

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): May 4, 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))

Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On May 4, 2017, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the first quarter ended March 31, 2017 ("Press Release"). A copy of the Press Release and the First 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 May 4, 2017, entitled "NewLink Genetics Corporation Reports First Quarter 2017 Financial Results and Updates Clinical Trial Guidance"
99.2	First Quarter 2017 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: May 4, 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 May 4, 2017, entitled "NewLink Genetics Corporation Reports First Quarter 2017 Financial Results and Updates Clinical Trial Guidance"
99.2	First Quarter 2017 Financial Results Presentation



FOR IMMEDIATE RELEASE

NewLink Genetics Reports First Quarter 2017 Financial Results and Updates Clinical Trial Guidance

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

AMES, Iowa, May 4, 2017 (GLOBAL NEWSWIRE) - [NewLink Genetics Corporation](#) (NASDAQ:NLNK), today reported consolidated financial results for the first quarter 2017, as well as progress in its clinical development programs.

Recent Highlights:

- Presented promising interim Phase 2 data of the IDO pathway inhibitor, indoximod, in combination with KEYTRUDA® (pembrolizumab) for patients with advanced melanoma at the American Association of Cancer Research (AACR) plenary session on April 4, 2017
- Presented a poster on NLG802, "*A novel prodrug of indoximod with enhanced pharmacokinetic properties,*" at AACR on April 4, 2017
- Abstract accepted for presentation at the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO) for a randomized double-blind, placebo-controlled Phase 2 study of indoximod in combination with the vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer
- Abstract accepted for presentation at the 2017 ASCO Annual Meeting submitted by our partner on a Phase 1b dose-escalation study of navoximod (GDC-0919) in combination with TECENTRIQ® (atezolizumab) in multiple solid tumors

"We believe that the emerging clinical data from NewLink Genetics and other companies are validating the fundamental hypothesis that the IDO pathway is central to immuno-suppression in cancer," said Charles J. Link, Jr. MD, Chairman, Chief Executive Officer and Chief Scientific Officer. "We have two distinct IDO pathway inhibitors advancing in the clinic, indoximod - which is wholly-owned by NewLink Genetics - and navoximod (GDC-0919), which is partnered to Genentech/Roche. In addition, we have a next-generation compound, a novel prodrug of indoximod, NLG802, which we expect to enter the clinic by the end of Q3 this year."

Guidance for remainder of 2017:

- Metastatic castration resistant prostate cancer: Randomized, placebo-controlled Phase 2 clinical trial data to be presented at ASCO on Monday, June 5, 2017
- Metastatic pancreatic cancer: Indoximod in combination with gemcitabine + ABRAXANE® (nab-paclitaxel) Phase 2 trial to be presented at an upcoming medical meeting in the second half of 2017
- Acute Myeloid Leukemia (AML): Interim data from a Phase 1b dose-escalation study of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed AML to be presented second half of 2017

The Company announced that it intends to initiate a pivotal trial of indoximod plus anti-PD-1 inhibitors for patients with advanced melanoma by the end of 2017. The trial is expected to use an adaptive design that incorporates a brief dose confirmation stage followed by a definitive randomized stage.

“The clinical data for indoximod in advanced melanoma establishes the basis for this pivotal trial,” said Nicholas N. Vahanian, MD, President and Chief Medical Officer.

Financial Results:

Cash Position: NewLink Genetics ended the first quarter with cash and cash equivalents totaling \$118.2 million compared to \$131.5 million for the year ending December 31, 2016.

We expect to end 2017 with approximately \$75 million in cash and equivalents, which excludes any cash that may be received from financings or milestones.

R&D Expenses: Research and development expenses were \$15.7 million in the first quarter of 2017 compared to \$21.9 million in the first quarter of 2016. The decrease was due primarily to a \$4.6 million decline in clinical trial and manufacturing-related spend, a decrease in personnel-related spend of \$1.4 million, and a decrease in licensing and consulting fees of \$1.0 million, offset by an increase in stock compensation expense of \$822,000.

G&A Expenses: General and administrative expenses in the first quarter of 2017 were \$8.2 million compared to \$9.2 million in the first quarter of 2016. The decrease was due to a decline of \$700,000 in consulting and legal fees, a decrease of \$700,000 in personnel-related spend, offset by an increase in stock compensation expense of \$437,000.

Net Loss: NewLink Genetics reported a net loss of \$20.9 million or loss of \$0.72 per diluted share for the first quarter of 2017 compared to a net loss of \$23.7 million or loss of \$0.82 per diluted share for the first quarter of 2016.

NewLink Genetics ended Q1 2017 with 29,219,661 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 7503837. 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>

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

TECENTRIQ® is a registered trademark of Genentech, a member of the Roche Group.

PROVENGE® is a registered trademark of Dendreon/Valeant Pharmaceuticals International, Inc.

