

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 28, 2020

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 February 28, 2020, 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, 2019 ("Press Release").

A copy of the Press Release is attached hereto as Exhibits 99.1, and is incorporated herein by reference.

The information in this Current Report, including Exhibit 99.1 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 28, 2020, entitled " NewLink Genetics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update "

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 28, 2020

NewLink Genetics Corporation

By: /s/ Carl W. Langren

Carl W. Langren

Its: Chief Financial Officer



FOR IMMEDIATE RELEASE

NewLink Genetics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

*- Special Meeting of Stockholders set for March 17, 2020 for vote on proposed merger of
NewLink Genetics and Lumos Pharma*

Ames, Iowa, February 28, 2020 -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced financial results for the fourth quarter and full year ended December 31, 2019, and provided an update on corporate activities.

“We continue to focus our work toward the anticipated completion of our proposed merger with Lumos Pharma,” stated Carl Langren, Chief Financial Officer, and member of NewLink’s Office of the CEO. “We believe that the newly combined company will be well positioned to increase stockholder value through the continued efforts to offer improved therapeutic options for patients suffering from PGHD and other rare diseases. We look forward to the close of the merger transaction, which we expect later this quarter.”

Eugene Kennedy, MD, Chief Medical Officer and member of NewLink’s Office of the CEO added, “We are also delighted by the FDA’s approval on December 19th of ERVEBO®, which we licensed to Merck in 2014. We applaud the FDA, as well as Merck and all those involved in achieving approval.”

Proposed Merger and Related Milestones

On February 13, 2020, NewLink filed a definitive proxy statement with the Securities and Exchange Committee (SEC) announcing the Special Meeting of Stockholders to be held on Tuesday, March 17th, 2020, for a stockholder vote on the issuance of shares in connection with the proposed merger of NewLink Genetics and Lumos Pharma, as well as other related proposals.

As previously reported, on September 30, 2019, NewLink announced its intent to merge with Lumos Pharma, a private clinical-stage biopharmaceutical company targeting rare and neglected diseases. Under the terms of the merger agreement, Lumos and NewLink stockholders will each own approximately 50% of the combined company, which will be renamed “Lumos Pharma, Inc.” at the close of the transaction. Rick Hawkins, current CEO of Lumos Pharma, is expected to become CEO of the combined company. The proposed merger has been approved by the boards of directors of both companies and by the stockholders of Lumos Pharma and NewLink’s largest stockholder have entered into a support agreement with NewLink to vote in favor of various proposals relating to the proposed merger.

The combined company expects to focus initially on the development of Lumos Pharma’s product candidate, LUM-201 (ibutamoren), an oral growth hormone (GH) secretagogue targeting pediatric growth hormone deficiency (PGHD) and other rare endocrine disorders. If approved, LUM-201 has the potential to be the first orally administered growth hormone stimulating therapy for a subset of PGHD patients, an established sizable market where daily recombinant human growth hormone injections represent current standard-of-care therapy.

The initiation of a Phase 2b trial for LUM-201 in a subset of PGHD patients meeting certain predictive enrichment markers (PEMs) is anticipated in mid-2020. The combined company is expected to have resources sufficient to support

clinical development through this planned Phase 2b trial. Other target indications are being evaluated for LUM-201 clinical development, including Turner Syndrome and children born small for gestational age (SGA).

Additional Updates for 2019

- Entered into an exclusive worldwide license agreement with Ellipses Pharma Limited (Ellipses), effective December 17, 2020, for the development of and rights to commercialize NLG207 (formerly CRLX101), a nanoparticle formulation of the topoisomerase 1 inhibitor camptothecin, and the rights to develop and commercialize CRLX-301, a nanoparticle formulation of docetaxel.
- On December 19, 2019, the U.S. Food and Drug Administration (FDA) announced that the agency had granted approval of ERVEBO®. A priority review voucher (PRV) was issued in conjunction with that approval and NewLink is entitled to 60% of the value of the PRV obtained through its sale, transfer or other disposition.

Financial Results for the Fourth Quarter and Full Year Ended December 31, 2019

Cash Position: NewLink Genetics ended the year on December 31, 2019, with cash and cash equivalents totaling \$90.5 million compared to \$120.7 million for the year ending December 31, 2018.

