

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 1, 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 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On November 1, 2016, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the third quarter ended September 30, 2016 ("Press Release"). A copy of the Press Release and the Third Quarter Financial Results Presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this Current Report, including Exhibits 99.1 and 99.2 attached hereto is furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

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 November 1, 2016, entitled "NewLink Genetics Reports Third Quarter 2016 Financial Results"
99.2	Third Quarter 2016 Financial Results Presentation

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 1, 2016

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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99.1	Press Release, dated November 1, 2016, entitled "NewLink Genetics Reports Third Quarter 2016 Financial Results"
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FOR IMMEDIATE RELEASE

NewLink Genetics Corporation Provides Operational Update and Reports Third Quarter 2016 Financial Results

-Management to Host Conference Call Today at 8:30 a.m. ET-

AMES, Iowa - November 1, 2016 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology therapies to patients with cancer, today reported consolidated financial results for the third quarter of 2016 and progress in its clinical and pipeline development programs.

“We continue to focus our clinical developmental efforts targeting the IDO pathway. We have two distinct IDO pathway inhibitors advancing in the clinic, GDC-0919 with our partner Genentech and indoximod, our proprietary IDO pathway inhibitor,” said Charles J. Link, Jr. MD, Chairman, Chief Executive Officer and Chief Scientific Officer. “We are also encouraged by recent clinical data that increasingly validate the IDO pathway as an important target in immuno-oncology.”

The Company hosted an investor day on October 25, outlining its vision and execution plans for the future. A webcast of the Company’s presentations can be found at <http://investors.linkp.com/events.cfm>.

“As described at our investor day, we believe 2017 will be an important year in the development of both GDC-0919 and indoximod and we look forward to providing further updates and results,” added Nicholas N. Vahanian, MD, President and Chief Medical Officer.

The program featured leaders in the field of immuno-oncology and pioneers in the science of IDO: 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 from the Investor Day included:

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. We believe 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 in cancer.
2. **NewLink's Two IDO Pathway Inhibitor Clinical Candidates.** NewLink Genetics is engaged in clinical trials for two IDO pathway inhibitor product candidates, each with its own distinct mechanism of action.

- **GDC-0919**, a direct IDO enzymatic inhibitor, is being developed in partnership with Genentech. GDC-0919 is currently in a Phase 1b trial, 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 being tested in the clinic in multiple indications including melanoma, pancreatic cancer, malignant brain tumors, breast cancer, acute myeloid leukemia, and non-small cell lung cancer.
3. **Indoximod Clinical Development.** The Company reported that it will evaluate the data and report on several clinical trials underway in 2017. Furthermore, our clinical development strategy for indoximod includes formulation optimization intended to improve the candidate's clinical and commercial potential.
 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 developing IDO as a potential pathway for immune suppression in cancer.

Financial Results for the Three-Month Period Ended September 30, 2016

Cash Position: NewLink Genetics ended the quarter on September 30, 2016, with cash and equivalents totaling \$148.3 million, compared to \$197.8 million for the year ending December 31, 2015.

R&D Expenses: Research and development expenses in the third quarter of 2016 were \$24.5 million, compared to \$22.5 million during the comparable period in 2015. The increase was primarily due to a \$3.2 million increase in contract manufacturing costs, a \$340,000 increase in stock compensation expense, and a \$400,000 increase in clinical trial expenses, offset by a decrease in equipment and supplies of \$1.3 million, wages of \$490,000 and a \$160,000 decrease in consulting.

G&A Expenses: General and administrative expenses in the third quarter of 2016 were \$7.7 million compared to \$7.4 million during the comparable period in 2015. The increase was due primarily to an increase of \$300,000 in consulting and personnel-related expenses.

Net Income/Loss: NewLink Genetics reported a net loss of \$15.5 million, or a loss of \$0.54 per diluted share, for the third quarter of 2016, compared to a net loss of \$15.9 million, or a loss of \$0.55 per diluted share, for the comparable period in 2015.

NewLink Genetics ended the quarter with 29,091,652 shares outstanding.

Financial Guidance and Upcoming Investor Meetings

NewLink Genetics expects to have approximately \$132 million in cash and equivalents on December 31, 2016.

We have presented at seven investor meetings and conferences since the beginning of the year, including our own investor day held last week. We expect to present at three upcoming conferences in New York City,

including the **Global Mizuho Investor Conference** on November 14, the **Stifel 2016 Healthcare Conference** on November 15, and the **Piper Jaffray 28th Annual Healthcare Conference** on November 29.

Conference Call

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss these results and to provide an update on clinical and pipeline development programs. NewLink Genetics' senior management team will host the conference call, which will be open to all listeners. There will also be a question and answer session following the prepared remarks. Access to the live call is available by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) five minutes prior to the start of the call. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 5960440.

