

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): September 30, 2013 (September 30, 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 September 30, 2013, NewLink Genetics (NASDAQ:NLNK) announced the presentation of data on its lead HyperAcute cancer immunotherapy product candidates at the 2013 European Cancer Congress (ESMO) in Amsterdam, The Netherlands.

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 September 30, 2013, entitled "NewLink Genetics Presents Data Demonstrating Potential Chemo-Sensitization Activity of its HyperAcute™ Cancer Immunotherapy Product Candidates"

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: September 30, 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 September 30, 2013, entitled “NewLink Genetics Presents Data Demonstrating Potential Chemo-Sensitization Activity of its HyperAcute™ Cancer Immunotherapy Product Candidates”



FOR IMMEDIATE RELEASE

NewLink Genetics Presents Data Demonstrating Potential Chemo-sensitization Activity of its HyperAcute™ Cancer Immunotherapy Product Candidates

Greater than Expected Responses to Salvage Chemotherapy Observed Following Treatment with Algenpantucel-L in Pancreatic Cancer and Tergenpumatumucel-L in NSCLC

Data Presented at the 2013 European Cancer Congress

Ames, IA - September 30, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced the presentation of data on its lead HyperAcute cancer immunotherapy product candidates at the 2013 European Cancer Congress (ESMO) in Amsterdam, The Netherlands. NewLink researchers presented data showing greater than expected responses to salvage chemotherapy following treatment with both algenpantucel-L in patients with pancreatic cancer and tergenpumatumucel-L in patients with non-small cell lung cancer (NSCLC). The clinical benefit of chemo-sensitization is being further investigated in a larger number of patients by assessing objective tumor responses to follow-on chemotherapy after HyperAcute immunotherapy in ongoing clinical trials.

“These data indicate that pretreatment with HyperAcute immunotherapy such as algenpantucel-L or tergenpumatumucel-L prior to salvage chemotherapy has the potential to increase the sensitivity of cancer cells to chemotherapy that may lead to durable objective and complete responses,” commented Nick Vahanian MD, President and Chief Medical Officer of NewLink. “In addition, the immunologic responses further support the mechanism for HyperAcute immunotherapy to stimulate the patient's immune system to recognize and attack cancer cells.”

In a poster presentation entitled “*Chemo-sensitization and immunological reactions to hyperacute immunotherapy, a novel approach to cancer treatment*,” NewLink researchers presented clinical data showing:

- Greater than expected responses to follow-on chemotherapy after treatment with algenpantucel-L or tergenpumatumucel-L HyperAcute immunotherapy.
- Three pancreatic cancer patients were followed for response to subsequent salvage chemotherapy treatment after progressing on algenpantucel-L therapy. All three patients experienced durable (12-36 months), complete responses.
- Sixteen NSCLC patients were followed for response to subsequent salvage chemotherapy treatment (list) after progressing on tergenpumatumucel-L therapy. Five of the sixteen (31%) achieved partial responses and four of the sixteen (25%) achieved stable disease.
- Immunologic responses, which correlated with improved survival, were observed with both algenpantucel-L and tergenpumatumucel-L indicating the ability of HyperAcute immunotherapy to elicit anti-cancer immune responses.

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 tergenpumatucl-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 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, indoximod 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 June 30, 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.

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