

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 3, 2018

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 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On May 3, 2018, 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, 2018 ("Press Release"). A copy of the Press Release and the First Quarter 2018 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 3, 2018, entitled " NewLink Genetics Reports First Quarter 2018 Financial Results "
99.2	First Quarter 2018 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 3, 2018

NewLink Genetics Corporation

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



FOR IMMEDIATE RELEASE

NewLink Genetics Reports First Quarter 2018 Financial Results

Management to Host Conference Call Today at 4:30 p.m. ET

Ames, Iowa, May 3, 2018 -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today reported consolidated financial results for the first quarter 2018 and reviewed recent highlights and upcoming milestones.

“NewLink Genetics continues to produce encouraging data supporting the differentiated mechanism of action of indoximod, its IDO pathway inhibitor, and the potential for indoximod in multiple therapeutic combinations to improve patient outcomes across a broad range of cancer indications,” said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer.

Highlights

- Abstracts accepted for presentation at the ASCO Annual Meeting, June 2018
 - [Abstract 4015](#) - *Phase 2 trial of the IDO pathway inhibitor indoximod plus gemcitabine / nab-paclitaxel for the treatment of patients with metastatic pancreas cancer* - to be presented during the discussion session, “Gastrointestinal (Noncolorectal) Cancer,” Sunday, June 3, 2018, 4:45 PM - 6:00 PM CT
 - [Abstract 9512](#) - *Phase 2 trial of the IDO pathway inhibitor indoximod plus checkpoint inhibition for the treatment of patients with advanced melanoma* - to be presented during the discussion session, “Melanoma/Skin Cancers,” Monday, June 4, 2018, 4:45 PM - 6:00 PM CT
- Abstracts presented at the American Association of Cancer Research (AACR) Annual Meeting, April 2018
 - [Abstract 3753](#) - *Indoximod modulates AhR-driven transcription of genes that control immune function*
 - [Abstract 10973](#) - *Front-line therapy of DIPG using the IDO pathway inhibitor indoximod in combination with radiation and chemotherapy*
- Abstract, *Radio-immunotherapy using the IDO pathway inhibitor indoximod for children with newly-diagnosed DIPG*, to be presented at the 18th International Symposium on Pediatric Neuro-Oncology (ISPNO), Poster Session 1, Sunday, July 1, 2018, 5:00 PM - 6:30 PM MT
- Data from Phase 1b trial of indoximod plus standard-of-care chemotherapy for patients with acute myeloid leukemia (AML) intended to be presented in the second half of 2018
- Finalized the novel formulation of indoximod

Update on Clinical Programs and Financial Guidance

NewLink Genetics previously reported that it was undertaking a review of its clinical programs and determined it will not initiate its Phase 3 study of indoximod in combination with PD-1 inhibitors for patients with advanced melanoma. In addition, we have deprioritized pancreatic cancer and have mutually agreed with AstraZeneca not to proceed with the Phase 2 trial.

Clinical opportunities under consideration include high quality randomized studies of indoximod in one or more target disease states for which we have developed promising single-arm data over the last few years. Indoximod has demonstrated encouraging clinical data in a number of cancer indications including AML in combination with chemotherapy, DIPG in combination with radiation and chemotherapy, and melanoma in combination with checkpoint

blockade. When we complete the review of our clinical programs, we expect to have substantially reduced the rate at which the Company will be using cash. We intend to update our financial guidance when we report results for the second quarter.

Financial Results

Cash Position: NewLink Genetics ended the quarter on March 31, 2018, with cash and cash equivalents totaling \$143.9 million compared to \$158.7 million for the year ending December 31, 2017.

R&D Expenses: Research and development expenses for the three months ended March 31, 2018 were \$20.3 million, an increase of \$4.6 million from \$15.7 million for the same period in 2017. The increase was due primarily to an increase of \$8.4 million in contract research and manufacturing spend, an increase of \$670,000 in clinical trial and legal and consulting expense, offset by a \$2.1 million decrease in supplies, a \$1.2 million decrease in personnel-related and stock compensation expense, and a \$1.2 million decrease in licensing expenses.

G&A Expenses: General and administrative expenses for the three months ended March 31, 2018 were \$8.3 million, an increase of \$58,000 from \$8.2 million for the same period in 2017. The increase was due to an increase of \$733,000 of legal and consulting and other expense, offset by a decline of \$675,000 in personnel-related and stock compensation.

