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): March 1, 2018

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2503 South Loop Drive **Ames, IA**	**50010**
(Address of principal executive offices)	(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 o

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 o

Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On March 1, 2018, 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, 2017 ("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 March 1, 2018, entitled “NewLink Genetics Reports Fourth Quarter, Year-End 2017 Financial Results and Provides Clinical Update for Indoximod Programs”
99.2	Fourth Quarter and Year-End 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: March 1, 2018

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 March 1, 2018, entitled "NewLink Genetics Reports Fourth Quarter, Year-End 2017 Financial Results and Provides Clinical Update for Indoximod Programs"
99.2	Fourth Quarter and Year-End 2017 Financial Results Presentation

FOR IMMEDIATE RELEASE

NewLink Genetics Reports Fourth Quarter, Year-End 2017 Financial Results and Provides Update for Indoximod Programs

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

Ames, Iowa, March 1, 2018 -- NewLink Genetics Corporation (NASDAQ:NLNK) today reported consolidated financial results for the fourth quarter and year ended 2017, as well as progress in its clinical development programs. The Company also outlined key 2018 business priorities related to the clinical programs for indoximod, its IDO pathway inhibitor drug candidate.

“NewLink Genetics has produced encouraging data supporting indoximod in several indications and looks forward to presenting additional data in 2018, further validating IDO pathway inhibition as a key target in immuno-oncology,” said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. “In addition, Indigo301, our pivotal trial for patients with metastatic melanoma, and Indigo201, our randomized Phase 2 trial in collaboration with AstraZeneca for patients with metastatic pancreatic cancer, are our core clinical priorities for 2018.”

Anticipated 2018 Highlights

- Initiate randomization portion of Indigo301, a pivotal Phase 3 trial for patients with advanced melanoma, in Q2-Q3 2018
- Full Phase 2 results of indoximod plus checkpoint inhibitors in metastatic melanoma in 1H:2018
- Initiate Indigo201, a randomized Phase 2 trial for patients with metastatic pancreatic cancer, in 1H:2018
- Full Phase 2 results from the single-arm trial of indoximod plus gemcitabine nab-paclitaxel in metastatic pancreatic cancer in 1H:2018
- Two abstract presentations at AACR Annual Meeting 2018 include data from a Phase 1 study of indoximod for pediatric patients with malignant brain tumors and data providing additional characterization of the differentiated mechanism of action of indoximod
- Continued evaluation of indoximod in additional oncology indications

2017 Highlights

- Presented updated Phase 2 data of indoximod plus pembrolizumab in advanced melanoma at the Third Annual International Cancer Immunotherapy Conference with encouraging overall and complete response rates and progression-free survival
- Commenced dose determination portion of Indigo301
- Entered into a collaboration with AstraZeneca on Indigo201
- Presented Phase 2 data from a randomized, double-blind study of indoximod plus cancer vaccine for patients with metastatic castration-resistant prostate cancer at ASCO Annual Meeting, indicating statistically significant improvement in median progression-free survival compared to monotherapy

- Presented Phase 1b data of indoximod plus chemotherapy in newly diagnosed AML suggesting the potential for indoximod in treatment regimens beyond PD-1
- Successfully raised $74.3 million, net of offering costs, and ended 2017 with $158.7 million cash and equivalents

Update on Current Clinical Timeline and Financial Guidance

NewLink Genetics reported an update of its clinical timeline and now expects to initiate Indigo301 randomization in Q2 to Q3 2018 and complete enrollment in 2019. The Company expects to end this year with approximately $75 million in cash. The shift in the timeline arises from an increased number of trial sites planned for Indigo301 and additional work related to manufacturing.

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2017, with cash and cash equivalents totaling $158.7 million compared to $131.5 million for the year ending December 31, 2016. The Company's cash position is sufficient to fund operations in the near and medium term.

R&D Expenses: Research and development expenses were $17.5 million and $69.9 million in the fourth quarter and year ended December 31, 2017 compared to $19.5 million and $93.3 million during the comparable periods in 2016. The decrease year-over-year was due primarily to higher restructuring charges of $11.1 million incurred in 2016, including a non-cash charge of $4.0 million related to impaired assets, as compared to $600,000 of charges incurred in 2017. Remainder of the decrease was due to decreases of $6.2 million in clinical trial costs, $4.4 million in supplies, equipment and licensing, $3.6 million in personnel-related expense, and $200,000 in manufacturing expense. Decreases were offset by increases of $1.0 million in stock compensation expense and $600,000 in legal and consulting.

G&A Expenses: General and administrative expenses in the fourth quarter and year ended December 31, 2017 were $6.7 million and $31.7 million compared to $7.2 million and $33.2 million during the comparable periods in 2016. The decrease was primarily due to a $2.3 million reduction in personnel-related spend and $1.2 million reduction in legal and consulting, offset by increases of $700,000 in stock compensation expense, $700,000 in supplies and equipment, and $600,000 in restructuring charges incurred in 2017.

Net Loss: NewLink Genetics reported a net loss of $13.7 million or $0.37 per diluted share for the fourth quarter of 2017 and a net loss of $72.0 million or $2.30 per diluted share for the year ended December 31, 2017, compared to 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.

NewLink Genetics ended 2017 with 37,109,556 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 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" or by clicking here. 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 9466627. The replay will be available for two weeks from the date of the call.

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 anti-PD-1/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies.

