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): September 7, 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 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 September 7, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "Updated Data for Indoximod Plus KEYTRUDA® (pembrolizumab) Demonstrate Improvement of Response Rate for Patients with Advanced Melanoma."

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 September 7, 2017, entitled “Updated Data for Indoximod Plus KEYTRUDA® (pembrolizumab) Demonstrate Improvement of Response Rate for Patients with Advanced Melanoma”

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: September 7, 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 September 7, 2017, entitled “Updated Data for Indoximod Plus KEYTRUDA® (pembrolizumab) Demonstrate Improvement of Response Rate for Patients with Advanced Melanoma”

Updated Data for Indoximod Plus KEYTRUDA® (pembrolizumab) Demonstrate Improvement of Response Rate for Patients with Advanced Melanoma

Pivotal Trial of Indoximod in Advanced Melanoma to Include Both PD-1 Inhibitors, KEYTRUDA (pembrolizumab) and OPDIVO® (nivolumab)

AMES, Iowa, September 07, 2017 -- NewLink Genetics Corporation (NASDAQ: NLNK) today announced updated data from the ongoing Phase 2 NLG2103 study of indoximod, NewLink Genetics' IDO pathway inhibitor, in combination with the PD-1 pathway inhibitor, KEYTRUDA (pembrolizumab). These data will be highlighted in an oral presentation at the Third International Cancer Immunotherapy Conference in Frankfurt/Mainz, Germany, on September 9, 2017 by Yousef Zakharia, M.D., Assistant Professor of Medicine, Division of Hematology, Oncology and Blood & Marrow Transplantation at the University of Iowa and Holden Comprehensive Cancer Center.

The presentation entitled, "Combined Inhibition of the IDO and PD-1 Pathways Improves the Response Rate for Patients with Advanced Melanoma", showed an improvement over previously reported results presented at the AACR Annual Meeting 2017 for both the Complete Response rate (CR) and the Overall Response Rate (ORR) for patients[1] who received indoximod plus pembrolizumab. Evaluable patients were defined as those having at least one on-treatment imaging study.

Key findings in the updated data reported today:

- Improvement in Complete Response (CR) to 20% (10/51 patients) compared to CR of 12% (6/51 patients)
- The Progression-Free Survival (PFS) by RECIST criteria was 56% at one year with median PFS (mPFS) of 12.9 months

"We are encouraged by the progression-free survival and the improvement in complete responses observed in the trial," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer, and Chief Scientific Officer. "The updated data further support our decision to initiate a pivotal trial for patients with advanced melanoma."

Indoximod plus Pembrolizumab Data from Phase 2 Trial in Advanced Melanoma	
n[1] = 51 patients	n (%)
ORR	**31 (61)**
CR	10 (20)
PR	21 (41)
SD	10 (20)
DCR	**41 (80)**
PD	10 (20)
mPFS (months)	**12.9**
PFS at 12 months	**56%**
overall response rate (ORR), complete response (CR), partial response (PR), stable disease (SD), disease control rate (DCR), progressive disease (PD), median progression-free survival (mPFS), progression-free survival (PFS)	
[1] Update includes only those patients with cutaneous, mucosal and melanoma of unknown primary origin	
Data as presented at Third International Cancer Immunotherapy Conference	

Indoximod in combination with pembrolizumab was well-tolerated. The most common all-grade adverse events were fatigue, headache, and nausea. Three patients experienced grade 3 serious adverse events (SAE) possibly attributed to indoximod. Three patients experienced SAEs that led to discontinuation of treatment. There were no treatment related deaths.

Pivotal Trial of Indoximod in Advanced Melanoma to Include Both PD-1 Inhibitors, KEYTRUDA (pembrolizumab) and OPDIVO (nivolumab)

The pivotal trial has been designed as a large-scale (600 patients) trial in Stage III unresectable and metastatic stage IV melanoma. The trial will have a one to one randomization between indoximod plus KEYTRUDA (pembrolizumab) or OPDIVO (nivolumab) compared to single agent PD-1 inhibitor. The co-primary endpoints of the study are PFS by RECIST criteria and Overall Survival (OS).

“Our team is excited to move forward with this pivotal trial,” said Eugene Kennedy, M.D., Vice President of Clinical and Medical Affairs. “We believe that allowing physicians the choice of either pembrolizumab or nivolumab accurately reflects current clinical care and should aid in enrolling the trial by the end of 2018.”

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 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.

KEYTRUDA® is a registered trademark of Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

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.

###

Investor Contact:
Lisa Miller
Director of Investor Relations

Exhibit 99.1

NewLink Genetics
515-598-2555
lmiller@linkp.com

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