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): February 27, 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 February 27, 2019, 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, 2018 ("Press Release").

A copy of the Press Release and the Fourth Quarter and Year-end 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.

Exhibit Number	Description
99.1	Press Release, dated February 27, 2019, entitled "NewLink Genetics Reports Fourth Quarter, Year-End 2018 Financial Results and Provides Update for Clinical Programs"
99.2	Fourth 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: February 27, 2019

NewLink Genetics Corporation

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

FOR IMMEDIATE RELEASE

NewLink Genetics Reports Fourth Quarter, Year-End 2018 Financial Results and Provides Update for Clinical Programs

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

Ames, Iowa, February 27, 2019 -- NewLink Genetics Corporation (NASDAQ:NLNK) today reported consolidated financial results for the fourth quarter and year ended 2018, as well as progress in its clinical development programs. The Company also outlined key 2019 priorities related to its clinical pipeline.

“In 2018, we published further clinical results on indoximod that suggest it has significant activity in combination therapy for a variety of cancer indications,” said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. “As we enter 2019 with a strong cash position, our intention is to focus on developing the best potential registration strategy for bringing indoximod forward and further developing our pipeline assets, especially NLG207. We would like to thank the investigators and patients who support our clinical trials year after year, and we remain committed to your care.”

Anticipated 2019 Outlook

- Updated results on the cohort of patients with newly diagnosed diffuse intrinsic pontine glioma (DIPG), from the efficacy portion of a Phase 1b study of indoximod for the treatment of pediatric patients with recurrent malignant brain tumors, are anticipated in 2019
- Results from a Phase 2 study of NLG207 (formerly CRLX101), a nanoparticle formulation of the topoisomerase 1 inhibitor, camptothecin, conducted by the Gynecological Oncology Group (GOG) for patients with recurrent ovarian cancer, has been accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting 2019, at the Georgia World Conference Center, in Atlanta, March 29 - April 3, 2019
- Updated results from a Phase 1 study of NLG802, a prodrug of indoximod with enhanced pharmacokinetic properties, are anticipated in 2019
- Updated results from a Phase 1b study of indoximod for pediatric patients with recurrent malignant brain tumors are anticipated in 2019
- Completion by Merck of the rolling Biologics License Application (BLA) filing for V920 (rVSVΔG-ZEBOV-GP), our partnered Ebola vaccine candidate, is expected in 2019

2018 Highlights

- Presented Phase 1 results of indoximod plus front-line radiation and maintenance chemotherapy for the treatment of pediatric patients with newly diagnosed DIPG at the American Association of Clinical Research (AACR) Annual Meeting, April 2018, and updated Phase 1 results at the International Symposium of Pediatric Neuro-Oncology (ISPNO) Annual Meeting, July 2018, showing symptomatic improvement and marked radiographic improvement in DIPG patients.

- Presented updated Phase 1 results for indoximod plus standard of care chemotherapy for younger, healthy patients with newly diagnosed acute myeloid leukemia (AML) in an oral session at the 60th American Society of Hematology (ASH) Annual Meeting, December 2018
- Presented final results from two Phase 2 studies of indoximod at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting with results for indoximod plus checkpoint inhibition in advanced melanoma which we believe showed encouraging overall and complete response rates which compared favorably to historical PD-1 monotherapy results and results for indoximod plus gemcitabine / nab-paclitaxel in metastatic pancreatic cancer demonstrating potentially promising activity that correlated with a measurable immune response
- At the Society for Immunotherapy of Cancer (SITC) 2018 Annual Meeting, we presented correlative immunologic assay results from biopsies obtained during both the advanced melanoma and the metastatic pancreatic cancer trials previously presented at ASCO 2018, illustrating indoximod's impact on the tumor microenvironment as well as first-in-human results showing significantly enhanced pharmacokinetic properties of our indoximod prodrug, NLG802
- November 13, 2018, our partner, Merck, announced that it had begun the rolling submission of licensure application for Ebola vaccine, V920 (rVSVΔG-ZEBOV-GP), to the FDA

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2018, with cash and cash equivalents totaling $120.7 million compared to $158.7 million for the year ending December 31, 2017. The Company projects its cash position is sufficient to fund planned operations through the end of 2021.

