

# NEWLINK GENETICS CORP

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

Filed 06/08/17 for the Period Ending 06/08/17

Address	2503 SOUTH LOOP DRIVE SUITE 5100 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 8, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

---

## Section 8 - Other Events

### Item 8.01. Other Events.

On June 8, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "NewLink Genetics to Regain Rights to GDC-0919."

A copy of the press release and the GDC-0919 update slide deck are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference.

Under the Company's License and Collaboration Agreement dated October 14, 2014 with Genentech, a member of the Roche Group, or the Genentech Agreement, the termination of Genentech's rights to GDC-0919 will become effective 180 days after the Company receives formal notice from Genentech. Upon such termination, Genentech will grant to the Company an exclusive, worldwide, royalty-bearing, sublicensable license, under certain Genentech intellectual property, to research, develop, manufacture and commercialize GDC-0919, and the Company will be required to pay a low single-digit royalty to Genentech on any sales of GDC-0919, should the Company proceed to develop and commercialize that compound. Genentech is obligated to transfer the Investigational New Drug Application for GDC-0919 to the Company and to assign to the Company all data arising from the studies that Genentech conducted on GDC-0919. The Company has the right to purchase Genentech's existing inventory of GDC-0919 at cost. At the Company's request, Genentech is obligated to supply the Company with GDC-0919 for one year after termination and to facilitate the Company's efforts to obtain an alternative source of supply for GDC-0919. Genentech will be responsible for all costs of winding down the clinical trials for GDC-0919 that Genentech was conducting at the time of termination.

---

**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 8, 2017, entitled "NewLink Genetics to Regain Rights to GDC-0919"
99.2	GDC-0919 Update Slide Deck

---

**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 8, 2017

**NewLink Genetics Corporation**

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

---

## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release, dated June 8, 2017, entitled "NewLink Genetics to Regain Rights to GDC-0919"
99.2	GDC-0919 Update Slide Deck



FOR IMMEDIATE RELEASE

## **NewLink Genetics to Regain Rights to GDC-0919**

### **Management to Host Conference Call Thursday, June 8 at 8:30 am ET**

AMES, Iowa, June 8, 2017 - NewLink Genetics Corporation (NASDAQ: NLNK) today announced that on June 6, 2017, Genentech, a member of the Roche Group, informed NewLink Genetics that it intends to return the rights to IDO inhibitor GDC-0919 (navoximod) pursuant to the License Agreement dated October 16, 2014. As a consequence of such decision and pursuant to the terms of the agreement, the rights that NewLink Genetics had licensed to Genentech with respect to GDC-0919 will revert to NewLink Genetics when the termination becomes effective. The research collaboration with Genentech for the discovery of next generation IDO/TDO (tryptophan 2,3-dioxygenase) inhibitors continues.

“We are obviously disappointed in this decision,” said Charles J. Link, Jr., M.D., Chief Executive Officer of NewLink Genetics. “We remain committed to advancing our IDO pathway inhibitor indoximod, which continues to generate exciting data in combination with anti-PD-1 agents, cancer vaccines, and chemotherapy in multiple cancer types including melanoma, prostate cancer, acute myeloid leukemia, and pancreatic cancer.”

#### **About NewLink Genetics Corporation**

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune system to combat cancer. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, prostate cancer, acute myeloid leukemia, and pancreatic cancer. For more information, please visit <http://www.newlinkgenetics.com>.

#### **Conference Call Details**

The Company has scheduled a conference call for 8:30 a.m. ET Thursday, June 8 to discuss this development. 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 37062641.

#### **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 forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include any 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.*

###

Contact:

Lisa Miller  
Director of Investor Relations  
NewLink Genetics  
(515) 598-2555  
[lmiller@linkp.com](mailto:lmiller@linkp.com)

Investor Contact:

Beth Kurth, VP  
LaVoieHealthScience  
617-374-8800, ext. 106  
[bkurth@lavoiehealthscience.com](mailto:bkurth@lavoiehealthscience.com)

Media Contact:

Andrew Mastrangelo, AVP  
LaVoieHealthScience  
617-374-8800, ext. 108  
[amastrangelo@lavoiehealthscience.com](mailto:amastrangelo@lavoiehealthscience.com)



Conference Call on GDC-0919 Program

NewLink Genetics Corporation

Nasdaq: NLNK  
June 8, 2017

## Forward-Looking Disclaimer

*This presentation contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation 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 2017; 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 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 represent NewLink’s views as of the date of this presentation. 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 Genetics’ views as of any date subsequent to the date of this presentation.*

