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 8, 2019

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 x

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 May 8, 2019, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release providing an operational update and reporting financial results for the first quarter and three months ended March 31, 2019 ("Press Release").

A copy of the Press Release and the First Quarter and three months ended March 31, 2019 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 May 8, 2019, entitled "NewLink Genetics Reports First Quarter 2019 Financial Results and Provides Clinical Activities Update"
99.2	First Quarter 2019 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 8, 2019

NewLink Genetics Corporation

By: /s/ Carl W. Langren
Carl W. Langren
Its: Chief Financial Officer

FOR IMMEDIATE RELEASE

NewLink Genetics Reports First Quarter 2019 Financial Results and Provides Clinical Activities Update

- Management to host conference call today at 4:30 p.m. ET

AMES, Iowa, May 8, 2019 - NewLink Genetics Corporation (NASDAQ:NLNK) today announced financial results for the first quarter ended March 31, 2019 and provided an update on clinical activities.

“We continued to make progress across our clinical programs this year. We look forward to presenting additional encouraging data later this month on NLG802. We were also pleased to present Phase 2 results for NLG207 in combination with weekly paclitaxel for patients with recurrent ovarian cancer at AACR, which demonstrated an encouraging safety profile supporting the potential of NLG207 as a best-in-class topoisomerase 1 inhibitor for those women who had received multiple lines of therapy,” said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer of NewLink Genetics. “With a strong cash position of $113.2 million at the end of the quarter, we are well positioned to continue moving our clinical programs forward, and we anticipate sharing additional data from our pipeline in the coming quarters as we prioritize clinical development programs with a focus on indications with high unmet need and a potential path forward to registration.”

Clinical Update and Anticipated Upcoming Milestones

The Company has had an abstract accepted, and plans to present updated data from a Phase 1 dose-escalation study of NLG802, a prodrug of indoximod, at the Immuno-Oncology 2019 2nd World Congress in Barcelona, Spain, May 23-24, 2019.

The Phase 2 study of NLG207 (formerly CRLX101) in combination with weekly paclitaxel for patients with recurrent ovarian cancer, conducted in conjunction with The GOG Foundation, is complete. The Company recently presented results from this study at the American Association for Cancer Research (AACR) Annual Meeting 2019, and we are evaluating NLG207 as a potential therapeutic in gynecologic malignancies.

Updated results from the cohort of patients with DIPG in the efficacy portion of a Phase 1b study of indoximod for the treatment of pediatric patients with recurrent malignant brain tumors are anticipated later in 2019.

In reference to NewLink Genetics’ partnered Ebola vaccine candidate, Merck recently announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application for this vaccine, V920 (rVSVΔG-ZEBOV-GP). In addition, completion of the rolling Biologics License Application (BLA) filing with the FDA by Merck is anticipated in 2019. Should this vaccine be approved by the FDA, a Priority Review Voucher (PRV) would be issued, in which NewLink Genetics owns a substantial financial interest.

Financial Results for the Three-Month Period Ended March 31, 2019

Cash Position: NewLink Genetics ended the quarter on March 31, 2019, with cash and cash equivalents totaling $113.2 million compared to $120.7 million December 31, 2018. The Company projects its cash position is sufficient to fund planned operations through the end of 2021.

R&D Expenses: Research and development expenses for the first quarter of 2019 were $5.2 million, a decrease of $15.1 million from $20.3 million for the same period in 2018. The decrease was primarily due to reductions of $9.9 million in contract research and manufacturing spend, $2.2 million in personnel-related and stock compensation

expense, $2.1 million in clinical trial expense, $500,000 in supplies and licensing, and $400,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses in the first quarter of 2019 were $5.6 million, a decrease of $2.7 million from $8.3 million for the same period in 2018. The decrease was due primarily to reductions of $2.1 million in personnel-related and stock compensation expense, $605,000 in legal and consulting expense, offset by an increase of $72,000 in supplies and travel expense.

Net Loss: NewLink Genetics reported a net loss of $10.0 million or ($0.27) per diluted share for the first quarter of 2019 compared to a net loss of $18.3 million or ($0.49) per diluted share for the first quarter of 2018.

