

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): July 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))

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 July 28, 2017, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the second quarter ended June 30, 2017 ("Press Release"). A copy of the Press Release and the Second 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 5 - Corporate Governance and Management

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On July 28, 2017, NewLink Genetics Corporation, a Delaware corporation, or the Company, announced that Nicholas Vahanian, M.D., President and Chief Medical Officer and a Director of the Company, will be on a temporary medical leave of absence, effective immediately. During his absence, other members of the management team will assume his duties.

(e) Amendment of Executive Employment Agreements

On July 26, 2017, in connection with a voluntary reduction in base salary, the Company entered into amendments to the employment agreement (the "**Amendments**") with each of Dr. Charles J. Link, Jr., Dr. Nicholas N. Vahanian, John B. Henneman and Brian Wiley that amend and restate certain terms of the current employment agreements between the Company and such named executive officers.

The material terms of the Amendments include: (i) a 10% percent reduction in annual base salary effective the next regular payroll cycle. Upon any covered termination under the terms of the employment agreements as amended, the 2017 Base Salary or the executive's then effective base salary under the agreement, whichever is greater, shall be used for purposes of calculating executive's severance.

The foregoing description of the Agreements is qualified in its entirety by reference to the Amendments, which NewLink intends to file as exhibits to its Quarterly Report on Form 10-Q for the current quarter.

Section 8 - Other Events

Item 8.01. Other Events.

On July 28, 2017, the Company also announced that it has implemented a significant restructuring program. The objective of the restructuring is to focus the company's resources on the development of indoximod and NLG802.

The restructuring is in process and includes the elimination of most spending for programs outside of indoximod and approximately a 50 percent reduction in headcount to approximately 70.

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 July 28, 2017, entitled "NewLink Genetics Corporation Reports Second Quarter 2017 Financial Results and Updates Indoximod Program"
99.2	Second 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: July 28, 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 July 28, 2017, entitled “NewLink Genetics Corporation Reports Second Quarter 2017 Financial Results and Updates Indoximod Program”
99.2	Second Quarter 2017 Financial Results Presentation



FOR IMMEDIATE RELEASE

NewLink Genetics Reports Second Quarter 2017 Financial Results and Updates Indoximod Program

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

AMES, Iowa, July 28, 2017 -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today reported consolidated financial results for the second quarter of 2017 and provided updates on its clinical development program for indoximod, NewLink Genetics' small molecule targeting the IDO pathway with a distinct mechanism of action.

"We continue to focus on indoximod, our leading drug candidate, as it advances into late-stage clinical development," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer, and Chief Scientific Officer. "We have made great progress since the end of the first quarter. We have strengthened the IP around this program with the USPTO Notice of Allowances for indoximod salts and prodrug formulations, and NLG802 entered the clinic."

Recent Highlights:

- NewLink Genetics recently completed a successful face-to-face meeting with the FDA to review the proposed design for the pivotal trial with indoximod for patients with advanced melanoma.
- First patient dosed in the Phase 1 study of NLG802, a novel prodrug of indoximod. NLG802 is a distinct investigational agent targeting the IDO pathway and represents an important step in the Company's product life-cycle planning.
- A Notice of Allowance (NOA) by the US Patent and Trade Office (USPTO) was received in early July for our patent application covering indoximod salts and prodrugs. When issued, this patent will provide exclusivity until 2036 and cover both the formulation of indoximod to be used in the pivotal trial and NLG802.
- Phase 2 data from a randomized trial of indoximod in combination with the cancer vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer (mCRPC) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 5th. These [data](#) showed a statistically significant improvement in radiographic progression-free survival (rPFS) of 10.3 months compared to 4.1 months in the placebo arm, with no difference in adverse events between the two arms.
- Phase 1b [data](#) from a trial of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML) were presented at the European Hematology Association (EHA) Annual Congress on June 23rd. These early data showed that after one cycle of induction therapy, 7/7 patients who achieved complete response (CR) were seen to have no evidence of minimal residual disease (MRD-neg), suggesting that the addition of indoximod has the potential to reduce the proportion of patients with evidence of leukemia after initial therapy.

