

# NEWLINK GENETICS CORP

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

Filed 07/10/17 for the Period Ending 07/10/17

Address	2503 SOUTH LOOP DRIVE SUITE 5100 AMES, IA 50010
Telephone	515-296-5555
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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): July 10, 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

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## **Section 8 - Other Events**

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

On July 10, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "NewLink Genetics Receives Notice of Allowance from USPTO Covering Indoximod Salts and Prodrugs."

A copy of the press release is attached hereto as Exhibit 99.1 and is 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 July 10, 2017, entitled "NewLink Genetics Receives Notice of Allowance from USPTO Covering Indoximod Salts and Prodrugs"

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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: July 10, 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 July 10, 2017, entitled "NewLink Genetics Receives Notice of Allowance from USPTO Covering Indoximod Salts and Prodrugs"



FOR IMMEDIATE RELEASE

## **NewLink Genetics Receives Notice of Allowance from USPTO Covering Indoximod Salts and Prodrugs**

AMES, Iowa, July 10, 2017 -- [NewLink Genetics Corporation](#) (NASDAQ: NLNK) today announced that it has received a Notice of Allowance for U.S. patent application number 15/171,031 from the United States Patent and Trademark Office (USPTO) covering claims to the salts and prodrugs of indoximod (1-methyl-D-tryptophan). Indoximod is NewLink's orally bioavailable, small molecule targeting the IDO pathway with a distinct mechanism of action.

"We are delighted to hear this positive news from the U.S. patent office," said Charles J. Link, Jr., M.D., Chief Executive Officer of NewLink Genetics. "Indoximod continues to make significant progress in the clinic with promising data across multiple indications. This decision by the U.S. patent office represents a key milestone in the alignment of indoximod's global patent strategy with our clinical development path."

Upon issuance, the new patent will provide NewLink with intellectual property protection covering the compounds and pharmaceutical compositions comprised of salts and prodrugs of indoximod.

"We believe indoximod's promising clinical activity and favorable safety profile, coupled with its differentiated mechanism of action, position indoximod as a key molecule to be considered in IO combinations," said Nicholas Vahanian, M.D., Chief Medical Officer of NewLink Genetics. "We are excited in our upcoming pivotal trial in metastatic melanoma and allowances of these patents align well with our strategy. Additionally, the preclinical data we presented in April at the AACR Annual Meeting illustrated how [NLG802](#), which is our prodrug of indoximod and a new chemical entity, increased the plasma concentrations of indoximod."

This Notice of Allowance concludes the substantive examination of our patent application and will result in the issuance of a U.S. patent after administrative processes are completed. The U.S. patent scheduled to issue from this application will expire in 2036.

### **About Indoximod**

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape.

NewLink Genetics is currently evaluating indoximod in multiple combination studies for patients with various types of cancer including melanoma, acute myeloid leukemia, pancreatic cancer and prostate cancer.

### **About NLG802**

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NLG802 is an investigational, orally available prodrug of indoximod, a small molecule targeting the IDO Pathway. The IDO Pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape.

NewLink Genetics will evaluate NLG802 in a Phase 1 dose-escalation clinical trial in cancer patients to assess the safety and pharmacokinetics of NLG802.

### **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>.

### **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.*

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