

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

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 OR 15(d) of  
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 28, 2013 (February 28, 2013)

**NewLink Genetics Corporation**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-35342**  
(Commission  
File Number)

**42-1491350**  
(IRS Employer  
Identification No.)

**2503 South Loop Drive**  
**Ames, IA**  
(Address of principal executive offices)

**50010**  
(Zip Code)

Registrant's telephone number, including area code: **(515) 296-5555**

**Not applicable**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## **Section 2 - Financial Information**

### **Item 2.02. Results of Operations and Financial Condition.**

On February 28, 2013, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release reporting financial results for the fourth quarter and full year ended December 31, 2012.

The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

**Section 9 - Financial Statements and Exhibits**

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated February 28, 2013, entitled "NewLink Genetics Reports Fourth Quarter and Full-Year 2012 Financial Results."

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 28, 2013

### **NewLink Genetics Corporation**

By: /s/ Gordon H. Link, Jr.  
Gordon H. Link, Jr.  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated February 28, 2013, entitled "NewLink Genetics Reports Fourth Quarter and Full-Year 2012 Financial Results."



Today's Discoveries . . . Tomorrow's Medicines

Contact:  
Gordon Link  
Chief Financial Officer  
515-598-2925  
[glink@linkp.com](mailto:glink@linkp.com)

FOR IMMEDIATE RELEASE

## NewLink Genetics Reports Fourth Quarter and Full-Year 2012 Financial Results

### Conference call scheduled for February 28, 2013

AMES, Iowa, February 28, 2013 - NewLink Genetics Corporation (Nasdaq NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today reported consolidated 2012 financial results and reviewed key 2012 accomplishments.

“We have made significant progress during this past year. The enrollment rate in our pivotal phase 3 IMPRESS trial with our active cellular immunotherapy product candidate for resected pancreatic cancer, algenpantucel-L, has exceeded our original expectations. We initiated both a Phase 3 study in patients with locally advanced pancreatic cancer using algenpantucel-L, and a Phase 2B/3 adaptive design study to evaluate our active cellular immunotherapy using tergenpumatumucel-L in patients with progressive or relapsed Stage IIIB/IV non-small cell lung cancer (NSCLC). In addition, we expect to move our HyperAcute melanoma immunotherapy into controlled phase 2 studies in 2013. We are also expanding our HyperAcute immunotherapy platform to include different tumor types. Furthermore, we expect to move the first of these into Phase 1 human studies in the second half of 2013,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. “Rapid enrollment rate in our pivotal phase 3 IMPRESS pancreatic cancer study should enable us to complete enrollment of this trial in the summer of 2013, ahead of our original schedule.”

### Full Year 2012 Financial Results

- Year-end cash, cash equivalents and marketable securities totaled \$21.7 million.
- Total grant revenues for 2012 were \$1.7 million compared with \$1.9 million for 2011.
- Research and development (R&D) expense increased \$3.5 million to \$17.8 million in 2012 due to higher personnel-related expenses and increased clinical trial costs.
- General and administrative (G&A) expense increased \$1.4 million to \$7.1 million in 2012 primarily due to higher personnel-related expenses and public-company costs.
- Net loss for 2012 was \$23.3 million compared with \$18.1 million in 2011.

### Financial Guidance

NewLink expects to end 2013 with about \$40 million in cash, cash equivalents and marketable securities.

### Recent Accomplishments

- **Closed Public Offering with aggregate net proceeds of approximately \$49.0 million.** On February 4, 2013, NewLink closed an underwritten public offering of 4.6 million shares of common stock including 600,000 shares of common stock sold pursuant to the underwriters' exercise of their over-allotment option, at a price to the public of \$11.40 per share.

- **Significant progress in our IMPRESS Phase 3 trial for resected pancreatic cancer patients treated with algenpantucel-L.** NewLink expects the first interim analysis in mid-2013 and completion of enrollment in the summer of 2013.
- **Continued Progress in NewLink's HyperAcute platform of IDO pathway inhibitor drug candidates.** NewLink plans to launch a Phase 2 study in metastatic breast cancer evaluating the combination of Taxotere with NewLink's indoximod. NewLink also announced the launch of an investigator sponsored study evaluating indoximod in combination with Dendreon's Provenge® in patients with asymptomatic or minimally symptomatic metastatic hormone refractory prostate cancer.

### Upcoming Activities

NewLink expects to present at the following conferences:

- 2013 Needham Healthcare Conference, April 30 - May 1, in NYC
- Jefferies 2013 Global Healthcare Conference taking place June 3-6 in NYC
- American Society of Clinical Oncology (ASCO) 2013 May 31 - June 4, 2013 in Chicago, IL.

### Today's Conference Call and Webcast Reminder

The NewLink management team will host a conference call discussing the company's financial results and recent corporate developments on Thursday, February 28, 2013, at 10:00am EST. The call can be accessed by dialing 1-(877) 363-5052 (domestic) or 1-(914) 495-8600 (international) five minutes prior to the start of the call and providing the passcode 16064630. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-(855) 859-2056 (domestic) or 1-(404) 537-3406 (international), providing the passcode 16064630. The replay will be available for two weeks from the date of the live call.

