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): November 6, 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)

[x] 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	NLNK	The Nasdaq Stock Market

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 ☐

Item 2.02. Results of Operations and Financial Condition.

On November 6, 2019, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release providing a corporate update and reporting financial results for the third quarter ended September 30, 2019 (the "Press Release").

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

The information included in this Item 2.02, including Exhibit 99.1 attached hereto, is furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 6, 2019, entitled "NewLink Genetics Reports Third Quarter 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: November 6, 2019

NewLink Genetics Corporation

By: /s/ Carl W. Langren
Name: Carl W. Langren
Title: Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

NewLink Genetics Reports Third Quarter 2019 Financial Results and Provides Corporate Update

Management to host conference call today at 8:30 a.m. ET

AMES, Iowa, November 6, 2019 - NewLink Genetics Corporation (NASDAQ:NLNK) today announced financial results for the third quarter ended September 30, 2019 and provided an update on corporate activities.

"We are excited about the proposed merger with Lumos Pharma that we announced at the close of the third quarter and continue to advance the process required to close the transaction," commented Brad Powers, General Counsel and member of NewLink's Office of the CEO. "We believe this merger positions the company to improve therapeutic options for patients with pediatric growth hormone deficiency and other rare and neglected diseases, and to bring greater value to our shareholders."

Eugene Kennedy, MD, Chief Medical Officer and member of NewLink's Office of the CEO added, "We are also pleased by the FDA's recent acceptance of the biologic licensing application for priority review of our partnered investigational Ebola vaccine, which we licensed to Merck in 2014. We are encouraged, as well, that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending a conditional marketing authorization for V920 Ebola Zaire vaccine. We believe these actions demonstrate the urgency with which regulatory bodies are addressing this deadly disease in order to help the affected individuals and communities."

Proposed Merger and Related Milestones

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" 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 both companies and the major stockholders of Lumos Pharma and NewLink's largest stockholder has entered into a support agreement with NewLink to vote in favor of various proposals relating to the Merger.

The combined company would focus initially on the development of Lumos Pharma's lead 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 PGHD, a well-established and 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 the readout of this planned Phase 2b trial. Additional target indications are being evaluated for LUM-201 clinical development, including Turner Syndrome and children born Small for Gestational Age (SGA).

NewLink will file a proxy statement with the Securities and Exchange Commission (SEC) providing additional information about the proposed merger. The transaction is expected to close in the first quarter of 2020, subject to the satisfaction of customary closing conditions, including approval of certain proposals by the stockholders of NewLink.

Additional Updates

The combined company may receive additional, non-dilutive financing should the U.S. Food and Drug Administration (FDA) approve NewLink's Ebola vaccine V920 partnered with Merck Sharp & Dohme Corp. (Merck). On September 17, 2019, Merck announced that the FDA has accepted its biologics license application (BLA) and granted priority review for the investigational Ebola vaccine V920 and the Prescription Drug User Fee Act (PDUFA), or target action date, is set for March 14, 2020. If the vaccine receives approval by the FDA, a priority review voucher will be issued, in which the Company owns a substantial interest and which the Company plans to monetize.

On October 18, 2019, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a conditional marketing authorization for investigational V920 Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP), as confirmed by our partner, Merck (NASDAQ:MRK). This Committee's recommendation will now be reviewed by the European Commission (EC) for a centralized marketing authorization of the vaccine (brand name ERVEBO®) across EU member countries.

Updated Phase 1b results for indoximod for the cohort of pediatric patients with newly diagnosed treatment-naïve diffuse intrinsic pontine glioma (DIPG) has been accepted for presentation at the upcoming ESMO Immuno-Oncology Congress 2019, 11-14 December 2019, Geneva, Switzerland. NewLink expects to continue to evaluate its oncology portfolio to determine value creation opportunities.

Financial Results for the Three-Month Period Ended September 30, 2019

Restructuring: On September 30, 2019, NewLink Genetics announced it had adopted a restructuring plan to reduce its headcount by approximately 60% to align with future priorities and to conserve resources. In conjunction with the restructuring and the departures of our former CEO and President, the company recorded restructuring and severance charges of $4.5 million during the third quarter.

Cash Position: NewLink Genetics ended the quarter on September 30, 2019, with cash and cash equivalents totaling $98.5 million compared to $120.7 million December 31, 2018.

R&D Expenses: Research and development expenses for the third quarter of 2019 were $7.0 million, a decrease of $546,000 from $7.6 million for the same period in 2018. The decrease was primarily due to reductions of $1.1 million in personnel-related and stock compensation expense, $255,000 in contract research and manufacturing spend, and $333,000 in legal and consulting and supplies expense, offset by increases of $1.1 million in restructuring costs and $87,000 in clinical trial and licensing expense.

G&A Expenses: General and administrative expenses in the third quarter of 2019 were $8.3 million, an increase of $691,000 from $7.6 million for the same period in 2018. The increase was due primarily to increases of $2.0 million in restructuring and severance expense, and $1.2 million in legal and consulting expense, offset by decreases of $1.7 million in stock compensation expense, $431,000 in personnel-related expense, and $353,000 in supplies.

