

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 8, 2013 (April 8, 2013)

**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 8, 2013, NewLink Genetics (NASDAQ:NLNK) announced that the company presented preclinical data for NLG919, a potent IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor, at the American Association for Cancer Research (AACR) 2013 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated April 8, 2013, entitled "NewLink Genetics Presents Preclinical Data on New IDO Pathway Inhibitor, NLG919, at AACR 2013 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 8, 2013

### **NewLink Genetics Corporation**

By: /s/ Gordon H. Link, Jr.  
Gordon H. Link, Jr.  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated April 8, 2013, entitled "NewLink Genetics Presents Preclinical Data on New IDO Pathway Inhibitor, NLG919, at AACR 2013 Annual Meeting"



Contact:  
 Gordon Link  
 Chief Financial Officer  
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FOR IMMEDIATE RELEASE

## **NewLink Genetics Presents Preclinical Data on New IDO Pathway Inhibitor, NLG919, at AACR 2013 Annual Meeting**

*Results Support Further Evaluation of NLG919 for the treatment of Immunosuppression Associated with Cancers*

Ames, IA - April 8, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company primarily focused on discovering, developing and commercializing immunotherapeutic products in oncology, announced today that the company presented preclinical data for NLG919, a potent IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor, at the American Association for Cancer Research (AACR) 2013 annual meeting. These data demonstrate that NLG919 potently inhibits the IDO pathway in vitro and in cell based assays, is orally bioavailable and has a favorable pharmacologic and toxicity profile. NLG919 is the second pipeline candidate from NewLink's IDO Pathway Inhibitor technology platform to be announced. This platform has also produced indoximod (NLG8189 or D1-MT) which is currently in Phase 2 clinical trials for the treatment of prostate cancer and metastatic breast cancer. Furthermore, NLG919 and indoximod show remarkable synergistic T-cell activation and antitumor activity.

“These data further support our view that IDO is a complex pathway with critical downstream immunomodulatory effects, and strategies that aim at multiple targets within this pathway may hold the most promise,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. “We are encouraged by NLG919's anti-tumor and pharmacological properties and will continue to evaluate it, along with other IDO pathway inhibitors in our preclinical and clinical pipeline, as an innovative approach to harnessing the immune system to treat cancer.”

In a poster presentation entitled “NLG919, a novel indoleamine-2,3-dioxygenase (IDO)-pathway inhibitor drug candidate for cancer therapy,” NewLink scientists presented preclinical data to demonstrate NLG919's on target anti-tumor effects as well as favorable oral bioavailability, pharmacokinetic and pharmacodynamic profiles.

The principal findings reported in the NLG919 study include:

- NLG919 potently inhibits the IDO pathway in vitro and in cell based assays.
- NLG919 potently blocks IDO-induced antigen-specific T-cell suppression and restores robust T-cell responses.
- NLG919 demonstrates single agent anti-tumor activity.
- NLG919 and indoximod show synergistic T-cell activation and antitumor activities.
- NLG919 is orally bioavailable and has a favorable pharmacokinetic and toxicity profile.

### **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 and PD-1 which represent a potential breakthrough approach to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell function and enabling 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 expressing TAAs that might otherwise be recognized and attacked by the immune system. NewLink has a number of active programs directed at synthesizing IDO pathway inhibitors. These small-molecule, anti-tolerogenic product candidates are intended to counteract this key mechanism by which tumors evade immune-mediated destruction.

### **About NewLink Genetics Corporation**

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for cancer patients. 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. NewLink's lead product candidate, algenpantucel-L (HyperAcute® Pancreas) is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (under a Special Protocol Assessment with the U.S. FDA) as well as in a separate study in locally advanced pancreatic cancer patients. NewLink has recently launched an adaptive design Phase 2B/3 clinical trial of tergenpumatucel-L (HyperAcute® Lung) in patients with non-small cell lung cancer. NewLink is developing indoximod, a small molecule, orally bioavailable product candidate from NewLink's proprietary indoleamine-(2,3)-dioxygenase, or IDO, pathway inhibitor technology. NewLink is studying indoximod in various chemotherapy and immunotherapy combination studies independently and in collaboration with the National Cancer Institute. For more information please visit <http://www.linkp.com>. Patient information is available at <http://www.pancreaticcancer-clinicaltrials.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 of algenpantucel-L, indoximod and our other HyperAcute product candidates and related clinical trials. 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 risks relating to: the initiation of clinical trials and the completion of enrollment; adverse general economic and industry conditions; and those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2012, 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 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.*