ABRAXANE® is a registered trademark of Celgene Corporation

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements 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, 2016 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 March 31,	
	2017	2016
Grant revenue	\$ 2,586	\$ 4,338
Licensing and collaboration revenue	175	1,370
Total operating revenues	2,761	5,708
Operating expenses:		
Research and development	15,725	21,937
General and administrative	8,234	9,164
Loss from operations	(21,198)	(25,393)
Other (expense) income, net	(25)	39
Net loss before taxes	(21,223)	(25,354)
Income tax benefit	310	1,634
Net loss	\$ (20,913)	\$ (23,720)
Basic and diluted loss per share	\$ (0.72)	\$ (0.82)
Basic and diluted average shares outstanding	29,213,488	28,856,944

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

	Year Ended	
	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 118,240	\$ 131,490
Prepaid expenses and other current assets	8,984	5,921
Income tax receivable	6,287	5,975
Other receivables	9,645	24,526
Total current assets	143,156	167,912
Property and equipment, net	6,466	6,835
Total assets	<u>\$ 149,622</u>	<u>\$ 174,747</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 27,423	\$ 37,192
Unearned revenue	223	391
Other current liabilities	325	322
Total current liabilities	27,971	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	229	285
Deferred rent	1,068	1,091
Total long-term liabilities	7,297	7,376
Total liabilities	35,268	45,281
Stockholders' equity:		
Common stock	292	292
Additional paid-in capital	301,573	295,535
Treasury stock, at cost	(1,090)	(853)
Accumulated deficit	(186,421)	(165,508)
Total stockholders' equity	114,354	129,466
Total liabilities and stockholders' equity	<u>\$ 149,622</u>	<u>\$ 174,747</u>



First Quarter 2017 Results

NewLink Genetics Corporation

Nasdaq: NLNK
May 4, 2017

Agenda

Introduction

- Jack Henneman, *Executive Vice President & CFO*

IDO Pathway Program Developments

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

Clinical Updates / Guidance on Timing of Data

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

First Quarter 2017 Financial Results

- Mr. Henneman

Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation 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 presentation represent NewLink' Genetics' views as of the date of this presentation. 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 presentation.

Q1 Takeaways

- Emerging clinical data are validating the IDO pathway as central to immunosuppression
- IDO pathway inhibition has the potential to enhance patient outcomes when used in combination with other cancer therapies
- NewLink has two distinct types of IDO pathway inhibitors in the clinic
 - Indoximod: wholly-owned by NewLink
 - Navoximod (GDC0919): partnered with Genentech/Roche
 - NLG802: NewLink's next generation prodrug of indoximod to enter clinic later this year
- Presented promising interim Phase 2 data of the IDO pathway inhibitor, indoximod, in combination with KEYTRUDA® (pembrolizumab) for patients with advanced melanoma at the American Association of Cancer Research (AACR) plenary session on April 4, 2017
- Presented a poster on NLG802, "*A novel prodrug of indoximod with enhanced pharmacokinetic properties,*" at AACR on April 4, 2017
- Abstract accepted for presentation at the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO) for a randomized double-blind, placebo-controlled Phase 2 study of indoximod in combination with the vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer
- Abstract accepted for presentation at the 2017 ASCO Annual Meeting submitted by our partner on a Phase 1b dose-escalation study of navoximod (GDC-0919) in combination with TECENTRIQ® (atezolizumab) in multiple solid tumors

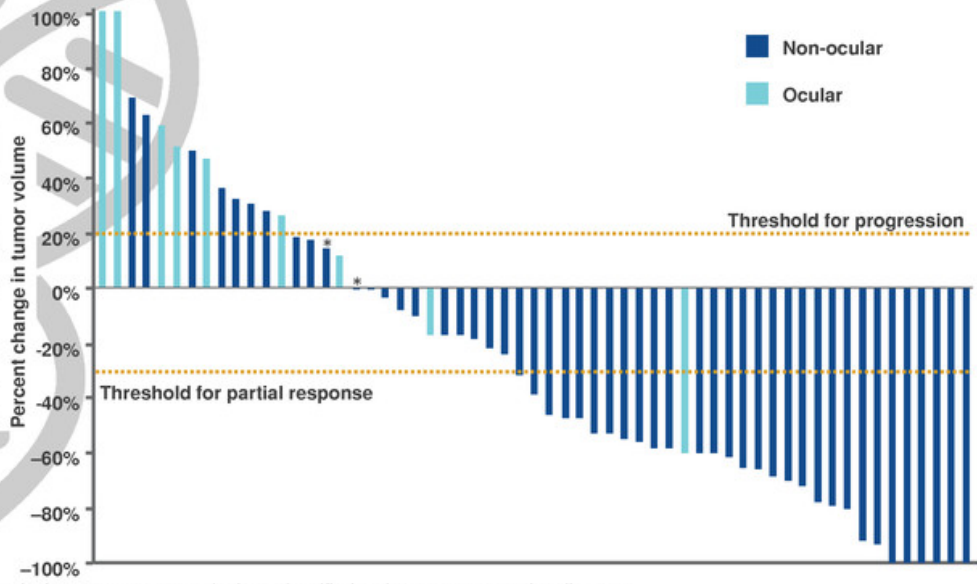
KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

TECENTRIQ® is a registered trademark of Genentech, a member of the Roche Group.