Guidance for remainder of 2017:

- First patients dosed with novel salt formulation of indoximod.

- Updated data from Phase 2 trial of indoximod plus gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer to be presented at an oncology meeting in late 2017 or early 2018.
- Initiation of a pivotal trial of indoximod in combination with PD-1 checkpoint blockade for patients with advanced melanoma, with the goal of full enrollment by end of 2018.

Financial Results for the Three-Month Period Ended June 30, 2017

Cash Position: NewLink Genetics ended the second quarter with cash and cash equivalents totaling \$107.8 million compared to \$131.5 million for the year ending December 31, 2016.

R&D Expenses: Research and development expenses were \$18.2 million in the second quarter of 2017 compared to \$27.4 million in the second quarter of 2016. The decrease was due primarily to a \$1.8 million decline in clinical trial spend, a decrease in supplies and other expense of \$6.8 million, a decrease in personnel-related spend of \$2.2 million, offset by an increase in manufacturing-related spend of \$1.3 million, and an increase in licensing and consulting fees of \$300,000.

G&A Expenses: General and administrative expenses in the second quarter of 2017 were \$8.9 million compared to \$9.1 million in the second quarter of 2016. The decrease was due to a decline of \$1.0 million in personnel-related spend, offset by an increase of \$261,000 in consulting and legal fees, an increase in stock compensation expense of \$64,000, and an increase in supplies and other expense of \$387,000.

Net Loss: NewLink Genetics reported a net loss of \$16.7 million or (\$0.57) per diluted share for the second quarter of 2017 compared to a net loss of \$32.4 million or (\$1.12) per diluted share for the second quarter of 2016.

NewLink Genetics ended the quarter with 29,281,301 shares outstanding.

Financial Guidance and Upcoming Investor Meetings

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

We look forward to presenting at the Baird Healthcare Conference and the Cantor Fitzgerald Healthcare Conference in September in New York City.

Conference Call Details

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to give an update. 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 can be accessed through the NewLink Genetics website at <http://investors.linkp.com/events.cfm>. 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 51432155.

About NewLink Genetics Corporation

NewLink Genetics is a late-stage 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. Indoximod is being evaluated in combination with treatment regimens including PD-1 checkpoint blockade, cancer vaccines, and chemotherapy across multiple indications such as melanoma, prostate cancer, acute myeloid leukemia, and pancreatic cancer. For more information, please visit <http://www.newlinkgenetics.com>

PROVENGE® is a registered trademark of Dendreon Pharmaceuticals LLC.

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 June 30,		Six Months Ended June, 30	
	2017	2016	2017	2016
Grant revenue	\$ 10,314	\$ 1,262	\$ 12,900	\$ 5,600
Licensing and collaboration revenue	56	750	231	2,120
Total operating revenues	10,370	2,012	13,131	7,720
Operating expenses:				
Research and development	18,200	27,410	33,925	49,347
General and administrative	8,897	9,130	17,131	18,294
Loss from operations	(16,727)	(34,528)	(37,925)	(59,921)
Other income (expense), net	1	60	(24)	99
Net loss before taxes	(16,726)	(34,468)	(37,949)	(59,822)
Income tax benefit	—	2,079	310	3,713
Net loss	\$ (16,726)	\$ (32,389)	\$ (37,639)	\$ (56,109)
Basic and diluted loss per share	\$ (0.57)	\$ (1.12)	\$ (1.29)	\$ (1.94)
Basic and diluted average shares outstanding	29,255,386	28,891,827	29,219,469	28,874,385

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

	Year Ended	
	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 107,777	\$ 131,490
Prepaid expenses and other current assets	4,916	5,921
Income tax receivable	6,287	5,975
Other receivables	11,258	24,526
Total current assets	130,238	167,912
Property and equipment, net	5,886	6,835
Total assets	\$ 136,124	\$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 25,822	\$ 37,192
Unearned revenue	167	391
Other current liabilities	314	322
Total current liabilities	26,303	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	173	285
Deferred rent	1,045	1,091
Total long-term liabilities	7,218	7,376
Total liabilities	33,521	45,281
Stockholders' equity:		
Common stock	292	292
Additional paid-in capital	306,556	295,535
Treasury stock, at cost	(1,098)	(853)
Accumulated deficit	(203,147)	(165,508)
Total stockholders' equity	102,603	129,466
Total liabilities and stockholders' equity	\$ 136,124	\$ 174,747



