

NEWLINK GENETICS CORP

FORM 8-K (Current report filing)

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Address	2503 SOUTH LOOP DRIVE SUITE 5100 AMES, IA 50010
Telephone	515-296-5555
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): February 28, 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))
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Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On February 28, 2017, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the fourth quarter and year ended December 31, 2016 ("Press Release"). A copy of the Press Release and the Fourth Quarter and Year End 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.

Exhibit Number	Description
99.1	Press Release, dated February 28, 2017, entitled "NewLink Genetics Corporation Provides Operational Update and Reports Fourth Quarter, Year End 2016 Financial Results"
99.2	Fourth Quarter and Year End 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: February 28, 2017

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 February 28, 2017, entitled "NewLink Genetics Corporation Provides Operational Update and Reports Fourth Quarter, Year End 2016 Financial Results"
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FOR IMMEDIATE RELEASE

NewLink Genetics Provides Operational & Clinical Update, Reports Fourth Quarter, Year-End 2016 Financial Results

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

AMES, Iowa, February 28, 2017 - [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 fourth quarter and year ended 2016, as well as progress in its clinical development programs. NewLink Genetics also outlined key 2017 business priorities related to the clinical development programs for the Company's immuno-oncology pipeline.

"NewLink Genetics has two separate and distinct IDO pathway inhibitors in clinical development. In 2017, we look forward to advancing clinical validation of IDO as an immuno-oncology target," said Charles J. Link, Jr. MD, Chairman, Chief Executive Officer and Chief Scientific Officer. "Our priorities going into 2017 are clear. For GDC-0919, we anticipate continued progress in the clinic in collaboration with our partner Genentech/Roche. We believe indoximod will emerge as one of the leading IDO pathway inhibitor programs in 2017."

2016 Highlights

- The IDO pathway, which helps cancer escape the patient's immune system, became increasingly validated as an immuno-oncology target, with clinical data coming from NewLink Genetics and others.
- Presented early Phase 2 clinical data of indoximod plus gemcitabine/nab-paclitaxel for the treatment of patients with metastatic pancreatic cancer at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting, suggesting evidence of safety and clinical activity.
- Presented promising interim Phase 2 clinical data from a cohort of patients with advanced melanoma treated with indoximod plus pembrolizumab at the 2016 ASCO Annual Meeting.
- Our Ebola vaccine candidate (rVSVΔG-ZEBOV GP), partnered with Merck, received breakthrough therapy designation from the FDA and PRIME status from the European Medicines Agency. In December 2016 the final results of the Guinea trial were published on-line in The Lancet and confirmed efficacy of the vaccine.
- Finished 2016 with \$131.5 million in cash and equivalents.

Anticipated Highlights in 2017

- Our investigators have submitted an abstract to the American Association for Cancer Research (AACR) on the Phase 2 study cohort of patients with advanced melanoma treated with indoximod in combination with pembrolizumab.
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- We have been informed by the AACR committee that our abstract concerning our new chemical entity NLG802, a novel prodrug of indoximod, has been accepted for a poster presentation.
- Genentech is expected to update on progress on a Phase 1b study of GDC-0919 in combination with atezolizumab for patients with solid tumors.
- We intend to update progress from the Phase 1b, dose-escalation study of indoximod and standard of care therapy in patients with Acute Myeloid Leukemia (AML).
- We expect to finish the year with approximately \$75 million in cash. This excludes potential payments from partners, the proceeds from any offering, and any costs associated with any strategic acquisitions.

“We are excited to be presenting clinical data for indoximod at upcoming scientific meetings in 2017 beginning at AACR next month,” said Nicholas Vahanian, M.D., President and Chief Medical Officer.

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2016, with cash, cash equivalents, and certificates of deposit totaling \$131.5 million compared to \$197.8 million for the year ending December 31, 2015. The Company’s cash position is sufficient to fund current operations in the near and medium term.

R&D Expenses: Research and development expenses were \$19.5 million and \$93.3 million in the fourth quarter and year ended December 31, 2016 compared to \$14.8 million and \$71.4 million during the comparable periods in 2015. The increase year-over-year was due primarily to \$11.1 million of charges incurred as a result of the restructuring during the second quarter of 2016, including a non-cash charge of \$4.0 million related to impaired assets, with the remainder of the increase due to increases in contract manufacturing costs, supplies and equipment and clinical trial expenses.

G&A Expenses: General and administrative expenses in the fourth quarter and year ended December 31, 2016 were \$7.2 million and \$33.2 million compared to \$7.7 million and \$30.7 million during the comparable periods in 2015. The increase was due to an increase of \$2.9 million in personnel-related expenses due to changes in transiently increased staffing levels, share-based compensation expense and compensation increases, an increase of \$500,000 due to charges incurred as a result of the restructuring, offset by a decrease of \$930,000 in consulting, legal and licensing fees, and supplies.

Net Loss: NewLink Genetics reported a net loss of \$13.5 million or \$0.46 per diluted share for the fourth quarter of 2016 and a net loss of \$85.2 million or \$2.94 per diluted share for the year ended December 31, 2016, compared to a net loss of \$21.6 million or \$0.75 per diluted share for the fourth quarter of 2015 and a net loss of \$40.4 million or \$1.41 per diluted share for the year ended December 31, 2015.

