

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): April 29, 2016

**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 April 29, 2016, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the first quarter ended March 31, 2016 ("Press Release"). A copy of the Press Release and the First Quarter Financial Results Presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this Current Report, including Exhibits 99.1 and 99.2 attached hereto 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 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 April 29, 2016, entitled "NewLink Genetics Reports First Quarter 2016 Financial Results"
99.2	First Quarter 2016 Financial Results Presentation

**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: April 29, 2016

**NewLink Genetics Corporation**

By: /s/ John B. Henneman III  
John B. Henneman III  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

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FOR IMMEDIATE RELEASE

## **NewLink Genetics Reports First Quarter 2016 Financial Results**

- **IMPRESS Phase 3 Top-line Results Now Expected in Second Quarter of 2016**
- **Pancreatic and Melanoma IDO Pathway Inhibitor Trial Updates at ASCO**

**-Management to Host Conference Call Today at 8:30 a.m. ET**

Ames, Iowa and Austin, Texas - April 29, 2016 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK), a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor programs, to improve the lives of patients with cancer, today reported consolidated financial results for the first quarter of 2016.

“We had a productive quarter and made solid progress in achieving our mission of bringing patients with cancer better treatment options,” said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer and Chief Scientific Officer. “The pivotal IMPRESS trial for patients with resected pancreatic cancer is moving rapidly toward final analysis. And, we are preparing for multiple updates from both our proprietary and partnered IDO pathway inhibitor clinical programs at key scientific meetings in 2016.”

Nicholas Vahanian M.D., President and Chief Medical Officer, added, “With the upcoming clinical trial read outs, we anticipate that these data will bring us closer to clinical validation of our IDO pathway inhibitor program. The team at NewLink Genetics continues with confidence and excitement as our partner, Genentech begins to report on the clinical development of GDC-0919 alone and in combination studies. We look forward to Genentech reporting on the results from these studies this year.”

### Program Updates:

#### **HyperAcute® Cellular Immunotherapy Program**

#### ***Algenpantucel-L/IMPRESS Trial***

Today, the company reported that it expects to report top-line results from the IMPRESS trial during the second quarter of 2016. Algenpantucel-L is the most advanced clinical program utilizing NewLink Genetics’ HyperAcute Cellular Immunotherapy platform technology. IMPRESS is a randomized, controlled, two-arm Phase 3 trial (n=722) for patients with resected pancreatic cancer designed to test algenpantucel-L in combination with the standard of care versus the standard of care alone.

## IDO Pathway Inhibitor Programs

### *Indoximod*

At the upcoming American Society of Clinical Oncology Annual Meeting from June 3 to 7, 2016 in Chicago, NewLink Genetics expects to report on clinical updates on its proprietary IDO pathway inhibitor programs. Abstracts that have been selected include:

- Interim data update from a Phase 2 trial with a target enrollment of 80 patients evaluating the addition of indoximod to gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer.
- Mid-trial and safety data update from a Phase 2 trial with a target enrollment of 96 patients of indoximod and ipilimumab or PD-1 inhibitors for patients with stage 3 or 4 advanced or metastatic melanoma.

Additional data updates expected in the second half of 2016 include:

- Mid-trial update from a Phase 2 trial with a target enrollment of 132 patients of indoximod for patients with refractory malignant brain tumors.
- Guidance on timing of preliminary results in a randomized Phase 2 trial with a target enrollment of 154 patients of indoximod for patients with metastatic breast cancer.

### *GDC-0919 Small Molecule Program*

The company is anticipating a clinical update from the combination study of GDC-0191. Genentech recently reported that it will update the Phase 1b study with a target enrollment of 224 patients in solid tumors at the European Society of Medical Oncology from October 7-11, 2016 in Denmark. The dose-escalation and expansion study combines GDC-0919 and atezolizumab (PD-L1 Mab).

In 2014, NewLink Genetics entered into an exclusive worldwide license agreement with Genentech, a member of the Roche Group, for the development of NLG919, NewLink Genetics' IDO pathway inhibitor. The parties also entered into a research collaboration for the discovery of next generation IDO/TDO compounds.