Second Quarter 2017 Results

NewLink Genetics Corporation

Nasdaq: NLNK
July 28, 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

- Eugene P. Kennedy, M.D., *Vice President Clinical & Medical Affairs*

Second Quarter 2017 Financial Results

- Mr. Henneman

Cautionary Note Regarding Forward-Looking Statements

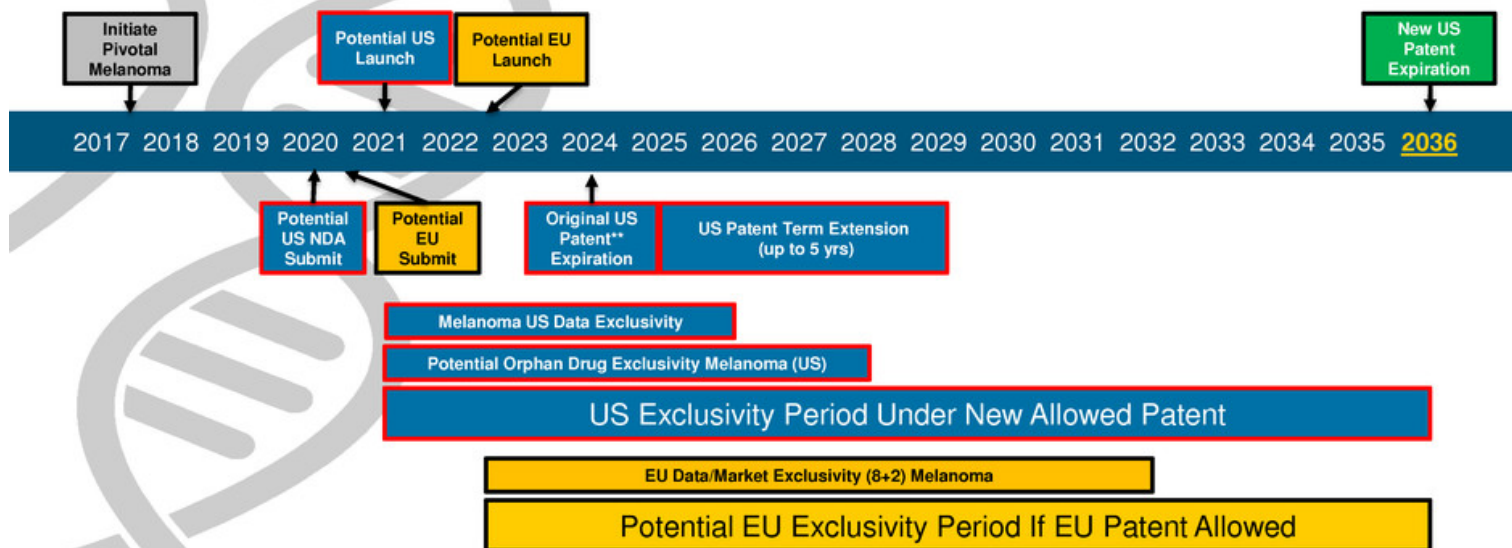
This presentation contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements, within the meaning of The Private Securities Litigation 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.