NewLink Genetics ended Q1 2019 with 37,276,102 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 its financial results and to give an update on clinical and business development activities. There will also be a question and answer session following management's prepared remarks.

Access to the live conference call is available five minutes prior to the start of the call by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) and using the conference ID 8457627. 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 10 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 conference ID 8457627. 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, suppressing immune response and allowing for immune escape by degrading tryptophan with the resultant production of kynurenine. Indoximod reverses the immunosuppressive effects of low tryptophan and high kynurenine through mechanisms that include modulation of the AhR-driven transcription of genes that control immune function. This results in increased proliferation of effector T cells, increased differentiation into helper T cells rather than regulatory T cells, and downregulation of IDO expression in dendritic cells. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications including DIPG, recurrent pediatric brain tumors, and AML.

About NLG802

NLG802 is an investigational, orally available prodrug of indoximod, a small molecule targeting the IDO Pathway. The IDO Pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape. NewLink Genetics is currently evaluating NLG802 in a Phase 1 dose-escalation clinical trial in cancer patients to assess the safety and pharmacokinetics of NLG802.

About NLG207

NLG207 (formerly CRLX101) is an investigational nanoparticle-drug conjugate (NDC) consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor. NDCs enhance drug delivery to tumors where gradual payload release inside cancer cells augments antitumor activity while reducing toxicity. Topoisomerase 1 inhibitors are a class of drugs that modify DNA damage responses in cancer cells. NewLink Genetics is evaluating NLG207 in a series of clinical trials in advanced refractory ovarian cancer patients.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on developing novel oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors, indoximod and its prodrug, NLG802, are immuno-oncology drug candidates designed to harness multiple components of the immune system to combat cancer. NewLink Genetics' drug candidate, NLG207, a nanoparticle formulation of camptothecin, a topoisomerase 1 inhibitor, is under development to combat refractory malignancies. 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 2019 and beyond; 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, 2018 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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Director of Investor Relations

NewLink Genetics

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Source: NewLink Genetics Corporation

NewLink Genetics Corporation
Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Operating Revenues:		
Grant revenue	$ —	$ 9,384
Licensing and collaboration revenue	106	516
Total operating revenues	106	9,900
Operating expenses:		
Research and development	5,203	20,314
General and administrative	5,567	8,292
Total operating expenses	10,770	28,606
Loss from operations	(10,664)	(18,706)
Other income and expense:		
Miscellaneous income	5	24
Interest income	624	385
Interest expense	(1)	(13)
Other income, net	628	396
Net loss before taxes	(10,036)	(18,310)
Income tax benefit	—	—
Net loss	$ (10,036)	$ (18,310)
Basic and diluted loss per share	$ (0.27)	$ (0.49)
Basic and diluted average shares outstanding	37,275,459	37,155,082

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 113,184	$ 120,738
Prepaid expenses and other current assets	4,447	5,536
Income tax receivable	341	339
Other receivables	305	459
Total current assets	118,277	127,072
Property and equipment, net	3,520	3,727
Right-of-use asset	7,334	$ —
Income tax receivable	140	$ 140
Total non-current assets	10,994	$ 3,867
Total assets	$ 129,271	$ 130,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 896	$ 555
Accrued expenses	6,950	8,139
Current portion of deferred rent	—	92
Current portion of lease liability	963	
Current portion of notes payable	63	61
Total current liabilities	8,872	8,847
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable	27	43
Lease Liability	7,353	
Deferred rent	—	906
Total long-term liabilities	13,380	6,949
Total liabilities	22,252	15,796
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at March 31, 2019 and December 31, 2018; issued and outstanding shares — 0 at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at March 31, 2019 and December 31, 2018; issued 37,387,876 and 37,343,547 at March 31, 2019 and December 31, 2018, respectively, and outstanding 37,276,102 and 37,251,220 at March 31, 2019 and December 31, 2018, respectively	373	373
Additional paid-in capital	409,143	407,199
Treasury stock, at cost: 111,774 and 92,327 shares at March 31, 2019 and December 31, 2018, respectively	(1,449)	(1,417)
Accumulated deficit	(301,048)	(291,012)
Total stockholders' equity	107,019	115,143
Total liabilities and stockholders' equity	$ 129,271	$ 130,939


First Quarter 2019 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
May 8, 2019