### About HyperAcute Immunotherapy

NewLink's HyperAcute immunotherapy technology 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 Alpha-GT, which is expressed in the cells of lower mammals but not present in human cells. The presence of this enzyme results in the incorporation of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or Alpha-Gal, on the surface of expressing cells. Introducing Alpha-Gal expressing cells to the human immune system activates an immune response resulting from pre-existing antibodies against Alpha-Gal. Antibodies directed against the Alpha-Gal epitope are potentially the most abundant natural antibody in humans and represent approximately 1% of circulating human antibodies.

NewLink's HyperAcute cancer immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes Alpha-Gal epitopes. This exposure to Alpha-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which Alpha-Gal is present by activating complement, an important component of the immune system capable of cell destruction. After destruction, NewLink believes the resulting cellular fragments bound by anti-Alpha-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.

### About indoximod and inhibition of the IDO pathway

IDO pathway inhibitors, including indoximod, represent a potential breakthrough approach to cancer therapy using small-molecule, anti-toleragenic product candidates intended to counteract a key mechanism by which tumors evade immune-mediated destruction. IDO is an enzyme that regulates immune response by suppressing T-cell function and enabling 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 tumor associated antigens (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. Indoximod is currently in multiple Phase 1B/2 studies evaluating the addition of indoximod to Taxotere in the treatment of breast cancer and the addition of indoximod to an autologous P-53 Dendritic Cell vaccine, also in the treatment of breast cancer patients. In addition to its clinical indoximod product candidate, NewLink has an active program directed at synthesizing other IDO pathway inhibitors.

### **About NewLink Genetics Corporation**

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for cancer patients. NewLink's portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. NewLink's lead product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (under a Special Protocol Assessment with the U.S. FDA) as well as in a separate study in locally advanced pancreatic cancer patients. NewLink has recently launched an adaptive design Phase 2B/3 clinical trial of tergenpumatucel-L (HyperAcute Lung) in patients with non-small cell lung cancer. NewLink is developing indoximod (d-1-methyltryptophan, or D-1MT), a small-molecule, orally bioavailable product candidate from NewLink's proprietary indoleamine-(2, 3)-dioxygenase, or IDO, pathway inhibitor technology. NewLink is studying indoximod in various chemotherapy and immunotherapy combination studies independently and in collaboration with the National Cancer Institute. For more information please visit <http://www.linkp.com>. Patient information is available at <http://www.pancreaticcancer-clinicaltrials.com>.

### **Cautionary Note Regarding Forward-Looking Statements**

*This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," 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. These forward-looking statements include, among others, statements about: the prospects of Algenpantucel-L, Indoximod and our other HyperAcute platforms and related clinical trials. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including risks relating to: the initiation of clinical trials and the completion of enrollment; adverse general economic and industry conditions; and those risks discussed in "Risk Factors" and elsewhere in NewLink's Quarterly Report on Form 10-Q for the period ended September 30, 2012, Form S-3 Registration Statement filed December 28, 2012 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this press release.*



NewLink Genetics Corporation  
Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Quarter Ended		Year Ended	
	December 31, 2012	December 31, 2011	December 31, 2012	December 31, 2011
Grant revenue	\$ 299	\$ 301	\$ 1,687	\$ 1,872
Operating expenses:				
Research and development	4,489	3,979	17,838	14,255
General and administrative	2,103	2,126	7,108	5,679
Loss from operations	(6,293)	(5,804)	(23,259)	(18,062)
Other (expense) income, net	(26)	(6)	(62)	(26)
Net loss	\$ (6,319)	\$ (5,810)	\$ (23,321)	\$ (18,088)
Net loss attributable to NewLink	\$ (6,319)	\$ (5,810)	\$ (23,321)	\$ (18,087)
Net loss per common share, basic and diluted	\$ (0.30)	\$ (0.44)	\$ (1.12)	\$ (2.98)
Weighted average number of common shares outstanding	20,929,184	13,237,960	20,779,450	6,064,542

NewLink Genetics Corporation  
Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	Year Ended	
	December 31, 2012	December 31, 2011
<b>Assets:</b>		
<b>Current assets:</b>		
Cash, cash equivalents and certificates of deposit	\$ 21,744	\$ 41,980
Prepaid expenses and other current assets	1,645	808
Total current assets	<u>23,389</u>	<u>42,788</u>
Property and equipment, net	<u>6,040</u>	<u>5,591</u>
Total assets	<u>\$ 29,429</u>	<u>\$ 48,379</u>
	December 31, 2012	December 31, 2011
<b>Liabilities and Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 2,631	\$ 3,537
Deferred rent	84	913
Other current liabilities	204	6,214
Total current liabilities	<u>2,919</u>	<u>10,664</u>
<b>Long term liabilities:</b>		
Notes payable	7,140	848
Obligations under capital leases	38	94
Deferred rent, excluding current portion	1,405	—
Total long term liabilities	<u>8,583</u>	<u>942</u>
Total liabilities	<u>11,502</u>	<u>11,606</u>
<b>Stockholders' equity:</b>		
Common stock	210	206
Additional paid-in capital, net	122,514	118,043
Deficit accumulated during the development stage	(104,797)	(81,476)
Total equity	<u>17,927</u>	<u>36,773</u>
Commitments		
Total liabilities and equity	<u>\$ 29,429</u>	<u>\$ 48,379</u>