Highlights

- Clinical data continue to support indoximod as a potent IDO pathway inhibitor with the potential to improve outcomes for patients with cancer when used in combination with other cancer therapies
- Progress toward initiation of a pivotal trial with indoximod for patients with advanced melanoma
 - Successful face-to-face meeting with the FDA to review the proposed development plan
- Improved IP for salt and prodrug formulations of indoximod
 - Received a Notice of Allowance (NOA) by the US Patent and Trade Office in early July; when issued, this patent will provide exclusivity until 2036 and cover both the formulation of indoximod to be used in the pivotal trial and NLG802
- First patient dosed in the Phase 1 study of NLG802, a novel prodrug of indoximod
- Promising Phase 2 data from a randomized trial of indoximod in combination with the cancer vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer (mCRPC) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 5th
- Encouraging early Phase 1b data from a trial of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML) were presented at the European Hematology Association (EHA) Annual Congress on June 23rd

Allowed US Patent for Indoximod Formulation (Salt)

Potential Market Exclusivity In Advanced Melanoma

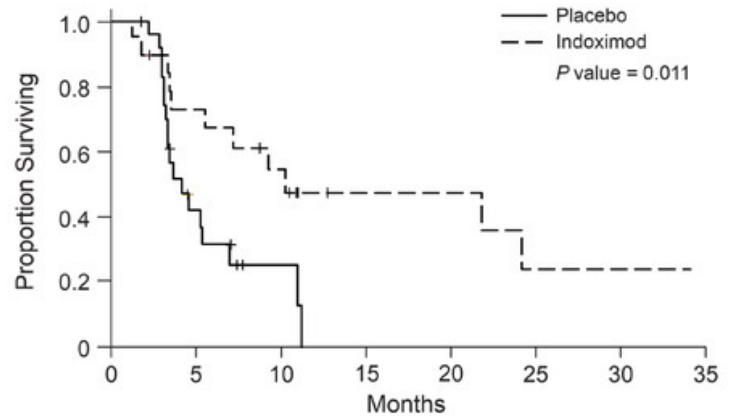


**Current patent will still apply along with salt patent because it covers inclusion of d-1-methyl-tryptophan (indoximod)

Indoximod plus Provenge (sipuleucel-T) Vaccine

Randomized, Double Blind, Placebo Controlled Phase 2 Study

- 46 Patients: Indoximod (22) vs Placebo (24)
- PA2024 ELISPOT response data showed no statistically significant difference*
- Statistically significant improvement in radiographic progression free survival (rPFS)
 - Median rPFS of 10.3 months for indoximod vs 4.1** months in placebo (p=0.011)
 - Median OS has not yet been reached
- Combination treatment was well tolerated



First positive randomized data reported for an IDO pathway inhibitor

*PA2024 response was evaluable in 35 patients

**Median time to objective progression for pivotal IMPACT trial of sipuleucel-T was 3.7 mo
Abstract 3066 Jha et al. 2017 ASCO Annual Meeting

Indoximod plus Standard of Care Chemotherapy

Phase 1/2 Evaluating the Feasibility of Combination with 7+3 Regimen

- Patients with newly diagnosed AML
- Surrogate efficacy endpoint being explored as potential fast to market strategy
- Currently completing initial Phase 1b dose escalation
- Planned expansion into randomized Phase 2

EHA '17 Abstract E-912, Emadi, et al June 23rd 2017

- 15 patients enrolled as of June 1, 2017
- Indoximod does not appear to add significant toxicity
- 7/9 patients who completed treatment per protocol (>80% compliance) achieved morphologic CR
- 7/7 patients who achieved CR had no evidence of minimal residual disease

Strong preclinical data and significant unmet need

Clinical Introduction: Indoximod (Salt) Formulation

2H 2017: Phase 1b for patients with AML

2H 2017: Healthy volunteers

Q4 2017: Dose escalation phase of pivotal trial

Second Quarter 2017 Financial Results

Cash and Equivalents	\$107.8 million
Debt	~\$0.4 million
YE 2017 Cash (Projected)	~\$75 million
Forecast Quarterly Negative Cash-Flow ¹	~\$14 million
Shares Outstanding	29.2 million
Market Capitalization	~\$210 million
Headcount ²	72

¹ Excludes the proceeds from any finance offerings or strategic collaborations.

² Reflects remaining headcount after internal restructuring announcement on July 26, 2017. Total headcount reduction of 59 employees, which includes the immediate departure of 25 employees and the remainder to leave over the course of the next several months after transitioning projects. Additional restructuring activities will include halting other programs to conserve resources to support the indoximod program.



Q & A