### Financial Results for the Three-Month Period Ended March 31, 2016

**Cash Position:** NewLink Genetics ended the quarter on March 31, 2016, with cash, cash equivalents, and certificates of deposit totaling \$178 million compared to \$197.8 million for the year ending December 31, 2015. The decrease was attributable primarily due to the increased operating expenses for R&D and pre-commercialization development, offset by amounts received under government contracts.

**R&D expenses:** Research and development expenses in the first quarter of 2016 were \$21.9 million compared to \$18 million during the comparable period in 2015. The increase was primarily due to increases in clinical trial and manufacturing expenses related to NewLink Genetics' broad pipeline of product candidates.

**G&A expenses:** General and administrative expenses in the first quarter of 2016 were \$9.2 million compared to \$8.4 million during the comparable periods in 2015. The increase was primarily due to an increase in share-based compensation expense, as well as increases in travel expenses and medical affairs and marketing.

**Net Income/Loss:** NewLink Genetics reported a net loss of \$23.7 million or a \$0.82 loss per diluted share for the first quarter of 2016 compared to net income of \$11.2 million or earnings of \$0.35 per diluted share for the comparable period in 2015.

NewLink Genetics ended the quarter with 28,860,925 shares outstanding.

### Financial Guidance and Upcoming Investor Meetings

NewLink Genetics has reiterated their goal and expectation is to finish 2016 with two years of cash on hand.

We have presented at five investor meetings since the beginning of the year and expect to present at Bank of America Healthcare Conference on May 12 and Cantor Fitzgerald Healthcare Conference on July 12 and 13.

### Conference Call Details

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to give an update on clinical and business development activities. NewLink Genetics' senior management team will host the call, which will be open to all listeners. There will also be a question and answer session following the prepared remarks.

Access to the live conference call is available by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) five minutes prior to the start of the call. The call and accompanying slides can also be accessed through a webcast via a link provided on the Investors and Media homepage of NewLink Genetics' website at [www.NewLinkGenetics.com](http://www.NewLinkGenetics.com). A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 86419353. The replay will be available for two weeks from the date of the call, and the webcast will also be archived on the website.

### HyperAcute® Cellular Immunotherapy Program

HyperAcute Cellular Immunotherapies are unique, tumor-specific product candidates that take advantage of a pre-existing human immune response to initiate a powerful cascade, potentially educating the body's natural defenses to identify and destroy cancer cells. Unlike certain immunology products, HyperAcute Cellular Immunotherapies do not require patient tissue or cancer cells and are designed to be easy to administer. HyperAcute Cellular Immunotherapies use allogeneic (disease-specific, not patient-specific), tumor-specific human cell lines that have been modified to express alpha-gal. Intact, whole cells are used rather than cell fragments or purified proteins, which we believe result in the stimulation of a more powerful immune response. Our most advanced clinical program utilizing this technology is for patients with pancreatic cancer. Additionally, there are ongoing clinical development programs and data on induced immune responses targeting non-small-cell lung cancer, melanoma, prostate cancer and kidney cancer.

### Indoleamine 2,3-Dioxygenase (IDO) Checkpoint Inhibitor Programs

The indoleamine 2,3-dioxygenase (IDO) pathway regulates immune response by suppressing T cell function and enabling local tumor immune escape. NewLink Genetics is researching two IDO pathway inhibitors, GDC-0919 (in partnership with Genentech) and indoximod, small-molecule product candidates that have the potential to disrupt mechanisms by which tumors evade the immune system.

NewLink Genetics' indoximod and GDC-0919 each have a distinct mechanism of action within the IDO pathway and are in Phase 1 or 2 clinical trials for a range of cancers, including breast cancer, melanoma, and other solid tumors.



## About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for patients with cancer. NewLink Genetics' portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink Genetics' 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. For more information please visit <http://www.newlinkgenetics.com>.

