# 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): April 9, 2014 (April 9, 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 8 - Other Events

### Item 8.01. Other Events.

On April 9, 2014, NewLink Genetics (NASDAQ:NLNK) presented preclinical data related to the immunostimulatory and anti-tumor effects of its two clinical-stage checkpoint inhibitors targeting the IDO pathway, indoximod and NLG919, in combination with anti-PD-1/PD-L antibodies. The data was presented in a poster session at the American Association for Cancer Research (AACR) 2014 Annual Meeting.

The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

# Section 9 - Financial Statements and Exhibits

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number 99.1 Description

Press Release, dated April 9, 2014, entitled "NewLink Genetics Presents Data at the AACR 2014 Annual Meeting"

# 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: April 9, 2014

# **NewLink Genetics Corporation**

By: <u>/s/ Gordon H. Link, Jr.</u> Gordon H. Link, Jr.

Its: Chief Financial Officer

# INDEX TO EXHIBITS

Exhibit Number

99.1

Description

Press Release, dated April 9, 2014, entitled "NewLink Genetics Presents Data at the AACR 2014 Annual Meeting"



# NewLink Genetics Presents Data at the AACR 2014 Annual Meeting

Data Demonstrate Synergistic Anti-Tumor Activity of IDO Pathway Inhibitors Indoximod and NLG919 in Combination with Other Checkpoint Inhibitors and Cancer Immunotherapies

TDO Inhibitors Discovered as Potential New Anti-cancer Agents

Ames, IA - April 9, 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, presented preclinical data related to the immunostimulatory and anti-tumor effects of its two clinical-stage checkpoint inhibitors targeting the IDO pathway, indoximod and NLG919, in combination with anti-PD-1/PD-L antibodies. The data was presented in a poster session at the American Association for Cancer Research (AACR) 2014 Annual Meeting. In addition, new compounds that mediate TDO (tryptophan-2,3-dioxygenase) activity were presented.

"Key immune checkpoints such as IDO and PD-1 are interrelated and as a result, combinatorial therapeutic interventions may prove more effective than single agents," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "These data demonstrate that combining multiple immunotherapies and in this case multiple checkpoint inhibitors that target the IDO pathway and PD1/PDL, is effective in reducing local tumor-mediated immunosuppression and providing potential for enhanced anti-tumor activity. In addition, we are exploring the role of TDO, an enzyme functionally and structurally related to IDO, and are beginning to develop TDO inhibitors as potential new anti-cancer compounds that function on their own and in combination with IDO inhibitors."

In a poster presentation entitled "Synergistic antitumor effects of combinatorial immune checkpoint inhibition with anti-PD-1/PD-L antibodies and the IDO pathway inhibitors NLG919 and indoximod in the context of active immunotherapy," NewLink researchers and collaborators at Georgia Regents University presented preclinical data demonstrating that combining IDO pathway inhibitors with agents targeting immune checkpoints provided enhanced anti-tumor effect compared to either agent alone in mouse models of established tumors.

 Demonstrated synergistic effects of combining NLG919, indoximod and anti-PD-1/PD-L1/PD-L2 antibodies to block both the IDO and PD pathways resulting in enhanced anti-tumor effects compared to blocking each pathway independently. This synergy was demonstrated in the context of established tumors treated with otherwise ineffective chemo-immunotherapy regimens.

In a second poster presentation entitled "Novel specific- and dual- tryptophan-2,3-dioxygenase (TDO) and indoleamine-2,3-dioxygenase (IDO) inhibitors for tumor immunotherapy," NewLink researchers presented preclinical data demonstrating novel TDO-specific, IDO-specific and TDO and IDO dual inhibitors as potential new anti-cancer compounds that could function individually or in combinations to control TDO and/or IDO activity.

• Discovered a novel class of compounds that show potent and selective TDO inhibition with 10-200-fold increased potency, as well as compounds that show potent IDO-specific inhibition and dual inhibition of TDO and IDO.

# About NewLink Genetics' IDO Pathway Inhibitors

NewLink is developing two distinct IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor product candidates, indoximod and NLG919, with different and potentially complementary mechanisms of action. IDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. These small molecule drug candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. In many different cancers, IDO can be overexpressed directly either by cancer cells or by antigen-presenting cells in the tumor microenvironment, representing a substantial drug development opportunity. When IDO is expressed by developing cancers, IDO pathway activity creates an immunosuppressive environment that shifts the immune response from anti-cancer to cancer tolerance. Multiple elements of the immune system are affected by this shift, including T-cells, regulatory T-cells, and dendritic cells, resulting in the survival of malignant cells that might otherwise be recognized and attacked by the immune system. Inhibiting the IDO pathway allows reprogramming of the immune response from tolerance back to an active anti-cancer response.

NewLink has an active drug discovery program focused on the IDO pathway. NewLink's most advanced IDO pathway inhibitor, indoximod, is in multiple Phase 1 and Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreas, melanoma and brain cancers. Additionally, NLG919 is currently in Phase 1 clinical development in patients with recurrent advanced solid tumors.

# About NewLink Genetics Corporation

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic 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 about: the prospects and efficacy of indoximod and NLG919 and any related clinical trials, plans to develop and commercialize our product candidates; ongoing and planned preclinical studies and clinical trials, the timing for completion of enrollment and outcomes of our other ongoing clinical studies; 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, Form S-3 Registration Statement filed December 28, 2012 and in its other 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 as representing NewLink's views as of any date subsequent to the date of this press release.

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**Media Contact:** 

Exhibit 99.1

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