 1998)
DFARS 252.246-7000	Material Inspection and Receiving Report	(JAN 2007)
DFARS 252.247-7023	Transportation of Supplies By Sea	(MAY 2002)



REPLY TO  
ATTENTION OF

DEPARTMENT OF THE ARMY  
U.S. ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND ACQUISITION  
CENTER  
RESEARCH TRIANGLE PARK DIVISION  
P.O. BOX 12211  
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709-2211

[stamp:] April 26, 2010

AMSRD-ACC-R 70-1t

Subject: Contract No. W911NF-09-C-0072 (Proposal 56273-CH-CBD2)

Bio Protection Systems Corporation  
Attn: Mr. Carl Langren  
2901 South Loop Drive  
Suite 2236  
Ames, IA 50010-8646

Dear Mr. Carl Langren:

Enclosed for your retention is a signed copy of subject contract that has been signed by all the parties.

All correspondence pertaining to the scientific and technical aspects of the contract should be directed to the Government technical monitor specified in the contract. Other correspondence should be directed to the undersigned at (919) 549-4237 or [leroy.r.hardy@us.army.mil](mailto:leroy.r.hardy@us.army.mil).

Sincerely,

/s/ Leroy R. Hardy Jr.

Leroy R. Hardy Jr.  
Contracting Officer

Enclosures

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AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE	PAGE OF PAGES	
2. AMENDMENT/MODIFICATION NO. P00002		3. EFFECTIVE DATE 21-Apr-2010	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO (If applicable)	
6. ISSUED BY US ARMY RDECOM ACQ CTR - W911NF 4300 S. MIAMI BLVD DURHAM NC 27703		CODE W911NF	7. ADMINISTERED BY (If other than item 6) DCM TWIN CITIES 3001 METRO DR BLOOMINGTON MN 55425-1573		CODE S2401A	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, county, State and Zip Code) BIOPROTECTION SYSTEMS CORPORATION 2901 S LOOP DR STE 3360 AMES IA 50010-3646				9A. AMENDMENT OF SOLICITATION NO.		
				9B. DATED (SEE ITEM 11)		
				X 10A. MOD. OF CONTRACT/ORDER NO. W911NF-09-C-0072		
				X 10B. DATED (SEE ITEM 13) 31-Jul-2009		
CODE 47EJ3		FACILITY CODE				
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS						
<input type="checkbox"/> The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods (a) By completing item 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.						
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule						
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.						
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.						
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).						
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:						
X D. OTHER (Specify type of modification and authority) LAW FAR Clause 52.243-2, Changes - Cost Reimbursement						
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.						
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible) Modification Control Number: hardy1101518 SEE CONTINUATION PAGES.  P-56273-CH-CBD2  Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.						
15A. NAME AND TITLE OF SIGNER (Type or print)				16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) LEROY R. HARDY/CONTRACTING OFFICER TEL 919-549-4237 EMAIL leroy.r.hardy@us.army.mil		
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)		_____ (Signature of Contracting Officer)		/s/ Leroy R. Hardy Jr. (Signature of Contracting Officer)		21-Apr-2010

EXCEPTION TO SF 30 APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

The purpose of this modification is to: (1) exercise contract line item number (CLIN) 0002 in accordance with the terms and conditions established in the above noted contract; and (2) fully fund CLIN 0002 in the amount of \$119,261.00. Therefore, the following changes are hereby incorporated:

SECTION A — SOLICITATION/CONTRACT FORM

- 1. The total cost of this contract was increased by \$119,261.00 from \$630,738.00 to \$749,999.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

- 2. CLIN 0002: The word "Option" is hereby deleted in its entirety and CLIN 0002 is exercised and fully funded as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
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0002	Scientific Research Services — Phase II	Dollars, U.S.
	Cost Plus Fixed Fee	
	Small Business Innovative Research (SBIR) Phase II proposal titled, “Improved Venezuelan Equine Encephalitis Virus Vaccines” sets forth the research to be completed under this contract line item number.	
	Purchase Request Number: 56273CHCBD209265	
	Project: CBD08-105	
	ESTIMATED COST	\$ 112,510.00
	FIXED FEE	\$ 6,751.00
	TOTAL EST COST + FEE	\$ 119,261.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE	AMOUNT
000201	Scientific Research Services — Phase II				
	Cost Plus Fixed Fee				
	Increment of Funding				
	Purchase Request Number: 56273CHCBD209265-0001				
	Project: CBD08-105				
	Total amount Funded: ACRN AB				\$ 372.00
	CIN: 56273CHCBD209265000201				

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT Dollars, U.S.	UNIT PRICE	AMOUNT
000202	Scientific Research Services — Phase II				
	Cost Plus Fixed Fee				
	Increment of Funding				
	Purchase Request Number: 56273CHCBD209265-0001				
	Project: CBD08-105				
	Total amount Funded: ACRN AC				\$ 118,889.00
	CIN: 56273CHCBD209265000202				

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**SECTION E - INSPECTION AND ACCEPTANCE**

3. The following Acceptance/Inspection Schedule is added for CLIN 0002:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

**SECTION F - DELIVERIES OR PERFORMANCE**

4. The Delivery Schedule for CLIN 0002 is shown below:

Period of Performance	Ship to Address	UIC
31-JUL-2010 through 30-JUL-2011	Transportation Office - W36QYT PR PROP BK ACCT Durham PO Box 12211 Research Triangle Park NC 27709-2211 FOB: Destination	W36QYT

**SECTION G - CONTRACT ADMINISTRATION DATA**

5. The accounting and appropriation data for CLIN 0002 is delineated below:

SubCLIN 000201 ACRN AB:	9790400260196N6N7C60605502BPM255YXR00009PM56273CH SAPM9XSAPM018129 CIN: 56273CHCBD209265000201	\$ 372.00
SubCLIN 000202 ACRN AC:	9700400260106N6N7C60605502BPM255YXR00000PM56273CHS APM0XSAPM018129 CIN: 56273CHCBD209265000202	\$ 118,889.00

6. As a result of this modification, the total funded amount for this document is increased by \$119,261.00 from \$630,738.00 to \$749,999.00.

7. The funding obligated under CLIN 0002, ACRN AB and ACRN AC, shall not be disbursed until the start of the performance period denoted in Section F provided herein.

Except as provided herein, all terms and conditions set forth in the above noted contract remains unchanged and in full force and effect.

(End of Summary of Changes)





Notice of Award  
**RESEARCH PROJECT COOPERATIVE AGREEMENT Issue Date: 08/26/2009**  
 Department of Health and Human Services  
 National Institutes of Health  
 NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES



**Grant Number: 5U01AI066327-05**

**Principal Investigator(s):  
 RAMON FLICK, PHD**

**Project Title: Rationally designed Rift Valley Fever Virus Vaccine**

**Carl Langren  
 CFO  
 BioProtection Systems Corporation  
 2901 South Loop Drive  
 Ames, IA 50010**

**Award e-mailed to: clangren@bpsys.net**

**Budget Period: 07/01/2009 — 06/30/2010  
 Project Period: 07/01/2005 — 06/30/2010**

**Dear Business Official:**

The National Institutes of Health hereby awards a grant in the amount of \$535,681 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to BIOPROTECTION SYSTEMS CORPORATION in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number U01AI066327 from the National Institute Of Allergy And Infectious Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Allergy And Infectious Diseases or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit <http://publicaccess.nih.gov/>.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other

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aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website <http://grants.nih.gov/grants/policy/coi/index.htm> provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

**Tamara A. Kees  
 Grants Management Officer  
 NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Additional information follows

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SECTION I — AWARD DATA — 5U01AI066327-05

Award Calculation (U.S. Dollars)

Salaries and Wages	\$	100,020
Fringe Benefits	\$	13,203
Supplies	\$	48,795
Travel Costs	\$	6,457
Other Costs	\$	30,989
Consortium/Contractual Cost	\$	192,204
Federal Direct Costs	\$	391,668
Federal F&A Costs	\$	144,013
Approved Budget	\$	535,681
Federal Share	\$	535,681
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$</b>	<b>535,681</b>
<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	<b>\$</b>	<b>535,681</b>

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
5	\$ 535,681	\$ 535,681

Fiscal Information:

CFDA Number: 93.855  
 EIN: 1202844633A1  
 Document Number: UAI066327B  
 Fiscal Year: 2009

IC	CAN	2009
AI	8472315	\$ 535,681

NIH Administrative Data:

PCC: M32B B / OC: 414P / Processed: KEEST 08/25/2009

SECTION II — PAYMENT/HOTLINE INFORMATION — 5U01AI066327-05

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III — TERMS AND CONDITIONS — 5U01AI066327-05

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award represents the final year of the competitive segment for this grant. Therefore, see the NIH Grants Policy Statement (12/1/2003 version) for closeout requirements at: [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600151](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600151).

A final Financial Status Report (FSR) (SF 269) must be submitted through the eRA Commons (Commons) within 90 days of the expiration date; see NIH Guide Notice NOT-OD-07-078 for additional information on this electronic submission requirement.

Furthermore, unless an application for competitive renewal is submitted, additional grant closeout documents consisting of a Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) and a final progress report must also be submitted within 90 days of the expiration date.

NIH also strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons. If the final progress report and final invention statement are not submitted electronically, copies of the HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>.

Submissions of the final progress report and HHS 568 may be e-mailed as PDF attachments to the NIH Central Closeout Center at: [deacentralized@od.nih.gov](mailto:deacentralized@od.nih.gov)

Paper submissions of the final progress report and the HHS 568 may be faxed to the NIH Central Closeout Center at 301-480-2304 or mailed to the NIH Central Closeout Center at the following address:

NIH/OD/OER/DEAS  
Central Closeout Center  
6705 Rockledge Drive, Room 2207  
Bethesda, MD 20892-7987 (for regular or U.S. Postal Service Express mail)  
Bethesda, MD 20817 (for other courier/express mail delivery only)

The final progress report should include, at a minimum, a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive and/or negative), a list of publications and the grant number. If human subjects were included in the research, the final progress report should also address the following:

- Report on the inclusion of gender and minority study subjects (using the gender and minority Inclusion Enrollment Form as provided in the PHS 2590 and available at <http://grants.nih.gov/grants/forms.htm>).
- Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see "Public Policy Requirements and Objectives-Requirements for Inclusiveness in Research Design-Inclusion of Children as Subjects in Clinical Research" in the PHS 398 at URL [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part5.htm#\\_Toc54600090](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600090))
- Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

Note, if this is the final year of a competitive segment due to the transfer of the grant to another institution, then not all the requirements stated above are applicable. Specifically a Final Progress

Report is not required. However, a final FSR is required and should be submitted electronically as noted above. In addition, if not already submitted, the Final Invention Statement is required and should be sent directly the assigned Grants Management Specialist.

#### Treatment of Program Income: Additional Costs

Total costs requested in the non-competing grant progress report exceed the amount previously committed, and therefore have been reduced accordingly.

This award includes funds awarded for consortium activity with INSTITUTE PASTEUR, PARIS, FRANCE and University of Texas Medical Branch. Consortia are to be established and administered as described in the NIH Grants Policy Statement. This written agreement with the consortium must address the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements for this grant.

This award is subject to the Terms and Conditions of Award as set forth in the SPECIAL REQUIREMENTS section of RFA AI-04-023, NIH Guide to Grants and Contracts, 07/02/2004. These special terms and conditions are incorporated in this award by reference.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

The research proposed in this grant may involve Select Agents and/or Highly Pathogenic Agents. NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that, under some circumstances, may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (<http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>), your Institutional Biosafety Committee (IBC) or equivalent body, or appropriate designated institutional biosafety official. If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an institutional committee or institutional official, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If the work involves Select Agents and/or Highly Pathogenic Agents. Also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s);
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.



For domestic work with Select Agents provide documentation of Registration status of all domestic organizations/entities where Select Agent(s) will be used

Please be advised that changes in the use of a Select Agent will likely be considered a change in scope and, therefore, require NIH awarding office prior approval.

#### STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist : Maggie C. Wells

Email: wellsmaggie@mail.nih.gov Phone: 301-594-9847 Fax: 301-493-0597

Program Official: Patricia M. Repik

Email: prepik@niaid.nih.gov Phone: 301-451-3504 Fax: 301-480-1594

#### SPREADSHEET SUMMARY

GRANT NUMBER: 5U01AI066327-05

#### INSTITUTION: BIOPROTECTION SYSTEMS CORPORATION

Budget		Year 5
Salaries and Wages	\$	100,020
Fringe Benefits	\$	13,203
Supplies	\$	48,795
Travel Costs	\$	6,457
Other Costs	\$	30,989
Consortium/Contractual Cost	\$	192,204
TOTAL FEDERAL DC	\$	391,668
TOTAL FEDERAL F&A	\$	144,013
TOTAL COST	\$	535,681

Facilities and Administrative Costs		Year 5
F&A Cost Rate 1		72.2%
F&A Cost Base 1	\$	199,464
F&A Costs 1	\$	144,013

**From:** commons@od.nih.gov  
**Sent:** Monday, May 03, 2010 2:12 PM  
**To:** Marilyn Moehlmann; raflick@utmb.edu  
**Subject:** eRA Commons:Project Extension Submitted for Grant: 5U01AI66327-5 to the NIH.

A Project Extension Request was completed by Signing Official: Marilyn Moehlmann for grant application: 5U01AI66327-5 associated with Principal Investigator FLICK, RAMON using the NIH Commons. The new project end date for this grant is: 06/30/2011

This new date will now be reflected in the Application Detail section of Commons. If you have any questions about this email, please contact Marilyn Moehlmann at mmoehlmann@bpsys.net, who initiated this action.

If you have any questions about this email, please contact the eRA Help Desk at our preferred method of contact <http://ithelpdesk.nih.gov/eRA/> or call 1-866-504-9552 (tty: 301-451-5939) or commons@od.nih.gov <<mailto:commons@od.nih.gov>>.

Please access the NIH Commons at <https://commons.era.nih.gov/commons>

## Notice of Award



SMALL BUSINESS INNOVATION RESEARCH PROG  
 Department of Health and Human Services  
 National Institutes of Health  
 NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Issue Date: 04/06/2010



Grant Number: 1R43AI084350-01A1

Principal Investigator(s):  
 Ramon Flick, PHD

Project Title: Development of Multivalent Vaccines Against Yellow Fever and Arena Viruses

Langren, Carl  
 Chief Financial Officer  
 2901 South Loop Drive Suite 3360  
 Ames, IA 50010

Award e-mailed to: clangren@bpsys.net

Budget Period: 04/06/2010 — 03/31/2011  
 Project Period: 04/06/2010 — 03/31/2012

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$299,975 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to BIOPROTECTION SYSTEMS CORPORATION in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 15 USC 638 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number R43AI084350 from the National Institute Of Allergy And Infectious Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Allergy And Infectious Diseases or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit <http://publicaccess.nih.gov/>.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors,

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or collaborators engaged by the Awardee under this award. The NIH website <http://grants.nih.gov/grants/policy/coi/index.htm> provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Donna R. Sullivan  
 Grants Management Officer  
 NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

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SECTION I — AWARD DATA — 1R43AI084350-01A1

Award Calculation (U.S. Dollars)

Salaries and Wages	\$	79,456
Fringe Benefits	\$	14,063
Consultant Services	\$	5,500
Supplies	\$	34,000
Travel Costs	\$	3,550
Other Costs	\$	19,400
Consortium/Contractual Cost	\$	18,360
<b>Federal Direct Costs</b>	<b>\$</b>	<b>174,329</b>
<b>Federal F&amp;A Costs</b>	<b>\$</b>	<b>113,389</b>
<b>Approved Budget</b>	<b>\$</b>	<b>287,718</b>
<b>Fee</b>	<b>\$</b>	<b>12,257</b>
<b>Federal Share</b>	<b>\$</b>	<b>299,975</b>
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$</b>	<b>299,975</b>
<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	<b>\$</b>	<b>299,975</b>

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
1	\$ 299,975	\$ 299,975
2	\$ 299,975	\$ 299,920

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Number: 93.855  
 EIN: 1202844633A1  
 Document Number: RAI084350A  
 Fiscal Year: 2010

IC	CAN	2010	2011
AI	8477153	\$ 299,975	\$ 299,920

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M32B B / OC: 4141 / Processed: SULLIVANDO 03/31/2010

SECTION II — PAYMENT/HOTLINE INFORMATION — 1R43AI084350-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III — TERMS AND CONDITIONS — 1R43AI084350-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

Treatment of Program Income:

Additional Costs

First-time NIH grantee organizations can find information about funding, policy, and administrative issues by visiting our “Welcome Wagon letter” (<http://grants.nih.gov/grants/funding/welcomewagon.htm>). See also our NIAID online tutorial, “How to Manage a Grant” ([http://www.niaid.nih.gov/ncn/grants/manage/manage\\_c5.htm](http://www.niaid.nih.gov/ncn/grants/manage/manage_c5.htm)), and our “Checklists for New Grantees” (<http://www.niaid.nih.gov/ncn/grants/charts/checklists.htm>) for more information about the responsibilities of a grantee.

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In addition to the PI, any absence, replacement, or substantial reduction in effort of the following individual(s) below, requires the written prior approval of the National Institutes of Health awarding component.

Alex Freiberg ? .54 CM (Consortium)

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**PAYMENT INFORMATION:** The awardee organization will receive information and forms from the Payment Management System of the Department of Health and Human Services regarding requests for cash, manners of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis. Cost reimbursements may be requested monthly, quarterly, or at other periodic intervals. Advance payments may be requested on a monthly basis only. The telephone number for the Payment Management System Office is 1-877-614-5533. Their website is: <http://www.dpm.psc.gov/>

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**INTELLECTUAL PROPERTY RIGHTS:** Normally, the awardee organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site ([www.iedison.gov](http://www.iedison.gov)) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C., Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

When purchasing equipment or products under this SBIR award, the grantee shall use only American-made items, whenever possible.

The fee provided as part of this Notice of Award is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the draw down of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The Code of Federal Regulations (Title 45 Part 74.26) stipulates that a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended \$500,000 or more under HHS awards and at least one award is an HHS grant or subgrant. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See threshold calculation examples, <http://oamp.od.nih.gov/dfas/faqexamples.html>.)

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This award includes funds awarded for consortium activity with the University of Texas Medical Branch in the amount of \$18,360 Total Costs (\$12,000 direct costs + \$6,360 facilities and administrative costs). Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at [http://grants1.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600251](http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251), pages 224-227.

