

NEWLINK GENETICS CORP

FORM 8-K (Current report filing)

Filed 11/20/17 for the Period Ending 11/20/17

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): November 20, 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 November 20, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "NewLink Genetics Announces the Presentation of Indoximod Data in Phase 1 Study for Children."

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 November 20, 2017, entitled “NewLink Genetics Announces the Presentation of Indoximod Data in Phase 1 Study for Children”

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: November 20, 2017

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated November 20, 2017, entitled “ NewLink Genetics Announces the Presentation of Indoximod Data in Phase 1 Study for Children .”



NewLink Genetics Announces the Presentation of Indoximod Data in Phase 1 Study for Children

AMES, Iowa, November 20, 2017 -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today announced the presentation of data from a Phase 1 study of indoximod, in combination with radiation, for children with progressive brain tumors. These data were presented at the Society for NeuroOncology, 22nd Annual Meeting, in San Francisco, CA, on November 19, 2017, by Theodore S. Johnson, M.D., Ph.D., Associate Professor of Pediatrics at Augusta University.

The presentation entitled, "Radio-chemo-immunotherapy using the IDO-inhibitor indoximod for children with progressive brain tumors in the phase 1 setting" showed the combination of indoximod plus radiation was well-tolerated.

"We are very pleased with early study data combining salvage radiation therapy with indoximod. This combination seems to be well-tolerated in children with recurrent brain tumors, despite their previous treatment with high-dose radiation plans," said Theodore S. Johnson, M.D., Ph.D., Associate Professor of Pediatrics at Augusta University. "We applaud NewLink Genetics for providing access to indoximod for the children enrolling in this first-in-children study."

A link to the presentation slides can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in the "Investors & Media" section under "[Events & Presentations.](#)" A second presentation, complete with scan images, given by Dr. Johnson at the Texas Children's Neuro-oncology Conference on November 10, 2017 can be found listed in the same location on NewLink's website. Additional information for this study, NLG2105 for pediatric patients with refractory malignant brain tumors, may be found [here](#).

About NewLink Genetics Corporation

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing novel immunoncology 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/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies. For more information, please visit www.newlinkgenetics.com and follow us on Twitter [@NLNKGenetics](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements 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 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 in this press release represent NewLink's views as of the date of this press release. 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 press release.

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