R&D Expenses: Research and development expenses for the fourth quarter of 2019 were \$4.7 million, a decrease of \$1.0 million from \$5.7 million for the same period in 2018. The decrease was primarily due to reductions of \$2.2 million in personnel-related and stock compensation expense and \$100,000 in contract research and manufacturing spend offset by increases of \$700,000 in restructuring costs and \$600,000 in clinical trial and licensing expense. For the year ended December 31, 2019, R&D expenses were \$22.2 million compared to \$45.7 million in the year ended December 31, 2018.

G&A Expenses: General and administrative expenses in the fourth quarter of December 31, 2019 were \$4.4 million, a decrease of \$1.0 million from \$5.4 million for the same period in 2018. The decrease was due primarily to decreases of \$1.5 million in personnel-related and stock compensation expense and a decrease of \$600,000 in supplies, travel and other expenses, offset by an increase of \$600,000 in legal and consulting fees and a \$500,000 increase in restructuring and severance expense. For the year ended December 31, 2019, G&A expenses were \$23.9 million compared to \$29.2 million in the year ended December 31, 2018.

Net Loss: NewLink Genetics reported a net loss of \$8.3 million or a net loss of \$0.22 per diluted share for the fourth quarter of 2019 and a net loss of \$43.0 million or a net loss of \$1.15 per diluted share for the year ended December 31, 2019, compared to a net loss of \$10.6 million or a net loss of \$0.28 per diluted share for the fourth quarter of 2018 and a net loss of \$53.6 million or a net loss of \$1.44 per diluted share for the year ended December 31, 2018.

NewLink Genetics ended 2019 with 37,325,091 shares outstanding.

ERVEBO® is a registered trademark of Merck Sharp & Dohme Corp ("Merck").

About NewLink Genetics Corporation

NewLink Genetics is a clinical-stage biopharmaceutical company that has historically focused on developing novel immunotherapeutic products for the treatment of patients with cancer. On September 30, 2019, NewLink announced its intent to merge with Lumos Pharma, a private clinical-stage biopharmaceutical company targeting rare and neglected diseases. At the close of the proposed merger, the combined company will operate as Lumos Pharma, which is expected to focus initially on Lumos Pharma's product candidate, LUM-201 (ibutamoren), an oral growth hormone (GH) secretagogue targeting pediatric growth hormone deficiency (PGHD) and other rare endocrine disorders. If approved, LUM-201 has the potential to become the first orally administered growth hormone stimulating therapy for PGHD, an established market where daily recombinant human growth hormone injections represent the current standard-of-care treatment regimen. For more information, please visit www.NewLinkGenetics.com.

Additional Information and Where to Find It

In connection with the proposed merger, NewLink filed the Definitive Proxy Statement with the SEC on February 10, 2020 and amended on February 13, 2020. The Definitive Proxy Statement was first mailed on or about February 10, 2020 to NewLink's stockholders of record as of the close of business on February 7, 2020. Stockholders of NewLink are urged to read these materials carefully because they contain important information about NewLink, Lumos, and the proposed merger and related transactions. The Definitive Proxy Statement and any amendments or supplements thereto (when such amendments or supplements become available) and other documents filed by NewLink with the SEC may be obtained free of charge through the SEC website at www.sec.gov. They may also be obtained free of charge either on NewLink's website by contacting the Corporate Secretary by written request to NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010 or by phone at (515) 598-2561.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under or applicable exemption from the securities laws of any such jurisdiction.

Participants in the Solicitation

NewLink and its directors and executive officers and Lumos and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of NewLink in connection with the proposed merger. Information regarding the special interests of these directors and executive officers in the proposed merger are included in the Definitive Proxy Statement referred to above. Additional information regarding the directors and executive officers of NewLink is also included in NewLink's Annual Report on Form 10-K for the year ended December 31, 2018 and the proxy statement for NewLink's 2019 Annual Meeting of Stockholders. These documents are available free of charge at the SEC web site (www.sec.gov) and from NewLink at the address described above.