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Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

~~~~~

The research proposed in this grant may involve Select Agents and/or Highly Pathogenic Agents. NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that, under some circumstances, may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (<http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm>), your Institutional Biosafety Committee (IBC) or equivalent body, or appropriate designated institutional biosafety official. If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an

institutional committee or institutional official, the highest recommended containment level must be used. When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If the work involves Select Agents and/or Highly Pathogenic Agents. Also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

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- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s);
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

For domestic work with Select Agents provide documentation of Registration status of all domestic organizations/entities where Select Agent(s) will be used

Please be advised that changes in the use of a Select Agent will likely be considered a change in scope and, therefore, require NIH awarding office prior approval.

#### STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist : Jay Colbert  
Email: colbertj@niaid.nih.gov Phone: 301-496-7075 Fax: 301-493-0597

Program Official: Patricia M. Repik  
Email: prepik@niaid.nih.gov Phone: 301-451-3504 Fax: 301-480-1594

SPREADSHEET SUMMARY  
GRANT NUMBER: 1R43AI084350-01A1

#### INSTITUTION: BIOPROTECTION SYSTEMS CORPORATION

<b>Budget</b>	<b>Year 1</b>	<b>Year 2</b>
Salaries and Wages	\$ 79,456	\$ 81,840
Fringe Benefits	\$ 14,063	\$ 14,485
Consultant Services	\$ 5,500	\$ 5,500
Supplies	\$ 34,000	\$ 31,000
Travel Costs	\$ 3,550	\$ 3,550
Other Costs	\$ 19,400	\$ 19,100
Consortium/Contractual Cost	\$ 18,360	\$ 25,796
FEE	\$ 12,257	\$ 5,619
TOTAL FEDERAL DC	\$ 174,329	\$ 181,271
TOTAL FEDERAL F&A	\$ 113,389	\$ 113,030
TOTAL COST	\$ 299,975	\$ 299,920

<b>Facilities and Administrative Costs</b>	<b>Year 1</b>	<b>Year 2</b>
F&A Cost Rate 1	72.7%	72.7%
F&A Cost Base 1	\$ 155,969	\$ 155,475
F&A Costs 1	\$ 113,389	\$ 113,030

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## AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER (the "Agreement") is made and entered into as of December 1, 2010, by and among: NEWLINK GENETICS CORPORATION, a Delaware corporation ("Parent"); BPS MERGER SUB, INC., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"); BIOPROTECTION SYSTEMS CORPORATION, a Delaware corporation (the "Company"); and BPS STOCKHOLDER REPRESENTATIVE, LLC as the Representative (as defined in Section 8.1). Certain capitalized terms used in this Agreement are defined in *Exhibit A*.

### RECITALS

- A. Parent, Merger Sub and the Company intend to effect a merger of Merger Sub into the Company (the "Merger") in accordance with this Agreement and the Delaware General Corporation Law (the "DGCL"). Upon consummation of the Merger, Merger Sub will cease to exist, and the Company will become a wholly owned subsidiary of Parent.
- B. This Agreement has been approved by the respective boards of directors of Parent, Merger Sub and the Company.
- C. Concurrently with the execution and delivery of this Agreement, Company Stockholders (i) holding Company Capital Stock with sufficient voting power to adopt this Agreement and approve the terms of the Merger and (ii) holding a majority of the Company Capital Stock held by those Company Stockholders who are "disinterested" in respect of the Merger (as determined in the sole discretion of the special committee of the board of directors of Parent formed to consider this Agreement and the Merger (the "Parent Special Committee") have executed a written consent in the form of *Exhibit B* (the "Written Consent") adopting this Agreement.

### AGREEMENT

The parties to this Agreement agree as follows:

#### SECTION 1. DESCRIPTION OF TRANSACTION

- 1.1 Merger of Merger Sub with and into the Company. Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time (as defined in Section 1.3), Merger Sub shall be merged with and into the Company, and the separate existence of Merger Sub shall cease. The Company will continue as the surviving corporation in the Merger (the "Surviving Corporation").
- 1.2 Effect of the Merger. The Merger shall have the effects set forth in this Agreement and in the applicable provisions of the DGCL.
- 1.3 Closing; Effective Time. The consummation of the transactions contemplated by this agreement (the "Closing") shall take place at the offices of Cooley LLP, 380 Interlocken Crescent, Suite 900, Broomfield, Colorado, at 10:00 a.m., Colorado time, on a date to be designated by Parent, which shall be no later than the fifth business day after the satisfaction or waiver of the last to be satisfied or waived of the conditions set forth in Section 5 (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of such conditions). The date on which the Closing actually takes place is referred to as the "Closing Date." Subject to the provisions of this Agreement, a certificate of merger satisfying the applicable requirements of the DGCL shall be duly executed by the Company in connection with the Closing and, concurrently with or as soon as practicable following the Closing, shall be filed with the Secretary of State of the State of Delaware. The Merger shall become effective at the time of the filing of such certificate of merger with the Secretary of State of the State of Delaware (the "Effective Time").

#### 1.4 Certificate of Incorporation and Bylaws; Certificate of Organization.

(a) The certificate of incorporation of the Surviving Corporation shall be amended and restated as of the Effective Time in a form acceptable to Parent.

(b) The Bylaws of the Surviving Corporation shall be amended and restated as of the Effective Time to conform to the Bylaws of Merger Sub as in effect immediately prior to the Effective Time.

(c) The directors and officers of the Surviving Corporation immediately after the Effective Time shall be those individuals designated by Parent in its sole discretion.

#### 1.5 Conversion of Shares.

(a) Subject to Sections 1.10 and 1.11, and subject to the provision for adjustment set forth below in Section 1.5(e), at the Effective Time, by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any Company Stockholder:

(i) each share of Company Series B Preferred Stock issued and outstanding immediately prior to the Effective Time shall be converted into 0.084 shares of Parent Series E Stock;

(ii) each share of Company Series A Preferred Stock and Company Series A Preferred Stock issued and outstanding immediately prior to the Effective Time shall be converted into 0.08985 shares of Parent Series E Stock; and

(iii) each share of Company Series B Common Stock issued and outstanding immediately prior to the Effective Time shall be converted into 0.03385 shares of Parent Series E Stock.

(b) At the Effective Time, by virtue of the Merger and without any further action on the part of Parent, Merger Sub, the Company or any Company Stockholder, (i) any shares of Company Common Stock held by the Company (or held in the Company's treasury) immediately prior to the Effective Time shall be canceled and retired and shall cease to exist, and no consideration shall be delivered in exchange therefor; (ii) each share of Company Capital Stock owned by Parent or Merger Sub immediately prior to the Effective Time shall be canceled without payment of any consideration with respect thereto; and (iii) each share of the common stock, par value \$0.01 per share, of Merger Sub outstanding immediately prior to the Effective Time shall be converted into one share of common stock of the Surviving Corporation (and each stock certificate of Merger Sub evidencing ownership of any such shares shall, as of the Effective Time, evidence ownership of such shares of common stock of the Surviving Corporation).

(c) If any shares of Company Series B Common Stock outstanding immediately prior to the Effective Time are unvested or are subject to a repurchase option, risk of forfeiture or other condition under any applicable restricted stock purchase agreement or other Contract or under which the Company has any rights, then the shares of Parent Series E Stock issued in exchange for such shares of Company Series B Common Stock will also be unvested and subject to the same repurchase option, risk of forfeiture or other condition, and the certificates representing such shares of Parent Series E Stock may accordingly be marked with appropriate legends. The Company shall take all action that may be necessary to ensure that, from and after the Effective Time: (i) any Merger Consideration payable to such holder shall remain so unvested and subject to such repurchase option, risk of forfeiture or other condition; (ii) such Merger Consideration need not be delivered until such time as such repurchase option, risk of forfeiture or other condition lapses or otherwise terminates; and (iii) Parent is entitled to exercise any such repurchase option or other right set forth in any such restricted stock purchase agreement or other Contract in accordance with the terms and conditions of such agreement or other Contract.

(d) No fractional shares of Parent Series E Stock shall be issued in connection with the Merger, and no certificates or scrip for any such fractional shares shall be issued. Any holder of Company Capital Stock who would otherwise be entitled to receive a fraction of a share of Parent Series E Stock (after aggregating all fractional shares of Parent Series E Stock issuable to such holder) shall, in lieu of each such fraction of a share and upon surrender of such holder's Company Stock Certificate(s) (as defined in Section 1.7), be paid in cash the dollar amount (rounded to the nearest whole cent), without interest, determined by multiplying each such fraction by \$31.25.

(e) To the extent that the amount of the outstanding principal balance and accrued interest under the Parent Note is decreased prior to the Note Conversion (as defined below), a corresponding adjustment will be made to the conversion ratios set forth above in Section 1.5(a) using the same methodology that was used by the parties to generate those conversion ratios but substituting the decreased amounts owed under the Parent Note for the amounts set forth in Part 2.5(a) of the Disclosure Schedule. If, for example, the amount of the outstanding principal balance plus accrued interest is decreased from the amount set forth in Part 2.5(a) of the Disclosure Schedule to \$2,550,000, then the ratios reflected in subsections (i), (ii) and (iii) of this Section 1.5(a) would become (i) 0.084 shares of Parent Series E Stock for each share of Company Series B Preferred Stock, (ii) 0.09065 shares of Parent Series E Stock for each share of Company Series A Preferred, and (iii) 0.03465 shares of Parent Series E Stock for each share of Company Series B Common, respectively.

**1.6 Holdback Amount.** The Holdback Amount shall be withheld from the Merger Consideration otherwise payable to the Company Stockholders at the Effective Time. The Holdback Amount shall constitute security for the indemnification obligations of the Company Stockholders pursuant to Section 7. Promptly following the Expiration Date, the shares of Parent Series E Stock that constitute the Holdback Amount, if any, shall be issued by Parent to the Company Stockholders in accordance with their respective Holdback Contribution Amount as set forth on the Spreadsheet. Notwithstanding the foregoing, Parent shall have the right to withhold and retain from the Holdback Amount any sum that may be owed (or that may be claimed to be owed) to any Indemnitee under Section 7 and *Exhibit D*. Any such Holdback Amount shall be retained by Parent and/or paid to the former Company Stockholders in accordance with *Exhibit D*.

### **1.7 Company Options.**

(a) At the Effective Time, each outstanding Company Option that is unexpired, unexercised and outstanding immediately before the Effective Time shall be assumed and converted into a right to receive that number of Parent Options equal to (rounded down to the nearest whole share) the product of (A) the number of shares of Company Common Stock subject to such Company Option immediately prior to the Effective Time, multiplied by (B) the Option Exchange Ratio, each with an exercise price applicable to the Parent Option (rounded up to the nearest whole cent) equal to the per share exercise price applicable to the Company Option as of immediately before the Effective Time divided by the Option Exchange Ratio. The adjustments provided in this Section 1.7 to any Company Options, whether or not they are "incentive stock options" as defined in Section 422 of the Code, are intended to be effected in a manner which is consistent with Sections 424(a) and 409A of the Code. Each such assumed and converted Company Option shall be subject to the same vesting schedule (including vesting commencement date) and have the same expiration date as applied to such Company Option as of immediately prior to the Effective Time. As of the Effective Time, Company Options shall terminate and cease to be outstanding. As soon as reasonably practicable after the Effective Time and delivery to Parent of the Parent Common Stock Appraisal, Parent shall deliver to the former holders of Company Options converted pursuant to this Section 1.7 appropriate notices setting forth such



holders' rights pursuant to the applicable Parent Equity Plan and stock option agreements evidencing the Parent Options into which such Company Options are converted.

(b) Notwithstanding anything in this Agreement to the contrary, to the extent that the amount of the outstanding principal balance and accrued interest under the Parent Note is decreased prior to the Note Conversion (as defined below), a corresponding adjustment will be made to the numerator of the Option Exchange Ratio using the same methodology that was used by the parties to generate the numerator as of the date of this Agreement but substituting the decreased amounts owed under the Parent Note for the amounts set forth in Part 2.5(a) of the Disclosure Schedule. If, for example, the amount of the outstanding principal balance plus accrued interest is decreased from the amount set forth in Part 2.5(a) of the Disclosure Schedule to \$2,550,000, then the numerator of the Option Exchange Ratio will be \$1.083.

**1.8 Closing of the Company's Transfer Books.** At the Effective Time: (a) all shares of Company Capital Stock outstanding immediately prior to the Effective Time shall automatically be canceled and retired and shall cease to exist, and all holders of certificates representing shares of Company Capital Stock that were outstanding immediately prior to the Effective Time shall cease to have any rights as Company Stockholders; and (b) the stock transfer books of the Company shall be closed with respect to all shares of Company Capital Stock outstanding immediately prior to the Effective Time. No further transfer of any such shares of Company Capital Stock shall be made on such stock transfer books after the Effective Time. If, after the Effective Time, a valid certificate previously representing any shares of Company Capital Stock outstanding immediately prior to the Effective Time (each, a "Company Stock Certificate") is presented to the Surviving Corporation or Parent, such Company Stock Certificate shall be canceled and shall be exchanged as provided in Section 1.9.

#### **1.9 Exchange of Certificates.**

(a) As soon as reasonably practicable following the Effective Time, Parent will deliver to the holders of Company Stock Certificates (i) a letter of transmittal in customary form and containing such provisions as Parent may reasonably specify (which letter of transmittal shall contain provisions allowing for each Company Stockholder to become a party to the Parent Financing Agreements and specifically providing that each Company Stockholder shall agree to enter into a customary lock-up agreement in the event of an initial public offering of Parent Common Stock identical in all material respects to the lock-up agreement that other holders of Parent Common Stock will be required to execute) (a "Letter of Transmittal"), and (ii) instructions for use in effecting the surrender of Company Stock Certificates. Upon surrender of a Company Stock Certificate to Parent for exchange, together with a duly executed Letter of Transmittal and such other documents as may be reasonably required by Parent, the holder of such Company Stock Certificate shall be entitled to receive in exchange therefor the Merger Consideration that such holder has the right to receive pursuant to the provisions of Section 1.5, and the Company Stock Certificate so surrendered shall be canceled. Until surrendered as contemplated by this Section 1.9, each Company Stock Certificate shall be deemed, from and after the Effective Time, to represent only the right to receive Merger Consideration upon such surrender as contemplated by this Section 1.9. If any Company Stock Certificate shall have been lost, stolen or destroyed, Parent may, in its discretion and as a condition precedent to the delivery of any Merger Consideration therefor, require the owner of such lost, stolen or destroyed Company Stock Certificate to provide an appropriate affidavit of lost certificate.

(b) To the fullest extent permitted by applicable law, Parent and the Surviving Corporation shall be relieved of any and all liability to any holder or former holder of Company Capital Stock or Company Options for any Merger Consideration delivered to any public official in good faith pursuant to any applicable abandoned property law, escheat law or similar Legal Requirement.

## 1.10 Dissenting Shares.

(a) Notwithstanding anything to the contrary contained in this Agreement, shares of Company Capital Stock held by a holder who has made a demand for appraisal of such shares of Company Capital Stock in accordance with Section 262 of the DGCL ("Dissenting Shares") shall not be converted into or represent the right to receive Merger Consideration in accordance with Section 1.5, but shall be entitled only to such rights as are granted by the DGCL to a holder of Dissenting Shares.

(b) If any Dissenting Shares shall lose their status as such (through failure to perfect or otherwise), then, as of the later of the Effective Time or the date of loss of such status, such shares shall automatically be converted into and shall represent only the right to receive Merger Consideration in accordance with Section 1.5, without interest thereon, upon surrender of the Company Stock Certificate representing such shares.

(c) The Company shall give Parent (i) prompt notice of any written demand for appraisal received by the Company prior to the Effective Time pursuant to the DGCL, any withdrawal of any such demand and any other demand, notice or instrument delivered to the Company prior to the Effective Time pursuant to the DGCL, and (ii) the opportunity to participate in all negotiations and proceedings with respect to any such demand, notice or instrument. The Company shall not make any payment or settlement offer prior to the Effective Time with respect to any such demand, notice or instrument unless Parent shall have given its written consent to such payment or settlement offer (which consent shall not be unreasonably withheld or delayed).

**1.11 Withholding Rights.** Parent and the Surviving Corporation shall be entitled to deduct and withhold from the consideration otherwise deliverable under this Agreement, and from any other payments otherwise required pursuant to this Agreement, to holders of Company Capital Stock and Company Options, such amounts as Parent or the Surviving Corporation is required to deduct and withhold with respect to any such deliveries and payments under the Code or any provision of state, local, provincial or foreign Tax law. To the extent that amounts are so withheld, such withheld amounts shall be treated for all purposes of this Agreement as having been delivered and paid to such holders in respect of which such deduction and withholding was made

**1.12 Further Action.** If, at any time after the Effective Time, any further action is determined by Parent or the Surviving Corporation to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Corporation with full right, title and possession of and to all rights and property of Merger Sub and the Company, then the officers and directors of Parent and Merger Sub shall be fully authorized to take such action.

## SECTION 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Subject to the disclosures and other responses set forth in the Disclosure Schedule (which exceptions and responses in order to be effective will specify the section or subsection to which they apply but will also qualify other sections or subsections in this Section 2 to the extent that it is reasonably apparent on the face of an exception or response that such exception or response is applicable to such other section or subsection), the Company represents and warrants to, and for the benefit of the Indemnitees, as follows:

### 2.1 Subsidiaries; Due Organization; Etc.

(a) *Organization.* The Company has been duly incorporated, and is validly existing and in good standing (to the extent that the laws of the jurisdiction of its formation recognize the concept of good standing), under the laws of the State of Delaware. The Company has full power and authority: (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own and use its assets in the manner in which its assets are currently owned and

used; and (iii) to perform its obligations under all Contracts to which it is a party or by which it is bound.

(b) *Qualification.* The Company is qualified, licensed or admitted to do business as a foreign corporation, and is in good standing (to the extent that the applicable jurisdiction recognizes the concept of good standing), under the laws of all jurisdictions where the property owned, leased or operated by it or the nature of its business requires such qualification, license or admission and where the failure to be so qualified, licensed or admitted would have a Material Adverse Effect. *Part 2.1(b)* of the Disclosure Schedule accurately sets forth each jurisdiction where the Company is qualified, licensed and admitted to do business.

(c) *Directors and Officers.* *Part 2.1(c)* of the Disclosure Schedule accurately sets forth: (i) the names of the members of the board of directors (or similar body) of the Company; (ii) the names of the members of each committee of the board of directors (or similar body) of the Company; and (iii) the names and titles of the officers of the Company.

(d) *Subsidiaries.* The Company has no Subsidiaries. The Company does not own or control, directly or indirectly, any equity or similar interest in, or any interest convertible into or exchangeable or exercisable for any equity or similar interest in, or have any commitment or obligation to invest in, purchase any securities or obligations of, fund, guarantee, contribute or maintain the capital of or otherwise financially support any corporation, partnership, joint venture or other business association or entity.

2.2 *Organizational Documents; Records.* The Company has delivered to Parent accurate and complete copies of: (a) the certificate of incorporation and bylaws, including all amendments thereto, of the Company; (b) the stock records of the Company; and (c) the minutes and other records of the meetings and other proceedings (including any actions taken by written consent or otherwise without a meeting) of the stockholders, the board of directors and all committees of the board of directors of the Company. The books of account, stock records, minute books and other records of the Company are accurate, up-to-date and complete in all material respects and have been maintained in accordance with prudent business practices.

### 2.3 Capitalization, Etc.

(a) As of the date hereof, the authorized capital stock of the Company consists of (i) 7,000,000 shares of Company Series A Common Stock, all of which are issued and are outstanding, (ii) 13,500,000 shares of Company Series B Common Stock, of which 2,935,814 shares are issued and outstanding, (iii) 1,444,721 shares of Company Series A Preferred Stock, all of which are issued and outstanding, and (iv) 3,055,279 shares of Company Series B Preferred Stock, of which 555,930 shares are issued and outstanding. The Company does not hold any shares of its capital stock in its treasury. All of the outstanding shares of Company Capital Stock have been duly authorized and validly issued and are fully paid and nonassessable. Each outstanding share of Company Series A Preferred Stock and Company Series B Preferred Stock is, as of the date hereof, and will be as of the Effective Time, convertible into Company Series B Common Stock on a one-for-one basis. The Company Capital Stock is held, as of the date hereof, by the holders and in the amounts set forth in *Part 2.3(a)* of the Disclosure Schedule. There are no declared or accrued but unpaid dividends with respect to any shares of Company Capital Stock. The Company Stockholders, together with Parent, are the owners of record of all the Company Capital Stock as of the date hereof. *Part 2.3(a)* of the Disclosure Schedule sets forth, as of the date hereof, a true, correct and complete list of all the Company's securityholders, their mailing addresses and the number of shares of Company Capital Stock and Company Options owned by each of them. With respect to holders of Company Options, *Part 2.3(a)* of the Disclosure Schedule indicates whether, as of the date hereof, the holder is an employee of the Company, the number of shares and class or series of Company Capital Stock issuable upon the exercise of each such Company Option, the

date of grant, the exercise price per share, whether such holder is an "accredited investor" within the meaning of Regulation D of the Securities Act (with respect to any holder who is not an employee of the Company), whether such Company Option qualifies as an incentive stock option, the vesting schedule and expiration date thereof, including the extent to which any vesting has occurred as of the date hereof and the extent to which such Company Option is subject to automatic acceleration upon the occurrence of any event.

(b) None of the outstanding shares of Company Capital Stock is entitled or subject to any preemptive right, right of participation or any similar right or subject to any right of first refusal or similar right in favor of the Company or any other Person. There is no Company Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Company Capital Stock. The Company is not under any obligation, or is bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Company Capital Stock or any other securities. None of the shares of Company Capital Stock is subject to a repurchase option in favor of the Company or any other Person.

(c) Except for outstanding options to purchase 395,000 shares of Company Series B Common Stock under the Company Option Plan, there is no: (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other securities of the Company; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of any of the Company; (iii) Contract under which any of the Company is or may become obligated to sell or otherwise issue any shares of its capital stock or any other securities; or (iv) condition or circumstance that could reasonably be expected to give rise to or provide a reasonable basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive (A) any shares of capital stock or other securities of the Company or (B) any portion of the Merger Consideration payable in connection with the Merger. Except for the Company Option Plan, the Company has never adopted, sponsored or maintained any stock option plan or any other plan or agreement providing for equity compensation to any person.

