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 12, 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 o

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 8 - Other Events

Item 8.01. Other Events.

On November 12, 2019, NewLink Genetics Corporation issued a press release titled "NewLink Genetics Announces European Commission Grant of Conditional Marketing Approval for Ebola Vaccine V920 (ERVEBO®)."

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

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 12, 2019, entitled "NewLink Genetics Announces European Commission Grant of Conditional Marketing Approval for 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.

Dated: November 12, 2019

NewLink Genetics Corporation

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

FOR IMMEDIATE RELEASE

NewLink Genetics Announces European Commission Grant of Conditional Marketing Approval for Ebola Vaccine V920 (ERVEBO®)

AMES, Iowa, November 12, 2019 - NewLink Genetics Corporation (NASDAQ:NLNK) announced that Monday, November 11th, the European Commission (EC) granted a conditional marketing authorization to ERVEBO®, investigational V920 Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP), as confirmed by our partner, Merck (NYSE:MRK), known as MSD outside the US and Canada. With this approval, the EC will grant a centralized marketing authorization for the vaccine with unified labeling that is valid in 31 European countries.

The granting of this approval by the EC follows the September 17th announcement by the FDA that it has accepted the Biologics License Application (BLA) and granted priority review for the investigational Ebola vaccine (V920). The Prescription Drug User Fee Act (PDUFA), or target FDA action date, is set for March 14, 2020. As NewLink has previously stated, the FDA's approval of this Ebola vaccine would trigger the issuance of a priority review voucher owned by Merck and in which NewLink Genetics has a substantial economic interest. Thereafter, NewLink would have the right to monetize its share of interest in the voucher.

"We are thrilled by the EC's decision to approve this Ebola vaccine, offering the potential for protection from this devastating disease," noted Eugene Kennedy, MD, Chief Medical Officer and member of NewLink Genetics' Office of the CEO. "We are also grateful to our partner Merck, and to the regulatory bodies involved for their diligent efforts to advance solutions to combat this deadly illness."

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' 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.

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 expectation regarding the centralized marketing authorization to be granted by the EC; the PDUFA date; 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.

###

Investor & Media Contact:

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