Net Loss: The net loss for the three months ended March 31, 2018 was \$18.3 million compared to net loss of \$20.9 million for the same period in 2017. The basic and diluted weighted average common shares outstanding for the three months ended March 31, 2018 were 37,155,082, resulting in a basic and diluted loss per share of \$0.49. For the three months ended March 31, 2017, the basic and diluted weighted average common shares outstanding were 29,213,488, resulting in basic and diluted loss per share of \$0.72.

NewLink Genetics ended Q1 2018 with 37,165,098 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 4:30 p.m. ET today to discuss the financial results and to review its clinical 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 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 can be accessed through the NewLink Genetics website at <https://edge.media-server.com/m6/p/7pbbadk4>. 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 for two weeks from the date of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 6768809.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target involved in regulating the tumor microenvironment and immune escape. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications such as AML, DIPG and melanoma.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology 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. For more information, please visit www.newlinkgenetics.com and follow us on Twitter [@NLNKGenetics](https://twitter.com/NLNKGenetics).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics 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 "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," 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 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; 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 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, 2017 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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NewLink Genetics Corporation
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2018	2017
Grant revenue	\$ 9,384	\$ 2,586
Licensing and collaboration revenue	516	175
Total operating revenues	9,900	2,761
Operating expenses:		
Research and development	20,314	15,725
General and administrative	8,292	8,234
Total operating expenses	28,606	23,959
Loss from operations	(18,706)	(21,198)
Other income and expense:		
Miscellaneous income (expense)	24	(4)
Interest income	385	85
Interest expense	(13)	(106)
Other income (expense), net	396	(25)
Net loss before taxes	(18,310)	(21,223)
Income tax benefit	—	310
Net loss	\$ (18,310)	\$ (20,913)
Basic and diluted loss per share	\$ (0.49)	\$ (0.72)
Basic and diluted average shares outstanding	37,155,082	29,213,488

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

	Year Ended	
	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 143,891	\$ 158,708
Prepaid expenses and other current assets	5,616	6,226
Income tax receivable	339	356
Other receivables	10,353	10,176
Total current assets	160,199	175,466
Property and equipment, net	4,698	5,091
Income tax receivable	140	\$ 140
Total non-current assets	4,838	\$ 5,231
Total assets	\$ 165,037	\$ 180,697
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,316	\$ 9,256
Accrued expenses	14,500	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	90	92
Current portion of notes payable and obligations under capital leases	112	160
Total current liabilities	20,018	22,031
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	90	111
Deferred rent	975	998
Total long-term liabilities	7,065	7,109
Total liabilities	27,083	29,140
Stockholders' equity:		
Blank check preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at March 31, 2018 and December 31, 2017; issued and outstanding shares - 0 at March 31, 2018 and December 31, 2017	—	—
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at March 31, 2018 and December 31, 2017; issued 37,252,384 and 37,168,122 at March 31, 2018 and December 31, 2017, respectively, and outstanding 37,165,098 and 37,109,556 at March 31, 2018 and December 31, 2017, respectively	373	372
Additional paid-in capital	394,711	389,786
Treasury stock, at cost: 87,286 and 58,566 shares at March 31, 2018 and December 31, 2017, respectively	(1,403)	(1,142)
Accumulated deficit	(255,727)	(237,459)
Total stockholders' equity	137,954	151,557
Total liabilities and stockholders' equity	\$ 165,037	\$ 180,697



First Quarter 2018 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
May 3, 2018

Agenda

Introduction

- Jack Henneman, *Executive Vice President & CFO*

IDO Pathway Program Developments & Outlook

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

Clinical Updates & Guidance on Timing of Data

- Eugene P. Kennedy, M.D., *Chief Medical Officer*

First Quarter 2018 Financial Results

- Jack 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, among others, statements about NewLink Genetics' financial guidance for 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; 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 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, 2017 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.

