

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): October 25, 2016

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))

Section 8 - Other Events

Item 8.01. Other Events.

On October 25, 2016, NewLink Genetics Corporation (the "Company") issued a press release titled "NewLink Genetics Shares Its Immunology Strategy 2016 Analyst and Investor Day."

The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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 October 25, 2016, entitled "NewLink Genetics Shares Its Immuno-Oncology Strategy 2016 Analyst and Investor Day"

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: October 25, 2016

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 October 25, 2016, entitled “NewLink Genetics Shares Its Immuno-Oncology Strategy 2016 Analyst and Investor Day”



NewLink Genetics Shares Its Immuno-Oncology Strategy 2016 Analyst and Investor Day

Two Distinct IDO Pathway Inhibitors in Clinical Development

- ***Indoximod, Exclusive to NewLink Genetics***
- ***GDC-0919 in Partnership with Genentech, a Member of the Roche Group***

AMES, Iowa & New York City, October 25, 2016 -- NewLink Genetics Corporation (Nasdaq:NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology therapies to patients with cancer, today shared its strategy for becoming a leading immuno-oncology company at the company's 2016 meeting for analysts and investors in New York City.

The program focused on the science and increasing validation of the IDO pathway as a target for oncology drug candidates and NewLink Genetics' clinical programs. A link to a replay of the webcast and the slides can be accessed in the events tab of the investor and media relations section of the company's website, <http://investors.linkp.com/events.cfm>.

"With data presentations from recent oncology medical meetings, there is a lot of excitement and promise in IDO as an important target. IDO pathway inhibitors are natural potential partners for combination treatments with other immuno-oncology checkpoint inhibitors and chemotherapies. We are excited to have two of the five IDO product candidates in clinical development now," said Charles J. Link, Jr., M.D., Chairman and Chief Executive Officer. "One is indoximod, which is our proprietary IDO pathway inhibitor, and the other is GDC-0919, which is partnered with Genentech, a member of the Roche Group."

Leaders in the field of immuno-oncology who presented at today's meeting include: George C. Prendergast, PhD, President & CEO, Lankenau Institute for Medical Research (LIMR) and Editor in Chief, Cancer Research; David H. Munn, MD, Professor of Pediatric Hematology-Oncology, Medical College of Georgia Augusta University; Montaser Shaheen MD, Associate Professor, University of New Mexico Cancer Center; and Ashkan Emadi, MD, PhD, Associate Professor, University of Maryland.

Key takeaways include:

1. **Validation of IDO as a Target.** The IDO pathway can allow cancer to escape the immune system. Many cancers have developed the ability to employ IDO to evade immune attack. Clinical results are increasingly validating the IDO pathway as a target for cancer therapies. Just as scientists discovered the role of PD-1/PD-L1 expression and the usefulness of PD-1/PD-L1 blockade, there is an increasing body of research into the role of the IDO pathway and the potential for its inhibition.
2. **NewLink's Two IDO Pathway Inhibitor Clinical Candidates.** NewLink Genetics is engaged in clinical trials for two IDO pathway inhibitor product candidates, with two distinct mechanisms of action.
 - **GDC-0919**, a direct IDO enzyme inhibitor, is being developed in partnership with Genentech. GDC-0919 is currently in Phase 1b trials, in combination with atezolizumab in solid tumors. In October, 2014, NewLink and Genentech entered in to a license and collaboration agreement with an upfront payment of \$150 million, more than \$1 billion in potential milestones and substantial royalties.

- **Indoximod**, an IDO pathway inhibitor, is proprietary to NewLink Genetics. Indoximod is in the clinic addressing multiple cancers including melanoma, pancreatic, glioblastoma multiforme, breast, acute myeloid leukemia and non-small cell lung.
3. **Indoximod Clinical Development.** Our clinical development strategy for indoximod includes formulation optimization intended to improve the candidate's commercial and clinical potential. The Company reported that it will evaluate the data and report on several clinical trials underway in 2017.
 4. **Future R&D.** NewLink also discussed its program targeting the PTEN pathway in regulatory T cells (Treg cells) as a central driver of tumor immunosuppression. NewLink Genetics is an early leader in the field of PTEN research just as it was in identifying IDO as a potential pathway for immune suppression.

Nicholas N. Vahanian, MD, Co-founder, President & Chief Medical Officer added, "We have built a strong management team, comprised of scientific, clinical and business leaders, with proven expertise in drug discovery and clinical development."

Dr. Vahanian continued, "With the early clinical results in IDO inhibition from NewLink Genetics and our partner, Genentech, we are very well positioned to execute our strategy in taking these immuno-oncology clinical programs forward. Further, we have a strong balance sheet which supports the execution of our clinical plan."

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat 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 facts, 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, 2015 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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