

NEWLINK GENETICS CORP

FORM 8-K (Current report filing)

Filed 06/23/17 for the Period Ending 06/23/17

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 23, 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 23, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "Positive Phase 1b Data for NewLink Genetics' IDO Pathway Inhibitor, Indoximod, in Combination with Chemotherapy for Patients with Newly Diagnosed Acute Myeloid Leukemia (AML) Presented at the European Hematologic Association (EHA) Congress in Madrid, Spain."

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 June 23, 2017, entitled “Positive Phase 1b Data for NewLink Genetics’ IDO Pathway Inhibitor, Indoximod, in Combination with Chemotherapy for Patients with Newly Diagnosed Acute Myeloid Leukemia (AML) Presented at the European Hematologic Association (EHA) Congress in Madrid, Spain”

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 23, 2017

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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FOR IMMEDIATE RELEASE

Positive Phase 1b Data for NewLink Genetics' IDO Pathway Inhibitor, Indoximod, in Combination with Chemotherapy for Patients with Newly Diagnosed Acute Myeloid Leukemia (AML) Presented at the European Hematologic Association (EHA) Congress in Madrid, Spain

AMES, Iowa, June 23, 2017 - [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announced the presentation of data from the Phase 1b portion of a study of indoximod, an IDO pathway inhibitor, in combination with idarubicin and cytarabine for patients with newly diagnosed acute myeloid leukemia (AML). [Abstract E-912](#), *Indoximod in Combination with Idarubicin and Cytarabine for Upfront Treatment of Patients with Newly Diagnosed Acute Myeloid Leukemia (AML): Phase 1 Report*, is being presented by Ashkan Emadi, M.D., Ph.D., Associate Professor of Medicine at the University of Maryland Greenebaum Comprehensive Cancer Center, during the European Hematology Association (EHA) Congress in Madrid, Spain on Friday, June 23, 2017, 9:30 AM to Saturday, June 24, 7:00 PM CET.

These data indicate indoximod does not appear to add significant toxicity to standard therapy for patients with newly diagnosed AML, and no regimen-limiting toxicities (RLT) have been observed to date. Initial data show that the morphological complete remission (CR) rate is as expected after one cycle of induction chemotherapy. Seven of seven patients who achieved CR were found to have no minimal residual disease (MRD-neg).

“While from a small number of patients, these data show an encouraging MRD negativity rate and may offer the potential for measurable clinical benefits for patients,” said Dr. Emadi, Principal Investigator of this study.

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.

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, 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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