**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): September 17, 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**<br>**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 September 17, 2019, NewLink Genetics Corporation issued a press release titled "NewLink Genetics Announces FDA Accepts Partnered Biologics License Application (BLA) and Grants Priority Review for Ebola Vaccine V920 (rVSVΔG-ZEBOV-GP)."

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 September 17, 2019, entitled "NewLink Genetics Announces FDA Accepts Partnered Biologics License Application (BLA) and Grants Priority Review for Ebola Vaccine V920 (rVSVΔG-ZEBOV-GP)." |

**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: September 17, 2019

**NewLink Genetics Corporation**

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

FOR IMMEDIATE RELEASE

# NewLink Genetics Announces FDA Accepts Partnered Biologics License Application (BLA) and Grants Priority Review for Ebola Vaccine V920 (rVSVΔG-ZEBOV-GP)

AMES, Iowa, September 17, 2019 (GLOBE NEWSWIRE) - NewLink Genetics Corporation (NASDAQ:NLNK) today announced that the U.S. Food and Drug Administration (FDA) has accepted Merck's Biologics License Application (BLA) and granted priority review for the investigational Ebola vaccine (V920), for the prevention of disease caused by the Ebola Zaire virus. Merck's rolling submission was made pursuant to the FDA's Breakthrough Therapy Designation for V920, a designation awarded to our partner, Merck, in July 2016. The Prescription Drug User Fee Act (PDUFA), or target 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. This Ebola vaccine candidate was originally developed by the Public Health Agency of Canada (PHAC) and thereafter licensed to NewLink Genetics.

"We are pleased with this morning's announcement from our partner, Merck. The global community, Merck and government partners have worked relentlessly to further the development of the investigational V920 Ebola vaccine," said Brad Powers, a member of the Office of the CEO. "We are thankful to those frontline responders who work tirelessly to help fight this devastating disease, and we believe this vaccine has the potential to impact many lives."

**About NewLink Genetics Corporation**

NewLink Genetics is a clinical stage biopharmaceutical company focused on developing novel oncology product candidates to improve the lives of patients with cancer where treatment options are limited. 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. 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 "will be," "may," "appear to," "has potential to," "look forward to," "are designed to," 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 results of NewLink's clinical trials for product candidates 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' Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and other reports filed with the U.S. Securities and Exchange Commission (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:

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