

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): December 13, 2012 (December 13, 2012)

**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 December 13, 2012, NewLink Genetics (NASDAQ:NLNK) announced that the results of a Phase 1 dose escalation study with its proprietary HyperAcute Prostate Cancer Immunotherapy were published in the *Journal of Immunotherapy*. The article, entitled “Cellular Immunotherapy Study of Prostate Cancer Patients and Resulting IgG Responses to Peptide Epitopes Predicted From Prostate Tumor-associated Autoantigens,” is featured in the current edition of the Journal.

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 December 13, 2012, entitled "Clinical Data from NewLink Genetics' HyperAcute Prostate Cancer Immunotherapy Published in <i>Journal of Immunotherapy</i> "

## 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: December 13, 2012

### **NewLink Genetics Corporation**

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

## INDEX TO EXHIBITS

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Contact:  
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Chief Financial Officer  
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FOR IMMEDIATE RELEASE

## **Clinical Data from NewLink Genetics' HyperAcute Prostate Cancer Immunotherapy Published in *Journal of Immunotherapy***

### **- Data Continues to Support the use of NewLink's HyperAcute® Immunotherapy to Elicit a Response in Tumor-Specific Antigens Common to both the Immunotherapy and the Patient's Tumor Cells -**

AMES, Iowa, December 13, 2012 - NewLink Genetics Corporation (Nasdaq:NLNK) today announced that the results of a Phase 1 dose escalation study with its proprietary HyperAcute Prostate Cancer Immunotherapy were published in the *Journal of Immunotherapy*. The article, entitled "Cellular Immunotherapy Study of Prostate Cancer Patients and Resulting IgG Responses to Peptide Epitopes Predicted From Prostate Tumor-associated Autoantigens," is featured in the current edition of the Journal.

The study was conducted at the University of Nebraska Medical Center and included eight patients. Patients were scheduled to receive a priming dose on day one, followed by eleven boost doses every two weeks and patients received up to 12 intradermal vaccinations at doses ranging from 30 million to 500 million cells per injection. Patients were tested for safety, immunological and clinical responses arising after immunotherapy.

The study demonstrated that the immunotherapy was safe, and that the first immunization differentially increased the anti-alphaGal IgG response in all patients compared with baseline levels. These data indicated that administration of HyperAcute Prostate immunotherapy increases the immune response against alphaGal epitopes, demonstrating the immunogenicity of the vaccine in prostate cancer patients.

The patients that received the highest dose of immunotherapy developed antibody responses against prostate tumor-associated antigens that were not seen in a control group of untreated volunteers. Data demonstrated that 37.5 percent (3/8) of patients responded with Prostate Specific Antigen (PSA) level stabilization for more than 100 days.

The adverse events data reported in this publication confirm the safety of this immunotherapy, consistent with previous studies on the safety of alpha-Gal-expressing allogeneic vaccines (HyperAcute immunotherapy) in the treatment of lung, melanoma and pancreatic cancers. Median overall survival for the study was 25.1 months with one patient with bone metastases surviving for more than 70 months.

"The favorable safety profile of this agent combined with evidence of vaccine induced immunologic responses in patients clearly suggests this therapy should be studied in a large controlled trial," said Dr. George P. Hemstreet, III, University of Nebraska Medical Center, the Principal Investigator for the study.

NewLink Genetics is currently evaluating its lead immunotherapy product candidate algenpantucel-L (HyperAcute Pancreas) in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients.

## About HyperAcute Prostate Cancer Immunotherapy

NewLink's HyperAcute Prostate Cancer immunotherapy product candidate consists of two allogeneic prostate cancer tumor cell lines modified to express alphaGal. These cell lines were chosen to provide a broad coverage of prostate cancer antigens. Each of the modified cell lines is grown in large cultures, harvested, packaged and irradiated. Each of the two vaccine components was administered separately.

## About Prostate Cancer

Prostate cancer is one of the most common forms of cancer affecting men. The American Cancer Society estimates that 241,740 new cases of prostate cancer will occur in the US during 2012. Increased screening over the past few decades has enabled physicians to detect prostate cancer in its early, more treatable stages. Nonetheless, while overall five-year survival rates for cases of prostate cancer approach 100%, the outlook for advanced, metastasized cases is poor, with a five-year survival rate of 29% according to the American Cancer Society.

## 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 tergenpumatul-L (HyperAcute Lung) in patients with non-small cell lung cancer. NewLink is developing indoximod (d-1-methyltryptophan, or D-1MT), 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>

## Safe Harbor Statement

*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 NewLink's HyperAcute 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 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, 2011, in its Quarterly Report on Form 10-Q for the period ended September 30, 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.*