## NewLink Participants and Agenda

### **Introduction**

- Jack Henneman, *Executive Vice President & CFO*

### **GDC-0919 Decision Review**

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

### **IDO Pathway Program Update**

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

### **Financial Update**

- Mr. Henneman

## Indoximod plus Pembrolizumab (PD-1)

*Best Response by RECIST Criteria*

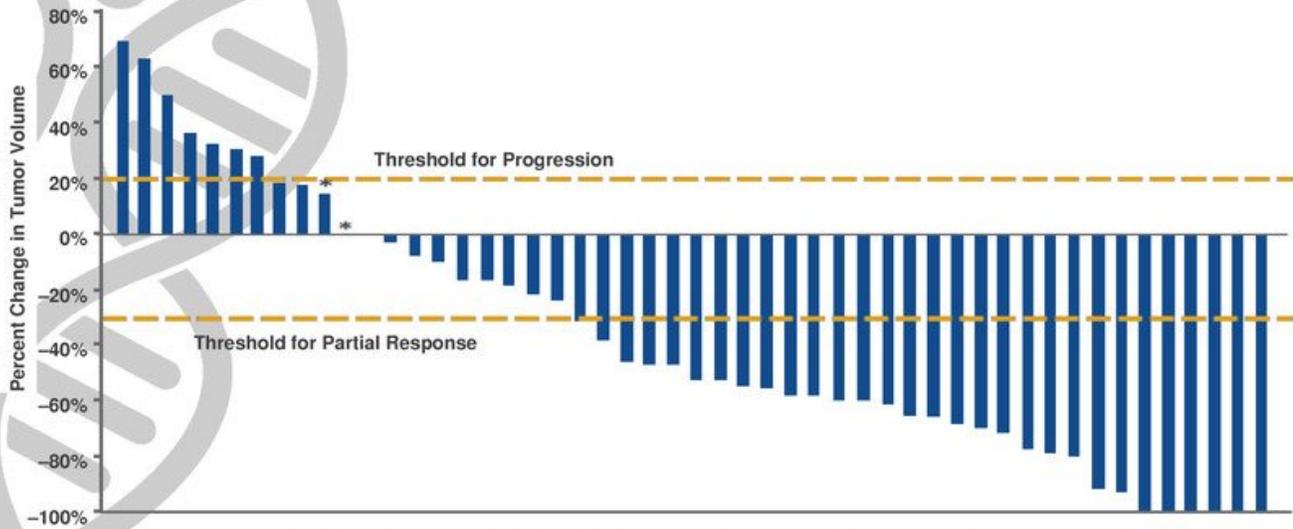
n (%)	n = 51 †
<b>Overall Response Rate</b>	<b>30 (59)</b>
Complete Response	6 (12)
Partial Response	24 (47)
Stable Disease	11 (22)
<b>Disease Control Rate</b>	<b>41 (80)</b>
Progressive Disease	10 (20)

\*Based RECIST guidelines version 1.1, †Non-ocular and cutaneous patients

Interim data support decision to initiate Pivotal Phase 3 vs single agent PD-1

## Indoximod plus Pembrolizumab (PD-1)

*Impressive Clinical Benefit and Disease Control Rate*

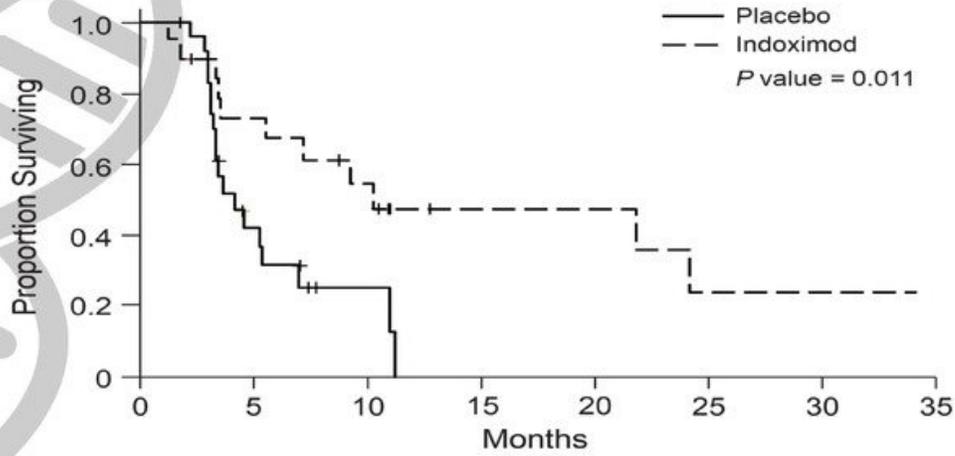


\*SD of primary lesion; new non-target lesions classified patients as PD, \*Based RECIST guidelines version 1.1, †Non-ocular and cutaneous patients

**Interim data support decision to initiate Pivotal Phase 3 vs single agent PD-1**

## Indoximod plus Provenge (sipuleucel-T) Vaccine

Randomized, Double Blind, Placebo Controlled Phase 2 Study



Median rPFS of 10.3 months for indoximod vs 4.1\* months in placebo (p=0.011)

\*Median time to objective progression for pivotal IMPACT trial of sipuleucel-T was 3.7 mo

Zakaria, Y, et al. Oral presentation at: 107th Annual Meeting of the American Association for Cancer Research (AACR); April 1-5, 2017; Washington, DC. Abstract CT117.