Net Loss: NewLink Genetics reported a net loss of $14.5 million or ($0.39) per diluted share for the third quarter of 2019 compared to a net loss of $7.4 million or ($0.20) per diluted share for the third quarter of 2018.

NewLink Genetics ended Q3 2019 with 37,314,076 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss its financial results and to give an update on clinical and business development activities.

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). 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 the link https://edge.media-server.com/mmc/p/sm3cyp39. 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 passcode 3794399. The replay will be available for two weeks from the date of the call.

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 focused on lead 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 represent the first orally administered growth hormone stimulating therapy for PGHD, a well-established and sizable 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 transaction, NewLink will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed transaction. The definitive proxy statement will be mailed to NewLink's stockholders in connection with the proposed transaction. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC's web site at www.sec.gov, on NewLink's website at www.newlinkgenetics.com or by contacting NewLink Genetics' Investor Relations at 515-598-2555.

Participants in the Solicitation

NewLink and Lumos Pharma and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from NewLink stockholders in connection with the proposed transaction. Information about NewLink's directors and executive officers and their ownership of NewLink's securities is set forth in NewLink Genetics' proxy statement for its 2019 Annual Meeting of Stockholders, which was filed with the SEC on April 5, 2019, as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of such filing. Other information regarding the proposed transaction, including information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be included in the proxy statements described above and other relevant materials to be filed with the SEC when they become available. These documents are or will be available free of charge at the SEC's web site at www.sec.gov and from other sources indicated 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 management, strategy and development focus of the combined company post consummation of the proposed merger; results of NewLink's and the combined company's clinical trials for product candidates; NewLink's and the combined company's timing of release of data from ongoing clinical studies; NewLink's and the combined company's plans related to execution of clinical trials; plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance; NewLink Genetics' expectations regarding the capitalization, resources, ownership structure, management structure and operations of the combined company; NewLink Genetics' expectations regarding the sufficiency of the combined company's resources to fund the advancement of any development program or the completion of any clinical trial; the potential benefits of the transaction; NewLink Genetics' plan to monetize its interest in the priority review voucher; the expected economic benefit from the issuance of the priority review voucher; 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' 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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Investor & Media Contact:

Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
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Exhibit 99.1

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating Revenues:				
Grant revenue	$ —	$ —	$ —	$ 11,268
Licensing and collaboration revenue	246	120	503	1,004
Total operating revenues	246	120	503	12,272
Operating expenses:				
Research and development	7,024	7,570	17,464	39,972
General and administrative	8,279	7,588	19,484	23,792
Total operating expenses	15,303	15,158	36,948	63,764
Loss from operations	(15,057)	(15,038)	(36,445)	(51,492)
Other income and expense:				
Miscellaneous (expense) income, net	(33)	(18)	(38)	16
Interest income	567	664	1,815	1,510
Interest expense	(25)	(2)	(50)	(51)
Other income, net	509	644	1,727	1,475
Net loss before taxes	(14,548)	(14,394)	(34,718)	(50,017)
Income tax benefit	—	6,991	—	6,991
Net loss	$ (14,548)	$ (7,403)	$ (34,718)	$ (43,026)
Basic and diluted loss per share	$ (0.39)	$ (0.20)	$ (0.93)	$ (1.16)
Basic and diluted average shares outstanding	37,308,523	37,214,363	37,286,930	37,178,542

Exhibit 99.1

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 98,527	$ 120,738
Prepaid expenses and other current assets	3,311	5,536
Income tax receivable	76	339
Other receivables	740	459
Total current assets	102,654	127,072
Property and equipment, net	2,889	3,727
Right-of-use asset	1,042	—
Income tax receivable	69	140
Total non-current assets	4,000	3,867
Total assets	$ 106,654	$ 130,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 145	$ 555
Accrued expenses	12,125	8,139
Current portion of deferred rent	—	92
Current portion of lease liability	1,712	—
Current portion of notes payable	58	61
Total current liabilities	14,040	8,847
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable	—	43
Lease Liability	217	—
Deferred rent	—	906
Total long-term liabilities	6,217	6,949
Total liabilities	20,257	15,796
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at September 30, 2019 and December 31, 2018; issued and outstanding shares — 0 at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at September 30, 2019 and December 31, 2018; issued 37,426,844 and 37,343,547 at September 30, 2019 and December 31, 2018, respectively, and outstanding 37,314,076 and 37,251,220 at September 30, 2019 and December 31, 2018, respectively	373	373
Additional paid-in capital	413,205	407,199
Treasury stock, at cost: 112,768 and 92,327 shares at September 30, 2019 and December 31, 2018, respectively	(1,451)	(1,417)
Accumulated deficit	(325,730)	(291,012)
Total stockholders' equity	86,397	115,143
Total liabilities and stockholders' equity	$ 106,654	$ 130,939