(d) All outstanding shares of capital stock, options, warrants and other securities of the Company have been issued and granted in compliance with all applicable securities laws and other applicable Legal Requirements and all requirements set forth in applicable Contracts. There are no stockholder agreements, voting trusts or other agreements or understandings to which the Company is a party relating to the voting or registration of any shares of Company Capital Stock. There is no Legal Proceeding pending or, to the Knowledge of the Company, threatened, based on a claim of breach of fiduciary duty by the Company's directors or officers arising out of actions taken by the Company's directors or officers prior to the Effective Time, nor is there any Basis that would give rise to such Legal Proceeding.

(e) The Company has not repurchased, redeemed or otherwise reacquired any shares of Company Capital Stock, other than in connection with the termination of a Company Employee's employment. All securities so reacquired by the Company were reacquired in compliance with (i) all applicable Legal Requirements and (ii) all requirements set forth in applicable restricted stock purchase agreements and other applicable Contracts.

(f) Each Company Employee Plan that is a nonqualified deferred compensation plan (within the meaning of Section 409A(d)(1) of the Code) has been maintained in compliance with Section 409A of the Code and all applicable IRS and Treasury Department guidance issued thereunder in both operation and documentation. None of the Transactions will constitute or result in a deferral of compensation under any Employee Benefit Plan that is subject to Section 409A of the Code. Each Company Option outstanding under the Company Option Plan was issued with an exercise price for purposes of Section 409A of the Code no less than the fair market value of the underlying stock on the date of grant and/or otherwise is exempt from Section 409A of the Code.

(g) The information contained in the Spreadsheet shall be complete and correct as of the Effective Time and shall accurately set forth the allocation of the Merger Consideration with respect to the Company Stockholders and holders of Company Options as of the Effective Time.

#### 2.4 Financial Statements; Internal Controls; Working Capital.

(a) *Delivery of Financial Statements.* The Company has delivered to Parent the following financial statements and notes (collectively, the "Company Financial Statements"): (i) the unaudited balance sheets of the Company as of December 31, 2009 and December 31, 2008 and the related unaudited statements of income and cash flows for the periods ended December 31, 2009 and December 31, 2008; and (ii) the unaudited balance sheet of the Company as of September 30, 2010 (the "Interim Balance Sheet") and the related statements of income and cash flows for the nine months then ended.

(b) *Fair Presentation.* The Company Financial Statements present fairly the financial position of the Company as of the respective dates thereof and the results of operations and cash flows of the Company for the periods covered thereby. The Company Financial Statements have been prepared in accordance with GAAP applied on a consistent basis throughout the periods covered; *provided, however*, that the unaudited Company Financial Statements are subject to normal recurring year-end audit adjustments (which are not expected to be material either individually or in the aggregate) and do not contain all footnotes required under GAAP

(c) *Internal Controls.* The Company maintains accurate books and records reflecting its assets and liabilities and maintains proper and adequate internal accounting controls that provide assurance that: (i) transactions are executed with management's authorization; (ii) transactions are recorded as necessary to permit preparation of the financial statements of the Company and to maintain accountability for the assets of the Company; (iii) access to the assets of the Company is permitted only in accordance with management's authorization; (iv) the reporting of the assets of the Company is compared with existing assets at regular intervals; and (v) accounts, notes and other receivables are recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis. To the Knowledge of the Company, there have been no instances of fraud by any officer or employee of the Company, whether or not material.

#### 2.5 Liabilities.

(a) *No Liabilities.* The Company does not have any accrued, contingent or other Liabilities of any nature, either matured or unmatured (whether or not required to be reflected in financial statements in accordance with GAAP and whether due or to become due), except for: (a) Liabilities identified as such in the "liabilities" column of the Interim Balance Sheet; (b) accounts payable or accrued salaries that have been incurred by the Company since the date of the Interim Balance Sheet in the ordinary course of business and consistent with the Company's past practices; (c) Liabilities under Company Contracts identified in *Part 2.11* of the Disclosure Schedule, to the extent the nature and magnitude of such liabilities can be specifically ascertained by reference to the text of such Company Contracts and provided that, in each case, the Company

is not in breach of, or default under, any such Company Contracts; and (d) Liabilities described in *Part 2.5(a)* of the Disclosure Schedule. To the Knowledge of the Company, no event has occurred, and no circumstance or condition exists, that has resulted in, or that could reasonably be expected to result in, any claim for indemnification or reimbursement by any Company Employee (other than a claim for reimbursement by the Company, in the ordinary course of business, of travel expenses, accrued vacation or other out-of-pocket expenses of a routine nature incurred by a Company Employee in the course of performing such Company Employee's duties for the Company) pursuant to (i) the terms of the Company's articles of incorporation, bylaws or other charter documents, (ii) any indemnification agreement or other Contract between the Company and any such Company Employee or (iii) any applicable Legal Requirement.

(b) *No "Off-Balance Sheet" Arrangements.* The Company has never effected or otherwise been involved in any "off-balance sheet arrangements" (as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended). Without limiting the generality of the foregoing, the Company has never guaranteed any debt or other obligation of any other Person.

**2.6 Absence of Changes.** Since the date of the Interim Balance Sheet, the Company has conducted its business only in the ordinary course of business and there has not occurred any change, event or condition (whether or not covered by insurance) that, individually or in the aggregate with any other changes, events or conditions, has resulted in, or could reasonably be expected to result in, a Material Adverse Effect on the Company.

**2.7 Title to Assets.**

(a) *Good Title.* The Company owns, and has good and valid title to, all of the assets purported to be owned by it, including (a) all assets reflected on the Interim Balance Sheet; (b) all assets acquired by the Company since such date; (c) all assets referred to in *Part 2.10(a)* of the Disclosure Schedule and all of the rights of the Company under the Company Contracts; and (d) all other assets reflected in the books and records of the Company as being owned by the Company. All of the foregoing assets listed in subsections (a) through (d) are owned by the Company free and clear of any Encumbrances, except for any lien for current Taxes not yet due and payable. The assets reflected on the Interim Balance Sheet collectively constitute all of the properties, rights, interests and other tangible and intangible assets necessary to enable the Company to conduct its business in the manner in which such business is currently being conducted and as presently contemplated to be conducted.

(b) *Leased Assets.* *Part 2.7(b)* of the Disclosure Schedule identifies all assets that are material to the business of the Company and that are being leased to the Company.

**2.8 Bank Accounts.** *Part 2.8* of the Disclosure Schedule provides the following information with respect to each account maintained by or for the benefit of any the Company at any bank or other financial institution: (a) the name of the bank or other financial institution at which such account is maintained; (b) the account number; (c) the type of account; and (d) the names of all Persons who are authorized to sign checks or other documents with respect to such account.

**2.9 Equipment; Real Property.**

(a) *Equipment.* All material items of equipment, fixtures and other tangible assets owned by or leased to the Company are adequate for the uses to which they are being put, are in good condition and repair (ordinary wear and tear excepted) and are adequate for the conduct of the Company's business in the manner in which such business is currently being conducted and as it is presently contemplated to be conducted.

(b) *Real Property.* The Company does not own any real property or any interest in real property, except for the leasehold created under the real property leases identified in *Part 2.9(b)* of the Disclosure Schedule.

## 2.10 Intellectual Property.

(a) *Products and Services.* *Part 2.10(a)* of the Disclosure Schedule accurately identifies each Company Product currently being designed, developed, manufactured, marketed, distributed, provided, licensed, or sold by the Company.

(b) *Registered IP.* *Part 2.10(b)* of the Disclosure Schedule accurately identifies: (i) each item of Registered IP in which the Company has or purports to have an ownership interest of any nature (whether exclusively, jointly with another Person, or otherwise); (ii) the jurisdiction in which such item of Registered IP has been registered or filed and the applicable registration or serial number; (iii) any other Person that has an ownership interest in such item of Registered IP and the nature of such ownership interest; and (iv) each Company Product identified in *Part 2.10(a)* of the Disclosure Schedule that embodies, utilizes, or is based upon or derived from (or, with respect to Company Products currently under development, that is expected to embody, utilize, or be based upon or derived from) such item of Registered IP. The Company has provided to Parent complete and accurate copies of all applications, correspondence with any Governmental Body, and other material documents related to each such item of Registered IP.

(c) *Inbound Licenses.* *Part 2.10(c)* of the Disclosure Schedule accurately identifies: (i) each Contract pursuant to which any Intellectual Property Right or Intellectual Property is or has been licensed, sold, assigned, or otherwise conveyed or provided to the Company (other than (x) agreements between the Company and its employees in the Company's standard form thereof and (y) non-exclusive licenses to third-party software that is not incorporated into, or used in the development, manufacturing, testing, distribution, maintenance, or support of, any Company Product and that is not otherwise material to the Company's business); and (ii) whether the licenses or rights granted to the Company in each such Contract are exclusive or non-exclusive.

(d) *Outbound Licenses.* *Part 2.10(d)* of the Disclosure Schedule accurately identifies each Contract pursuant to which any Person has been granted any license under, or otherwise has received or acquired any right (whether or not currently exercisable) or interest in, any Company IP. The Company is not bound by, and no Company IP is subject to, any Contract containing any covenant or other provision that in any way limits or restricts the ability of the Company to use, exploit, assert, or enforce any Company IP anywhere in the world.

(e) *Royalty Obligations.* *Part 2.10(e)* of the Disclosure Schedule contains a complete and accurate list and summary of all royalties, fees, commissions, and other amounts payable by the Company to any other Person (other than sales commissions paid to employees according to the Company's standard commissions plan) upon or for the manufacture, sale, or distribution of any Company Product or the use of any Company IP.

(f) *Standard Form IP Agreements.* The Company has provided to Parent a complete and accurate copy of each standard form of Company IP Contract used by the Company at any time, including each standard form of (i) Company Employee Agreement containing any assignment or license of Intellectual Property Rights; (ii) consulting or independent contractor agreement containing any intellectual property assignment or license of Intellectual Property Rights; and (iii) confidentiality or nondisclosure agreement. *Part 2.10(f)* of the Disclosure Schedule accurately identifies each Company IP Contract that deviates in any material respect from the corresponding standard form agreement provided to Parent, including any agreement with an employee, consultant, or independent contractor in which the employee, consultant, or independent contractor expressly reserved or retained rights in any Intellectual Property or Intellectual Property

Rights incorporated into or used in connection with any Company Product or otherwise related to the Company's business, research, or development.

(g) *Ownership Free and Clear.* The Company exclusively owns all right, title, and interest to and in the Company IP (other than Intellectual Property Rights exclusively licensed to the Company, as identified in *Part 2.10(c)* of the Disclosure Schedule) free and clear of any Encumbrances (other than licenses and rights granted pursuant to the Contracts identified in *Part 2.10(d)* of the Disclosure Schedule). Without limiting the generality of the foregoing:

(i) *Perfection of Rights.* All documents and instruments necessary to establish, perfect, and maintain the rights of the Company in the Company IP have been validly executed, delivered, and filed in a timely manner with the appropriate Governmental Body.

(ii) *Employees and Contractors.* Each Person who is or was an employee or contractor of the Company and who is or was involved in the creation or development of any Company Product or Company IP has signed a valid, enforceable agreement containing an assignment of Intellectual Property Rights pertaining to such Company Product or Company IP to the Company and confidentiality provisions protecting the Company IP. No current or former shareholder, officer, director, or employee of the Company has any claim, right (whether or not currently exercisable), or interest to or in any Company IP. No employee of the Company is (a) bound by or otherwise subject to any Contract restricting him from performing his duties for the Company or (b) in breach of any Contract with any former employer or other Person concerning Intellectual Property Rights or confidentiality due to his activities as an employee of the Company.

(iii) *Government Rights.* No funding, facilities, or personnel of any Governmental Body or any public or private university, college, or other educational or research institution were used, directly or indirectly, to develop or create, in whole or in part, any Company IP.

(iv) *Protection of Proprietary Information.* The Company has taken all reasonable steps to maintain the confidentiality of and otherwise protect and enforce their rights in all proprietary information pertaining to the Company or any Company Product. Without limiting the generality of the foregoing, no portion of the source code for any software ever owned or developed by the Company has been disclosed or licensed to any escrow agent or other Person.

(v) *Past IP Dispositions.* The Company has not assigned or otherwise transferred ownership of, or agreed to assign or otherwise transfer ownership of, any Intellectual Property Right to any other Person.

(vi) *Standards Bodies.* The Company is not and has never been a member or promoter of, or a contributor to, any industry standards body or similar organization that could require or obligate the Company to grant or offer to any other Person any license or right to any Company IP.

(vii) *Sufficiency.* The Company owns or otherwise has, and after the Closing Parent will have, all Intellectual Property Rights needed to conduct its business as currently conducted and as presently contemplated to be conducted.

(h) *Valid and Enforceable.* All Company IP is valid, subsisting, and enforceable. Without limiting the generality of the foregoing:

(i) *Misuse and Inequitable Conduct.* The Company has not engaged in patent or copyright misuse or any fraud or inequitable conduct in connection with any Company IP that is Registered IP.



(ii) *Trademarks.* No trademark or trade name owned, used, or applied for by the Company conflicts or interferes with any trademark or trade name owned, used, or applied for by any other Person. To the Knowledge of the Company, no event or circumstance (including a failure to exercise adequate quality controls and an assignment in gross without the accompanying goodwill) has occurred or exists that has resulted in, or could reasonably be expected to result in, the abandonment of any trademark (whether registered or unregistered) owned, used, or applied for by the Company.

(iii) *Legal Requirements and Deadlines.* Each item of Company IP that is Registered IP is and at all times has been in compliance with all legal requirements and all filings, payments, and other actions required to be made or taken to maintain such item of Company IP in full force and effect have been made by the applicable deadline. No application for a patent or a copyright, mask work, or trademark registration or any other type of Registered IP filed by or on behalf of the Company has been abandoned, allowed to lapse, or rejected.

(iv) *Interference Proceedings and Similar Claims.* No interference, opposition, reissue, reexamination, or other Legal Proceeding is or has been pending or, to the Knowledge of the Company, threatened, in which the scope, validity, or enforceability of any Company IP is being, has been, or could reasonably be expected to be contested or challenged. To the Knowledge of the Company, there is no basis for a claim that any Company IP is invalid or unenforceable.

(i) *Third-Party Infringement of Company IP.* To the Knowledge of the Company, no Person has infringed, misappropriated, or otherwise violated, and no Person is currently infringing, misappropriating, or otherwise violating, any Company IP. *Part 2.10(i)* of the Disclosure Schedule accurately identifies (and the Company has provided to Parent a complete and accurate copy of) each letter or other written or electronic communication or correspondence that has been sent or otherwise delivered by or to the Company or any representative of the Company regarding any actual, alleged, or suspected infringement or misappropriation of any Company IP, and provides a brief description of the current status of the matter referred to in such letter, communication, or correspondence.

(j) *Effects of This Transaction.* Neither the execution, delivery, or performance of this Agreement (or any of the ancillary agreements) nor the consummation of any of the transactions contemplated by this Agreement (or any of the ancillary agreements) will, with or without notice or lapse of time, result in, or give any other Person the right or option to cause or declare, (i) a loss of, or Encumbrance on, any Company IP; (ii) a breach of or default under any Company IP Contract; (iii) the release, disclosure, or delivery of any Company IP by or to any escrow agent or other Person; or (iv) the grant, assignment, or transfer to any other Person of any license or other right or interest under, to, or in any of the Company IP.

(k) *No Infringement of Third Party IP Rights.* The Company has never infringed (directly, contributorily, by inducement, or otherwise), misappropriated, or otherwise violated or made unlawful use of any Intellectual Property Right of any other Person or engaged in unfair competition. No Company Product, and no method or process used in the manufacturing of any Company Product, infringes, violates, or makes unlawful use of any Intellectual Property Right of, or contains any Intellectual Property misappropriated from, any other Person. There is no legitimate basis for a claim that the Company or any Company Product has infringed or misappropriated any Intellectual Property Right of another Person or engaged in unfair competition or that any Company Product, or any method or process used in the manufacturing of any Company Product, infringes, violates, or makes unlawful use of any Intellectual Property Right of, or contains any Intellectual Property misappropriated from, any other Person.

(l) *Infringement Claims.* No infringement, misappropriation, or similar claim or Legal Proceeding is pending or, to the Knowledge of the Company, threatened against the Company or against any other Person who is or may be entitled to be indemnified, defended, held harmless, or reimbursed by the Company with respect to such claim or Legal Proceeding. The Company has never received any notice or other communication (in writing or otherwise) relating to any actual, alleged, or suspected infringement, misappropriation, or violation by the Company, any of their employees or agents, or any Company Product of any Intellectual Property Rights of another Person, including any letter or other communication suggesting or offering that the Company obtain a license to any Intellectual Property Right of another Person.

(m) *Other Infringement Liability.* The Company is not bound by any Contract to indemnify, defend, hold harmless, or reimburse any other Person with respect to, or otherwise assumed or agreed to discharge or otherwise take responsibility for, any existing or potential intellectual property infringement, misappropriation, or similar claim (other than indemnification provisions in the Company's standard forms of Company IP Contracts).

(n) *Infringement Claims Affecting In-Licensed IP.* To the Knowledge of the Company, no claim or Legal Proceeding involving any Intellectual Property or Intellectual Property Right licensed to the Company is pending or has been threatened, except for any such claim or Legal Proceeding that, if adversely determined, would not adversely affect (i) the use or exploitation of such Intellectual Property or Intellectual Property Right by the Company or (ii) the design, development, manufacturing, marketing, distribution, provision, licensing or sale of any Company Product.

## 2.11 Contracts.

(a) Part 2.11(a) of the Disclosure Schedule sets forth a complete and accurate list of all Company Contracts in effect as of the date hereof, as follows (each such Company Contract required to be disclosed in Part 2.11(a) of the Disclosure Schedule, a "Material Contract" and collectively, the "Material Contracts"):

(i) any employment or consulting agreement, contract or commitment with any employee or consultant, any agreement, contract or commitment to grant any severance or termination pay to any Person, other than (A) offer letters in the Company's standard form that do not contain severance, change in control or similar payments and (B) agreements in the Company's standard form relating to acquisition of equity securities of the Company that do not involve any ongoing obligations of the Company thereunder.

(ii) any agreement or plan, including any stock option plan, stock appreciation rights plan or stock purchase plan, any of the benefits of which will be increased, or the vesting of benefits of which will be accelerated, by the occurrence of any of the transactions contemplated by this Agreement or the value of any of the benefits of which will be calculated on the basis of any of the transactions contemplated by this Agreement;

(iii) any fidelity or surety bond or completion bond;

(iv) any lease of personal property currently in effect;

(v) any agreement of indemnification or guaranty;

(vi) any agreement, contract or commitment relating to capital expenditures;

(vii) any agreement, contract or commitment relating to the disposition or acquisition of assets or any interest in any business enterprise;

(viii) any mortgages, indentures, guarantees, loans or credit agreements, security agreements or other agreements or instruments relating to the borrowing of money or extension of credit;

(ix) any pending purchase order or contract for the purchase of materials;

(x) any dealer, distribution, joint marketing, strategic alliance, affiliate or development agreement;

(xi) all licenses, sublicenses and other Company Contracts pursuant to which any Person is authorized to use Company Intellectual Property;

(xii) other than "shrink wrap" and similar generally available commercial end-user licenses to software that is not redistributed with or used in the development or provision of the Company Products that have an individual acquisition cost of \$2,500 or less, all licenses, sublicenses and other Company Contracts pursuant to which the Company acquired or is authorized to use any third-party Intellectual Property Rights;

(xiii) other than Material Contracts listed in *Part 2.11(a)* of the Disclosure Schedule, any sales representative, original equipment manufacturer, manufacturing, value added reseller or independent software vendor or other agreement for use or distribution of the products, technology or services of the Company;

(xiv) any other agreement, contract or commitment that involves in excess of \$10,000 in the current or any future fiscal year and is not cancelable without penalty within 30 days; or

(xv) any other agreement that is material to the Company's business.

(b) A true and complete copy of each Material Contract has been delivered to Parent. Each Material Contract is in executed written form and is a valid and binding agreement of the Company, enforceable against the Company (and, to the Knowledge of the Company, the other parties thereto) in accordance with its terms and is in full force and effect with respect to the Company (and, to the Knowledge of the Company, with respect to the other parties thereto). The Company is in compliance with and has not breached, violated or defaulted under, or received notice that it has breached, violated or defaulted under, any of the terms or conditions of any such Material Contract. The Company has fulfilled all obligations required to have been performed by the Company pursuant to each Material Contract. Immediately following the Effective Time, the Surviving Corporation will be able to maintain its rights under the Material Contracts without the payment of any additional amounts of consideration other than ongoing fees, royalties or payments that the Company would otherwise be required to pay in accordance with the terms of such Material Contracts had the Transaction not occurred.

#### 2.12 Compliance with Legal Requirements; Governmental Authorizations.

(a) The Company is, and has at all times been, in compliance in all material respects with each Legal Requirement that is applicable to it, to the conduct of its business or to the ownership or use of any of its assets. To the Knowledge of the Company, no event has occurred that could reasonably be expected to (with or without notice or lapse of time) constitute or result directly or indirectly in a violation by the Company of, or a failure on the part of the Company to comply with, any Legal Requirement. The Company has never received, at any time, any notice or other communication (in writing or otherwise) from any Governmental Body or any other Person regarding any actual, alleged, possible or potential violation of, or failure to comply with, any Legal Requirement.