NewLink Genetics ended 2016 with 29,163,673 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss the results and to give an update on clinical and business development activities. NewLink Genetics’ senior management team will host the 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 conference call is available by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) five minutes prior to the start of the call. The conference call will be webcast live and a link to the webcast can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in

the "Investors & Media" section under "Events and Presentations." To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast. 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 71940747. The replay will be available for two weeks from the date of the call.

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 2017; 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 December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Grant revenue	\$ 12,184	\$ 6,064	\$ 32,242	\$ 32,358
Licensing and collaboration revenue	518	1,588	3,526	36,143
Total revenue	12,702	7,652	35,768	68,501
Operating expenses:				
Research and development	19,490	14,795	93,300	71,414
General and administrative	7,182	7,682	33,226	30,689
Loss from operations	(13,970)	(14,825)	(90,758)	(33,602)
Other income (expense), net	128	(11)	247	(41)
Net loss before taxes	(13,842)	(14,836)	(90,511)	(33,643)
Income tax benefit (expense)	336	(6,738)	5,356	(6,738)
Net loss	\$ (13,506)	\$ (21,574)	\$ (85,155)	\$ (40,381)
Basic loss per share	\$ (0.46)	\$ (0.75)	\$ (2.94)	\$ (1.41)
Diluted loss per share	\$ (0.46)	\$ (0.75)	\$ (2.94)	\$ (1.41)
Basic and diluted average shares outstanding	29,147,247	28,788,615	28,979,327	28,586,585

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

	Year Ended	
	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 131,490	\$ 197,800
Prepaid expenses and other current assets	30,447	10,342
Income tax receivable	5,975	—
Total current assets	167,912	208,142
Property and equipment, net	6,835	10,400
Total assets	\$ 174,747	\$ 218,542
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 37,192	\$ 12,422
Unearned revenue	391	892
Other current liabilities	322	667
Income taxes payable	—	859
Total current liabilities	37,905	14,840
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	285	368
Deferred rent	1,091	1,153
Unearned revenue, excluding current portion	—	407
Total long-term liabilities	7,376	7,928
Total liabilities	45,281	22,768
Stockholders' equity:		
Common stock	292	288
Additional paid-in capital, net	295,535	276,610
Treasury stock, at cost	(853)	(771)
Retained deficit	(165,508)	(80,353)
Total equity	129,466	195,774
Total liabilities and equity	\$ 174,747	\$ 218,542



Fourth Quarter and Year-End 2016 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
February 28, 2017

Agenda

Introduction

- Jack Henneman, *Executive Vice President & CFO*

2017 Ongoing Priorities

- Charles J. Link, Jr., M.D., *Chairman, CEO & CSO*

Clinical Updates / Anticipated News Flow

- Nicholas N. Vahanian, M.D., *President & CMO*

Fourth Quarter and Year-End 2016 Financial Results

- Mr. Henneman

Cautionary Note Regarding Forward-Looking Statements

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NewLink Genetics – 2016 Takeaways

- The IDO pathway is central to immune escape in many types of cancers
- The IDO pathway is becoming increasingly validated as an immuno-oncology target
- Two product candidates that target the IDO pathway, with distinct mechanisms of action
 - GDC-0919; Targets the enzyme directly (partnered with Genentech/Roche)
 - Indoximod; Inhibits effects of IDO pathway by supplying a “tryptophan-sufficiency” signal
- Proven track record in both in-licensing and out-licensing
- Strong balance sheet to advance current preclinical and clinical programs

IDO Pathway Inhibitor Clinical Development

AGENT	INDICATION	REGIMEN	PHASE 1	PHASE 2	PHASE 3
Indoximod	Advanced Melanoma	Indoximod + PD-1 inhibitors or ipilimumab	ENROLLING 		
	Metastatic Pancreatic Cancer	Indoximod + gemcitabine and nab-paclitaxel	ENROLLED 		
	Metastatic Breast Cancer	Indoximod + taxane	ENROLLED 		
	Malignant Brain Tumors	Indoximod + temozolomide	ENROLLING 		
	Castrate Resistant Prostate Cancer (CRPC)	Indoximod + sipuleucel-T	ENROLLED 		
	Newly Diagnosed Acute Myeloid Leukemia (AML)	Indoximod + standard of care	 ENROLLING		
	Advanced Non-Small Cell Lung Cancer (NSCLC)	Indoximod + teregenpumatucel-L + chemotherapy	 ENROLLING		
GDC-0919*	Solid Tumors	GDC-0919 + atezolizumab (PDL-1)	 ENROLLING		
	Solid Tumors	GDC-0919	 ENROLLED		

*Partnered with Genentech/Roche

Fourth Quarter and Year-End 2016 Financial Results

YE Cash and Equivalents	\$131.5 million
Debt	~\$0.5 million
YE 2017 Cash (Projected)	~\$75 million
Quarterly Negative Cash-Flow	~\$13 million
Shares Outstanding	29.2 million
Market Capitalization	\$435 million*
Headcount	122

Major 2017 YE Cash Projection Assumptions: This excludes potential payments from partners, the proceeds from any offerings, and any costs associated with any strategic transactions.

*As of February 21, 2017



Q & A