Agenda

Introduction

- Lisa Miller, *Director of Investor Relations*

Clinical Priorities

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

Clinical Updates and Guidance on Timing of Data

- Eugene Kennedy, MD, *Chief Medical Officer*

First Quarter 2019 Financial Results

- Carl Langren, *Chief Financial Officer*

Cautionary Note Regarding Forward-Looking Statements

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Clinical Programs

NLG207	Recurrent ovarian cancer	**NLG207 plus paclitaxel in recurrent ovarian cancer** ▪ Encouraging GOG Phase 2 results presented at AACR in April 20
Indoximod	Front-line diffuse intrinsic pontine glioma (DIPG)	**Indoximod plus radiotherapy for pediatric patients with DIPG** ▪ Early data show all patients demonstrated initial symptomatic improvement on therapy with evidence of radiographic respons
	NLG802, prodrug of indoximod	**NLG802 in patients with advanced solid tumors** ▪ Early Phase 1 data showed significantly improved PK properties ▪ Upcoming data presentation May 2019
	Recurrent malignant pediatric brain tumors	**Indoximod plus radio-chemotherapy for pediatric patients with recurrent malignant brain tumors** ▪ Early Phase 1 data showed treatment was well tolerated ▪ Phase 1b trial ongoing
	Front-line acute myeloid leukemia (AML)	**Indoximod plus standard-of-care chemotherapy for patients with front-line** ▪ Phase 1b data at ASH in December 2018 showed promising MRD-negativity with indoximod ▪ Phase 1b trial ongoing

Other Opportunities

Ebola VSV-ZEBOV (V920) vaccine

- Merck has announced that the EMA has recently accepted the Marketing Authorization Application (MAA) of this Ebola vaccine candidate
- Merck also announced in 2018 that they had begun a rolling BLA submission with expected filing completion in 2019
- NewLink holds a substantial interest in potential Priority Review Voucher (PRV)

Continue to pursue additional opportunities to expand our pipeline

NLG207

NLG207 *(formerly CRLX101)*

- Nanoparticle formulation of the topoisomerase 1 inhibitor camptothecin
- Acquired from Cerulean Pharma in 2017
- Encouraging results from Phase 2 trial in combination with paclitaxel presented at AACR 2019
- Reviewing other potential opportunities in multiple gynecological malignancies

Ovarian Cancer

Approximately **22,530** women will be diagnosed with ovarian cancer in 2018[1]

Roughly 70 perc of patients diagnc with ovarian car will have a recurrer

Woman have a **1 in 78** chance to have ovarian cancer during her lifetime[1]

Majority diagnosed at advanced stage[2]

References: 1. American Cancer Society. Cancer Facts & Figures 2018. Atlanta, GA: American Cance 2018. 2. National Cancer Institute. http://seer.cancer.gov/statfacts/html/ovary.html
3. Ovarian Cancer Research Alliance. https://ocrahope.org/patients/about-ovarian-cancer/recurrence/

Financial Position

Q1 2019 End Cash and Equivalents	$113.2 Million
Average Quarterly Cash Use Projected	~$10 Million
Cash Runway Projected	Through 2021
Shares Outstanding as of March 31, 2019	37.28 Million

NewLink Genetics: Key Takeaways

Targeting Indications of Need

- Current clinical development program focus:
  - NLG207 in recurrent ovarian cancer
  - Indoximod in frontline DIPG, recurrent malignant pediatric brain tumors and frontline AML
  - NLG802 in solid tumors
- Continue to pursue opportunities to expand pipeline

Strong Cash Position

- ✓ Cash on hand at Q1 end $113.2 million
- ✓ Estimated cash runway to year end 2021 excluding Ebola Priority Review Voucher (PRV) monetization
- ✓ Substantial financial interest in PRV issued if approval of the Ebola vaccine out-licensed by NewLink Genetics

Presentations 2019

- ❑ April 2019: Encouraging Phase 2 results for NLG207 in recurrent refractory ovarian, fallopian tube primary peritoneal cancer preser at AACR
- ❑ Updated Phase 1 data for NLG8 indoximod prodrug
- ❑ Updated Phase 1 data for indoxi plus radiotherapy in DIPG

Q & A