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 4, 2018

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 o

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 o

Section 8 - Other Events

Item 8.01. Other Events.

On June 4, 2018, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "NewLink Genetics Announces Final Results from Two Phase 2 Studies of Indoximod Presented at ASCO 2018."

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 4, 2018, entitled "NewLink Genetics Announces Final Results from Two Phase 2 Studies of Indoximod Presented at ASCO 2018"

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 4, 2018

NewLink Genetics Corporation

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

NewLink Genetics Announces Final Results from Two Phase 2 Studies of Indoximod Presented at ASCO 2018

Ames, Iowa, June 4, 2018 -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced that data from two Phase 2 studies of indoximod, used in combination with other agents, were presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

“Our data in advanced melanoma suggest that indoximod in combination with checkpoint blockade shows encouraging response rates potentially in both PD-L1 positive and negative patients,” said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. “We wish to thank the patients and their caregivers who participated in both of these studies.”

Indoximod in combination with checkpoint inhibition in advanced melanoma

Results from a single-arm Phase 2 study of indoximod in combination with checkpoint inhibitors for patients with advanced melanoma were presented today by Yousef Zakharia, MD, Assistant Professor of Medicine, Division of Hematology, Oncology and Blood & Marrow Transplantation at the University of Iowa and Holden Comprehensive Cancer Center.

In this study, of 102 total patients enrolled, 101 patients with advanced melanoma were treated with indoximod plus standard-of-care checkpoint inhibition as approved for melanoma. 70 patients with cutaneous or mucosal melanoma were treated with pembrolizumab plus indoximod and had an on-treatment imaging, meeting the per-protocol, pre-specified definition of evaluable for efficacy. Of the remaining 32 patients, 15 had uveal melanoma, 4 received ipilimumab, 4 received nivolumab, and one patient was never treated. In addition, 8 patients came off study prior to the first on-treatment imaging study. The full data set, including the expanded biopsy cohort, is provided on the company’s website in the “Posters & Presentations” section under the “Investors & Media” tab.

Key findings from the 70 evaluable for efficacy patients presented from the study include:

- ORR for combination therapy of 56%
- CR of 19%
- Median PFS of 12.4 months
- PD-L1 ≥ 1% staining of 54% (22/41 patients with archival tissue)
- ORR by PD-L1 status
  - PD-L1 (+) patients: ORR of 77%
  - PD-L1 (-) patients: ORR of 42%
- Combination was well tolerated

Indoximod in combination with chemotherapy in metastatic pancreatic cancer

Results from a Phase 2 study of indoximod plus chemotherapy for patients with metastatic pancreatic cancer were presented at ASCO by Nathan Bahary, MD, PhD, Associate Professor in the Division of Oncology and Medical Director of the Pancreatic Cancer Program at the University of Pittsburgh Medical Center. Key findings from this study show that the combination was well tolerated with a median Overall Survival (mOS) of 10.9 months and an Overall Response Rate (ORR) of 46.1%. Although the study did not meet the prespecified primary goal of a 30% decrease in the risk of death compared with historical controls, the combination demonstrated potentially promising activity with an immunologic correlation for response to therapy. These data may be found on the company’s website in the “Posters & Presentations” section under the “Investors & Media” tab.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target involved in regulating the tumor microenvironment and immune escape. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications such as AML, DIPG and melanoma.

About NewLink Genetics Corporation

NewLink Genetics is a clinical 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. 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 Genetics 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 "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," 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 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; 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 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, 2017 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 Contact:

Sharon Correia
VP, Integrated Communications
LaVoieHealthScience
617-374-8800, ext. 105
scorreia@lavoiehealthscience.com