(b) The Governmental Authorizations held by the Company are valid, in full force and effect and constitute all of the Governmental Authorizations necessary to enable the Company to

conduct its business in the manner in which such business is currently being conducted and as it is presently contemplated to be conducted. The Company is and has at all times been in compliance in all material respects with all of the terms and requirements of each such Governmental Authorization, and no event has occurred that could reasonably be expected to (with or without notice or lapse of time) result in a violation of any requirement of any such Governmental Authorization, or result in the termination or modification of any such Governmental Authorization.

(c) The Company is, and has at all times been, in compliance in all material respects with all Legal Requirements relating to the export, re-export, import and transfer of products, commodities, services and technology from the jurisdiction of one Governmental Body to another.

2.13 Certain Business Practices. The Company has not, and (to the Knowledge of the Company) no director, officer, agent or employee of the Company has, (a) used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, (b) made any unlawful payment to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns or violated any provision of the Foreign Corrupt Practices Act of 1977, as amended, or (c) made any other unlawful payment.

#### 2.14 Tax Matters.

(a) All Tax Returns required to be filed by or on behalf of the Company have been timely and properly filed and are true, accurate and complete. Each Tax required to have been paid, or claimed by any Governmental Body to be payable, by the Company has been duly paid in full on a timely basis. Any Tax required to have been withheld or collected by the Company has been duly withheld and collected; and (to the extent required) each such Tax has been paid to the appropriate Governmental Body.

(b) No written claim has ever been made by an authority in a jurisdiction where the Company does not file Tax Returns that any of them is or may be subject to taxation by that jurisdiction. There are no liens for Taxes (other than Taxes not yet due and payable) upon any of the assets of the Company. The Company does not have a permanent establishment in any country outside of the United States.

(c) No examination or audit of any Tax Return of the Company has been conducted since its inception. The Company has never received from any Governmental Body any (i) notice indicating an intent to open an audit or other review, (ii) request for information related to Tax matters, or (iii) notice of deficiency or proposed adjustment of or any amount of Tax proposed, asserted, or assessed by any Governmental Body against the Company. No claim or other Legal Proceeding is pending or has been threatened against or with respect to the Company in respect of any Tax.

(d) The Company is not a party to any Contract that has resulted or would reasonably be expected to result, separately or in the aggregate, in the payment of (i) any "excess parachute payment" within the meaning of Section 280G of the Code (or any corresponding provisions of state, local or foreign Tax law) and (ii) any amount that will not be fully deductible as a result of Section 162(m) of the Code (or any corresponding provisions of state, local or foreign Tax law).

(e) The Company is not a party to any Tax-sharing agreement, Tax allocation agreement or similar agreement under which it is obligated to indemnify any Person for any Taxes that may be payable by such Person, other than an agreement with Parent.

(f) The Company has delivered to (or made available for inspection by) Parent accurate and complete copies of all Tax Returns that have been filed on behalf of or with respect to the Company since its inception.

(g) The Company has not waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency. The Company has never been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code. The Company has disclosed on its federal income Tax Returns all positions taken therein that could give rise to a substantial understatement of federal income Tax within the meaning of Section 6662 of the Code.

(h) The Company will not be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion there) ending after the Closing Date as a result of any: (i) change in method of accounting for taxable period ending on or prior to the Closing Date; (ii) "closing agreement" as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign income Tax law) executed on or prior to the Closing Date; (iii) intercompany transactions or any excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding or similar provisions of state, local or foreign income Tax law); (iv) installment sale or open transaction disposition made on or prior to the Closing Date; or (v) prepaid amount received on or prior to the Closing Date.

## 2.15 Employee and Labor Matters; Benefit Plans.

(a) *Part 2.15(a)* of the Disclosure Schedule accurately sets forth (i) the name, title, hire date of each current employee and independent contractor of the Company and (ii) the combined annual salary received from Parent and Company by Charles Link Jr., MD Chief Executive Officer; Nicholas N. Vahanian, MD, Chief Scientific Officer; Carl Langren, Chief Financial Officer; Ramon Flick Chief Scientific Officer; and Joseph Lucas, Sr. VP for Government Affairs (including wages, salary, commissions, fringe benefits, bonuses and other payments or benefits of any type) in 2009 and 2010 to date. The Company is not a party to or bound by any employment agreement, union contract, collective bargaining agreement or similar Contract, and the employment of each employee of the Company is terminable at will. To the Knowledge of the Company, (a) no employee or independent contractor of any the Company intends to terminate his employment or relationship with the Company or intends not to undertake employment with Parent if given an offer and (b) no employee or independent contractor is a party to or is bound by any confidentiality agreement, noncompetition agreement or other Contract with any Person (other than Company) that could reasonably be expected to have an adverse effect on the performance by such employee or independent contractor of any of his duties with respect to the Company or its business. No former employee of the Company is receiving or is scheduled to receive (nor any spouse or other dependent is receiving or is scheduled to receive) any benefits (whether from any of the Company or otherwise) relating to such former employee's employment with the Company.

(b) *Part 2.15(b)* of the Disclosure Schedule identifies each Company Employee Plan. Each Company Employee Plan is being and has at all times been operated and administered in compliance with the provisions thereof. Each contribution or other payment that is required to have been accrued or made under or with respect to any Company Employee Plan has been duly accrued and made on a timely basis. Each Company Employee Plan has at all times complied and been operated and administered in compliance with all applicable Legal Requirements. No Company Employee Plan is subject to Title IV of ERISA. With respect to any employee of Company who becomes an employee of Parent or any Subsidiary of Parent, neither Company nor any entity that is deemed to be one employer together with Company pursuant to Section 414 of the Code has within five (5) years prior to the date hereof contributed to (or been obligated to contribute to) any multiemployer plan within the meaning of ERISA. The Company has neither maintained nor contributed to a defined benefit pension plan (as defined in Section 3(35) of ERISA). The Company Employee Plan that is intended to meet the requirements of a "qualified plan" under Code Section 401(a) received a determination letter from the Internal Revenue

Service to the effect that it meets the requirements of Code Section 401(a). Each nonqualified deferred compensation plan of Company complies with the requirements of Section 409A of the Code by its terms and has been operated in accordance with such requirements. No nonqualified deferred compensation plan has been "materially modified" (within the meaning of IRS Notice 2005-1) at any time after October 3, 2004 based on a reasonable interpretation of the term "materially modified" or, if materially modified, such plans, as modified, are compliant with Section 409A of the Code.

(c) There are no claims or Legal Proceedings pending, or, to the Knowledge of the Company, threatened against any Company Employee Plan or against the assets of any Company Employee Plan. Each Company Employee Plan can be amended, terminated or otherwise discontinued after the Closing in accordance with its terms, without liability to Parent, the Company or any of their Affiliates (other than ordinary administration expenses), subject to applicable Legal Requirements. There are no audits, inquiries or Legal Proceedings pending or, to the Knowledge of the Company, threatened by the IRS, the DOL, or any other Governmental Body with respect to any Company Employee Plan. The Company has not incurred any penalty or tax with respect to any Company Employee Plan under Section 502(i) of ERISA, under Sections 4975 through 4980 of the Code or under any other applicable Legal Requirement. The Company has timely made all contributions and other payments required by and due under the terms of each Company Employee Plan. No Company Employee Agreement and no Company Employee Plan has or can reasonably be expected to result in gross income inclusion pursuant to Section 409A(a)(1)(A) of the Code.

(d) The Company does not and has not ever maintained, established, sponsored, participated in, or contributed to any: (i) Company Pension Plan subject to Title IV of ERISA; (ii) "multiemployer plan" within the meaning of Section (3)(37) of ERISA; or (iii) Company Pension Plan in which stock of any of the Company or any of their Affiliates is or was held as a plan asset.

(e) No Company Employee Plan provides, or reflects or represents any liability of any of the Company or any of its Affiliates to provide, retiree life insurance, retiree health benefits or other retiree employee welfare benefits to any Person for any reason, except as may be required by COBRA or other applicable Legal Requirements. The Company has not ever represented, promised or contracted (whether in oral or written form) to any Company Employee (either individually or to Company Employees as a group) or any other Person that any such Company Employee or other Person would be provided with retiree life insurance, retiree health benefits or other retiree employee welfare benefits, except to the extent required by applicable Legal Requirements.

(f) Except as expressly required or provided by this Agreement, neither the execution or delivery of this Agreement nor the consummation of any of the transactions contemplated by this Agreement will (either alone or upon the occurrence of any additional or subsequent events) constitute an event under any Company Employee Plan, Company Employee Agreement, trust or loan that will or could reasonably be expected to result (either alone or in connection with any other circumstance or event) in any payment (whether of severance pay or otherwise), acceleration of any right, obligation or benefit, forgiveness of indebtedness, vesting, distribution, increase in benefits or obligation to fund benefits with respect to any Company Employee.

(g) The Company has not: (i) except as would not reasonably be expected to have a Material Adverse Effect, violated or otherwise failed to comply with any Legal Requirement respecting employment, employment practices, terms and conditions of employment or wages and hours, including the health care continuation requirements of COBRA, the requirements of FMLA, the requirements of HIPAA and the provisions of any similar Legal Requirement; (ii) failed to

withhold or report any amounts required by applicable Legal Requirements or by Contract to be withheld or reported with respect to wages, salaries and other payments to Company Employees; (iii) become liable for any arrears of wages or any taxes or any penalty for failure to comply with the Legal Requirements applicable to any of the foregoing; and (iv) become liable for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Body with respect to unemployment compensation benefits, social security or other benefits or obligations for Company Employees (other than routine payments to be made in the normal course of business and consistent with past practice). There are no pending or, to the Knowledge of the Company, threatened or reasonably anticipated claims or Legal Proceedings against the Company under any worker's compensation policy or long-term disability policy.

(h) To the Knowledge of the Company, no stockholder of the Company and no Company Employee, is obligated under any Contract or subject to any Order that would interfere with such Person's efforts to promote the interests of the Company or that would interfere with the business of the Company. Neither the execution nor the delivery of this Agreement, nor the carrying on of the business of the Company as presently conducted or as presently proposed to be conducted nor any activity of such stockholder or Company Employees in connection with the carrying on of the business of the Company as presently conducted will, to the Knowledge of the Company, conflict with, result in a breach of the terms, conditions or provisions of, or constitute a default under, any Contract under which any of such stockholders or Company Employees has any rights or obligations.

2.16 Environmental Matters. The Company possesses all permits and other Governmental Authorizations required under applicable Environmental Laws, and is in compliance with the terms and conditions thereof. The Company has not received any notice or other communication (in writing or otherwise), whether from a Governmental Body, citizens group, employee or otherwise, that alleges that the Company is not in compliance with any Environmental Law. To the Knowledge of the Company, (a) all property that is leased to, controlled by or used by the Company, and all surface water, groundwater and soil associated with or adjacent to such property, is free of any material environmental contamination of any nature, (b) none of the property leased to, controlled by or used by the Company contains any underground storage tanks, asbestos, equipment using PCBs, underground injection wells, and (c) none of the property leased to, controlled by or used by the Company contains any septic tanks in which process wastewater or any Materials of Environmental Concern have been disposed of.

2.17 Insurance. The Company maintains insurance policies of the type and amounts of coverage as are usual and customary in the context of the business and operations in which the Company is engaged. The Company has not received any notice or other communication (in writing or otherwise) regarding any actual or possible (a) cancellation or invalidation of any insurance policy, (b) refusal of any coverage or rejection of any claim under any insurance policy, or (c) material adjustment in the amount of the premiums payable with respect to any insurance policy.

2.18 Related Party Transactions. Except as otherwise set forth in the audited financial statements of Parent or in any draft of a Registration Statement prepared by or on behalf of Parent in anticipation of an initial public offering of the securities of Parent (a) no Related Party has, and no Related Party has had, any direct or indirect interest in any material asset used in or otherwise relating to the Company's business; (b) no Related Party is, or has been, indebted to the Company; (c) no Related Party has entered into, or has had any direct or indirect material financial interest in, any material Contract, transaction or business dealing involving the Company; (d) no Related Party is competing, or has competed, directly or indirectly, with the Company; and (e) no Related Party has any claim or right against the Company (other than rights to receive compensation for services performed as an employee of the Company). (For purposes of this Agreement, each of the following shall be deemed to be a "Related Party": (i) each individual who is, or who has at any time been, an officer or

director of the Company; (ii) each member of the immediate family of each of the Person referred to in clause "(i)"; and (iii) any trust or other Entity (other than the Company) in which any one of the Persons referred to in clauses "(i)" and "(ii)" above holds (or in which more than one of such individuals collectively hold), beneficially or otherwise, a material voting, proprietary or equity interest.).

#### 2.19 Legal Proceedings; Orders.

(a) There have been no previous Legal Proceedings, there is no pending Legal Proceeding, and no Person, to the Knowledge of the Company, has threatened to commence any Legal Proceeding, that involves the Company or that otherwise relates to or might affect its business, its prospects or any of the assets or properties of the Company (whether or not the Company is named as a party thereto), and no event has occurred that could reasonably be expected to give rise to or serve as a basis for the commencement of any such Legal Proceeding. There is no Order to which the Company or any of its assets, is or may be subject; and no Related Party is subject to any Order that relates to the Company or to any of its assets. There is no proposed Order that, if issued or otherwise put into effect, could reasonably be expected to have an adverse effect on its business, its prospects or the assets or properties of the Company. To the Knowledge of the Company, no event has occurred, and no claim or dispute or other condition or circumstance exists, that could reasonably be expected to give rise to or serve as a basis for the commencement of any such Legal Proceeding.

(b) There is no Order to which the Company, or any of the assets owned by the Company, is subject. To the Knowledge of the Company, no officer or key employee of the Company is subject to any Order that prohibits such officer or other employee from engaging in or continuing any conduct, activity or practice relating to the Company's business.

#### 2.20 Authority; Binding Nature of Agreement; Non-Contravention.

(a) The Company has the corporate power and authority to enter into and to perform its obligations under this Agreement; and the execution, delivery and performance by the Company of this Agreement have been duly authorized by all necessary action on the part of the Company and its board of directors and no other action is required on the part of the Company to authorize this Agreement, other than the adoption of this Agreement by the Company Stockholders, which will be obtained prior to the date hereof. This Agreement has been duly executed and delivered by the Company and, assuming the due authorization, execution and delivery by the other Parties hereto, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to (i) laws of general application relating to bankruptcy, insolvency, reorganization, moratorium and the enforcement of creditors' rights generally and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies (the "Enforceability Exception").

(b) The board of directors of the Company (at a meeting duly called and held) has (a) unanimously determined that the Merger is advisable and fair and in the best interests of the Company and the Company Holders, (b) unanimously authorized and approved the execution, delivery and performance of this Agreement by the Company and unanimously approved the Merger, and (c) unanimously recommended the approval of this Agreement by the Company Holders and directed that this Agreement and the Merger be submitted for consideration by the Company Holders. The affirmative vote or action by written consent of holders of a majority of the Company Preferred Stock, voting together as a single class on an as-converted to Company Series B Common Stock basis, and the holders of a majority of the Company Common Stock and Company Preferred Stock, voting together on an as-converted to Company Series B Common Stock basis, are the only votes (or consents) required of the Company Holders to adopt this Agreement under the DGCL, the Company's certificate of incorporation and bylaws, or any



Contract to which the Company is a party (the "Required Votes"). Company Holders represented the Required Vote, by and through the execution and delivery of the Written Consents on the date hereof following the execution of this Agreement (and not thereafter modified or rescinded) in accordance with the DGCL, shall have adopted this Agreement and approved the Merger.

(c) No state or foreign takeover statute or similar Legal Requirement applies or purports to apply to the Merger, this Agreement or any of the transactions contemplated hereby.

(d) Neither the execution, delivery or performance of this Agreement or any of the other agreements, documents or instruments referred to in or contemplated by this Agreement by the Company nor the consummation by the Company of the Merger or any of the other transactions contemplated by this Agreement will (with or without notice or lapse of time):

(i) contravene, conflict with or result in a violation of (i) any of the provisions of the certificate of incorporation or bylaws of the Company, or (ii) any resolution adopted by the Company Stockholders, the board of directors or any committee of the board of directors of the Company;

(ii) contravene, conflict with or result in a violation of any Legal Requirement or any Order to which the Company, or any of the assets owned or used by the Company, is or may be subject;

(iii) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by the Company or that otherwise relates to the business of the Company or to any of the assets owned or used by the Company;

(iv) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Company Contract or give any Person the right to (i) declare a default or exercise any remedy under any such Company Contract, (ii) a rebate, chargeback, penalty or change in delivery schedule under any such Company Contract, (iii) accelerate the maturity or performance of any obligation under any such Company Contract, or (iv) cancel, terminate or modify any term of any such Company Contract;

(v) result in the imposition or creation of any Encumbrance upon or with respect to any material asset owned or used by the Company; or

(vi) result in, or increase the likelihood of, the disclosure or delivery to any escrow holder or other Person of any source code for any Company Intellectual Property, or the transfer of any material asset of the Company to any Person.

Except as may be required by the DGCL and except as set forth in *Part 2.20(d)* of the Disclosure Schedule, the Company has not, nor will it be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (x) the execution, delivery or performance of this Agreement or any of the other transactions contemplated by this Agreement or (y) the consummation of the Merger or any of the other transactions contemplated by this Agreement. (For purposes of this Agreement, the Company will be deemed to be or to have been "required" to obtain a Consent if the failure to obtain such Consent (i) could result in the imposition of any liability or obligation on, or the expansion of any liability or obligation of, the Company, (ii) could result in the termination, modification or limitation of any contractual or other right of any of the Company, or (iii) could otherwise have an adverse effect on the business, condition, capitalization, assets, Intellectual Property, liabilities, results of operations, financial performance or prospects of the Company.)

**2.21 Financial Advisor.** No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the Merger or any of the other transactions contemplated by this Agreement based upon arrangements made by or on behalf of the Company or any Company Stockholder.

**2.22 Government Contracts.**

(a) With respect to each Contract between the Company and any Governmental Body and each outstanding bid, quotation or proposal by the Company (each, a "Bid") that if accepted or awarded could lead to a Contract between the Company and any Governmental Body (each such Contract or Bid, a "Company Government Contract") and each Contract between the Company and any prime contractor or upper-tier subcontractor relating to a Contract or between such Person and any Governmental Body, and each outstanding Bid that if accepted or awarded could lead to a Contract between the Company and a prime contractor or upper-tier subcontractor, relating to a Contract between such Person and any Governmental Body (each such Contract or Bid, a "Company Government Subcontract"):

(i) each such Company Government Contract or Company Government Subcontract was legally awarded, is binding on the Company and is in full force and effect with respect to the Company in accordance with its terms and, to the Knowledge of the Company, each such Company Government Contract or Company Government Subcontract was legally awarded, is binding on the other party thereto and is in full force and effect with respect to the other party thereto in accordance with its terms (except as the enforceability thereof may be limited by general principles of equity, regardless of whether considered in a proceeding in equity or at Law); *provided* that for purposes of this clause (i), the terms Company Government Contract and Company Government Subcontract shall not include any Bids;

(ii) neither any Governmental Authority nor any prime contractor, subcontractor or other Person or entity has notified the Company, in writing, that the Company has, or may have, breached or violated in any material respect any Law, certification, representation, clause, provision or requirement pertaining to any such Company Government Contract or Company Government Subcontract;

(iii) to the Knowledge of the Company, all facts set forth in or acknowledged by any representations, claims or certifications submitted by or on behalf of the Company or either of the Company Subsidiaries in connection with any such Company Government Contract or Company Government Subcontract were current, accurate and complete in all material respects as of their effective date;

(iv) the Company has not received any written notice of termination or cure notice pertaining to any such Company Government Contract or Company Government Subcontract;

(v) no cost in excess of \$10,000 incurred by the Company pertaining to such Company Government Contract or Company Government Subcontract has been questioned in writing by any Governmental Authority, is the subject of any audit (other than routine audits and similar inquiries) or, to the Knowledge of the Company, has been disallowed by any Governmental Body;

(vi) since January 1, 2006, no payment in excess of \$10,000 due to the Company pertaining to any such Company Government Contract or Company Government Subcontract has been withheld or set off, and the Company is entitled to all progress or other payments received to date with respect thereto; and

(viii) to the Knowledge of the Company, with respect to any Company Government Contract or Company Government Subcontract, no Principal, Employee, Agent, or

