

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): July 30, 2019 (July 29, 2019)

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))

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 July 30, 2019, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing a corporate update and reporting financial results for the second quarter ended June 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Retirement of Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors

On July 29, 2019, Charles J. Link, Jr, M.D. retired from his posts as Chairman, Chief Executive Officer and Chief Scientific Officer and as a member of the Board of Directors of the Company (the "Board"), effective August 3, 2019. Dr. Link's decision to resign was not related to a disagreement with the Company over any of its operations, policies or practices

Appointment of the Office of the CEO

On July 29, 2019, the Board formed the Office of the Chief Executive Officer with the purpose to allow for effective management of the Company's business during the transition in leadership and the further advancement of the Company's strategic goals. Effective August 3, 2019, the members of the Office of the Chief Executive Officer are: Carl Langren, Chief Financial Officer; Eugene Kennedy, M.D., Chief Medical Officer; Brad Powers, General Counsel; and Lori Lawley, Vice President, Finance and Controller. Reporting to the Board, the members of the Office of the Chief Executive Officer have been given full executive authority and will oversee the execution of the Company's operations and strategic initiatives.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated July 30, 2019, entitled " NewLink Genetics Provides Corporate Update and Reports Second Quarter 2019 Financial Results "

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: July 30, 2019

NewLink Genetics Corporation

By: /s/ Carl W. Langren

Carl W. Langren

Its: Chief Financial Officer



FOR IMMEDIATE RELEASE

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

Announces management transition; Charles J. Link Jr, M.D. to retire as CEO and Chairman of the Board

AMES, Iowa, July 30, 2019 (GLOBE NEWSWIRE) - NewLink Genetics Corporation (NASDAQ:NLNK) ("NewLink Genetics" or the "Company") today announced financial results for the second quarter ended June 30, 2019 and provided an update on clinical and corporate developments, including a transition of management. Charles J. Link, Jr, M.D. has chosen to retire from his posts as Chairman, Chief Executive Officer and Chief Scientific Officer, and has also resigned from the Board, effective August 3, 2019. Dr. Link cofounded NewLink Genetics in 1999 and served as the Company's Chief Scientific Officer until his additional appointment to CEO and Chairman in 2003.

NewLink Genetics' Board of Directors has established an Office of the CEO. Effective August 3rd, members of the Office of the CEO will lead the company to advance its strategic goals. The Board of Directors has elected Carl Langren, Chief Financial Officer; Eugene Kennedy, M.D., Chief Medical Officer; Brad Powers, General Counsel; and Lori Lawley, Vice President, Finance and Controller to the Office of the CEO. Reporting to the Board of Directors, the members of the Office of the CEO have been given full executive authority and will oversee the execution of the Company's operations and strategic initiatives.

"I am grateful and deeply honored to have had the opportunity to lead NewLink Genetics and work alongside some incredibly talented people on projects dedicated to patients with great unmet medical need," said Charles J. Link Jr, M.D. "I have confidence that the company and its leadership have the resources to move forward and succeed and I look forward to watching the company's progress. I plan to enjoy spending more time with my family as well."

"NewLink Genetics is grateful to our co-founder, Charles Link, for his 20 years of service in building the Company," said Thomas A. Raffin, M.D., Lead Independent Director of NewLink Genetics. "The Board of Directors and Company are thankful to Chuck for his many contributions and for fostering our mission of improving the lives of patients and their families. Moving forward, we are fully confident that the leadership team in the Office of the CEO is positioned to advance the Company's goals following Chuck's retirement."

NewLink Genetics ended the second quarter with \$105.4 million in cash. The Company continues to evaluate potential acquisition, in-licensing, or other opportunities to broaden its pipeline, assist patients, and create value for shareholders.

Clinical Update

The Company presented 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.

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 licensing application for this vaccine, V920 (rVSVΔG-ZEBOV-GP), is under review at the FDA, the European Medicines Agency (EMA), the World Health Organization (WHO), and African countries. 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 June 30, 2019

Cash Position: NewLink Genetics ended the quarter on June 30, 2019, with cash and cash equivalents totaling \$105.4 million compared to \$120.7 million on 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 second quarter of 2019 were \$5.2 million, a decrease of \$6.9 million from \$12.1 million for the same period in 2018. The decrease was primarily due to reductions of \$2.4 million in contract research and manufacturing spend, \$2.0 million in clinical trial expense, \$1.8 million in personnel-related and stock compensation expense, \$400,000 in supplies and licensing, and \$300,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses in the second quarter of 2019 were \$5.6 million, a decrease of \$2.3 million from \$7.9 million for the same period in 2018. The decrease was due primarily to reductions of \$1.9 million in personnel-related and stock compensation expense and \$400,000 in supplies.