Recent Highlights

- Presented two abstracts at AACR Annual Meeting, April 2018
 - Abstract 3753 – *Indoximod modulates AhR-driven transcription of genes that control immune function*
 - Abstract 10973 – *Front-line therapy of DIPG using the IDO pathway inhibitor indoximod in combination with radiation and chemotherapy*
- Finalized novel formulation of indoximod
- Appointed two new members to the Board of Directors

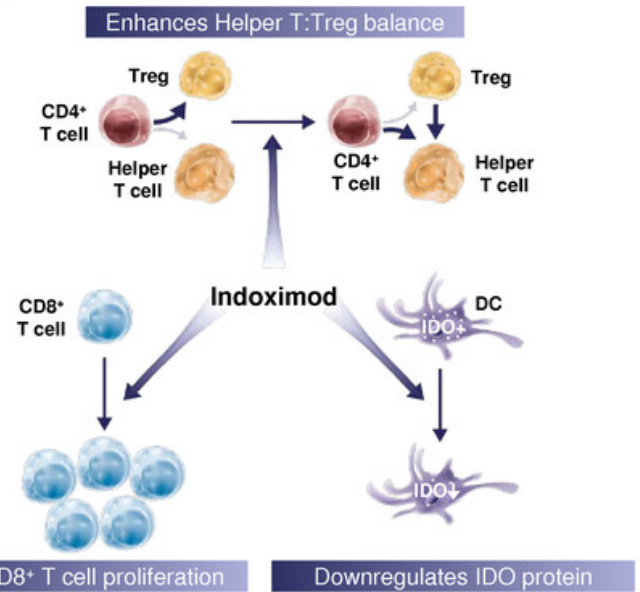
Upcoming Milestones 2018

- Abstracts accepted for presentation at ASCO Annual Meeting, June 2018
 - Abstract 9512 – *Phase 2 trial of the IDO pathway inhibitor indoximod plus checkpoint inhibition for the treatment of patients with advanced melanoma*
 - Abstract 4015 – *Phase 2 trial of the IDO pathway inhibitor indoximod plus gemcitabine / nab-paclitaxel for the treatment of patients with metastatic pancreas cancer*
- Accepted for presentation at the 18th International Symposium on Pediatric Neuro-Oncology (ISPNO), July 2018
 - *Radio-immunotherapy using the IDO pathway inhibitor indoximod for children with newly-diagnosed DIPG*
- Data from Phase 1b trial of indoximod plus standard-of-care chemotherapy for patients with newly diagnosed acute myeloid leukemia (AML) intended to be presented 2H 2018

Indoximod Mechanism of Action

A Unique Approach to Reversing Immunosuppression

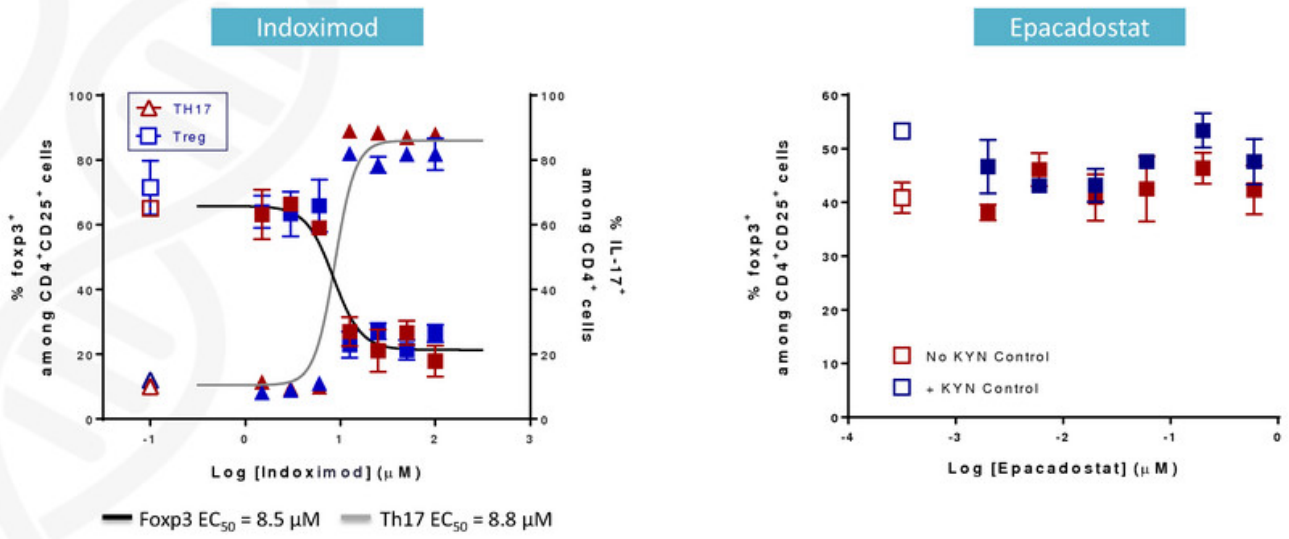
- Indoximod is an orally administered, small-molecule IDO pathway inhibitor that reverses the immunosuppressive effects of low tryptophan and high kynurenine that result from IDO activity
- Indoximod has immunostimulatory effects involving 4 main cell types: CD8⁺ T cells, CD4⁺ T helper cells, T regulatory cells, and dendritic cells
 - Reverses the effects of low tryptophan by increasing proliferation of effector T cells
 - Drives differentiation into T helper cells vs regulatory T cells
 - Downregulates IDO expression in dendritic cells
- Potential synergy has been shown with checkpoint blockade, chemotherapy, radiation and vaccines