Subcontractor (as such terms are defined by Federal Acquisition Regulation (FAR) 52.203-13(a)) of the Company or either Company Subsidiary has committed a violation of the criminal law of any jurisdiction involving fraud, conflict of interest, bribery, or gratuity violation.

(b) The Company is not, nor has it ever been, suspended or debarred from doing business with a Governmental Body or, to the Knowledge of the Company, proposed for suspension or debarment by a Governmental Body and, to the Knowledge of the Company, the Company has not received any written notice indicating that the Company has been found nonresponsible or ineligible for contracting with a Governmental Body.

**2.23 Information Statement.** The information supplied by the Company for inclusion in the information statement sent to the Company Holders in connection with the solicitation of the Written Consents (the "Information Statement") did not, on the date the Information Statement was first mailed to the Company Holders, and, will not, at the Effective Time, contain any statement that, at such time and in light of the circumstances under which it is made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Information Statement, in light of the circumstances under which they were made, not false or misleading. If, at any time prior to the Effective Time, any event or information should be discovered by the Company that should be set forth in an amendment to the Information Statement, the Company shall promptly inform Parent and shall communicate such information to the applicable Company Holders in an appropriate manner. Notwithstanding the foregoing, the Company makes no representation, warranty or covenant with respect to any information supplied by or on behalf of Parent for inclusion in the Information Statement.

**2.24 Full Disclosure.** (a) None of the representations or warranties made by the Company (as modified by the Disclosure Schedule) in this Agreement and (b) none of the statements made in any exhibit, schedule or certificate furnished by the Company pursuant to this Agreement contains, or will contain at the Effective Time, any untrue statement of a material fact, or omits or will omit at the Effective Time to state any material fact necessary in order to make the statements contained herein or therein, in the light of the circumstances under which made, not misleading.

### SECTION 3. REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Parent and Merger Sub represent and warrant to the Company as follows:

**3.1 Due Organization.** Parent is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Merger Sub is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware.

**3.2 Authority; Binding Nature of Agreement.** Each of Parent and the Merger Sub has the corporate or other power and authority to enter into and to perform its obligations under this Agreement; and the execution, delivery and performance by Parent and Merger Sub of this Agreement have been duly authorized by all necessary action on the party of Parent, Merger Sub and their respective board of directors (subject to the approval, as necessary, of the stockholders of Parent or Merger Sub, as applicable). This Agreement has been duly executed and delivered by Parent and Merger Sub, as applicable, and, assuming the due authorization, execution and delivery by the other parties hereto, constitutes the legal, valid and binding obligation of the Parent and Merger Sub, enforceable against Parent and Merger Sub in accordance with its terms, subject to the Enforceability Exception.

**3.3 Parent Series E Stock.** The Parent Series E Stock issuable pursuant to the provisions of Section 1.5 (and the shares of Parent Common Stock issuable upon conversion of the shares of Parent Series E Stock (the "Conversion Shares")) shall have been, as of the Effective Time, duly and validly

reserved for issuance. When issued in compliance with the provisions of this Agreement and Parent's Certificate of Incorporation, the shares of Parent Series E Stock issuable pursuant to the provisions of Section 1.5 will be validly issued, fully paid and nonassessable and will be free of any Encumbrances; *provided, however*, that such shares of Parent Series E Stock may be subject to restrictions on transfer under state and/or federal securities laws.

**3.4 Information Statement.** The information supplied by or on behalf of Parent for inclusion in the Information Statement did not, on the date the Information Statement was first mailed to the Company Holders and, will not, at the Effective Time, contain any statement that, at such time and in light of the circumstances under which it is made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Information Statement, in light of the circumstances under which they were made, not false or misleading. Notwithstanding the foregoing, Parent makes no representation, warranty or covenant with respect to any information supplied by or on behalf of the Company for inclusion in the Information Statement.

**3.5 Absence of Changes.** Since September 30, 2010, (a) Parent has conducted its business only in the ordinary course of business and (b) there has not occurred any change, event or condition (whether or not covered by insurance) that, individually or in the aggregate with any other changes, events or conditions, has resulted in, or could reasonably be expected to result in, a material adverse effect on Parent.

#### SECTION 4. ADDITIONAL AGREEMENTS.

**4.1 Conduct of Business of the Company.** During the period from the date of this Agreement and continuing until the earlier of the termination of this Agreement and the Closing (the "Pre-Closing Period"), the Company shall carry on its business in the ordinary course in substantially the same manner as conducted prior to the date of this Agreement, shall preserve intact its present business organizations, keep available the services of its present service providers and preserve its relationships with present and potential customers, partners, suppliers, distributors, landlords, creditors, licensors, licensees and others having present or potential business relationships with it. For the avoidance of doubt, during the Pre-Closing Period, the Company shall not, without the prior written approval of Parent, (a) issue, deliver or sell or authorize or propose the issuance, delivery or sale of or authorization of the purchase of, any shares of Company Capital Stock or securities convertible into, or subscriptions, rights, warrants or options to acquire, or other agreements or commitments of any character obligating it to issue any such shares or other convertible securities, other than the issuance of shares of Company Capital Stock pursuant to the Company's obligations under the Cornerstone Agreement, the issuance of shares of Company Series B Common Stock upon the exercise of Company Options outstanding on the date of this Agreement and the issuance of shares of Company Series B Preferred Stock in connection with the Note Conversion (as defined in Section 5.3(b) below); (b) make any change with respect to its personnel, provide for any increases in or modification of the compensation or severance or other benefits payable or to become payable to such individuals or terminate the employment of any employees; or (c) make any change with respect to any Company Employee Plan. During the Pre-Closing Period, the Company shall promptly notify Parent of any event or occurrence not in the ordinary course of business of the Company, and any circumstance, change, event or effect of any character that has had or would reasonably be expected to have a Material Adverse Effect with respect to the Company.

**4.2 Access to Information.** The Company shall afford Parent and its accountants, counsel and other representatives, reasonable access during normal business hours during the Pre-Closing Period to (i) all properties, books, contracts, commitments and records, including all Tax Returns and all other papers and other documentation relating to Taxes, and (ii) all other information concerning the business, properties and personnel of the Company as may reasonably be requested, provided that any

information furnished pursuant hereto or any investigation by each party hereto shall not affect such Party's right to rely on and shall not be deemed to modify any representations, warranties, agreements and covenants made by the other party herein.

**4.3 No Solicitation. During the Pre-Closing Period:**

(a) The Company shall not, and shall not cause or permit, directly or indirectly, through any officer, director, employee, Company Stockholder, agent or representative (including, without limitation, investment bankers, attorneys, accountants and consultants), or otherwise, any Person to:

(i) solicit, initiate or further the submission of proposals or offers from, or enter into any agreement with, any Person, individually or collectively with any other Person (including, without limitation, any directors or employees of the Company or any of their affiliates), other than Parent (a "Third Party"), relating to any acquisition or purchase of all or any substantial portion of the assets of, or any debt or equity interests in, the Company or any stock acquisition, merger, consolidation or business combination with the Company (an "Acquisition Proposal");

(ii) participate in any discussions or negotiations regarding, or furnish to any Third Party, any information with respect to the Company or Parent in connection with any Acquisition Proposal; or

(iii) cooperate in any way with, or assist or participate in, facilitate or encourage, any effort or attempt by any Third Party to undertake or seek to undertake any Acquisition Proposal;

(iv) *provided*, however, that notwithstanding anything to the contrary elsewhere in this Agreement, the Company may take actions described in clause (ii) or (iii) of this subsection (a) if (A) such action is taken in connection with an unsolicited Acquisition Proposal, (B) in the good faith judgment of the board of directors of the Company or the Company Special Committee, after consultation with outside counsel, the failure to take such action would not be consistent with the fiduciary duties of the board of directors under applicable law. Moreover, prior to the Closing, notwithstanding anything to the contrary elsewhere in this Agreement, the board of directors of the Company may, in response to an unsolicited Acquisition Proposal, (Y) withdraw or modify its approval or recommendation of the Merger or this Agreement or (Z) approve or recommend any such Acquisition Proposal if, in the case of any action described in clause (Y) or (Z), in the good faith judgment of the directors of the Company, after consultation with outside counsel, the failure to take such action would not be consistent with the fiduciary duties of the directors of the Company under applicable law.

(b) In the event that the Company or any of its Affiliates receives any offer or indication of interest from any Third Party relating to any Acquisition Proposal, the Company shall promptly, and in any event within 24 hours, notify Parent in writing of receipt of such offer or indication of interest, and shall in any such notice, set forth in reasonable detail the identity of the Third Party and, to the extent known by the Company, the terms and conditions of any offer or indication of interest.

(c) The Company shall immediately cease any activities, discussions or negotiations with any Third Party conducted on or prior to the date of this Agreement with respect to any Acquisition Proposal to the extent such activities, discussions or negotiations would breach any covenant of the Company in this Agreement.

**4.4 Tax Matters.** The Parties agree, for income tax and all other purposes, to report the Merger as a reorganization under Section 368(a) of the Code, but each party is relying on its own tax advisors concerning the tax implications of the Merger and will not be liable to any other party in the event that the Merger fails to qualify as a reorganization.

**4.5 Commercially Reasonable Efforts.**

(a) During the Pre-Closing Period, (a) the Company shall use commercially reasonable efforts to cause the conditions set forth in Section 5.2 to be satisfied on a timely basis and (b), Parent and Merger Sub shall use commercially reasonable efforts to cause the conditions set forth in Section 5.3 to be satisfied on a timely basis.

(b) During the Pre-Closing Period, the Company shall use commercially reasonable efforts to redeem the shares of Company Capital Stock held by each Company Stockholder who is not "accredited" within the meaning of Regulation D of the Securities Act pursuant to the terms of a redemption agreement, in substantially the form attached hereto as *Exhibit C* (the "Redemption Agreement").

(c) During the Pre-Closing Period, the Company shall use commercially reasonable efforts to obtain from each Company Stockholder a questionnaire (in a form reasonably acceptable to Parent) executed by each Company Stockholder (other than holders of Company Capital Stock who have executed and delivered a Redemption Agreement) certifying that such holder is "accredited" within the meaning of Regulation D of the Securities Act.

(d) During the Pre-Closing Period, Parent shall use commercially reasonable efforts to obtain the written consent of the holders of a majority of the capital stock of Parent (voting on an as-converted basis) who are "disinterested" in respect of the Merger (as determined in the sole discretion of the Parent Special Committee) (the "Parent Approval").

**4.6 FIRPTA Matters.** At the Closing, the Company shall deliver to Parent (a) a statement (in such form as may be reasonably requested by counsel to Parent) conforming to the requirements of Section 1.897-2(h)(1)(i) of the United States Treasury Regulations and (b) the notification required under Section 1.897-2(h)(2) of the United States Treasury Regulations, dated as of the Closing Date and executed by the Company, together with written authorization for Parent to deliver such notice to the IRS on behalf of Parent after the Closing.

**4.7 Spreadsheet.** The Company will cause to be prepared and delivered to Parent, three business days before the Closing, a spreadsheet, in a form reasonably acceptable to Parent, dated and setting forth as of the Closing the following information relating to the Company Stockholders and holders of Company Options: (a) the names of all such holders; (b) the number and type of Company Capital Stock held by, or subject to the Company Options held by, such Persons; (c) in the case of outstanding Company Capital Stock, the respective Company Stock Certificate numbers; (d) the exercise price in effect for each Company Option and the Tax status of each Company Option; (e) the number of shares of Parent Series E Stock issuable (as applicable) to each Company Stockholder in respect of the cancellation of such holder's Company Capital Stock pursuant to Section 1.5; and (f) the Holdback Contribution Amount of each Company Stockholder (the "Spreadsheet").

**4.8 Expenses.** If the Transaction is not consummated, all transaction expenses, including all fees, costs and expenses, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the party incurring such expense.

**4.9 Notification.**

(a) During the Pre-Closing Period, (a) the Company will notify Parent promptly after becoming aware of any matter hereafter arising or any information obtained after the date hereof that, if existing, occurring or known at or before the date of this Agreement, would have been

required to be set forth or described in the Disclosure Schedule or that is required to be disclosed in order that such schedule be complete and correct and (b) each party will notify the other party promptly of the occurrence or non-occurrence of any event whose occurrence or non-occurrence would be likely to cause either (i) any representation or warranty made by it in this Agreement to be untrue or inaccurate in any material respect or (ii) any condition of the other party set forth herein to be unsatisfied in any material respect, or (c) any material failure of such notifying party, any Affiliate of such notifying party or any of their respective representatives to comply with or satisfy any covenant, condition or agreement to be complied with or satisfied by it hereunder, in each case such that the conditions in Section 5 would reasonably be expected not to be met. No provision of, and no information provided under, this Section 4.9 will, or will be deemed to, limit, modify or otherwise affect any representation or warranty contained herein, the conditions to the obligations of the parties hereto to consummate the Merger or any party's rights hereunder (including rights under Section 7).

(b) No later than 10 days prior to the Expiration Date, the Representative shall notify Parent as to the number of shares of Company Capital Stock or Parent capital stock that as of the date of such notice are required to be issued to Cornerstone in respect of the Cornerstone Agreement with respect to any period ending on or prior to December 31, 2010.

## SECTION 5. CONDITIONS TO THE MERGER.

5.1 **Conditions to Obligations of Each Party.** The respective obligations of each party to consummate the Merger will be subject to the satisfaction at or before the Closing of each of the following conditions, which to the extent permitted by Law may be waived in a written agreement of the Company and Parent (for itself and Merger Sub):

(a) *No Injunctions or Restraints; Illegality.* No Order or other legal or regulatory restraint or prohibition preventing the consummation of the Transactions will be in effect, nor will any Legal Proceeding brought by a Governmental Body seeking any of the foregoing be pending or threatened. No action taken by any Governmental Body, and no statute, rule, regulation or Order will have been enacted, entered, enforced or deemed applicable to the Transaction, which makes the consummation of the Transaction illegal.

(b) *Governmental Authorizations.* Parent and the Company will have timely obtained from each Governmental Body all approvals, waivers and consents, if any, necessary for consummation of, or in connection with, the Transaction.

5.2 **Conditions to Obligations of Parent and Merger Sub.** The obligations of Parent and Merger Sub to consummate the Merger will be subject to the satisfaction, or written waiver by Parent, at or before the Closing of each of the following conditions:

(a) *Representations, Warranties and Covenants.* Each of the representations and warranties made by the Company in this Agreement that is qualified by reference to materiality or Material Adverse Effect will be true and correct, and each of the other representations and warranties made by the Company in this Agreement will be true and correct in all material respects, in each case as of the date of this Agreement and at and as of the Closing Date as if made on that date (except in any case that representations and warranties that expressly speak as of a specified date or time need only be true and correct or true and correct in all material respects, as applicable, as of such specified date or time).

(b) *No Material Adverse Change.* There will not have occurred any event or condition of any character that has had or is reasonably likely to have a Material Adverse Effect on the Company since the date of this Agreement.

- (c) *Written Consents.* The Written Consents shall remain in full force and effect..
- (d) *Consents and Approvals.* Parent shall have been furnished with evidence satisfactory to it that the Company has obtained the consents, approvals and waivers listed (or required to be listed) on *Part 2.20(d)* of the Disclosure Schedule.
- (e) *Parent Approval.* Parent shall have received the Parent Approval.
- (f) *Redemption Agreement.* The Company shall have effected the redemption of all shares of Company Capital Stock held by Persons who executed Redemption Agreements.
- (g) *Closing Deliveries.* Parent will have received each of the following agreements and documents, each of which shall be in full force and effect:
- (i) a certificate, dated as of the Closing Date, executed on behalf of the Company by an officer of the Company, to the effect that each of the conditions set forth in Sections 5.2(a), (b) and (c) has been satisfied;
  - (ii) a certificate, dated as of the Closing Date, of the secretary of the Company, certifying that attached are true and correct copies of the Company's certificate of incorporation and bylaws and resolutions of the board of directors of the Company and Company Holders evidencing approval of this Agreement and the Merger;
  - (iii) a long-form good standing certificate for the Company issued by the Secretary of State of the State of Delaware within two days of the Closing Date;
  - (iv) a good standing certificate for the Company issued by the Secretary of State of the State of Iowa and each other State in which the Company is qualified to do business;
  - (v) a certificate of the Company's Chief Financial Officer (or most senior financial officer) certifying as to the accuracy of the Spreadsheet;
  - (vi) written resignations of all officers and directors of the Company, effective as of immediately prior to the Effective Time, to the extent requested by Parent;
  - (ix) questionnaires (in a form reasonably acceptable to Parent) executed by each Company Stockholder (other than, for the avoidance of doubt, any former Company Stockholder who had all shares of Company Capital Stock held by it redeemed pursuant to a Redemption Agreement) certifying that such holder is "accredited" within the meaning of Regulation D of the Securities Act;
  - (x) a copy of the Certificate of Merger duly executed by the Company;
  - (xi) evidence that the Company Financing Agreements have been terminated; and
  - (xii) such other documents as may reasonably be requested by Parent.

5.3 *Conditions to Obligations of the Company.* The obligation of the Company to consummate the Merger will be subject to the satisfaction, or written waiver by the Company, at or before the Closing of each of the following conditions:

- (a) *Representations, Warranties and Covenants.* Each of the representations and warranties made by Parent and Merger Sub in this Agreement that is qualified by reference to materiality or Material Adverse Effect will be true and correct, and each of the other representations and warranties made by Parent and Merger Sub in this Agreement will be true and correct in all material respects, in each case as of the date of this Agreement and at and as of the Closing Date as if made on that date (except in any case that representations and warranties that expressly speak as of a specified date or time need only be true and correct or true and correct in all material respects, as applicable, as of such specified date or time).



(b) *Parent Note.* Parent covenants and agrees that prior to Closing it will convert all principal and interest outstanding under that certain Convertible Secured Promissory Note issued by the Company to Parent on September 1, 2009 (the "Parent Note") into shares of Company Series B Preferred Stock in accordance with the terms of such Note (the "Note Conversion"). It is currently anticipated that Parent shall effect the Note Conversion on December 1, 2010, and the Company acknowledges such. The Company agrees to effect the Note Conversion on December 1, 2010 or such other date, prior to the Closing, that Parent elects to effect the Note Conversion.

(c) *No Material Adverse Change.* There will not have occurred any event or condition of any character that has had or is reasonably likely to have a material adverse effect on Parent since the date of this Agreement.

(d) *Registration Statement Filing.* Parent shall have filed with the SEC a Registration Statement in connection with its first underwritten public offering of Parent Common Stock and such Registration Statement shall not have been withdrawn by Parent.

(e) *Closing Deliveries.* The Company will have received each of the following agreements and documents, each of which shall be in full force and effect:

(i) a certificate, dated as of the Closing Date, executed on behalf of the Parent by an officer of the Parent, to the effect that the condition set forth in Section 5.3(a) has been satisfied;

(ii) a certificate, dated as of the Closing Date, of the secretary of the Parent, certifying that attached are true and correct copies of the certificate of incorporation and bylaws of Parent and Merger Sub, and resolutions of the board of directors and sole stockholder of Merger Sub evidencing approval of this Agreement and Merger;

(iii) a long-form good standing certificate for Merger Sub issued by the Secretary of State of the State of Delaware within two days of the Closing Date; and

(iv) a copy of the Certificate of Merger duly executed by Merger Sub.

## SECTION 6. TERMINATION PROVISIONS.

6.1 *Termination.* This Agreement may be terminated at any time prior to the Effective Time (with respect to Section 6.1(a) through Section 6.1(d), by written notice by the terminating party to the other party):

(a) by the mutual written consent of Parent and the Company;

(b) by Parent or Company if Merger shall not have been consummated by December 31, 2010; *provided, however*, that the right to terminate this Agreement under this Section 6.1(b) shall not be available if the terminating party's failure to comply with or perform in any material respect any covenant under this Agreement has been the cause of or resulted in the failure of the Merger to occur on or before such date;

(c) by either Parent or the Company if a court of competent jurisdiction or other Governmental Body shall have issued a nonappealable final order, decree or ruling or taken any other action, in each case having the effect of permanently restraining, enjoining or otherwise prohibiting Merger; or

(d) by either Parent or the Company, if (i) there has been a breach of or inaccuracy in any representation, warranty, covenant or agreement on the part of the other party set forth in this Agreement, such that the conditions set forth in Section 5.2 (in the case of termination by Parent) or Section 5.3 (in the case of termination by the Company) will not be satisfied and (ii) such breach or inaccuracy shall not have been cured within 30 days following receipt by the breaching

party of written notice of such breach or inaccuracy from the other party (*provided, however*, that no such cure period will be available or applicable to any such breach that by its nature cannot be cured) (*provided, further*, that the right to terminate this Agreement under this Section 6.1(d) shall not be available to the Company if the Company is at that time in material breach of this Agreement).

**6.2 Effect of Termination.** In the event of termination of this Agreement as provided in Section 6.1, there shall be no Liability on the part of Parent, the Company, Merger Sub or their respective officers, directors or stockholders, except to the extent that such termination results from the breach by such party of any of its representations, warranties or covenants set forth in this Agreement; *provided, however*, that the provisions of Section 4.8 and 8 shall remain in full force and effect and survive any termination of this Agreement.

## SECTION 7. INDEMNIFICATION, ETC.

### 7.1 Survival of Representations, Etc.

(a) *General Survival.* Subject to Section 7.1(c), the representations and warranties made by the Company in this Agreement shall survive the Effective Time and shall expire on the Expiration Date; *provided, however*, that if, at any time prior to the Expiration Date, any Indemnitee delivers to the Representative a written notice alleging the existence of an inaccuracy in or a breach of any of such representations and warranties and asserting a claim for recovery under Section 7.2(a) based on such alleged inaccuracy or breach, then the claim asserted in such notice shall survive the Expiration Date until such time as such claim is fully and finally resolved.