### Cautionary Note Regarding Forward-Looking Statements

*This press release contains forward-looking statements of NewLink Genetics 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 NewLink Genetics' financial guidance for 2016; enrollment in or results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development and regulatory matters; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink Genetics makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2015 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink Genetics' views as of the date of this press release. NewLink Genetics 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 Genetics' views as of any date subsequent to the date of this press release.*

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**NewLink Genetics Corporation**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**  
**(In thousands, except share and per share amounts)**

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Grant revenue	\$ 4,338	\$ 9,649
Licensing and collaboration revenue	1,370	29,546
<b>Total revenue</b>	<b>5,708</b>	<b>39,195</b>
Operating expenses:		
Research and development	21,937	17,981
General and administrative	9,164	8,366
<b>(Loss) income from operations</b>	<b>(25,393)</b>	<b>12,848</b>
Other income, net	39	11
<b>Net (loss) income before taxes</b>	<b>(25,354)</b>	<b>12,859</b>
Income tax benefit (expense)	1,634	(1,669)
<b>Net (loss) income</b>	<b>\$ (23,720)</b>	<b>\$ 11,190</b>
Basic (loss) earnings per share	\$ (0.82)	\$ 0.40
Diluted (loss) earnings per share	\$ (0.82)	\$ 0.35
Basic average shares outstanding	28,856,944	28,218,631
Diluted average shares outstanding	28,856,944	31,919,318

**NewLink Genetics Corporation**  
**Condensed Consolidated Balance Sheets**  
(unaudited)  
(In thousands)

	Year Ended	
	March 31, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 177,983	\$ 197,800
Prepaid expenses and other current assets	9,516	10,342
Income tax receivable	1,926	—
Total current assets	189,425	208,142
Property and equipment, net	10,498	10,400
Total assets	\$ 199,923	\$ 218,542
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,104	\$ 12,422
Unearned revenue	864	892
Other current liabilities	337	667
Income taxes payable	—	859
Total current liabilities	15,305	14,840
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	453	368
Deferred rent	1,129	1,153
Unearned revenue	223	407
Total long-term liabilities	7,805	7,928
Total liabilities	23,110	22,768
Stockholders' equity:		
Common stock	289	288
Additional paid-in capital	281,368	276,610
Treasury stock, at cost	(771)	(771)
Accumulated deficit	(104,073)	(80,353)
Total stockholders' equity	176,813	195,774
Total liabilities and stockholders' equity	\$ 199,923	\$ 218,542



# First Quarter 2016 Operational and Financial Results

Nasdaq: NLNK  
April 29, 2016

# Agenda

## Introduction

- Jack Henneman, *Executive Vice President & CFO*

## 2016 Priorities

- Charles J. Link, Jr., M.D., *Chairman, CEO & CSO*

## IDO Pathway Inhibitor Programs Update

- Nicholas N. Vahanian, M.D., *President & CMO*

## GDC-0919 Update

- Dr. Vahanian

## First Quarter 2016 Financial Results

- Mr. Henneman



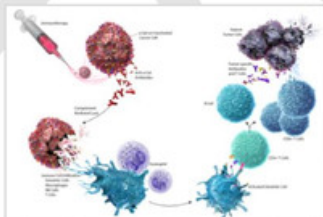
## Safe Harbor Statement

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NASDAQ: NLNK

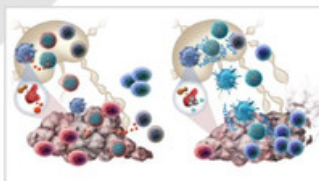
# NewLink Genetics Programs

## HyperAcute® Cellular Immunotherapies



- Pancreatic
- NSCLC
- Advanced Melanoma
- Prostate
- Kidney

## IDO Pathway Inhibitors



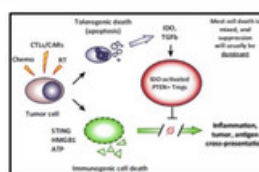
- Breast
- Prostate
- Pancreatic
- Advanced Melanoma
- Refractory Malignant Brain Tumors
- Solid Tumors