R&D Expenses: Research and development expenses were $5.7 million and $45.7 million in the fourth quarter and year ended December 31, 2018 compared to $17.5 million and $69.9 million during the comparable periods in 2017. The decrease year-over-year was due primarily to a $15.2 million reduction in contract research and manufacturing expense, $3.0 million in personnel-related expense, $3.3 million in supplies and equipment, $1.8 million in clinical trial costs, $1.3 million in technology and licensing, and reduction in restructuring expenses of $100,000, offset by a $500,000 increase in consulting and other costs.

G&A Expenses: General and administrative expenses in the fourth quarter and year ended December 31, 2018 were $5.4 million and $29.2 million compared to $6.7 million and $31.7 million during the comparable periods in 2017. The year-over-year decrease of $2.5 million was due to a reduction of $2.5 million in personnel-related spend, $550,000 reduction in consulting and other costs, reduction in restructuring expenses of $300,000, offset by an $850,000 increase in supplies and other expense.

Net Loss: NewLink Genetics reported a net loss of $10.6 million or a loss of $0.28 per diluted share for the fourth quarter of 2018 and a net loss of $53.6 million or a loss of $1.44 per diluted share for the year ended December 31, 2018, compared to 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.

NewLink Genetics ended 2018 with 37,251,220 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 through this link: https://edge.media-server.com/m6/p/dqg32drc. 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 1279102. 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 recurrent pediatric brain tumors, DIPG, and AML.

About NLG207

NLG207 (formerly CRLX101) is an investigational nanoparticle-drug conjugate (NDC) composed of a cyclodextrin-based polymer backbone conjugated 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 are immuno-oncology drug candidates designed to harness multiple components of the immune system to combat cancer. NewLink Genetics’ nanoparticle drug candidate, NLG207, conjugated to 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, 2017 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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Exhibit 99.1

Investor & Media Contact:
Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Grant revenue	$ —	$ 10,042	$ 11,268	$ 28,321
Licensing and collaboration revenue	202	56	1,206	390
Total operating revenues	202	10,098	12,474	28,711
Operating expenses:				
Research and development	5,721	17,461	45,694	69,866
General and administrative	5,427	6,688	29,218	31,726
Total operating expenses	11,148	24,149	74,912	101,592
Loss from operations	(10,946)	(14,051)	(62,438)	(72,881)
Other income and expense:				
Miscellaneous expense	(118)	(24)	(102)	(126)
Interest income	519	263	2,029	616
Interest expense	(2)	(4)	(52)	(119)
Other income, net	399	235	1,875	371
Net loss before taxes	(10,547)	(13,816)	(60,563)	(72,510)
Income tax (expense) benefit	(22)	130	6,968	559
Net loss	$ (10,569)	$ (13,686)	$ (53,595)	$ (71,951)
Basic and diluted loss per share	$ (0.28)	$ (0.37)	$ (1.44)	$ (2.30)
Basic and diluted average shares outstanding	37,229,006	36,770,490	37,191,262	31,304,309

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

	Year Ended	
	December 31, 2018	**December 31, 2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 120,738	$ 158,708
Prepaid expenses and other current assets	5,536	6,226
Income tax receivable	339	356
Other receivables	459	10,176
Total current assets	127,072	175,466
Property and equipment, net	3,727	5,091
Income tax receivable	140	$ 140
Total non-current assets	3,867	$ 5,231
Total assets	$ 130,939	$ 180,697
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 555	$ 9,256
Accrued expenses	8,139	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	92	92
Current portion of notes payable and obligations under capital leases	61	160
Total current liabilities	8,847	22,031
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	43	111
Deferred rent	906	998
Total long-term liabilities	6,949	7,109
Total liabilities	15,796	29,140
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares - 5,000,000 at December 31, 2018 and 2017; issued and outstanding shares - 0 at December 31, 2018 and 2017	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at December 31, 2018 and 2017; issued 37,343,547 and 37,168,122 at December 31, 2018 and 2017, respectively, and outstanding 37,251,220 and 37,109,556 at December 31, 2018 and 2017, respectively	373	372
Additional paid-in capital	407,199	389,786
Treasury stock, at cost: 92,327 and 58,566 shares at December 31, 2018 and 2017, respectively	(1,417)	(1,142)
Accumulated deficit	(291,012)	(237,459)
Total stockholders' equity	115,143	151,557
Total liabilities and stockholders' equity	$ 130,939	$ 180,697