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. For more information, please visit www.NewLinkGenetics.com and follow us on Twitter @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 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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Investor Contact:
Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com

Media Contact:
Sharon Correia
VP, Integrated Communications
LaVoieHealthScience
617-374-8800, ext. 105
scorreia@lavoiehealthscience.com

Source: NewLink Genetics Corporation

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,	
	2017	2016	2017	2016
Grant revenue	$ 10,042	$ 12,185	$ 28,321	$ 32,242
Licensing and collaboration revenue	56	518	390	3,526
Total operating revenues	10,098	12,703	28,711	35,768
Operating expenses:				
Research and development	17,461	19,490	69,866	93,300
General and administrative	6,688	7,183	31,726	33,226
Loss from operations	(14,051)	(13,970)	(72,881)	(90,758)
Other income, net	235	129	371	247
Net loss before taxes	(13,816)	(13,841)	(72,510)	(90,511)
Income tax benefit	130	335	559	5,356
Net loss	$ (13,686)	$ (13,506)	$ (71,951)	$ (85,155)
Basic and diluted loss per share	$ (0.37)	$ (0.46)	$ (2.30)	$ (2.94)
Basic and diluted average shares outstanding	36,770,490	29,147,247	31,304,309	28,979,327

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

	Year Ended	
	December 31, 2017	**December 31, 2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 158,708	$ 131,490
Prepaid expenses and other current assets	6,226	5,921
Income tax receivable	356	5,975
Other receivables	10,176	24,526
Total current assets	175,466	167,912
Non-current Assets		
Property and equipment, net	5,091	6,835
Income Tax Receivable	140	—
Total non-current assets	5,231	6,835
Total assets	$ 180,697	$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,723	$ 37,192
Unearned revenue	56	391
Other current liabilities	252	322
Total current liabilities	22,031	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	111	285
Deferred rent	998	1,091
Total long-term liabilities	7,109	7,376
Total liabilities	29,140	45,281
Stockholders' equity:		
Common stock	372	292
Additional paid-in capital	389,786	295,535
Treasury stock, at cost	(1,142)	(853)
Accumulated deficit	(237,459)	(165,508)
Total stockholders' equity	151,557	129,466
Total liabilities and stockholders' equity	$ 180,697	$ 174,747

Fourth Quarter and Year-End 2017 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
March 1, 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*

Fourth Quarter and Year-End 2017 Financial Results

- Jack Henneman

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2017 Highlights

- Presented updated Phase 2 data of indoximod plus pembrolizumab indicating encouraging overall and complete responses and progression-free survival
- Commenced dose determination portion of Indigo301, a pivotal Phase 3 trial for patients with advanced melanoma
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- Presented Phase 1b data of indoximod plus chemotherapy in acute myeloid leukemia suggesting the potential for indoximod in treatment regimens beyond PD-1
- Successfully raised $74.3 million, net of offering costs, and ended 2017 with $158.7 million cash and equivalents

2018 Highlights

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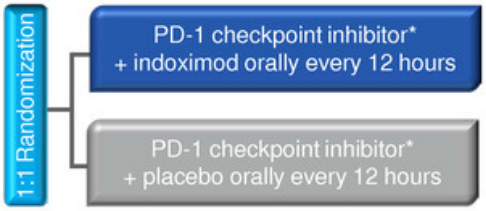
- Full Phase 2 results of indoximod plus checkpoint inhibitors in metastatic melanoma 1H:2018
- Initiate Indigo201, a randomized Phase 2 in metastatic pancreatic cancer in 1H:2018
- Full Phase 2 results of indoximod plus gemcitabine nab-paclitaxel in metastatic pancreatic cancer in 1H:2018
- Two abstracts to be presented at AACR Annual Meeting in April 2018
  - Phase 1 study of indoximod for pediatric patients with malignant brain tumors
  - Additional characterization of the differentiated mechanism of action of indoximod
- Continued evaluation of indoximod in additional oncology indications

Indigo301

A Phase 3 Study of Indoximod or Placebo Plus Pembrolizumab or Nivolumab For Patients With Unresectable or Metastatic Melanoma

PATIENT POPULATION

- Adults ≥18 years of age with unresectable stage III or IV advanced melanoma
- No prior melanoma therapy, except
  - BRAF/MEK inhibitor
  - Prior adjuvant or neoadjuvant therapy ≥4 weeks before randomization
  - Prior adjuvant immunotherapy (no relapse during treatment or ≤6 months of treatment discontinuation)
- Stable brain metastases allowed



*Standard-of-care dosing per country.

- Randomization (via an interactive web randomization system) stratified by:
  - Choice of checkpoint inhibitor (pembrolizumab or nivolumab)
  - Prior BRAF/MEK therapy
  - M stage at randomization
- Treatment until disease progression or unacceptable toxicity

EFFICACY ENDPOINTS

Co-primary endpoints

- Progression-free survival
- Overall survival

Secondary endpoint

- Objective response rate

ENROLLMENT

- Total planned enrollment: 624 patients
- ~100 sites in multiple countries

Clinicaltrials.gov NCT03301636

Financial Position

YE 2017 Cash and Equivalents	$158.7 million
Debt	~$0.3 million
YE 2018 Cash (Projected)[1]	~$75 million
Forecast Quarterly Cash Use	~$20-22 million
Shares Outstanding as of December 31,2017	37.1 million

[1] Excludes projections of proceeds, if any, from potential future financings

Financially well-positioned to execute our business strategy

NewLink Genetics

Key Takeaways for 2018

- Initiation of two key randomized trials with indoximod plus checkpoint inhibition
  - Indigo301 for patients with advanced melanoma
  - Indigo201 in collaboration with AstraZeneca for patients with metastatic pancreatic cancer
- Presentation of results from two Phase 2 trials
  - Full Phase 2 results of indoximod plus checkpoint inhibitors for patients with advanced melanoma
  - Full Phase 2 results of indoximod plus chemotherapy for patients with metastatic pancreatic cancer
- Additional data supporting the opportunity for indoximod to improve the lives of patients with cancer across a range of indications

Q & A