## Partnerships

**Genentech**  
A Member of the Roche Group



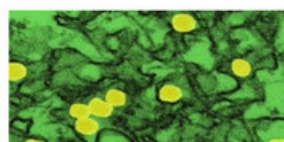
## PTEN Pathway Inhibitors



## Infectious Diseases



Ebola vaccine program



Zika vaccine program



# 2016 Business Priorities

Charles J. Link, Jr., M.D., Chairman, CEO, & CSO

## HyperAcute Cellular Immunotherapy

- IMPRESS Phase 3
  - Report on top-line results in 2Q-2016
  - Execute on regulatory strategy with FDA
  - Continue U.S. commercialization planning
  - Explore partnering strategy outside U.S.
- HyperAcute Cellular Immunotherapies continue to move forward with clinical programs in pancreatic, NSCLC, melanoma and kidney cancers

## IDO Pathway Inhibitors

- Validation of IDO pathway inhibitors with additional data readouts
  - Indoximod in multiple combination Phase 2 combination trials
  - GDC-0919 partnered with Genentech in expanded combination trials

# IDO Pathway Inhibitor Programs Update

Nicholas Vahanian, M.D., President & Chief Medical Officer

## IDO Pathway Inhibitors

- Provide clinical update at ASCO in June 2016 on the following trials:
  - Interim data update from a Phase 2 trial with a target enrollment of 80 patients evaluating the addition of indoximod to gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer
  - Mid-trial and safety data update from a Phase 2 trial with a target enrollment of 96 patients of indoximod and ipilimumab or PD-1 inhibitors for patients with stage 3 or 4 advanced metastatic melanoma

# IDO Pathway Inhibitor Programs Update

Nicholas Vahanian, M.D., President & Chief Medical Officer

## IDO Pathway Inhibitors

- Additional data updates expected in Q2 2016 include:
  - Mid-trial from a Phase 2 trial with a target enrollment of 132 patients of indoximod in combination with temozolomide for patients with refractory malignant brain tumors
  - Guidance on timing of preliminary results in a Phase 2 trial with a target enrollment of 154 patients of indoximod in combination with taxane chemotherapy for patients with metastatic breast cancer

# GDC-0919 Clinical Update

Nicholas Vahanian, M.D., President & Chief Medical Officer

## GDC-0919: Partnered with Genentech

- Genentech to present an update on GDC-0919 at ESMO in October

Molecule	Indoleamine 2, 3-dioxygenase (IDO) Inhibitor (RG6078, GDC-0919, NLG919)	
Indication	Solid tumours	Solid tumours
Phase	Phase I	Phase I
# of patients	N=36	N=224
Design	<ul style="list-style-type: none"> <li>Dose escalation study</li> </ul>	<ul style="list-style-type: none"> <li>Dose escalation and expansion study of IDO and atezolizumab (PD-L1 MAb) combination</li> </ul>
Primary endpoint	<ul style="list-style-type: none"> <li>Safety</li> </ul>	<ul style="list-style-type: none"> <li>Safety, tolerability, and PK</li> </ul>
Status	<ul style="list-style-type: none"> <li>FPI Q1 2014</li> <li>Safety and PK/PD data presented at ECC 2015</li> </ul>	<ul style="list-style-type: none"> <li>FPI Q3 2015</li> </ul>
Collaborator	NewLink Genetics	

# First Quarter 2016 Financial Results

Jack Henneman, EVP and Chief Financial Officer

## Strong Capital Position

- Stable and reliable cash position - \$178M at Q1 2016 / \$197.8M at YE 2015
- Goal and expectation to finish 2016 with two years of cash-on-hand

## Increased Investment

- Planning for the success of the IMPRESS trial, the filing of a BLA and the commercialization of algenpantucel-L in the U.S.
- Significantly increasing our clinical programs, especially indoximod, and building the pipeline of new opportunities
- Managing spending carefully before read-out of top-line IMPRESS data

## Multiple Value Drivers

- Potential for combinations of HyperAcute® Cellular Immunotherapy candidates with other cancer treatments, including checkpoint inhibitors
- Potential for combinations of IDO pathway inhibitors
- Infectious disease initiatives



# Q & A