NewLink GENETICS

Fourth Quarter and Full Year 2018 Financial Results

NewLink Genetics Corporation

Nasdaq: NLNK
February 27, 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*

Fourth Quarter 2018 Financial Results

- Carl Langren, *Chief Financial Officer*

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NewLink Genetics Clinical Programs

NLG207	Recurrent ovarian cancer	**NLG207 plus paclitaxel in recurrent ovarian cancer** ▪ NLG207 is a nanoparticle formulation of topoisomerase 1 inhibitor, camptothecin ▪ Phase 2 results accepted for presentation at AACR in April 2019
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 responses ▪ Phase 1b trial ongoing with updated data anticipated 2019
	NLG802, prodrug of indoximod	**NLG802 in patients with advanced solid tumors** ▪ Early Phase 1 data showed significantly improved PK properties ▪ Updated Phase 1 trial data anticipated 2019
	Recurrent malignant pediatric brain tumors	**Indoximod plus radio-chemotherapy for pediatric patients with recurrent malignant brain tumors** ▪ Phase 1b trial ongoing with updated data anticipated 2019
	Front-line acute myeloid leukemia (AML)	**Indoximod plus standard-of-care chemotherapy for patients with front-line AML** ▪ Updated Phase 1 data December 2018 showed promising MRD-negativity with indoximod ▪ Phase 1b trial ongoing

Other Opportunities

Ebola VSV-ZEBOV (V920) vaccine

- Merck has announced they began rolling BLA submission process
- NewLink holds 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
- Originally acquired from Cerulean Pharma in 2017
- Phase 2 trial to evaluate NLG207 plus weekly paclitaxel in recurrent ovarian cancer completed, conducted in conjunction with GOG
- Data will be presented at upcoming AACR meeting in April 2019
- Initial focus on our Phase 2 ovarian cancer trial, and reviewing other potential opportunities in multiple malignancies

Ovarian Cancer

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

Roughly **70** percent of patients diagnosed with ovarian cancer will have a recurrence[3]

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 Cancer Society; 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/

Indoximod Pipeline

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 deep radiographic responses ▪ Phase 1b trial ongoing with updated data anticipated 2019
NLG802, prodrug of indoximod	NLG802 in patients with advanced solid tumors ▪ Early Phase 1 data show significantly improved PK properties ▪ Updated Phase 1 trial data anticipated 2019
Recurrent malignant pediatric brain tumors	Indoximod plus radio-chemotherapy for pediatric patients with recurrent malignant brain tumors ▪ Phase 1b trial ongoing with updated data anticipated 2019
Front-line acute myeloid leukemia (AML)	Indoximod plus standard-of-care chemotherapy for patients with front-line AML ▪ Updated data December 2018 showed promising MRD-negativity with indoximod ▪ Phase 1b trial ongoing

Financial Position

Q4 2018 End Cash and Equivalents	$120.7 Million
Average Quarterly Cash Use Projected	~$10 Million
Cash Runway Projected	Through 2021
Shares Outstanding as of December 31, 2018	37.25 Million

NewLink Genetics: Key Takeaways

Targeting Indications of Need

- Current clinical development programs include:
  - ✓ NLG207
    - Ovarian cancer
  - ✓ Indoximod
    - Frontline DIPG
    - Recurrent pediatric brain tumors
    - Frontline AML
  - ✓ NLG802
- Continue to pursue opportunities to expand pipeline

Strong Cash Position

- ✓ Cash on hand at Q4 end $120.7 million
- ✓ Estimated cash runway to year end 2021 excluding Ebola PRV monetization
- ✓ Substantial financial interest in Priority Review Voucher (PRV) issued if approval of the Ebola vaccine licensed by NewLink Genetics

Upcoming Presentations

- ❑ April 2019: Phase 2 results for NLG207 in recurrent refractory ovarian, fallopian tube, or primary peritoneal cancer to be presented at AACR
- ❑ 2019: Updated Phase 1 data for indoximod plus radiotherapy in DIPG
- ❑ 2019: Updated Phase 1 data for NLG802, indoximod prodrug
- ❑ 2019: Updated Phase 1 data for indoximod plus radio-chemotherapy in recurrent pediatric brain tumors

Q & A