IDO, indoleamine 2,3-dioxygenase; Treg, T regulatory cell; DC, dendritic cell.
 Brincks EL, et al. AACR 2018. Abstract 3753.

Indoximod vs Epacadostat: A Different Mechanism of Action

Indoximod Drives Differentiation of Helper vs Regulatory T Cells



Encouraging Early Results for Patients with Newly Diagnosed DIPG

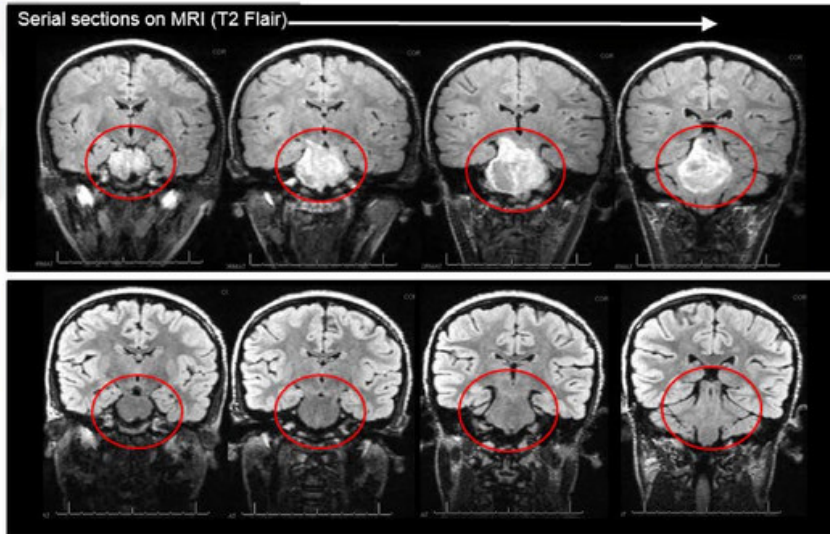
- Example of significant response in 9.4-yr-old patient

Baseline
(pretreatment)

DIPG scans reviewed by
Tina Young-Poussaint, M.D.,
Boston Children's Hospital

Patient 037 classified as:
"Significant response"

After 6 weeks of
indoximod +
radiation (54 Gy)



Financial Position

Q1 2018 End Cash and Equivalents	\$143.9 million
YE 2018 Cash Projected	To be updated on Q2 call
Shares Outstanding as of March 31, 2018	37.2 Million

NewLink Genetics: Key Takeaways

Indoximod, an Immuno-oncology Candidate with Differentiated MOA

- Indoximod has a differentiated mechanism of action (MOA)
 - Reverses the effects of low tryptophan by increasing proliferation of effector T cells
 - Drives differentiation into T helper cells vs regulatory T cells
 - Downregulates IDO expression in dendritic cells
- Promising clinical activity of indoximod in combination with
 - Chemotherapy in AML
 - Radiation and chemotherapy in DIPG
 - Checkpoint blockade in melanoma
- Additional indoximod data to be presented at upcoming medical conferences
 - Melanoma & Pancreatic Cancer: Final Phase 2 results at ASCO, June 2018
 - DIPG: Updated Phase 1b data at ISPNO, July 2018
 - AML: Updated Phase 1b data intended 2H 2018

Q & A

