

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 25, 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 7 - Regulation FD

Item 7.01. Regulation FD Disclosure.

NewLink Genetics Corporation, a Delaware corporation (the “Company”), expects to provide certain revised forward-looking guidance concerning its financial position and use of cash, and certain additional information concerning its Phase 2 clinical trial of indoximod in combination with PD-1 inhibitors for patients with advanced melanoma, at the Cantor Fitzgerald Global Healthcare Conference (the “Cantor conference”) on September 25, 2017. A copy of the Company’s presentation to be presented at the Cantor conference is available in the Investor Relations section of the Company’s website at www.newlinkgenetics.com. The revisions to the financial guidance include (i) a new forecast that the Company will have approximately \$100 million in cash and cash equivalents on its balance sheet as of December 31, 2017, (ii) that the Company expects to use \$14 - \$16 million in cash from operations (excluding future financings and milestone or other payments from collaborators) on a quarterly basis for the foreseeable future, (iii) that the Company had sold approximately 1.9 million shares under its “at-the-market” offering after June 30, 2017, and (iv) that the Company estimates it has approximately two years of cash and equivalents as of the date hereof. The Company has approximately 31 million shares of common stock outstanding as of the date hereof.

The information in this Item 7.01 and in the presentation referenced herein shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the presentation referenced herein shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Section 8 - Other Events

Item 8.01. Other Events.

On September 25, 2017, the Company issued a press release titled "NewLink Genetics Announces Clinical Collaboration to Evaluate IO-Based Combination Therapies in Pancreatic Cancer."

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

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including but not limited to, all statements about the Company's revised financial guidance. Actual results could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in the Company's 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. The forward-looking statements represent the Company's views as of the date of this Current Report on Form 8-K. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Current Report on Form 8-K as a result of new information, future events or changes in its expectations.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated September 25, 2017, entitled "NewLink Genetics Announces Clinical Collaboration to Evaluate IO-Based Combination Therapies in Pancreatic Cancer"

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 25, 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 25, 2017, entitled "NewLink Genetics Announces Clinical Collaboration to Evaluate IO-Based Combination Therapies in Pancreatic Cancer"



NewLink Genetics Announces Clinical Collaboration to Evaluate IO-Based Combination Therapies in Pancreatic Cancer

Phase 2, randomized, double-blind, placebo-controlled trial of indoximod in combination with durvalumab, an immune checkpoint inhibitor, along with gemcitabine/ABRAXANE[®] (nab-paclitaxel) and durvalumab with gemcitabine/ABRAXANE[®] versus gemcitabine/ABRAXANE[®]

AMES, Iowa, September 25, 2017 -- [NewLink Genetics Corporation](#) (Nasdaq: NLNK) today announced that it has entered into a clinical collaboration agreement with [AstraZeneca](#) to evaluate the combination of indoximod, NewLink Genetics' small molecule IDO pathway inhibitor, and durvalumab, AstraZeneca's anti-PD-L1 monoclonal antibody, along with standard of care chemotherapy for patients with metastatic pancreatic cancer.

The primary objective for this randomized placebo-controlled, Phase 2 study is to evaluate the efficacy and safety of the immuno-oncology-based combination compared to gemcitabine/ABRAXANE alone. Patients will also be enrolled into a smaller cohort evaluating the combination of durvalumab with gemcitabine/ABRAXANE.

The Phase 2 trial will be funded equally by both companies, with NewLink Genetics serving as the study sponsor. NewLink Genetics' share of the aggregate expense of the trial is not expected to have a material effect on its financial position.

"We are pleased to initiate a joint immuno-oncology clinical collaboration with AstraZeneca," said Dr. Charles J. Link, Jr., Chairman, Chief Executive Officer and Chief Scientific Officer of NewLink Genetics. "As recent data have indicated, indoximod combinations with immunotherapy and chemotherapy show promise of improving outcomes for patients with multiple tumor types."

About Durvalumab

[Durvalumab](#) (*Imfinzi*[™]), a human monoclonal antibody directed against PD-L1, blocks PD-L1 interaction with PD-1 and CD80 on T cells, countering the tumour's immune-evading tactics and inducing an immune response.

Durvalumab is being assessed in Phase III trials as a monotherapy in various stages of NSCLC, in small-cell lung cancer (SCLC), in metastatic urothelial cancer (mUC) and in head and neck squamous cell carcinoma (HNSCC). The combination of durvalumab and tremelimumab is being assessed in Phase III trials in NSCLC, SCLC, mUC and HNSCC and in Phase I/II trials in hepatocellular carcinoma and haematological malignancies.

Imfinzi received accelerated approval from the US Food and Drug Administration for previously treated patients with advanced bladder cancer and is under review in Canada and Australia for similar use.

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 Metastatic (Stage IV) Pancreatic Cancer¹

Approximately 53,670 new cases of pancreatic cancer in the US will be diagnosed in 2017 according to the National Cancer Institute (NCI), and a little over 43,000 people will die of the disease this year. Pancreatic cancer is difficult to detect in its early stages. Because of this, approximately 52% of all pancreatic cancers are metastatic, or advanced, in nature and are associated with a poor prognosis. The 5-year survival rate for pancreatic cancer overall is only 8.2%, and drops to a low of 2.7% for individuals whose pancreatic cancer has metastasized to farther regions of the body.

[¹National Cancer Institute: Pancreas Cancer](#)

About NewLink Genetics Corporation

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing novel immunology 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, prostate cancer, acute myeloid leukemia, and pancreatic cancer. For more information, please visit www.newlinkgenetics.com and follow us on Twitter [@NLNKGenetics](https://twitter.com/NLNKGenetics).

IMFINZI™ is a registered trademark of AstraZeneca.

ABRAXANE® is a registered trademark of Celgene Corporation.

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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