

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): May 16, 2013 (May 16, 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 May 16, 2013, NewLink Genetics (NASDAQ:NLNK) announced that several clinical presentations on its two proprietary platform technologies have been selected for the upcoming 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO).

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

On May 16, 2013, NewLink Genetics (NASDAQ:NLNK) also announced that it has been selected for addition to the NASDAQ Biotechnology Index ® (Nasdaq: NBI), effective prior to the market open on Monday, May 20, 2013.

The press release is attached hereto as Exhibit 99.2 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 May 16, 2013, entitled "NewLink Genetics to Present Data on Cancer Immunotherapy Programs at the ASCO 2013 Annual Meeting"
99.2	Press Release, dated May 16, 2013, entitled "NewLink Genetics to be added to NASDAQ Biotechnology Index"

**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: May 16, 2013

**NewLink Genetics Corporation**

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

## INDEX TO EXHIBITS

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Today's Discoveries . . . Tomorrow's Medicines

Contact:

Media:                      Investors:  
 Gina Nugent              Gordon Link  
 The Yates Network      Chief Financial Officer  
 617-460-3579              515-598-2925  
[gina@theyatesnetwork.com](mailto:gina@theyatesnetwork.com)      [glink@linkp.com](mailto:glink@linkp.com)

FOR IMMEDIATE RELEASE

**NewLink Genetics to Present Data on Cancer Immunotherapy Programs at the ASCO 2013 Annual Meeting**

*Clinical Data Presented on Lead Drug Candidates from HyperAcute™ and IDO Pathway Platforms in Pancreatic Cancer, Non-Small Cell Lung Cancer and other Metastatic Solid Tumors*

Ames, IA - May 16, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced that several clinical presentations on its two proprietary platform technologies have been selected for the upcoming 2013 Annual Meeting of the American Society of Clinical Oncology (ASCO). The meeting will be held May 31 to June 4, 2013 in Chicago, IL. NewLink's HyperAcute technology will be featured in one oral presentation on the company's most advanced drug candidate, algenpantucel-L, in pancreatic cancer, and in one poster presentation on tergenpumatucel-L in non-small cell lung cancer (NSCLC). The company's lead small molecule drug candidate, indoximod, which targets the IDO pathway will be highlighted in one poster discussion and one poster presentation involving patients with metastatic solid tumors.

"These clinical presentations describe the potential benefits generated from NewLink's two proprietary immunotherapy platforms: HyperAcute technology products stimulate the human immune system to recognize and attack cancer cells while our IDO pathway products break down the defense mechanisms of cancer cells," commented Charles Link, Jr., MD, Chairman and Chief Executive Officer of NewLink.

**Oral Presentation:**

- (Abstract #3007): Monday, June 3, 2013, 5:15-5:30 PM, "*Effect of algenpantucel-L immunotherapy for pancreatic cancer on anti-mesothelin antibody (Ab) titers and correlation with improved overall survival,*" Caio Max S. Rocha Lima, MD, Oral Presentation Session: Developmental Therapeutics - Immunotherapy, Location: Room S406, McCormick Place Convention Center

**Poster Discussion:**

- (Abstract #3026, Poster Board #18): Saturday, June 1, 2013, 1:15-5:15 PM, "*A phase I study of indoximod in combination with docetaxel in metastatic solid tumors,*" Erica Jackson, BS, MS, Poster Session: Developmental Therapeutics, Location: Room S405, McCormick Place Convention Center.

**Poster Presentations:**

- (Abstract # 8094): Saturday, June 1, 2013, 8:00-11:45 AM, “*Potential chemo-sensitization effect of tergenpumatu cel-L immunotherapy in treated patients with advanced non-small cell lung cancer (NSCLC)*,” John C. Morris, MD, Poster Session: Lung Cancer: Non-Small Cell Metastatic, Location: S Hall A2, McCormick Place Convention Center.
- (Abstract #3069): Monday, June 3, 2013, 8:00 -11:45 AM, “*A phase I study of ad.p53 DC vaccine in combination with indoximod in metastatic solid tumors*,” Hatem H. Soliman, MD, Poster Session: Developmental Therapeutics, Location: S Hall A2, McCormick Place Convention Center.

**About HyperAcute Immunotherapy**

NewLink's HyperAcute immunotherapy platform creates novel biologic products that are designed to stimulate the human immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human cancer cells that are tumor specific, but not patient specific. These cells have been modified to express alpha-gal, a carbohydrate for which humans have pre-existing immunity. These alpha-gal-modified cells stimulate a rapid and powerful human immune response that trains the body's natural defenses to seek out and destroy cancer cells. The objective of HyperAcute immunotherapies is to elicit an antitumor response by “educating” the immune system to attack a patient's own cancer cells. HyperAcute immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of HyperAcute products result in the stimulation of a robust immune response.

NewLink's lead product candidate, algenpantucel-L (HyperAcute pancreas), is being studied in a Phase 3 trial (IMPRESS: “Immunotherapy for Pancreatic Resectable cancer Survival Study”) under a Special Protocol Assessment with the U.S. Food and Drug Administration. This trial involves up to 722 patients with surgically resected pancreatic cancer. Algenpantucel-L is also being tested in a second Phase 3 study (PILLAR: “Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable”), involving patients with locally advanced pancreatic cancer.

NewLink has several HyperAcute product candidates focused on other tumor types in various stages of development, including tergenpumatu cel-L, which is in an adaptive design, randomized Phase 2B/3 clinical trial currently accruing up to 240 patients with non-small cell lung cancer.

**About IDO pathway inhibition**

NewLink's IDO pathway platform is focused on developing small molecule drugs that disrupt mechanisms by which tumors evade a patient's immune system. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4 and PD-1 that are potential breakthroughs in cancer therapy. NewLink's IDO pathway inhibitors are orally administered small molecules that can be used in combination with other cancer therapeutics.

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 resulting in peripheral tolerance to tumor associated antigens (TAAs). Cancers may use the IDO pathway to facilitate survival, growth, invasion and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system.

NewLink is actively developing two IDO pathway inhibitors. The most advanced is indoximod, which is being studied in various chemotherapy and immunotherapy combination clinical studies. The second IDO pathway inhibitor, NLG919, has shown promising preclinical results and is expected to enter clinical trials by the end of 2013.

### **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>. 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, tergenpumatucl-L, indoximid and our other HyperAcute and/or IDO pathway product candidates and related trials; 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, 2012, Quarterly Report on Form 10-Q for the period ended March 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 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.*



**Contact:**

Gordon Link  
Chief Financial Officer  
515-598-2925  
[glink@linkp.com](mailto:glink@linkp.com)

FOR IMMEDIATE RELEASE

**NewLink Genetics to be Added to NASDAQ Biotechnology Index**

Ames, IA - May 16, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced that it has been selected for addition to the NASDAQ Biotechnology Index<sup>®</sup> (Nasdaq: NBI), effective prior to the market open on Monday, May 20, 2013.

The NASDAQ Biotechnology Index is designed to track the performance of a set of NASDAQ-listed securities classified according to the Industry Classification Benchmark (ICB) as either Biotechnology or Pharmaceuticals. These companies must meet eligibility criteria that include a minimum market capitalization of \$200 million and minimum average daily trading volume of 100,000 shares, amongst other requirements. The Index Securities are evaluated semi-annually in May and November and serve as the basis for the iShares NASDAQ Biotechnology Index Fund (AMEX:IBB). For more information about the NASDAQ Biotechnology Index, including eligibility criteria, visit [www.nasdaq.com](http://www.nasdaq.com).

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