(b) *Parent Representations.* The representations and warranties made by Parent and Merger Sub in this Agreement shall survive until the Effective Time.

(c) *Intentional Misconduct and Misrepresentation; Fraud.* Notwithstanding anything to the contrary contained in Section 7.1(a), the limitations set forth in Section 7.1(a) shall not apply in the case of claims based upon intentional misconduct, intentional misrepresentation or fraud (collectively, "Fraud").

(d) *Representations Not Limited; Exception.* The representations, warranties, covenants and obligations of the Company, and the rights and remedies that may be exercised by the Indemnitees, shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by, or knowledge of, any of the Indemnitees; *provided, however*, that for all purposes in this Agreement, including but not limited to Section 5.2(a), each representation and warranty of the Company shall be deemed to be qualified (as if actually scheduled in all relevant parts of the Disclosure Schedule as exceptions to the relevant representations and warranties) by the actual knowledge, as of the Closing Date, of any Current Parent Executive of a specific fact or circumstance that would, but for this proviso, result in a breach of the applicable representation or warranty, and the rights and remedies in respect of a breach of a representation or warranty that may be exercised by the Indemnitees shall be limited accordingly.

(e) *Disclosure Schedule.* For purposes of this Agreement, each statement or other item of information set forth in the Disclosure Schedule or in any update to the Disclosure Schedule shall be deemed to be a representation and warranty made by the Company in this Agreement.

### 7.2 Indemnification.

(a) *Indemnification.* From and after the Effective Time (but subject to Section 7.1), the Company Stockholders (collectively, the "Indemnitors"), shall, subject to the limitations set forth in Sections 7.2(c) and 7.3 of this Agreement, hold harmless and indemnify each of the Indemnitees

from and against, and shall compensate and reimburse each of the Indemnitees for any Damages that are directly or indirectly suffered or incurred by any of the Indemnitees or to which any of the Indemnitees may otherwise directly or indirectly become subject (regardless of whether or not such Damages relate to any third party claim) and that arise directly or indirectly from or as a result of, or are directly or indirectly connected with:

(i) any inaccuracy in or breach of any representation or warranty made by the Company in this Agreement as of the date of this Agreement and as of the Closing Date;

(ii) any breach of any covenant or obligation of the Company in this Agreement;

(iii) any amounts (including interest) required to be paid to holders of Dissenting Shares in excess of that portion of the Merger Consideration otherwise payable to such holder pursuant to Section 1.5;

(iv) any shares of Company Capital Stock or Parent capital stock that are required to be issued to Cornerstone in respect of the Cornerstone Agreement with respect to any period ending on or prior to December 31, 2010; or

(v) any Legal Proceeding relating to any breach or alleged breach or any other matter of the type referred to in clause "(i)", "(ii)", "(iii)" or "(iv)" above (including any Legal Proceeding commenced by any Indemnitee for the purpose of enforcing any of its rights under this Section 7.2(a)).

(b) *Damage to Parent.* The parties acknowledge and agree that, if the Surviving Corporation suffers, incurs or otherwise becomes subject to any Damages as a result of or in connection with any inaccuracy in or breach of any representation, warranty, covenant or obligation, then (without limiting any of the rights of the Surviving Corporation as an Indemnitee) Parent shall also be deemed, by virtue of its ownership of the stock of the Surviving Corporation, to have incurred Damages as a result of and in connection with such inaccuracy or breach.

(c) *Determination of Damages.* Solely for purposes of determining the amount of any Damages, all representations, warranties and covenants that are qualified as to "materiality" or by reference to a "Material Adverse Effect" or similar terms shall be deemed to be not so qualified. With respect to any claim for Damages, the Indemnitors shall be liable for 36% of the Damages in respect of each specific claim.

(d) *Mitigation of Damages.* An Indemnitee shall act in good faith and in a commercially reasonable manner to mitigate any Damages it may suffer.

### 7.3 Certain Limitations; Exclusive Remedy.

(a) *Recourse to the Holdback Amount.* Except in the case of Fraud, recourse by the Indemnitees to the Holdback Amount shall be the Indemnitees' sole and exclusive remedy for monetary Damages resulting from the matters referred to in Section 7.2(a).

(b) *Value of Parent Series E Stock.* For all purposes under this Section 7, the shares of Parent Series E Stock shall have a value of \$31.25 (subject to adjustment for stock splits, stock dividends and the like after the date hereof).

(c) *Exclusive Remedy.* From and after the Closing, except for claims based on Fraud, the provisions of this Section 7 shall constitute the sole and exclusive remedy of any Indemnitee for Damages related to the subject matter of this Agreement; *provided, however,* that this exclusive remedy for Damages shall not preclude a Party from bringing an action for specific performance or other equitable remedy to require a party to perform its obligations under this Agreement or any agreement entered into in connection herewith.

**7.4 No Contribution.** Each Indemnitor waives, and acknowledges and agrees that it shall not have and shall not exercise or assert (or attempt to exercise or assert), any right of contribution, right of indemnity or other right or remedy against Merger Subs or the Company in connection with any indemnification obligation or any other liability to which it may become subject under or in connection with this Agreement or any other agreement or document delivered to Parent in connection with this Agreement.

**7.5 Defense of Third Party Claims.** In the event of the assertion or commencement by any Person of any claim or Legal Proceeding with respect to which any Indemnitor may become obligated to hold harmless, indemnify, compensate or reimburse any Indemnitee pursuant to Section 7, Parent shall have the right, at its election, to proceed with the defense of such claim or Legal Proceeding on its own with counsel reasonably satisfactory to the Representative. If Parent so proceeds with the defense of any such claim or Legal Proceeding:

- (a) subject to the other provisions of Section 7, all reasonable expenses relating to the defense of such claim or Legal Proceeding shall be borne and paid exclusively by the Indemnitors;
- (b) each Indemnitor shall make available to Parent any documents and materials in his possession or control that may be necessary to the defense of such claim or Legal Proceeding; and
- (c) Parent shall have the right to settle, adjust or compromise such claim or Legal Proceeding.

Parent shall give the Representative prompt notice of the commencement of any such Legal Proceeding against Parent, the Surviving Corporation or the Company; *provided, however*, that any failure on the part of Parent to so notify the Representative shall not limit any of the obligations of the Indemnitors under Section 7 (except to the extent such failure materially prejudices the defense of such Legal Proceeding). If Parent does not elect to proceed with the defense of any such claim or Legal Proceeding, the Representative may proceed with the defense of such claim or Legal Proceeding with counsel reasonably satisfactory to Parent; *provided, however*, that the Representative may not settle, adjust or compromise any such claim or Legal Proceeding without the prior written consent of Parent, which consent shall not be unreasonably withheld.

## SECTION 8. MISCELLANEOUS PROVISIONS

### 8.1 Representative.

(a) *Appointment.* By virtue of the adoption of this Agreement, the Indemnitors irrevocably nominate, constitute and appoint BPS Stockholder Representative, LLC as the agent and true and lawful attorney in fact of the Company Stockholders (the "Representative"), with full power of substitution, to act in the name, place and stead of the Indemnitors for purposes of executing any documents and taking any actions that the Representative may, in his sole discretion, determine to be necessary, desirable or appropriate in connection with any claim for indemnification, compensation or reimbursement under Section 4. BPS Stockholder Representative, LLC hereby accepts its appointment as Representative.

(b) *Authority.* The Indemnitors grant to the Representative full authority to execute, deliver, acknowledge, certify and file on behalf of such Indemnitors (in the name of any or all of the Indemnitors or otherwise) any and all documents that the Representative may, in his sole discretion, determine to be necessary, desirable or appropriate, in such forms and containing such provisions as the Representative may, in his sole discretion, determine to be appropriate, in performing its duties as contemplated by Section 8.1(a). Notwithstanding anything to the contrary contained in this Agreement or in any other agreement executed in connection with the transactions contemplated hereby: (i) each Indemnitee shall be entitled to deal exclusively with the Representative on all matters relating to any claim for indemnification, compensation or

reimbursement under Section 4; and (ii) each Indemnitee shall be entitled to rely conclusively (without further evidence of any kind whatsoever) on any document executed or purported to be executed on behalf of any Indemnitor by the Representative, and on any other action taken or purported to be taken on behalf of any stockholder by the Representative, as fully binding upon such shareholder.

(c) *Power of Attorney.* The Indemnitors recognize and intend that the power of attorney granted in Section 8.1(a): (i) is coupled with an interest and is irrevocable; (ii) may be delegated by the Representative; and (iii) shall survive the death or incapacity of each of the Indemnitors.

(d) *Replacement.* If the Representative shall die, resign, become disabled or otherwise be unable to fulfill its responsibilities hereunder, the Indemnitors shall (by consent of those Persons entitled to a majority of the Merger Consideration), within 10 days after such death, disability or inability, appoint a successor to the Representative (who shall be reasonably satisfactory to Parent) and immediately thereafter notify Parent of the identity of such successor. Any such successor shall succeed the Representative as Representative hereunder. If for any reason there is no Representative at any time, all references herein to the Representative shall be deemed to refer to the former Company Stockholders.

8.2 *Further Assurances.* Each party hereto shall execute and cause to be delivered to each other party hereto such instruments and other documents and shall take such other actions as such other party may reasonably request (at or after the Closing) for the purpose of carrying out or evidencing any of the transactions contemplated by this Agreement.

8.3 *Attorneys' Fees.* If any Legal Proceeding relating to this Agreement or the enforcement of any provision of this Agreement is brought against any party hereto, the prevailing party shall be entitled to recover reasonable attorneys' fees, costs and disbursements (in addition to any other relief to which the prevailing party may be entitled).

8.4 *Notices.* Any notice or other communication required or permitted to be delivered to any party under this Agreement shall be in writing and shall be deemed properly delivered, given and received: (a) if delivered by hand, when delivered; (b) if sent by facsimile transmission before 5:00 p.m. Mountain time on a business day, when transmitted and the sender receives electronic confirmation of receipt; (c) if sent by facsimile transmission after 5:00 p.m. Mountain time on a business day (or on a non-business day in Colorado) and the sender receives electronic confirmation of receipt, on the following business day; (d) if sent by electronic mail, telegram, cablegram or other electronic transmission, upon delivery; (e) if sent by registered, certified or first class mail, the third business day after being sent; and (f) if sent by overnight delivery via a national courier service, one business day after being sent, in each case to the address or facsimile telephone number set forth beneath the name of such party below (or to such other address or facsimile telephone number as such party shall have specified in a written notice given to the other parties hereto) (any notice to Steve Stahly shall be sent by electronic mail):

if to Parent or Merger Sub:

NewLink Genetics Corporation  
2503 South Loop Drive, Suite 5100  
Ames, IA 50010  
Attention: Chief Financial Officer  
Facsimile: (515) 296-3520  
Email: [glink@linkp.com](mailto:glink@linkp.com)

with a copy (which shall not constitute notice) to:

**Cooley LLP**  
380 Interlocken Crescent, Suite 900  
Broomfield, CO 80021  
Attention: James C. T. Linfield, Esq.  
Facsimile: (720) 566-4099  
Email: jlinfield@cooley.com

and

**Lindquist and Vennum**  
4200 IDS Center  
80 South Eighth Street  
Minneapolis, MN 55402  
Facsimile: (612) 371-3207  
Email: jlevy@lindquist.com

if to the Company:

**BioProtection Systems Corporation**  
2901 South Loop Dr., Building 3  
Ames, IA 50010  
Attention: Chief Financial Officer  
Facsimile: (515) 296-3820  
Email: clangren@ops.net

with a copy (which shall not constitute notice) to:

**Shesky & Froelich Ltd.**  
111 E. Wacker Dr., Ste. 2800  
Chicago, IL, 60601  
Attention: Mitchell D. Goldsmith  
Facsimile: (312)527-4011  
Email: mgoldsmith@shesksylaw.com

if to the Representative:

**BPS Stockholder Representative, LLC**

**Thomas A. Raffin, M.D.**  
Telegraph Hill Partners  
360 Post Street, Suite 601  
San Francisco, CA 94108  
Email: tar@stanford.edu

and

**Steve Stahly**  
447 46<sup>th</sup> Street  
West Des Moines, IA 50265  
Email: steve@stahlyinvestments.com

and

**Ernie Talarico**  
333 N. Jefferson St., #602  
Chicago, IL 60661  
Email: ktalarico@sbcglobal.net

with a copy (which shall not constitute notice) to:

Shefsky & Froelich Ltd.  
111 E. Wacker Dr., Ste. 2800  
Chicago, IL, 60601  
Attention: Mitchell D. Goldsmith  
Facsimile: (312)527-4011

**8.5 Headings.** The headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

**8.6 Counterparts and Exchanges by Facsimile Transmission.** This Agreement may be executed in several counterparts, each of which shall constitute an original and all of which, when taken together, shall constitute one agreement. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission in .PDF format or by facsimile shall be sufficient to bind the parties to the terms and conditions of this Agreement.

**8.7 Governing Law; Venue.**

(a) *Governing Law.* This Agreement shall be construed in accordance with, and governed in all respects by, the internal laws of the State of Iowa (without giving effect to principles of conflicts of laws).

(b) *Venue.* Except as otherwise provided in Section 8.7(c), any Legal Proceeding relating to this Agreement or the enforcement of any provision of this Agreement (including a Legal Proceeding based upon Fraud) may be brought or otherwise commenced in any state or federal court located in the State of Iowa. Each party to this Agreement: (i) expressly and irrevocably consents and submits to the jurisdiction of each state and federal court located in the State of Iowa (and each appellate court located in the State of Iowa) in connection with any such Legal Proceeding; (ii) agrees that each state and federal court located in the State of Iowa shall be deemed to be a convenient forum; and (iii) agrees not to assert (by way of motion, as a defense or otherwise), in any such Legal Proceeding commenced in any state or federal court located in the State of Iowa, any claim that such party is not subject personally to the jurisdiction of such court, that such Legal Proceeding has been brought in an inconvenient forum, that the venue of such proceeding is improper or that this Agreement or the subject matter of this Agreement may not be enforced in or by such court.

(c) *Indemnification Claims.* Any claim for indemnification, compensation or reimbursement pursuant to Section 7 (and, at the option of any Indemnatee, any other claim for a monetary remedy, such as in the case of a claim based upon intentional misconduct, intentional misrepresentation or fraud, relating to this Agreement or the Transaction after the Closing) shall be brought and resolved exclusively in accordance with *Exhibit D* (it being understood that, for the avoidance of doubt and without limiting any portion of Section 8.7(b): (i) at the option of any Indemnatee, any claim based upon Fraud may be brought and resolved in accordance with Section 8.7(b) rather than in accordance with *Exhibit D*; and (ii) nothing in this Section 8.7(c) shall prevent Parent from seeking preliminary injunctive relief from a court of competent jurisdiction).

**8.8 Successors and Assigns.** This Agreement shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors and assigns. Parent may freely assign any or all of its rights under this Agreement (including its indemnification rights under Section 5), in whole or in part, to any other Person without obtaining the consent or approval of any other party hereto or of any other Person. The Company may not assign its rights under this Agreement without the consent of Parent.

**8.9 Remedies Cumulative; Specific Performance.** The rights and remedies of the parties hereto shall be cumulative (and not alternative). The parties to this Agreement agree that, in the event of any breach or threatened breach by any party to this Agreement of any covenant, obligation or other provision set forth in this Agreement, for the benefit of any other party to this Agreement: (a) such other party shall be entitled (in addition to any other remedy that may be available to it) to: (i) a decree or order of specific performance or mandamus to enforce the observance and performance of such covenant, obligation or other provision; and (ii) an injunction restraining such breach or threatened breach; and (b) such other party shall not be required to provide any bond or other security in connection with any such decree, order or injunction or in connection with any related action or Legal Proceeding; *provided*, however, that nothing in this Section 8.9 shall be construed to create a right or remedy that would result in the violation of a fiduciary duty by a director or officer of the Company.

**8.10 Waiver.** No failure on the part of any Person to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Person in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy. No Person shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Person; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

**8.11 Waiver of Jury Trial.** To the maximum extent permitted by law, each of the parties hereto hereby irrevocably waives any and all right to trial by jury in any Legal Proceeding arising out of or related to this Agreement or the transactions contemplated hereby.

**8.12 Amendments.** Except as otherwise required by applicable Law after the Company Holders approve the Merger, this Agreement may not be amended, modified, altered or supplemented other than by means of a written instrument duly executed and delivered on behalf of all the parties hereto.

**8.13 Severability.** In the event that any provision of this Agreement, or the application of any such provision to any Person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to Persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, shall not be impaired or otherwise affected and shall continue to be valid and enforceable to the fullest extent permitted by law.

**8.14 Parties in Interest.** Except for the provisions of Section 7, none of the provisions of this Agreement is intended to provide any rights or remedies to any Person other than the parties hereto and their respective successors and assigns (if any).

**8.15 Entire Agreement.** This Agreement and the other agreements referred to herein set forth the entire understanding of the parties hereto relating to the subject matter hereof and thereof and supersede all prior agreements and understandings among or between any of the parties relating to the subject matter hereof and thereof.

**8.16 Construction.**

(a) *Gender, Etc.* For purposes of this Agreement, whenever the context requires: the singular number shall include the plural and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include the masculine and feminine genders.



(b) *Ambiguities.* The parties hereto agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement.

(c) *Including.* As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(d) *References.* Except as otherwise indicated, all references in this Agreement to "Sections," "Schedules" and "Exhibits" are intended to refer to Sections of this Agreement and Schedules and Exhibits to this Agreement.

*[Remainder of page intentionally left blank]*

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered as of the date first set forth above.

**NEWLINK GENETICS CORPORATION,**  
a Delaware corporation

By: /s/ Gordon Link  
\_\_\_\_\_

Name: Gordon Link  
Title: CFO

**BPS MERGER SUB, INC.,**  
a Delaware corporation

By: /s/ Gordon Link  
\_\_\_\_\_

Name: Gordon Link  
Title:

**BIOPROTECTION SYSTEMS CORPORATION,**  
a Delaware corporation

By: /s/ Carl Langren  
\_\_\_\_\_

Name: Carl Langren  
Title: CFO

**BPS STOCKHOLDER REPRESENTATIVE, LLC,**  
as the Representative

By: /s/ Thomas A. Raffin  
\_\_\_\_\_

Name: Thomas A. Raffin  
Title: Manager

By: /s/ Steve Stahly  
\_\_\_\_\_

Name: Steve Stahly  
Title: Manager

**AGREEMENT AND PLAN OF MERGER SIGNATURE PAGE**

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EXHIBIT A

CERTAIN DEFINITIONS

For purposes of the Agreement (including this Exhibit A and the Company Disclosure Schedule):

**Affiliate.** "Affiliate," when used with reference to any Person, means another Person that directly or indirectly, through one or more intermediaries, Controls, is Controlled by, or is under common Control with such first Person.

**Agreement.** "Agreement" shall mean the Agreement and Plan of Merger which this Exhibit A is attached (including the Disclosure Schedule), as it may be amended from time to time.

**Basis.** "Basis" means any past or present fact, situation, circumstance, status, condition, activity, practice, plan, occurrence, event, incident, action, failure to act or transaction that could form the basis for any specific consequence.

**COBRA.** "COBRA" shall mean the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

**Code.** "Code" shall mean the Internal Revenue Code of 1986, as amended.

**Company Capital Stock.** "Company Capital Stock" shall mean the Company Series A Common Stock, Company Series B Common Stock, Company Series A Preferred Stock and Company Series B Preferred Stock, collectively.

**Company Common Stock.** "Company Common Stock" shall mean the Company Series A Common Stock and Company Series B Common Stock, collectively.

**Company Contract.** "Company Contract" shall mean any Contract: (a) to which the Company is a party; (b) by which the Company or any of its assets is or may become bound or under which the Company has, or may become subject to, any obligation; or (c) under which the Company has or may acquire any right or interest.

**Company Employee.** "Company Employee" shall mean any current or former employee, consultant, independent contractor or director of the Company or any of its Affiliates.

**Company Employee Agreement.** "Company Employee Agreement" shall mean any management, employment, severance, change in control, transaction bonus, consulting, relocation, repatriation or expatriation agreement or other Contract between the Company or any of its Affiliates and any Company Employee, other than any such Contract that is terminable "at will" and without any obligation on the part of the Company or any of its Affiliates to make any payments or provide any benefits in connection with termination of such Contract.

**Company Employee Plan.** "Company Employee Plan" shall mean any plan, program, policy, practice, Contract or other arrangement providing for compensation, severance, termination pay, deferred compensation, performance awards, stock or stock-related awards, fringe benefits or other employee benefits or remuneration of any kind, whether written, unwritten or otherwise, and whether funded or unfunded, including each "employee benefit plan," within the meaning of Section 3(3) of ERISA (whether or not ERISA is applicable to such plan), that is or has been maintained, contributed to or required to be contributed to by the Company or any of its Affiliates for the benefit of any Company Employee, or with respect to which the Company or any of its Affiliates has or may have any liability or obligation; *provided, however*, that a Company Employee Agreement shall not be considered an "Company Employee Plan."

**Company Financing Agreements.** "Company Financing Agreements" means the Amended and Restated Investor Rights Agreement and Amended and Restated Stockholders Agreement, each among the Company and the other parties named therein.

**Company Holder.** "Company Holder" shall mean any holder of record of the Company's Capital Stock.

**Company IP.** "Company IP" shall mean (a) all Intellectual Property Rights in or pertaining to the Company Products or methods or processes used to manufacture the Company Products, and (b) all other Intellectual Property Rights owned by or exclusively licensed to the Company.

**Company IP Contract.** "Company IP Contract" shall mean any Contract to which the Company is a party or by which the Company is bound, that contains any assignment or license of, or covenant not to assert or enforce, any Intellectual Property Right or that otherwise relates to any Company IP or any Intellectual Property developed by, with, or for the Company.

**Company Option.** "Company Option" shall mean a subscription, option, call, warrant, or right of any kind to acquire any shares of Company Capital Stock, whether vested or unvested.

**Company Option Plan.** "Company Option Plan" shall mean the Company's 2006 Equity Incentive Plan.

**Company Pension Plan.** "Company Pension Plan" shall mean any (a) Company Employee Plan that is an "employee pension benefit plan," within the meaning of Section 3(2) of ERISA, or (b) other occupational pension plan, including any final salary or money purchase plan.

**Company Preferred Stock.** "Company Preferred Stock" shall mean the Company Series A Preferred Stock and Company Series B Preferred Stock, collectively.

**Company Product.** "Company Product" shall mean any product or service designed, developed, manufactured, marketed, distributed, provided, licensed, or sold at any time by the Company.

**Company Series A Common Stock.** "Company Series A Common Stock" shall mean the Company's Series A Common Stock, par value \$0.01 per share.

**Company Series B Common Stock.** "Company Series B Common Stock" shall mean the Company's Series B Common Stock, par value \$0.01 per share.

**Company Series A Preferred Stock.** "Company Series A Preferred Stock" shall mean the Company's Series A Preferred Stock, par value \$0.01 per share.

**Company Series B Preferred Stock.** "Company Series B Preferred Stock" shall mean the Company's Series A Preferred Stock, par value \$0.01 per share.

**Company Stockholder.** "Company Stockholder" shall mean any holder of record of the Company's Capital Stock, excluding Parent.

**Consent.** "Consent" shall mean any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

**Contract.** "Contract" shall mean any written, oral or other agreement, contract, subcontract, lease, understanding, instrument, note, certificate, warranty, proxy, insurance policy, benefit plan or legally binding commitment, arrangement or undertaking of any nature.

**Cornerstone Agreement.** "Cornerstone Agreement" shall mean that certain Consulting Agreement, dated as of August 1, 2007, between Cornerstone Government Affairs LLC and the

Company, as such agreement may be amended or extended in writing or otherwise, including any new agreement that may be entered into by the Company or the Surviving Corporation (whether before or after the Effective Time) with Cornerstone Government Affairs LLC (or any affiliated entity) (together, "Cornerstone").

