NEWLINK GENETICS CORP

FORM 8-K
(Current report filing)

Filed 07/27/17 for the Period Ending 07/27/17

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): July 27, 2017

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2503 South Loop Drive **Ames, IA**	**50010**
(Address of principal executive offices)	(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 July 27, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "NewLink Genetics Announces First Patient Dosed in Phase 1 Study of IDO Pathway Inhibitor NLG802."

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated July 27, 2017, entitled “NewLink Genetics Announces First Patient Dosed in Phase 1 Study of IDO Pathway Inhibitor NLG802”

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 27, 2017

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 July 27, 2017, entitled "NewLink Genetics Announces First Patient Dosed in Phase 1 Study of IDO Pathway Inhibitor NLG802"

FOR IMMEDIATE RELEASE

NewLink Genetics Announces First Patient Dosed in Phase 1 Study of IDO Pathway Inhibitor NLG802

AMES, Iowa, July 27, 2017 -- NewLink Genetics Corporation (NASDAQ: NLNK) today announced first patient dosed in the Phase 1 study of NLG802, a novel prodrug of indoximod. NLG802 is an investigational agent targeting the IDO pathway and represents an important step in the company's strategic planning and intellectual property (IP) management.

The NLG802 trial is a Phase 1 open-label clinical trial for patients with advanced solid tumors designed to evaluate the safety, tolerability, and pharmacokinetics of escalating oral doses. The trial will utilize a standard 3+3 dose-escalation design.

"Preclinical data for NLG802 have shown an advantageous pharmacokinetic profile in preclinical models and were presented in April at the AACR annual meeting," said Charles J. Link, Jr., MD, Chairman, Chief Executive Officer and Chief Scientific Officer. "NLG802 further expands the lifecycle and IP surrounding our evolving immuno-oncological platform."

Trial specific information is available on clinicaltrials.gov

About NLG802

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 is currently evaluating 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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Investor Contact:
Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com

Media:
Andrew Mastrangelo
AVP, Public & Media Relations
LaVoieHealthScience
617-374-8800, ext. 108
amastrangelo@lavoiehealthscience.com