

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): October 20, 2014 (October 16, 2014)

**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))

## Section 1 - Registrant's Business and Operations

### Item 1.01. Entry into a Material Definitive Agreement.

On October 16, 2014, NewLink Genetics Corporation (“NewLink”) and Genentech, Inc., a member of the Roche Group, (“Genentech”) entered in to an exclusive, worldwide license agreement (the “Collaboration Agreement”) for the development and commercialization of NLG919, NewLink's clinical stage IDO pathway inhibitor, and a research collaboration for the discovery of next generation IDO/TDO inhibitors to be developed and commercialized under the Collaboration Agreement.

Under the terms of the Collaboration Agreement, NewLink will receive an upfront payment of \$150 million. NewLink will be eligible to receive in excess of \$1 billion in milestone payments based on achievement of certain development, regulatory and sales milestones. In addition, NewLink will receive escalating double-digit percentage royalties on Genentech's sales of NLG919 and other products resulting from the collaboration. The rates of such royalties will vary based on the stage of the compound at the signing of the Collaboration Agreement, regulatory exclusivity, intellectual property status, and other considerations.

Genentech will be responsible for and will fund future research, development, manufacturing and commercialization of NLG919 and next generation IDO/TDO compounds. Genentech will also provide funding to NewLink to support its participation in the research collaboration. NewLink has the right to continue to pursue development activities associated with the combination of NLG919 with NewLink's novel HyperAcute vaccine platform.

In addition, NewLink has retained the option under the Collaboration Agreement to co-promote NLG919 and next generation IDO/TDO products with Genentech in the United States, subject to certain conditions, if and when such products are approved for sale.

Under the Collaboration Agreement, NewLink granted to Genentech an exclusive, sublicensable, royalty-bearing license under certain of NewLink's patents and know-how relating to IDO/TDO, and NewLink has agreed to work exclusively with Genentech with respect to IDO/TDO compounds for a specified number of years.

Unless earlier terminated, the Collaboration Agreement will continue in effect for as long as Genentech has payment obligations to NewLink. Each party may terminate the Collaboration Agreement for the other party's uncured material breach of the Collaboration Agreement or the other party's bankruptcy or insolvency. After the end of the research collaboration, Genentech may terminate the Collaboration Agreement for convenience upon 180 days written notice.

The effectiveness of the Collaboration Agreement is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, as amended.

NewLink retains all rights to Indoximod, including the ability to develop, commercialize, license and divest Indoximod in its discretion.

The foregoing description of the Collaboration Agreement does not purport to be complete and is qualified in its entirety by reference to such agreement, which NewLink intends to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2014.

A copy of the press release issued by NewLink announcing the entry into the Collaboration Agreement 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated October 20, 2014, entitled "NewLink Genetics Announces Exclusive Worldwide Licensing Agreement for Development of NLG919, an IDO Inhibitor in Phase 1, and Research Collaboration for the Discovery of Next Generation IDO/TDO Inhibitors"

## 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: October 20, 2014

### **NewLink Genetics Corporation**

By: /s/ John B. Henneman, III

John B. Henneman, III

Its: Executive Vice President and Chief Financial Officer

## INDEX TO EXHIBITS

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99.1	Press Release, dated October 20, 2014, entitled "NewLink Genetics Announces Exclusive Worldwide Licensing Agreement for Development of NLG919, an IDO Inhibitor in Phase 1, and Research Collaboration for the Discovery of Next Generation IDO/TDO Inhibitors"



## **NewLink Genetics Announces Exclusive Worldwide Licensing Agreement for Development of NLG919, an IDO Inhibitor in Phase 1, and Research Collaboration for the Discovery of Next Generation IDO/TDO Inhibitors**

AMES, IA -- October 20, 2014 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on discovering, developing, and commercializing novel immunotherapeutics to improve treatment options for patients with cancer, announced today that they have entered into an exclusive worldwide license agreement with Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), for the development of NLG919, NewLink's IDO pathway inhibitor. The parties also entered into a research collaboration for the discovery of next generation IDO/TDO compounds.

Under the terms of the agreement, NewLink will receive an upfront payment of \$150 million. NewLink will be eligible to receive in excess of \$1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech.

Genentech will fund future research, development, manufacturing and commercialization costs. Genentech will also provide research funding to NewLink for support of the research collaboration. NewLink will continue to pursue development activities associated with NLG919 in combination with its novel HyperAcute vaccine platform.

NewLink will retain the option for co-promotion rights for NLG919 and potential next generation IDO/TDO compounds in the U.S. The completion of the agreement is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

"This alliance enables us to accelerate and expand development of NLG919 while we continue to advance our other promising clinical and preclinical development programs," said Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "Genentech's oncology development expertise, commercial leadership and history of successful strategic alliances make it an ideal collaborator to bring the potential benefits of NLG919 to patients."

"We are intrigued by the biology of the IDO and TDO compounds and are very interested in the potential to combine them with Genentech's portfolio of novel therapies," said James Sabry, Senior Vice President and Global Head of Genentech Partnering. "We are delighted to have initiated this significant partnership with NewLink. We hope this collaboration will lead to new therapies for people with cancer."

### ***About inhibition of the IDO pathway***

IDO pathway inhibitors are another class of immune check point inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1, and PD-L1 that represent potential breakthrough approaches to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell activation which enables local tumor immune escape. Recent studies have demonstrated that the IDO pathway is active in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen

presenting cells in tumor draining lymph nodes whereby this pathway promotes peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system. NewLink has a number of active programs directed at synthesizing inhibitors to the IDO pathway and additionally has discovered novel tryptophan-2,3-dioxygenase (TDO) specific inhibitors that are potential anti-cancer compounds which could function individually or in combination with IDO inhibition.

### **About NewLink Genetics Corporation**

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for patients with cancer. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. For more information please visit <http://www.linkp.com>.

### **Cautionary Note Regarding Forward-Looking Statements**

*This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," 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 regarding the following: plans to develop and commercialize our product candidates; the possibility of receiving milestone and royalty payments in the future; 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 makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2013, and subsequent filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink 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's views as of any date subsequent to the date of this press release.*

### **Investor Contact:**

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