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' 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 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, among others, statements about NewLink Genetics' financial guidance for 2016; 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, 2015 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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NewLink Genetics Corporation
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Grant revenue	\$ 14,457	\$ 13,365	\$ 20,057	\$ 26,294
Licensing and collaboration revenue	888	844	3,008	34,555
Total revenue	15,345	14,209	23,065	60,849
Operating expenses:				
Research and development	24,463	22,508	73,810	56,619
General and administrative	7,749	7,384	26,043	23,007
Loss from operations	(16,867)	(15,683)	(76,788)	(18,777)
Other income (expense), net	19	(63)	118	(30)
Net loss before taxes	(16,848)	(15,746)	(76,670)	(18,807)
Income tax benefit (expense)	1,308	(160)	5,021	—
Net loss	\$ (15,540)	\$ (15,906)	\$ (71,649)	\$ (18,807)
Basic and diluted loss per share	\$ (0.54)	\$ (0.55)	\$ (2.48)	\$ (0.66)
Basic and diluted average shares outstanding	28,983,561	28,734,768	28,911,042	28,518,503

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands)

	September 30,	December 31,
	2016	2015
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 148,276	\$ 197,800
Prepaid expenses and other current assets	25,683	10,342
Income tax receivable	5,197	—
Total current assets	179,156	208,142
Property and equipment, net	7,188	10,400
Total assets	\$ 186,344	\$ 218,542
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 39,626	\$ 12,422
Unearned revenue	693	892
Other current liabilities	326	667
Income taxes payable	—	859
Total current liabilities	40,645	14,840
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	333	368
Deferred rent	1,089	1,153
Unearned revenue	—	407
Total long-term liabilities	7,422	7,928
Total liabilities	48,067	22,768
Stockholders' equity:		
Common stock	291	288
Additional paid-in capital	290,772	276,610
Treasury stock, at cost	(784)	(771)
Accumulated deficit	(152,002)	(80,353)
Total stockholders' equity	138,277	195,774
Total liabilities and stockholders' equity	\$ 186,344	\$ 218,542



Third Quarter 2016 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
November 1, 2016

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Investor Day – Distinguished Speakers



IDO Combinations with Checkpoint Inhibitors

George C. Prendergast, PhD, President & Chief Executive Officer, Lanckenau Institute for Medical Research (LIMR), Editor-in-Chief, Cancer Research



Immunoregulatory Role of Tryptophan Metabolism

David H. Munn, MD, Medical College of Georgia, Augusta University



Understanding Current Melanoma Clinical Data

Montaser Shaheen MD, Associate Professor, University of New Mexico Cancer Center



Indoximod in Treatment of Patients with Acute Myeloid Leukemia (AML)

Ashkan Emadi, MD, PhD, Associate Professor of Medicine, Pharmacology & Experimental Therapeutics, University of Maryland

NewLink Genetics

Investor Day Takeaways

- IDO pathway is central to immune escape
- IDO pathway is becoming increasingly validated as a target for drugs
- Two promising candidates that target the IDO pathway, with distinct mechanisms of action
 - GDC-0919, which targets the enzyme directly (partnered with Genentech)
 - Indoximod, which inhibits the effects of IDO by supplying a “tryptophan-sufficiency” signal
- Proven track record in both in-and-out licensing
- Strong balance sheet to advance current clinical programs

Indoximod Strategy

Optimize Formulation, Enhance Commercial Opportunity and Extend Lifecycle

Current State	Next 6-12 Months	2018 and Beyond
<p>IDO target increasingly validated with early clinical data*</p> <ul style="list-style-type: none"> ▪ Clinical results support preclinical combination data ▪ Promising data in melanoma, brain and pancreatic cancers ▪ Distinct mechanism of action ▪ Potential for IP extension 	<p>Emerging IDO data may provide additional validation</p> <ul style="list-style-type: none"> ▪ Updated clinical data for indoximod in melanoma, brain and pancreas cancers ▪ Formulation improvements to optimize clinical and commercial potential 	<p>IDO combination data may support multiple indications</p> <ul style="list-style-type: none"> ▪ Potential for large scale indoximod trials ▪ Commercial formulation established ▪ Potential for regulatory exclusivity

*Includes indoximod, epacadostat and GDC-0919

Financial Position

Cash and Equivalents	\$148 million (September 30, 2016)
Debt	~\$0.6 million
YE 2016 Cash (Projected)	~\$132 million
Quarterly Negative Cash-Flow	~\$13 million
Shares Outstanding	29.1 million
Market Capitalization	\$450 million*
Headcount	130

*As of October 5, 2016