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 "forecast," "projected," "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," "potential," 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's expectation regarding the strategy and development focus of the combined company post consummation of the proposed merger; NewLink's and the combined company's plans related to execution of clinical trials; plans related to moving additional indications into clinical development; NewLink's expectations regarding the capitalization, resources, ownership structure, management structure and operations of the combined company; the potential benefits of the transaction; the expected economic benefit from the issuance of the PRV; the expected completion and timing of the transaction and other information relating to the transaction; 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 (i) the risk that the transaction may not be completed in a timely manner or at all, which may adversely affect the NewLink Genetics' business and the price of the common stock of NewLink Genetics, (ii) the failure to satisfy the conditions to the consummation of the transaction, including approval of the issuance of shares of NewLink Genetics common stock in the transaction or the contemplated reverse stock split, (iii) the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement, (iv) the risk that the definitive merger agreement may be terminated in circumstances that require NewLink Genetics to pay a termination fee to Lumos Pharma; (v) risks related to the ability to realize the anticipated benefits of the transaction, including the risk that the businesses will not be integrated successfully, (vi) the effect of the announcement or pendency of the transaction on NewLink Genetics' business relationships, operating results and business generally, (vii) risks that the proposed transaction disrupts

current plans and operations, (viii) risks related to diverting management's attention from NewLink Genetics' ongoing business operations, (ix) other business effects, including the effects of industry, market, economic, political or regulatory conditions, future exchange and interest rates, and changes in tax and other laws, regulations, rates and policies, (x) the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data, (xi) the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; (xii) risks related to cost reduction efforts; and (xiii) the outcome of any legal proceedings that may be instituted against NewLink Genetics related to the merger agreement or the transaction. Further risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements are discussed in "Risk Factors" and elsewhere in NewLink Genetics' Definitive Proxy Statement Filed on February 13, 2020, Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and other reports filed with the 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

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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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Grant revenue	\$ —	\$ —	\$ —	\$ 11,268
Licensing and collaboration revenue	433	202	936	1,206
Total operating revenues	<u>433</u>	<u>202</u>	<u>936</u>	<u>12,474</u>
Operating expenses:				
Research and development	4,741	5,722	22,205	45,694
General and administrative	4,381	5,426	23,865	29,218
Total operating expenses	<u>9,122</u>	<u>11,148</u>	<u>46,070</u>	<u>74,912</u>
Loss from operations	(8,689)	(10,946)	(45,134)	(62,438)
Other income and expense:				
Miscellaneous expense	19	(118)	(19)	(102)
Interest income	411	519	2,226	2,029
Interest expense	—	(1)	(50)	(52)
Other income, net	<u>430</u>	<u>400</u>	<u>2,157</u>	<u>1,875</u>
Net loss before taxes	(8,259)	(10,546)	(42,977)	(60,563)
Income tax (expense) benefit	(12)	(23)	(12)	6,968
Net loss	<u>\$ (8,271)</u>	<u>\$ (10,569)</u>	<u>\$ (42,989)</u>	<u>\$ (53,595)</u>
Basic and diluted loss per share	<u>\$ (0.22)</u>	<u>\$ (0.28)</u>	<u>\$ (1.15)</u>	<u>\$ (1.44)</u>
Basic and diluted average shares outstanding	37,316,983	37,229,006	37,294,505	37,191,262

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 90,549	\$ 120,738
Prepaid expenses and other current assets	3,046	5,536
Income tax receivable	69	339
Other receivables	755	459
Total current assets	94,419	127,072
Property and equipment, net	1,633	3,727
Right-of-use asset	735	—
Income tax receivable	—	140
Total non-current assets	2,368	3,867
Total assets	\$ 96,787	\$ 130,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 475	\$ 555
Accrued expenses	10,198	8,139
Income taxes payable	11	—
Current portion of deferred rent	—	92
Current portion of lease liability	1,100	—
Current portion of notes payable and obligations under capital leases	43	61
Total current liabilities	11,827	8,847
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	—	43
Lease liability	82	—
Deferred rent	—	906
Total long-term liabilities	6,082	6,949
Total liabilities	17,909	15,796
Stockholders' equity:		
Blank check preferred stock, \$0.01 par value: Authorized shares — 5,000,000 at December 31, 2019 and 2018; issued and outstanding shares — 0 at December 31, 2019 and 2018	—	—
Common stock, \$0.01 par value: Authorized shares — 75,000,000 at December 31, 2019 and 2018; issued 37,440,094 and 37,343,547 at December 31, 2019 and 2018 and outstanding 37,325,091 and 37,251,220 at December 31, 2019 and December 31, 2018	374	373
Additional paid-in capital	413,959	407,199
Treasury stock, at cost: 115,003 and 92,327 shares at December 31, 2019 and 2018	(1,454)	(1,417)
Accumulated deficit	(334,001)	(291,012)
Total stockholders' equity	78,878	115,143
Total liabilities and stockholders' equity	\$ 96,787	\$ 130,939