Net Loss: NewLink Genetics reported a net loss of \$(10.1) million or \$(0.27) per diluted share for the second quarter of 2019 compared to a net loss of \$(17.3) million or \$(0.47) per diluted share for the second quarter of 2018.

NewLink Genetics ended the second quarter of 2019 with 37,300,960 shares outstanding.

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. The IDO Pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape. NewLink Genetics' drug candidate, NLG207 (formerly CRLX101), a nanoparticle formulation of camptothecin, a topoisomerase 1 inhibitor, is under development to combat refractory malignancies. For more information, please visit www.NewLinkGenetics.com.

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, impact of management changes, 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 Genetics 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 Genetics's 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.

Investor & Media Contact:

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating Revenues:				
Grant revenue	\$ —	\$ 1,884	\$ —	\$ 11,268
Licensing and collaboration revenue	151	368	257	884
Total operating revenues	<u>151</u>	<u>2,252</u>	<u>257</u>	<u>12,152</u>
Operating expenses:				
Research and development	5,237	12,088	10,440	32,402
General and administrative	5,638	7,912	11,205	16,204
Total operating expenses	<u>10,875</u>	<u>20,000</u>	<u>21,645</u>	<u>48,606</u>
Loss from operations	(10,724)	(17,748)	(21,388)	(36,454)
Other income and expense:				
Miscellaneous (expense) income, net	(10)	10	(5)	34
Interest income	624	461	1,248	846
Interest expense	(24)	(36)	(25)	(49)
Other income, net	590	435	1,218	831
Net loss before taxes	<u>(10,134)</u>	<u>(17,313)</u>	<u>(20,170)</u>	<u>(35,623)</u>
Income tax benefit	—	—	—	—
Net loss	<u>\$ (10,134)</u>	<u>\$ (17,313)</u>	<u>\$ (20,170)</u>	<u>\$ (35,623)</u>
Basic and diluted loss per share	<u>\$ (0.27)</u>	<u>\$ (0.47)</u>	<u>\$ (0.54)</u>	<u>\$ (0.96)</u>
Basic and diluted average shares outstanding	37,276,443	37,165,529	37,275,954	37,160,334

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 105,372	\$ 120,738
Prepaid expenses and other current assets	4,015	5,536
Income tax receivable	353	339
Other receivables	458	459
Total current assets	110,198	127,072
Property and equipment, net	3,314	3,727
Right-of-use asset	7,159	—
Income tax receivable	140	140
Total non-current assets	10,613	3,867
Total assets	\$ 120,811	\$ 130,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 689	\$ 555
Accrued expenses	7,235	8,139
Current portion of deferred rent	—	92
Current portion of lease liability	641	—
Current portion of notes payable	63	61
Total current liabilities	8,628	8,847
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable	11	43
Lease Liability	7,485	—
Deferred rent	—	906
Total long-term liabilities	13,496	6,949
Total liabilities	\$ 22,124	\$ 15,796
Stockholders' equity:		
Blank check preferred stock, \$0.01 par value: Authorized shares — 5,000,000 at June 30, 2019 and December 31, 2018; issued and outstanding shares — 0 at June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.01 par value: Authorized shares — 75,000,000 at June 30, 2019 and December 31, 2018; issued 37,413,093 and 37,343,547 at June 30, 2019 and December 31, 2018, respectively, and outstanding 37,300,960 and 37,251,220 at June 30, 2019 and December 31, 2018, respectively	373	373
Additional paid-in capital	410,946	407,199
Treasury stock, at cost: 112,133 and 92,327 shares at June 30, 2019 and December 31, 2018, respectively	(1,450)	(1,417)
Accumulated deficit	(311,182)	(291,012)
Total stockholders' equity	98,687	115,143
Total liabilities and stockholders' equity	\$ 120,811	\$ 130,939