**Current Parent Executive.** "Current Parent Executive" shall mean (a) any individual who is an officer or director of Parent on the date hereof but who is not an officer or director of the Company on the date hereof; and (b) Carl Langren.

**Damages.** "Damages" shall include any loss, damage, injury, decline in value, settlement, judgment, award, fine, lost profits, penalty, Tax, fee (including reasonable attorneys' fees), charge, cost (including costs of investigation) or expense of any nature.

**Disclosure Schedule.** "Disclosure Schedule" means the Disclosure Schedule dated as of the date hereof and delivered by the Company to Parent.

**DOL.** "DOL" shall mean the United States Department of Labor.

**Encumbrance.** "Encumbrance" shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, claim or restriction of any nature.

**Entity.** "Entity" shall mean any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any limited liability company or joint stock company), firm or other enterprise, association, organization or entity.

**Environmental Law.** "Environmental Law" shall mean any applicable federal, state, local or foreign Legal Requirement relating to pollution or protection of worker health or safety (with respect to exposure to Materials of Environmental Concern) or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any Legal Requirement relating to emissions, discharges, releases or threatened releases of Materials of Environmental Concern, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Materials of Environmental Concern.

**ERISA.** "ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended.

**Expiration Date.** "Expiration Date" shall mean the earlier of: (i) June 30, 2011 or (ii) the expiration, termination or waiver of the lock-up agreements required of holders of Parent Common Stock.

**FMLA.** "FMLA" shall mean the Family Medical Leave Act of 1993, as amended.

**GAAP.** "GAAP" shall mean generally accepted accounting principles in the United States.

**Governmental Authorization.** "Governmental Authorization" shall mean any: (a) permit, license, certificate, franchise, permission, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Legal Requirement; or (b) right under any Contract with any Governmental Body.

**Governmental Body.** "Governmental Body" shall mean any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, instrumentality, official,

organization, unit, body or Entity and any court or other tribunal); or (d) self-regulatory organization (including the NASD).

**HIPAA.** "HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996, as amended.

**Holdback Amount.** "Holdback Amount" means the *product* of (a) 0.20 *multiplied* by (b) the number of shares of Series E Stock issuable to the Company Stockholders pursuant to Section 1.5.

**Holdback Contribution Amount.** "Holdback Contribution Amount" means, with respect to each Company Stockholder, the *quotient* of (a) the number of shares of Series E Stock issuable to such Person pursuant to Section 1.5 *divided* by (b) the Merger Consideration payable to all Company Stockholders.

**Indemnitees.** "Indemnitees" shall mean the following Persons: (a) Parent; (b) Parent's current and future affiliates (including the Surviving Corporation); (c) the respective officers, directors, employees, agents, attorneys, accountants and advisors of the Persons referred to in clauses "(a)" and "(b)" above; and (d) the respective successors and assigns of the Persons referred to in clauses "(a)", "(b)" and "(c)" above; *provided, however*, that no securityholder of the Company shall be deemed to be an "Indemnitee."

**Intellectual Property.** "Intellectual Property" shall mean and include all algorithms, application programming interfaces, apparatus, assay components, biological materials, cell lines, clinical data, chemical compositions or structures, circuit designs and assemblies, databases and data collections, diagrams, formulae, gate arrays, IP cores, inventions (whether or not patentable), know-how, logos, marks (including brand names, product names, logos, and slogans), methods, network configurations and architectures, net lists, photomasks, processes, proprietary information, protocols, schematics, specifications, software, software code (in any form including source code and executable or object code), subroutines, test results, test vectors, user interfaces, techniques, URLs, web sites, works of authorship, and other forms of technology (whether or not embodied in any tangible form and including all tangible embodiments of the foregoing such as instruction manuals, laboratory notebooks, prototypes, samples, studies, and summaries).

**Intellectual Property Rights.** "Intellectual Property Rights" shall mean and include all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights, and mask works; (b) trademark and trade name rights and similar rights; (c) trade secret rights; (d) patents and industrial property rights; (e) other proprietary rights in Intellectual Property of every kind and nature; and (f) all registrations, renewals, extensions, continuations, divisions, or reissues of, and applications for, any of the rights referred to in clauses (a) through (e) above.

**IRS.** "IRS" shall mean the United States Internal Revenue Service.

**Knowledge.** An individual shall be deemed to have "Knowledge" of a particular fact or other matter if: (a) such individual is actually aware of such fact or other matter; or (b) a prudent individual could be expected to discover or otherwise become aware of such fact or other matter in the course of conducting a commercially reasonable investigation concerning the truth or existence of such fact or other matter. The Company shall be deemed to have "Knowledge" of a particular fact or other matter if any director or officer of the Company (who is not a Current Parent Executive, except Carl Langren) or any employee who reports directly to an officer of the Company has Knowledge of such fact or other matter.

**Law.** "Law" means the law of any jurisdiction, whether international, multilateral, multinational, national, federal, state, provincial, local or common law, an Order or act, statute, ordinance, regulation, rule, collective bargaining agreement, extension order or code promulgated by a Governmental Body.

**Legal Proceeding.** "Legal Proceeding" shall mean any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Body or any arbitrator or arbitration panel.

**Legal Requirement.** "Legal Requirement" shall mean any federal, state, local, municipal, foreign or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, order, award, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body.

**Liability.** "Liability" shall mean any debt, obligation, duty or liability of any nature (including any unknown, undisclosed, unmaturred, unaccrued, unasserted, contingent, indirect, conditional, implied, vicarious, derivative, joint, several or secondary liability), regardless of whether such debt, obligation, duty or liability would be required to be disclosed on a balance sheet prepared in accordance with GAAP and regardless of whether such debt, obligation, duty or liability is immediately due and payable.

**Material Adverse Effect.** "Material Adverse Effect" shall mean any change, event, effect, claim, circumstance or matter (each, an "Effect") that (considered together with all other Effects) is, or could reasonably be expected to be or to become, materially adverse to the business, condition, assets, capitalization, Company Intellectual Property, Liabilities, operations, results of operations, financial performance or prospects of the Company, taken as a whole, or the ability of such Person to perform its obligations hereunder or to consummate the Merger.

**Materials of Environmental Concern.** "Materials of Environmental Concern" include chemicals, pollutants, contaminants, wastes, toxic substances, petroleum and petroleum products and any other substance that is now regulated by any Environmental Law.

**Merger Consideration.** "Merger Consideration" shall mean, with respect to a Company Stockholder and holder of Company Options, the consideration that such Person is entitled to receive pursuant to Section 1.5 or Section 1.7 in exchange for such Person's shares of Company Capital Stock or Company Options.

**Order.** "Order" shall mean any order, writ, injunction, judgment or decree.

**Option Exchange Ratio.** "Option Exchange Ratio" means a fraction, the numerator of which is \$1.058 and the denominator of which is the fair market value of one share of Parent Common Stock, which will be determined as soon as practicable after the Effective Time by the Parent Common Stock Appraisal.

**Parent Common Stock.** "Parent Common Stock" shall mean the common stock, par value \$0.01 per share, of Parent.

**Parent Common Stock Appraisal.** "Parent Common Stock Appraisal" means an independent appraisal (satisfactory to Parent in Parent's sole and absolute discretion) of Parent's Common Stock dated as of September 30, 2010.

**Parent Equity Plan.** "Parent Equity Plan" means Parent's 2009 Equity Incentive Plan, as amended and restated.

**Parent Financing Agreements.** "Parent Financing Agreements" means the amended and restated investor rights agreement and amended and restated stockholders agreement of Parent.

**Parent Options.** "Parent Options" means stock options to be granted pursuant to the Parent Equity Plan.

**Parent Series E Stock.** "Parent Series E Stock" shall mean the Series E Preferred Stock, par value \$0.01 per share, of Parent; *provided, that*, in the event that the Parent Series E Stock has been converted into Parent Common Stock, all references to Parent Series E Stock shall be deemed to refer to the equivalent number of shares of Parent Common Stock as were or would have been issued upon conversion of such Parent Series E Stock.

**PBGC.** "PBGC" shall mean the United States Pension Benefit Guaranty Corporation.

**Person.** "Person" shall mean any individual, Entity or Governmental Body.

**Registered IP.** "Registered IP" shall mean all Intellectual Property Rights that are registered, filed, or issued under the authority of any Governmental Body, including all patents, registered copyrights, registered mask works, and registered trademarks and all applications for any of the foregoing.

**SEC.** "SEC" shall mean the United States Securities and Exchange Commission.

**Securities Act.** "Securities Act" shall mean the Securities Act of 1933, as amended.

**Subsidiary.** An Entity shall be deemed to be a "Subsidiary" of another Person if such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities of other interests in such Entity that is sufficient to enable such Person to elect a majority of the members of such Entity's board of directors or other governing body or (b) a majority of the outstanding equity or financial interests of such Entity.

**Tax.** "Tax" shall mean any federal, state, local, foreign or other tax (including any income tax, franchise tax, capital gains tax, gross receipts tax, value-added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, withholding tax or payroll tax), levy, assessment, tariff, duty (including any customs duty), deficiency or fee, and any related charge or amount (including any fine, penalty or interest), imposed, assessed or collected by or under the authority of any Governmental Body.

**Tax Return.** "Tax Return" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information, and any amendment to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Legal Requirement relating to any Tax.



**EXHIBIT B**

**FORM OF WRITTEN CONSENT**

MAJORITY WRITTEN CONSENT OF THE  
CAPITAL STOCKHOLDERS OF  
BIOPROTECTION SYSTEMS CORPORATION

The undersigned, being the holders of a majority of the shares entitled to vote of the Series A Common Stock, Series B Common Stock, Series A Preferred Stock and Series B Preferred Stock (collectively, the "*Capital Stockholders*"), voting as one class on an as-converted basis, of BioProtection Systems Corporation, a Delaware corporation (the "*Company*"), acting pursuant to Section 228 and any other applicable provisions of the Delaware General Corporation Law, do hereby waive all notice of the time, place and purpose of a meeting of the Capital Stockholders and do hereby consent to the adoption of, and do hereby adopt, the following resolutions:

WHEREAS, the board of directors of the Company (the "*Board*") approved and unanimously recommended that the stockholders approve a merger of the Company with a wholly owned subsidiary of NewLink Genetics Corporation, a Delaware corporation ("*NewLink*"), pursuant to which the stockholders of the Company will receive shares of Series E Preferred Stock of NewLink in exchange for their shares of capital stock of the Company (the "*Merger*");

WHEREAS, the proposed terms of the Merger are set forth in that certain draft Agreement and Plan of Merger (the "*Merger Agreement*"), among the Company, NewLink, BPS Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of NewLink, and BPS Stockholder Representative, LLC as the Stockholders' Representative, a copy of which is attached hereto as *Exhibit A* and the principal terms of which are described in the Information Statement dated November 19, 2010, attached hereto as *Exhibit B*;

WHEREAS, pursuant to Section 7 of the Merger Agreement, the Capital Stockholders other than NewLink will be obligated to indemnify NewLink, NewLink's affiliates and certain other related persons, such as NewLink's officers and directors, for costs and damages specified in the Merger Agreement in an amount up to 20% of the consideration to be paid to such Capital Stockholders, which amount will be withheld until such indemnification obligation expires, and which costs and damages generally include costs and damages resulting from (i) a Capital Stockholder's exercise of dissenter's rights under Delaware law, (ii) breaches by the Company of its representations, warranties, covenants or obligations and (iii) legal proceedings related to such matters (the "*Indemnity Obligation*");

WHEREAS, the Merger must be approved by the holders of at least a majority of the outstanding shares of (i) Series A Common Stock, Series B Common Stock, Series A Preferred Stock and Series B Preferred Stock, voting together as a single class on an as-converted basis; and (ii) Series A Preferred Stock and Series B Preferred Stock, voting together as a single class on an as-converted basis;

WHEREAS, pursuant to the Third Amended and Restated Certificate of Incorporation of the Company (the "*Articles*"), the holders of Series A Common Stock are entitled to cast the number of votes equal to the number of shares of Series B Common Stock into which a share of Series A Common Stock is then convertible;

WHEREAS, pursuant to the Articles, the holders of the Series A Preferred Stock are entitled to cast the number of votes equal to the number of shares of Series B Common Stock into which a share of Series A Preferred Stock is then convertible;

WHEREAS, pursuant to the Articles, the holders of the Series B Preferred Stock are entitled to cast the number of votes equal to the number of shares of Series B Common Stock into which a share of Series B Preferred Stock is then convertible;

**NOW, THEREFORE, BE IT RESOLVED, that the Merger and the Merger Agreement, including the Indemnity Obligation, be and they hereby are adopted and approved in substantially the form previously furnished to the undersigned;**

**FURTHER RESOLVED, that the appropriate officers of the Company be and they hereby are authorized and empowered to cause a certificate of merger, in substantially the form attached hereto as *Exhibit C*, to be filed with the Secretary of State of Delaware and to do all acts and things whatsoever, whether within or without the State of Delaware, which may be in anywise necessary or proper to effect said merger;**

**FURTHER RESOLVED, BPS Stockholder Representative, LLC, pursuant to the terms of the Merger Agreement be, and he hereby is, appointed as the Representative, as that term is defined in the Merger Agreement, to pursue and resolve all claims and remedies on behalf of the shareholders in accordance with the terms of the Merger Agreement.**

**FURTHER RESOLVED, that each of the BioProtection Systems Corporation Amended and Restated Stockholders Agreement and the BioProtection Systems Corporation Amended and Restated Investor Rights Agreement shall terminate immediately prior to Closing (as that term is defined in the Merger Agreement);**

**FURTHER RESOLVED, that the appropriate officers of the Company be and they hereby are authorized and empowered, in the name and on behalf of the Company, to take such additional action and to execute and deliver such additional agreements, documents and instruments as any of them may deem necessary or appropriate to implement the provisions of the foregoing resolutions, the authority for the taking of such action and the execution and delivery of such agreements, documents and instruments to be conclusively evidenced thereby;**

**FURTHER RESOLVED, that all actions heretofore taken by the officers of the Company in furtherance of the foregoing resolutions or as otherwise taken prior to the date hereof be and they hereby are ratified, confirmed and approved in all respects; and**

**FURTHER RESOLVED, that any officer of the Company be and each hereby is authorized and may certify that this consent has been duly adopted, is in full force and effect and is in accordance with the provisions of the Articles and the Bylaws of the Company.**

This consent may be signed in one or more counterparts, all of which together shall constitute one and the same consent. This consent shall be filed with the minutes of the Company.

DATED: \_\_\_\_\_, 2010

CAPITAL STOCKHOLDER:

\_\_\_\_\_  
*[Print Name]*

\_\_\_\_\_  
*[Signature]*

\_\_\_\_\_  
*[Title, if applicable]*

**CAPITAL STOCKHOLDER CONSENT  
SIGNATURE PAGE**

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**MAJORITY WRITTEN CONSENT OF THE  
PREFERRED STOCKHOLDERS OF  
BIOPROTECTION SYSTEMS CORPORATION**

The undersigned, being the holders of a majority of the shares entitled to vote of the Series A Preferred Stock and the Series B Preferred Stock (collectively, the "*Preferred Stockholders*"), voting as one class on an as-converted basis, of BioProtection Systems Corporation, a Delaware corporation (the "*Company*"), acting pursuant to Section 228 and any other applicable provisions of the Delaware General Corporation Law, do hereby waive all notice of the time, place and purpose of a meeting of the Preferred Stockholders and do hereby consent to the adoption of, and do hereby adopt, the following resolutions:

WHEREAS, the board of directors of the Company (the "*Board*") approved and unanimously recommended that the stockholders approve a merger of the Company with a wholly owned subsidiary of NewLink Genetics Corporation, a Delaware corporation ("*NewLink*"), pursuant to which the stockholders of the Company will receive shares of Series E Preferred Stock of New Link in exchange for their shares of capital stock of the Company (the "*Merger*");

WHEREAS, the proposed terms of the Merger are set forth in that certain draft Agreement and Plan of Merger (the "*Merger Agreement*"), among the Company, NewLink, BPS Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of NewLink, and BPS Stockholder Representative, LLC as the Stockholders' Representative, a copy of which is attached hereto as *Exhibit A* and the principal terms of which are described in the Information Statement dated November 19, 2010, attached hereto as *Exhibit B*;

WHEREAS, pursuant to Section 7 of the Merger Agreement, the Preferred Stockholders other than NewLink will be obligated to indemnify NewLink, NewLink's affiliates and certain other related persons, such as NewLink's officers and directors, for costs and damages specified in the Merger Agreement in an amount up to 20% of the consideration to be paid to such Preferred Stockholders, which amount will be withheld until such indemnification obligation expires, and which costs and damages generally include costs and damages resulting from (i) a Preferred Stockholder's exercise of dissenter's rights under Delaware law, (ii) breaches by the Company of its representations, warranties, covenants or obligations and (iii) legal proceedings related to such matters (the "*Indemnity Obligation*");

WHEREAS, the Merger must be approved by the holders of at least a majority of the outstanding shares of (i) Series A Common Stock, Series B Common Stock, Series A Preferred Stock and Series B Preferred Stock, voting together as a single class on an as-converted basis; and (ii) Series A Preferred Stock and Series B Preferred Stock, voting together as a single class on an as-converted basis;

WHEREAS, pursuant to the Third Amended and Restated Certificate of Incorporation of the Company (the "*Articles*"), the holders of the Series A Preferred Stock are entitled to cast the number of votes equal to the number of shares of Series B Common Stock into which a share of Series A Preferred Stock is then convertible;

WHEREAS, pursuant to the Articles, the holders of the Series B Preferred Stock are entitled to cast the number of votes equal to the number of shares of Series B Common Stock into which a share of Series B Preferred Stock is then convertible;

NOW, THEREFORE, BE IT RESOLVED, that the Merger and the Merger Agreement, including the Indemnity Obligation, be and they hereby are adopted and approved in substantially the form previously furnished to the undersigned;

FURTHER RESOLVED, that the appropriate officers of the Company be and they hereby are authorized and empowered to cause a certificate of merger, in substantially the form attached hereto as *Exhibit C*, to be filed with the Secretary of State of Delaware and to do all acts and

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things whatsoever, whether within or without the State of Delaware, which may be in anywise necessary or proper to effect said merger;

**FURTHER RESOLVED**, that the appropriate officers of the Company be and they hereby are authorized and empowered, in the name and on behalf of the Company, to take such additional action and to execute and deliver such additional agreements, documents and instruments as any of them may deem necessary or appropriate to implement the provisions of the foregoing resolutions, the authority for the taking of such action and the execution and delivery of such agreements, documents and instruments to be conclusively evidenced thereby;

**FURTHER RESOLVED**, that all actions heretofore taken by the officers of the Company in furtherance of the foregoing resolutions or as otherwise taken prior to the date hereof be and they hereby are ratified, confirmed and approved in all respects; and

**FURTHER RESOLVED**, that any officer of the Company be and each hereby is authorized and may certify that this consent has been duly adopted, is in full force and effect and is in accordance with the provisions of the Articles and the Bylaws of the Company.

This consent may be signed in one or more counterparts, all of which together shall constitute one and the same consent. This consent shall be filed with the minutes of the Company.

DATED: \_\_\_\_\_, 2010

PREFERRED STOCKHOLDER:

\_\_\_\_\_  
*[Print Name]*

\_\_\_\_\_  
*[Signature]*

\_\_\_\_\_  
*[Title, if applicable]*

**PREFERRED STOCKHOLDER CONSENT  
SIGNATURE PAGE**

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EXHIBIT C

REDEMPTION AGREEMENT

THIS REDEMPTION AGREEMENT (the "Agreement") is made as of this [ ] day of [ ], 2010, by and between BioProtection Systems Corporation, a Delaware corporation (the "Company"), and [Stockholder's printed name] (the "Stockholder").

RECITALS:

A. The Company has entered into an Agreement and Plan of Merger (the "Merger Agreement"), with NewLink Genetics Corporation, a Delaware corporation ("Parent"), BPS Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"), and the other parties named therein, pursuant to which Merger Sub will merge with and into the Company (the "Merger") and as a result of the Merger, the Company will become a wholly owned subsidiary of Parent;

B. the Stockholder is the record owner of [insert number of shares] shares of \$0.01 par value Company Series B Common Stock (as such term is defined in the Merger Agreement) (the "Shares");

C. the Company proposes to redeem from the Stockholder all of the Shares owned by such Stockholder (the "Redemption") at a purchase price equal to \$ per share;

D. the board of directors of the Company has determined that the Redemption is in the best interests of the Company; and

E. the Company has requested, as a condition to the Redemption, that the Stockholder execute and deliver this Agreement.

NOW, THEREFORE, in consideration of the foregoing, the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE I

PURCHASE AND SALE OF SHARES

Section 1.1 *Repurchase of Shares.* Stockholder agrees to sell, transfer and convey to the Company, and the Company agrees to purchase from Stockholder, the Shares at a price per share of \$ , for an aggregate purchase price of \$ (the "Purchase Price"). As a condition to the obligations of the Company to consummate the Redemption, on the date hereof, the Stockholder shall deliver to the Company (i) a Stock Assignment Separate from Certificate, in the form attached hereto as Exhibit A, and (ii) the original stock certificate for the Shares (or a loss affidavit in a form acceptable to the Company). The closing of the Redemption under this Agreement (the "Closing") shall occur at a time and place designated by the Company. At the Closing, the Company shall deliver the Purchase Price to the Stockholder. This Agreement shall become null and void and of no further force and effect if the Company notifies Stockholder that it has determined not to proceed with the Redemption.

ARTICLE II

SELLER'S REPRESENTATIONS AND WARRANTIES

The Stockholder represents, warrants and covenants to the Company that the following statements are true and correct upon execution of this Agreement and at all times through the Closing:

Section 2.1 *Authority.* The Stockholder has the legal capacity and all other power and authority necessary to execute, deliver and perform his, her or its obligations under, and to consummate the transactions contemplated by, this Agreement. This Agreement has been duly executed and delivered by the Stockholder, and this Agreement is, and each of the other related documents when executed and

