

# NEWLINK GENETICS CORP

## **FORM 8-K** (Current report filing)

Filed 06/02/17 for the Period Ending 06/02/17

|             |   |
|-------------|---|
| Address     | 2503 SOUTH LOOP DRIVE<br>SUITE 5100<br>AMES, IA 50010 |
| Telephone   | 515-296-5555  |
| CIK         | 0001126234  |
| Symbol      | NLNK  |
| SIC Code    | 2834 - Pharmaceutical Preparations                    |
| Industry    | Biotechnology & Medical Research                      |
| Sector      | Healthcare  |
| Fiscal Year | 12/31   |

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): June 2, 2017

**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))
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## **Section 8 - Other Events**

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

On June 2, 2017, NewLink Genetics Corporation (the "Company") issued a press release titled "Results from Clinical Trial of Indoximod Plus Chemotherapy for Patients with Metastatic Breast Cancer."

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

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**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 June 2, 2017, entitled "Results from Clinical Trial of Indoximod Plus Chemotherapy for Patients with Metastatic Breast Cancer" |

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## 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: June 2, 2017

### **NewLink Genetics Corporation**

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

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## INDEX TO EXHIBITS

| <b>Exhibit Number</b> | <b>Description</b>  |
|-----------------------|---|
| 99.1                  | Press Release, dated June 2, 2017, entitled "Results from Clinical Trial of Indoximod Plus Chemotherapy for Patients with Metastatic Breast Cancer" |



## Results from Clinical Trial of Indoximod Plus Chemotherapy for Patients with Metastatic Breast Cancer

AMES, Iowa, June 2, 2017 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announced the results from a Phase 2 trial of indoximod in combination with taxane chemotherapy for patients with metastatic breast cancer.

Top line data from the study show that the trial did not meet its pre-specified endpoints of a statistically significant difference between the two treatment groups as to progression-free survival, overall survival or objective response rate.

“As demonstrated by multiple studies that have been reported since the start of this clinical trial, breast cancer unfortunately remains a challenging disease in immuno-oncology,” said Primary Investigator Hatem Soliman MD, Associate Member Breast, Tumor Biology, and Immunology Departments, Chair Clinical Research Advisory Committee, H. Lee Moffitt Cancer Center and Research Institute, Associate Professor, Division of Oncologic Sciences University of South Florida.

In this study, [NLG2101](#), 169 first line metastatic breast cancer patients were selected to receive either docetaxel or paclitaxel by their treating physicians. Once the choice of backbone chemotherapy was made, patients were then randomized to receive either indoximod or placebo.

“We would like to thank all the patients, families, investigators, and research teams who supported the completion of this trial,” said Charles J. Link, Jr., M.D., Chairman and CEO of NewLink Genetics. “Independent of these results, we continue to be highly encouraged by indoximod as an IDO pathway inhibitor and look forward to future opportunities to share data from ongoing trials in multiple cancer types including melanoma, prostate cancer, acute myelogenous leukemia, and pancreatic cancer.”

Full results of the trial will be presented at an upcoming academic meeting.

### About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat cancer. 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 fact, 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*

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*forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about 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 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, 2016 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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