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Best Response by Patient

Distinct Difference in Non-ocular Versus Ocular Patients



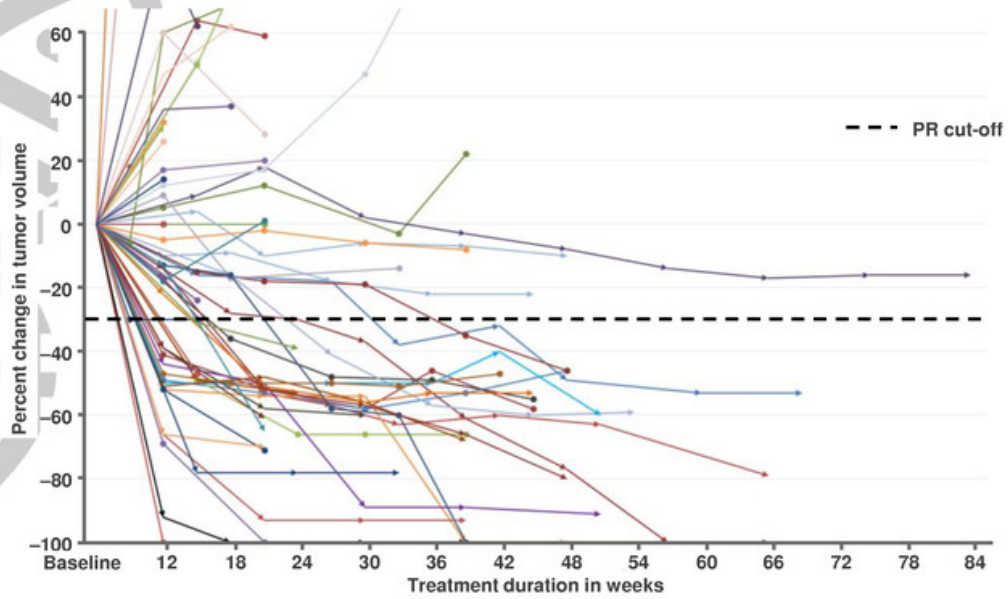
*Stable disease of primary lesion; new non-target lesions classified patients as progressive disease.

Note: 1 patient was unevaluable for response due to pleural effusion/collapsed left lung; the patient progressed based on several new non-target lesions at Week 13.

Zakharia Y, et al. Oral presentation at: 107th Annual Meeting of the American Association for Cancer Research (AACR); April 1-5, 2017; Washington, DC. Abstract CT117.

Change in Tumor Volume Over Time

Durable and Ongoing Responses



PR, partial response.

Note: 1 patient was unevaluable for response due to pleural effusion/collapsed left lung; the patient progressed based on several new non-target lesions at Week 13.
Zakharia Y, et al. Oral presentation at: 107th Annual Meeting of the American Association for Cancer Research (AACR); April 1-5, 2017; Washington, DC. Abstract CT117.

Anticipated Highlights for 2017 Clinical Programs

- Metastatic castration resistant prostate cancer:
 - Abstract 3066: Randomized placebo-controlled Phase 2 clinical trial data to be presented at ASCO on *Monday, June 5, 2017, 9:00 AM ET-12:30 PT ET*
- Metastatic pancreatic cancer:
 - Indoximod in combination with gemcitabine + ABRAXANE® (nab-paclitaxel) Phase 2 trial data available at an upcoming medical meeting in the second half of 2017
- Acute Myeloid Leukemia (AML):
 - Interim data from a Phase 1b dose-escalation study of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed AML available second half of 2017
- Multiple solid tumors:
 - Phase 1b dose-escalation trial data for navoximod (GDC-0919) plus TECENTRIQ® (atezolizumab) to be presented at ASCO on *Sunday, June 4, 2017 from 10:45 AM ET-12:15 PM ET* by our partner (Abstract 105)
- NLG802: next-generation, novel prodrug to enter clinic by end of Q3 2017
- Advanced Melanoma:
 - Initiate a pivotal trial of indoximod + anti-PD-1 inhibitors with dose confirmation stage in 2017 followed by a randomized stage

ABRAXANE® is a registered trademark of Celgene Corporation

First Quarter 2017 Financial Results

Cash and Equivalents	\$118.2 million
Debt	~\$0.5 million
YE 2017 Cash (Projected)	~\$75 million
Quarterly Negative Cash-Flow	~\$13 million
Shares Outstanding	29.2 million
Market Capitalization	~\$500 million
Headcount	127

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.



Q & A