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delivered will be, a legal, valid and binding obligation of the Stockholder enforceable against the Stockholder in accordance with its terms, except as enforceability may be limited by applicable principles of equity and insolvency laws.

**Section 2.2 *No Conflicts.*** The execution and delivery of this Agreement by Stockholder and the consummation of the transactions contemplated hereby: (i) will not conflict or violate any court order, judgment or decree applicable to the Stockholder or by which the property of Stockholder is bound or affected, (ii) will not conflict with or result in any breach of or constitute a default under any contract or agreement to which Stockholder is a party or by which Stockholder or Stockholder's property is bound or affected, which conflict, violation, breach or default would adversely affect Stockholder's ability to perform Stockholder's obligations hereunder, and (iii) do not and will not require any consent or other action by any third party under any provision of any agreement, contract or other instrument binding on Stockholder.

**Section 2.3 *Title.*** Stockholder has good and valid title to the Shares, and upon payment of the Purchase Price for the Shares, in accordance with the terms hereof, the Company will acquire good and valid title to the Shares, free and clear of any liens, encumbrances, equities and claims.

**Section 2.4 *Waiver.*** At the Closing, all of Stockholder's right, title and interest in and to the Shares shall terminate, and Stockholder thereafter relinquishes and waives any and all rights and benefits it previously had with respect to the Shares, except for the right to receive the Purchase Price for the Shares in accordance with the terms of this Agreement.

**Section 2.5 *Adequate Opportunity; Independent Counsel.*** The Stockholder has received a copy of an information statement dated [ ] that contains information about the proposed Merger and includes a copy of the Merger Agreement. Stockholder acknowledges and understands that by entering into this Agreement and accepting the Redemption, Stockholder is foregoing participation in the Merger and will not receive the securities of Parent being offered as consideration to Merger participants. Stockholder has had adequate opportunity to discuss the terms of the Merger, as well as the Company's and Parent's business, management and financial affairs with the Company's management and to obtain any additional information necessary to assess the value of the Shares and the Stockholder's decision to sell the Shares, verify the accuracy of the information provided to the Stockholder and such other information as it considers necessary or appropriate to evaluate the merits and risks of engaging in the transactions contemplated hereby. Stockholder has been provided with an adequate opportunity to consult with Stockholder's own counsel with respect to this Agreement.

### ARTICLE III

#### MISCELLANEOUS

**Section 3.1 *Notices.*** Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or upon deposit in any United States Post Office Box, by registered or certified mail with postage and fees prepaid, addressed to the other party hereto at his address hereinafter shown below his or its signature or at such other address as such party may designate by ten (10) days' advance written notice to the other party hereto.

**Section 3.2 *Governing Law.*** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware as such laws are applied by Delaware courts to contracts made and to be performed entirely in Delaware by residents of that State. The parties agree that the courts sitting in Iowa shall have the exclusive jurisdiction over them for purposes of any actions arising out of or as a result of this Agreement.

**Section 3.3 *Further Assurances.*** The parties agree to execute such further instruments and to take such further action as reasonably may be necessary to carry out the intent of this Agreement.

**Section 3.4 Successors and Assigns.** This Agreement shall bind and inure to the benefit of the successors and assigns of the Company and, subject to the restrictions on transfer herein set forth, inure to the benefit of and be binding upon Stockholder, his heirs, executors, administrators, successors, and assigns.

**Section 3.5 No Representation as to Fair Market Value.** The Company makes no representation as to the fair market value of the Shares. Stockholder recognizes and acknowledges that (a) Stockholder has made his/her/its own determination as to the adequacy of the price being offered and has not relied on any assessment of the adequacy of the offer price by the Company or any officer or representative of the Company; (b) the purchase price for the Shares has been negotiated in good faith and at arms length; (c) future events, including a possible initial public offering of the securities of Parent into which the securities being offered as consideration in the Merger are convertible, could cause the value of the securities being offered as Merger consideration to increase substantially; and (d) Stockholder will receive cash for the Shares and will have no right to participate in any such increase in the value of Parent securities.

**Section 3.6 Entire Agreement.** This Agreement and the other documents delivered hereto constitute the entire agreement between the parties with respect to the subject matter hereof and supersedes and merges all prior agreements or understandings, whether written or oral. This Agreement may be modified only by an agreement in writing signed by the parties. This Agreement shall automatically terminate and be of no force or effect in the event the Merger Agreement is terminated prior to Closing (as such term is defined in the Merger Agreement).

**Section 3.7 Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable law. If any provision of this Agreement shall be unenforceable or invalid under applicable law, the provision shall be ineffective only to the extent necessary to render the remaining portion of this Agreement binding and enforceable except to the extent that the unenforceable or invalid provision materially impacts the intent of the parties hereunder.

**Section 3.8 Waiver of Breach.** No waiver of a breach of any provision of this Agreement by any party shall be effective unless made expressly in writing and no such waiver shall constitute or be construed as a waiver by such party of any future breach of the same or any other provisions of this Agreement.

**Section 3.9 Counterparts.** This Agreement may be executed and delivered in two or more counterparts, each of which shall be an original document and all of which together shall constitute a single binding agreement.

**Section 3.10 No Attorney-Client Relationship with Company Counsel.** Stockholder acknowledges that this Agreement has been prepared on behalf of the Company by counsel to the Company and that counsel to the Company does not represent, and is not acting on behalf of, Stockholder.

**Section 3.11 Attorneys' Fees; Specific Performance.** Stockholder shall reimburse the Company for all costs incurred by the Company in enforcing the performance of, or protecting its rights under, any part of this Agreement, including reasonable costs of investigation and attorneys' fees. Furthermore, it is expressly agreed between the parties that money damages are inadequate to compensate the Company for the Shares and that the Company shall be entitled to specific enforcement of its rights to purchase and receive said Shares.

**Section 3.12 Indemnity.** Stockholder agrees to indemnify and hold harmless the Company and its officers, directors, employees and agents from any and all claims, liabilities, demands, causes of action, attorneys' fees, damages or obligations of every kind and nature, arising from, and in connection with, the redemption of the Shares.

**Section 3.13 *Captions/Recitals.*** The captions and numbers of the various sections hereof are included for convenience of reference only and do not in any way affect the meaning or interpretation of the substantive provisions hereof. The recitals set forth above are hereby incorporated in and made a part of this Agreement by this reference.

**Section 3.14 *Survival of Representations and Warranties.*** All representations, warranties, covenants and agreements made by any party to this Agreement shall survive the execution, delivery and consummation of this Agreement.

#### ARTICLE IV

##### RELEASE OF ALL CLAIMS

**Section 4.1 *Release of All Claims.*** Stockholder, on behalf of itself, and its successors, assigns, heirs, executors, legatees, administrators, beneficiaries, representatives, agents and affiliates, hereby releases, acquits and forever discharges the Company, Parent and Merger Sub and each of their respective officers, directors, predecessors, successors and assigns, and the beneficiaries, heirs, executors, personal or legal representatives, insurers and attorneys of any of them from any and all claims, liabilities, demands, causes of action, costs, expenses, attorneys' fees, damages, indemnities and obligations of every kind and nature, in law, equity, or otherwise, known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to this Agreement, the Merger Agreement and the transactions contemplated by this Agreement and the Merger Agreement, other than the right to receive the aggregate Purchase Price payable hereunder in respect of the Shares upon the Closing.

**Section 4.2 *Covenant Not to Sue.*** To the maximum extent permitted by law, the Stockholder covenants not to sue or to institute or cause to be instituted any action based on claims released herein in any federal, state or local agency or court. In the event that either party brings a claim covered by this release or seeks to recover damages in any claim brought by a governmental agency on such party's behalf, this Agreement shall serve as a complete defense to such claims.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date set forth in the first paragraph above.

COMPANY:

SELLER:

BIOPROTECTION SYSTEMS CORPORATION, a  
Delaware corporation

\_\_\_\_\_  
*[Signature of Stockholder]*

Signed:

By: Charles Link  
Its: Chief Executive Officer

\_\_\_\_\_  
*[Print Name of Stockholder]*

Address:

Address:  
2901 South Loop Drive  
Suite 3360  
Ames, Iowa 50010

\_\_\_\_\_  
*[Social Security Number of Stockholder]*

EXHIBIT A

ASSIGNMENT SEPARATE FROM CERTIFICATE

FOR VALUE RECEIVED, I, *[Print Stockholder's Name]*, do hereby sell, assign and transfer unto BioProtection Systems Corporation, a Delaware corporation (the "Company"), *[Number of Shares sold]* shares of \$.01 par value Company Series B Common Stock (the "Shares") standing in my name on the books of the Company, represented by Certificate No.: *[Insert Certificate Numbers]*, together with any uncertificated Shares that I may own and wish to sell to the Company, and do hereby irrevocably designate [the Secretary of the Company], as attorney-in-fact, to transfer the Shares on the books and records of the Company and to cancel the Shares with full power of substitution in the premises.

Dated as of this [ ] day of [ ], 2010.

\_\_\_\_\_  
*[Stockholder's Signature]*

WITNESS:

\_\_\_\_\_  
*[Stockholder's Printed Name]*

\_\_\_\_\_  
*[Witness Signature]*

EXHIBIT D

DISPUTE RESOLUTIONS PROCEDURES

Subject to the provisions of Section 8.7(c) of the Agreement, any claim for indemnification, compensation or reimbursement pursuant to Section 7 of the Agreement (and, at the option of any Indemnitee, any other claim for a monetary remedy, such as in the case of a claim based upon Fraud, relating to the Agreement or the Merger after the Closing) shall be brought and resolved exclusively as follows:

(a) If any Indemnitee has or claims in good faith to have incurred or suffered Damages for which it is or may be entitled to indemnification, compensation or reimbursement under Section 7 of the Agreement or for which it is or may otherwise be entitled to a monetary remedy relating to the Agreement or the Merger, such Indemnitee may deliver a claim notice (a "Claim Notice") to the Representative. Each Claim Notice shall: (i) state that the Indemnitee believes in good faith that the Indemnitee is entitled to indemnification, compensation or reimbursement under Section 7 of the Agreement or is or may otherwise be entitled to a monetary remedy relating to the Agreement or the Transaction; (ii) contain a brief description of the facts and circumstances supporting the Indemnitee's claim; and (iii) contain a non-binding, preliminary, good faith estimate of the amount to which the Indemnitee claims to be entitled (the aggregate amount of such estimate, as it may be modified by the Indemnitee in good faith from time to time, being referred to as the "Claimed Amount").

(b) During the 20 day period commencing upon receipt by the Representative of a Claim Notice from an Indemnitee (the "Dispute Period"), the Representative may deliver to the Indemnitee a written response (the "Response Notice") in which the Representative: (i) agrees that the full Claimed Amount is owed to the Indemnitee; (ii) agrees that part, but not all, of the Claimed Amount is owed to the Indemnitee; or (iii) indicates that no part of the Claimed Amount is owed to the Indemnitee. If the Response Notice is delivered in accordance with clause "(ii)" or "(iii)" of the preceding sentence, the Response Notice shall also contain a brief description of the facts and circumstances supporting the Representative's claim that only a portion or no part of the Claimed Amount is owed to the Indemnitee, as the case may be (any part of the Claimed Amount that is not agreed to be owed to the Indemnitee pursuant to the Indemnitee's Claim Notice being referred to as the "Contested Amount"). If a Response Notice is not received by the Indemnitee from the Representative prior to the expiration of the Dispute Period, then the Representative shall be conclusively deemed to have agreed that an amount equal to the full Claimed Amount is owed to the Indemnitee.

(c) If the Representative in its Response Notice agrees that the full Claimed Amount is owed to the Indemnitee, the Representative shall include in such Response Notice the Representative's irrevocable written agreement that the full Claimed Amount (up to the amount of the Holdback Amount) may be retained by Parent from the Holdback Amount. If no Response Notice is received by the Indemnitee from the Representative prior to the expiration of the Dispute Period, it shall be conclusively agreed that Parent shall be entitled to retain the full Claimed Amount from the Holdback Amount.

(d) If the Representative in the Response Notice agrees that part, but not all, of the Claimed Amount is owed to the Indemnitee (the "Agreed Amount"), the Representative shall include in such Response Notice the Representative's irrevocable written agreement that the Agreed Amount may be retained by Parent from the Holdback Amount.

(e) If any Response Notice expressly indicates that there is a Contested Amount, the Representative and the Indemnitee shall attempt in good faith to resolve the dispute related to the Contested Amount. If the Representative and the Indemnitee resolve such dispute, such resolution

shall be binding on the Representative, the Indemnitors and such Indemnitee and a settlement agreement stipulating the amount owed to such Indemnitee (the "Stipulated Amount") shall be signed by such Indemnitee and the Representative. The Representative shall cause to be included in such settlement agreement its irrevocable written agreement that the Stipulated Amount may be retained by Parent from the Holdback Amount.

(f) In the event that there is a dispute relating to any Claim Notice or Contested Amount (whether it is a matter between the Indemnitee, on the one hand, and the Representative, on the other hand, or it is a matter that is subject to a claim or Legal Proceeding asserted or commenced by a third party brought against the Indemnitee or the Company in a litigation or arbitration), such dispute (an "Arbitrable Dispute") shall be settled by binding arbitration. Notwithstanding the preceding sentence, nothing in this Exhibit D shall prevent the Indemnitee from seeking preliminary injunctive relief from a court of competent jurisdiction pending settlement of any Arbitrable Dispute.

(i) Except as herein specifically stated, any Arbitrable Dispute shall be resolved by arbitration in Ames, Iowa in accordance with JAMS' Comprehensive Arbitration Rules and Procedures (the "JAMS Rules") then in effect. However, in all events, the provisions contained herein shall govern over any conflicting rules which may now or hereafter be contained in the JAMS Rules. Any judgment upon the award rendered by the arbitrator shall be entered in any court having jurisdiction over the subject matter thereof. The arbitrator shall have the authority to grant any equitable and legal remedies that would be available if any judicial proceeding was instituted to resolve an Arbitrable Dispute. The final decision of the arbitrator, as entered by a court of competent jurisdiction, will be furnished by the arbitrator to the Representative and the Indemnitee in writing and will constitute a final, conclusive and non-appealable determination of the issue in question, binding upon the Representative, the Indemnitors and the Indemnitee, and an order with respect thereto may be entered in any court of competent jurisdiction.

(ii) Any such arbitration will be conducted before a single arbitrator who will be compensated for his or her services at a rate to be determined by the Indemnitee and the Representative or by JAMS, but based upon reasonable hourly or daily consulting rates for the arbitrator in the event the parties are not able to agree upon his or her rate of compensation.

(iii) The arbitrator shall be mutually agreed upon by the Indemnitee and the Representative. In the event the Indemnitee and the Representative are unable to agree within 20 days following submission of the dispute to JAMS by one of the parties, JAMS will have the authority to select an arbitrator from a list of arbitrators who satisfy the criteria set forth in clause "(iv)" hereof.

(iv) No arbitrator shall have any past or present family, business or other relationship with the Indemnitee, Parent, the Surviving Corporation, the Company, the Representative, any of the Indemnitors or any "affiliate" (as such term is defined in Rule 12b-2 of the Securities Act), director or officer thereof, unless following full disclosure of all such relationships, the Indemnitee and the Representative agree in writing to waive such requirement with respect to an individual in connection with any dispute.

(v) The arbitrator shall be instructed to hold an up to eight hour, one day hearing regarding the disputed matter within 60 days of his designation and to render an award (without written opinion) no later than 10 days after the conclusion of such hearing, in each case unless otherwise mutually agreed in writing by the Indemnitee and the Representative.

(vi) No discovery other than an exchange of relevant documents may occur in any arbitration commenced under the provisions of this *Exhibit D*. The Indemnitee and the Representative agree to act in good faith to promptly exchange relevant documents.

(vii) The Indemnitee and the Representative (on behalf of the Indemnitors) will each pay 50% of the initial compensation to be paid to the arbitrator in any such arbitration and 50% of the costs of transcripts and other normal and regular expenses of the arbitration proceedings; *provided, however*, that: (A) the prevailing party in any arbitration will be entitled to an award of attorneys' fees and costs; and (B) all costs of arbitration, other than those provided for above, will be paid by the losing party and the arbitrator will be authorized to determine the identity of the prevailing party and the losing party.

(viii) The arbitrator chosen in accordance with these provisions will not have the power to alter, amend or otherwise affect the terms of these arbitration provisions or any other provisions contained in this *Exhibit D* or the Agreement.

(ix) Except as specifically otherwise provided in this *Exhibit D* or the Agreement, arbitration will be the sole and exclusive remedy of the parties for any Arbitrable Dispute or any other dispute arising out of or relating to this *Exhibit D* or the Agreement.

(g) Upon resolution of the arbitration described in clause "(f)" of this *Exhibit D*, the Representative shall, within two business days following the entry of the arbitrator's decision by a court of competent jurisdiction, or such other period of time as may be set forth in the arbitrator's decision, provide Parent with its irrevocable written agreement that the amount of the award specified in the arbitrator's decision, if any, may be retained by Parent from the Holdback Amount.

(h) If: (i) Parent has retained any Holdback Amount; and (ii) it is subsequently agreed to by Parent and the Representative (or determined by binding arbitration as described above) that the Indemnitees are not entitled to retain any portion of the Holdback Amount, then, within five business days after such agreement or determination is made, Parent shall pay to the former Company Stockholders entitled thereto (in accordance with their Holdback Contribution Amount as set forth in the Spreadsheet) their portion of the Holdback Amount.



## QuickLinks

[Exhibit 10.75](#)

[AGREEMENT AND PLAN OF MERGER](#)

[RECITALS](#)

[AGREEMENT](#)

[EXHIBIT A](#)

[CERTAIN DEFINITIONS](#)

[EXHIBIT B](#)

[FORM OF WRITTEN CONSENT](#)

[MAJORITY WRITTEN CONSENT OF THE CAPITAL STOCKHOLDERS OF BIOPROTECTION SYSTEMS CORPORATION](#)

[MAJORITY WRITTEN CONSENT OF THE PREFERRED STOCKHOLDERS OF BIOPROTECTION SYSTEMS CORPORATION](#)

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[ARTICLE I PURCHASE AND SALE OF SHARES](#)

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# Delaware

*The First State*

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

“BPS MERGER SUB, INC.”, A DELAWARE CORPORATION,

WITH AND INTO “BIOPROTECTION SYSTEMS CORPORATION” UNDER THE NAME OF “BIOPROTECTION SYSTEMS CORPORATION”, A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE THE SEVENTH DAY OF JANUARY, A.D. 2011, AT 7:24 O’CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

3959980 8100M

110025189

You may verify this certificate online  
at [corp.delaware.gov/authver.shtml](http://corp.delaware.gov/authver.shtml)





Jeffrey W. Bullock, Secretary of State  
AUTHENTICATION: 8483893  
DATE: 01-10-11

State of Delaware  
Secretary of State  
Division of Corporations  
Delivered 07:26 PM 01/07/2011  
FILED 07:24 PM 01/07/2011  
SRV 110025189 - 3959980 FILE

**CERTIFICATE OF MERGER**

**OF**

**BPS MERGER SUB, INC.  
(A DELAWARE CORPORATION)**

**INTO**

**BIOPROTECTION SYSTEMS CORPORATION  
(A DELAWARE CORPORATION)**

**(Pursuant to Section 251 of the Delaware General Corporation Law)**

**BioProtection Systems Corporation, a corporation organized and existing under the laws of the State of Delaware, does hereby certify that:**

**FIRST: That the name and state of incorporation of each of the constituent corporations of the merger is as follows:**

Name	State Of Incorporation
BioProtection Systems Corporation	Delaware
BPS Merger Sub, Inc.	Delaware

**SECOND: That an Agreement and Plan of Merger between the parties to the merger has been approved, adopted, executed and acknowledged by each of the constituent corporations in accordance with the requirements of section 251 of the General Corporation Law of Delaware.**

**THIRD: That the name of the surviving corporation of the merger is BioProtection Systems Corporation, a Delaware corporation.**

**FOURTH: Upon effectiveness of the merger, the Certificate of Incorporation of the surviving corporation shall be amended and restated in its entirety as set forth on Exhibit A.**

FIFTH: That the executed Agreement and Plan of Merger is on file at an office of the surviving corporation, the address of which is BioProtection Systems Corporation, 2901 S. Loop Dr., Suite 3360, Ames, Iowa 50010.

SIXTH: That a copy of the Agreement and Plan of Merger will be furnished by the surviving corporation, on request and without cost, to any stockholder of any constituent corporation.

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IN WITNESS WHEREOF, the undersigned have executed this Certificate of Merger as of this 7th day of January, 2011.

**BIOPROTECTION SYSTEMS CORPORATION,**  
a Delaware corporation

By: /s/ Charles J. Link

Name: Charles J. Link, Jr., M.D.

Title: Chief Executive Officer, President and Chairman

**CERTIFICATE OF MERGER  
SIGNATURE PAGE**

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**EXHIBIT A**

**CERTIFICATE OF INCORPORATION OF SURVIVING CORPORATION**

**CERTIFICATE OF MERGER  
SIGNATURE PAGE**

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**AMENDED AND RESTATED  
CERTIFICATE OF INCORPORATION  
OF  
BIOPROTECTION SYSTEMS CORPORATION**

**I.**

The name of this corporation is BioProtection Systems Corporation.

**II.**

The address of the registered office of the corporation in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, and the name of the registered agent of the corporation in the State of Delaware at such address is The Corporation Trust Company.

**III.**

The purpose of this corporation is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law.

**IV.**

This corporation is authorized to issue only one class of stock, to be designated Common Stock. The total number of shares of Common Stock presently authorized is one hundred (100), each having a par value of one cent (\$0.01).

**V.**

The management of the business and the conduct of the affairs of the corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed by the Board of Directors in the manner provided in the Bylaws.

**VI.**

A. The liability of the directors for monetary damages shall be eliminated to the fullest extent under applicable law. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

B. Any repeal or modification of this Article VI shall be prospective and shall not affect the rights under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

**VII.**

The corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by

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statute, and all rights conferred upon the stockholders herein are granted subject to this reservation.

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**Consent of Independent Registered Public Accounting Firm**

**The Board of Directors  
NewLink Genetics Corporation:**

We consent to the use of our report included herein and to the reference to our firm under the heading “Experts” in the prospectus.

Our report refers to the adoption of new guidance on the presentation and disclosure of noncontrolling interests.

/s/ KPMG LLP

Des Moines, Iowa  
February 25, 2011

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Consent of Valuation Specialist

February 21, 2011

The Board of Directors  
NewLink Genetics Corporation:

We consent to the reference to our firm under the heading “Experts” in the prospectus and to the use of our valuations of common stock as discussed in the Critical Accounting Policies and Significant Judgments and Estimates, Stock-Based Compensation, Common Stock Fair Value, Common Stock Valuations section of the Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The Mentor Group, Inc.  
/s/ The Mentor Group, Inc.

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