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): December 20, 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))

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 7.01. Regulation FD Disclosure.

On December 20, 2019, NewLink Genetics Corporation ("**NewLink**" or the "**Company**") issued a press release titled "NewLink Genetics Announces FDA Approval of Ebola Vaccine V920 (ERVEBO®)." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being 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 by the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On December 20, 2019, the Company announced that, after priority review, the U.S. Food and Drug Administration ("**FDA**") had granted approval of ERVEBO®, or Zaire Ebola virus vaccine V920 (rVSVΔG-ZEBOV-GP). The approval represents the first vaccine approved by the FDA for the Ebola virus and follows the November 11, 2019 grant by the European Commission of a marketing authorization for ERVEBO® across 31 European countries. The FDA's approval of this Ebola vaccine will trigger the issuance of a priority review voucher owned by Merck Sharp and Dohme Corp. and in which NewLink has a substantial economic interest. Thereafter, NewLink will have the right to monetize its share of interest in the voucher.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated December 20, 2019, entitled "NewLink Genetics Announces FDA Approval of Ebola Vaccine V920 (ERVEBO®)."

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.

NEWLINK GENETICS CORPORATION

Dated: December 20, 2019

By: /s/ Brad J. Powers

Name: Brad J. Powers
Title: General Counsel
(Principal Executive Officer)

EXHIBIT 99.1

NewLink Genetics Announces FDA Approval of Ebola Vaccine V920 (ERVEBO®)

AMES, Iowa, December 20, 2019 – NewLink Genetics Corporation (NASDAQ:NLNK) announced today that, after priority review, the FDA has granted approval of ERVEBO®, or Zaire Ebola virus vaccine V920 (rVSVΔG-ZEBOV-GP), as confirmed by our partner, Merck (NYSE:MRK), known as MSD outside the US and Canada. This represents the first vaccine approved by the FDA for the Ebola virus and follows the November 11th grant by the European Commission (EC) of a marketing authorization for ERVEBO® across 31 European countries.

Yesterday's approval comes almost three months prior to the Prescription Drug User Fee Act (PDUFA), or target FDA action date, originally set for March 14, 2020. As NewLink has previously stated, the FDA's approval of this Ebola vaccine will trigger the issuance of a priority review voucher (PRV) owned by Merck and in which NewLink Genetics has a substantial economic interest. Thereafter, NewLink will have the right to monetize its share of interest in the voucher.

"We are delighted by the FDA's decision to approve this Ebola vaccine and by the agency's recognition of the potential this vaccine may offer to protect individuals who may be exposed to Ebola from contracting this deadly disease," commented Eugene Kennedy, MD, Chief Medical Officer and member of NewLink Genetics' Office of the CEO. "We are grateful to our partner Merck, and to the regulatory bodies involved, for their dedication to advancing solutions to combat this deadly illness."

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 focused on Lumos's sole 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 a subset of PGHD patients, 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.

Information Regarding the Proposed Merger with Lumos and Where to Find It

In connection with the proposed merger (the "Merger") among NewLink, Cyclone Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (the "Merger Sub"), and Lumos, pursuant to the terms of the Agreement and Plan of Merger dated September 30, 2019 (the "Lumos Merger Agreement") by and among NewLink, Merger Sub and Lumos, the Company intends to file relevant materials with the Securities and Exchange Commission (the "SEC"), including a proxy statement for its stockholders containing the information with respect to the Merger and the Lumos Merger Agreement specified in Schedule 14A promulgated under the Securities Exchange Act of 1934, as amended and describing the proposed Merger. The proxy statement and other relevant materials (when they become available), and any other documents filed by the Company with the SEC, may be obtained free of charge at the SECwebsite at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by the Company by directing a written request to: NewLink Genetics Corporation, 2503 South Loop Drive, Ames, IA 50010. Investors and security holders are urged to read the proxy statement and the other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

Participants in the Solicitation

The Company 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 the Company in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger will be included in the proxy statement referred to above. Additional information regarding the directors and executive officers of the Company is also included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and the proxy statement for the Company's 2019 Annual Meeting of Stockholders. These documents are available free of charge at the SEC web site (www.sec.gov) and from the Company 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 right to monetize its share of the priority review voucher owned by Merck; 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 the risks related to the ability to monetize and realize the anticipated benefits of the priority review voucher and risks that the conditional authorization does not covert into a standard marketing authorization. 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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Source: NewLink Genetics Corporation