

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): May 9, 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 8 - Other Events**

### **Item 8.01. Other Events.**

On May 9, 2016, NewLink Genetics Corporation (the "Company") announced results of its Phase 3 clinical trial for algenpantucel-L for patients with resected pancreatic cancer.

The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

**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 May 9, 2016, entitled "NewLink Genetics Announces Results from Phase 3 IMPRESS Trial of Algenpantucel-L for Patients with Resected Pancreatic Cancer"

## 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: May 9, 2016

### **NewLink Genetics Corporation**

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

## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated May 9, 2016, entitled "NewLink Genetics Announces Results from Phase 3 IMPRESS Trial of Algenpantucel-L for Patients with Resected Pancreatic Cancer"



## **NewLink Genetics Announces Results from Phase 3 IMPRESS Trial of Algenpantucel-L for Patients with Resected Pancreatic Cancer**

**Management to Host Conference Call  
Tuesday, May 10<sup>th</sup> at 8:30 a.m. ET**

AMES, Iowa, May 9, 2016 -- NewLink Genetics Corporation (NASDAQ:NLNK) announced today results of its Phase 3 clinical trial for algenpantucel-L for patients with resected pancreatic cancer.

The IMPRESS Phase 3 study of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint. Overall survival from time of randomization was 29.3 months for both groups combined. There was no statistically significant difference between the two groups. The median survival was 30.4 months and 27.3 months for the control and study groups, respectively. There was also no statistical difference for long-term survival. Three year survival was 41.4% and 42.1% and four year survival was 32.6% and 32.7% for the control and study groups, respectively.

“We are deeply disappointed for patients that the IMPRESS Phase 3 study was not successful,” said Nicholas N. Vahanian, M.D., President and Chief Medical Officer of NewLink Genetics. “We want to extend our sincere appreciation to all the patients, caregivers, investigators, research nurses, employees and others who contributed to the study. Given these results, we are evaluating the future of the HyperAcute® platform. We remain committed to achieving our mission of developing immunotherapies to bring patients with cancer better treatment options.”

The **IM**munotherapy for **P**ancreatic **RE**sectable cancer Study (IMPRESS) trial is a randomized, controlled, two-arm Phase 3 trial for patients with resected pancreatic cancer testing algenpantucel-L (300M cells every two weeks for six months followed by every month for another six months) in combination with the standard of care versus standard of care alone. A total of 722 patients with surgically removed cancers were enrolled at more than 70 sites in the United States from May 2010 to September 2013.

“Immunotherapy is rapidly establishing a role in the management of multiple malignancies,” said George Fisher, M.D., Ph.D., Professor of Medicine at Stanford University, one of the investigators in the IMPRESS study. “The median overall survival of 29.3 months in this study represents a significant increase compared with prior trials and may be due to multiple factors, including the emergence of more effective treatment regimens for recurrent or metastatic disease. Although a negative study, these results represent an important and meaningful contribution to the understanding of the modern treatment of resected pancreatic cancer.”

“In light of these negative results, our scientific and clinical teams will focus on other promising opportunities in our pipeline,” said Charles Link, Jr., M.D., Chairman and Chief Executive Officer. “Our lead projects focus on our IDO checkpoint inhibitor technology employing indoximod and GDC-0919. We have substantial near-term catalysts in 2016 for these IDO inhibitor programs, including [multiple trial updates](#) from our proprietary and partnered IDO pathway inhibitors, and the financial resources to realize the potential of our product pipeline.”

NewLink Genetics ended the first quarter on March 31, 2016, with cash, cash equivalents, and certificates of deposit totaling \$178 million. The Company reiterates that its goal and expectation is to finish 2016 with two years of cash on hand.

## Conference Call Details

The Company has scheduled a conference call for 8:30 a.m. ET Tuesday, May 10 to discuss the IMPRESS trial results. 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. 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 10318415.

## **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; 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.*

### **Corporate Contact:**

Jack Henneman  
Chief Financial Officer  
(515) 598-2561  
[Investor@linkp.com](mailto:Investor@linkp.com)

### **Investor Contact:**

Donna LaVoie or Rachel Girard  
LaVoieHealthScience  
617-374-8800, ext. 107/102  
[dlavoie@lavoiehealthscience.com](mailto:dlavoie@lavoiehealthscience.com)  
[rgirard@lavoiehealthscience.com](mailto:rgirard@lavoiehealthscience.com)

**Media:**

David Connolly

LaVoieHealthScience

617-374-8800, ext. 108

[dconnolly@lavoiehealthscience.com](mailto:dconnolly@lavoiehealthscience.com)