

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 17, 2013 (September 17, 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 17, 2013, NewLink Genetics (NASDAQ:NLNK) announced that a major milestone has been reached in the IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) Phase 3 clinical trial of algenpantucel-L. The accrual goal of 722 subjects with surgically resected pancreatic cancer has been met.

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 17, 2013, entitled "NewLink Genetics Completes Patient Enrollment in Phase 3 Algenpantucel-L (IMPRESS) Clinical Study"

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 17, 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 17, 2013, entitled "NewLink Genetics Completes Patient Enrollment in Phase 3 Algenpantucel-L (IMPRESS) Clinical Study"



FOR IMMEDIATE RELEASE

NewLink Genetics Completes Patient Enrollment in Phase 3 Algenpantucel-L (IMPRESS) Clinical Study

Largest Company-Sponsored Resected Pancreatic Cancer Study Yet Conducted

Ames, IA - September 17, 2013 -- NewLink Genetics Corporation (NASDAQ: NLNK), an oncology-focused biopharmaceutical company specializing in immunotherapy, today announced that a major milestone has been reached in the IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) Phase 3 clinical trial of algenpantucel-L. The accrual goal of 722 subjects with surgically resected pancreatic cancer has been met. The study examines the lead product candidate from NewLink's proprietary HyperAcute™ immunotherapy platform, algenpantucel-L, which is designed to stimulate the human immune system to recognize and attack cancer cells. Two interim analyses and a final analysis are planned for the IMPRESS study. In addition to the IMPRESS trial, algenpantucel-L is also being studied in a second Phase 3 trial involving patients with locally advanced pancreatic cancer (PILLAR).

“On behalf of the entire NewLink organization, I would like to take this opportunity to extend our deepest gratitude to all the patients who participated in this pivotal study as well as to their families. I would also like to thank all the health care professionals including physicians, nurses and study coordinators who have contributed to the successful enrollment of this landmark trial” commented Charles Link, Jr., M.D., Chairman and CEO of NewLink Genetics.

“Our promising Phase 2 results enabled us to successfully collaborate with many major medical centers and the leaders within those institutions,” Dr. Link remarked. “To date, IMPRESS is the largest corporate sponsored resected pancreatic cancer study yet conducted. We are confident in the stringency of this study design and the statistical power provided by the large number of patients participating in this trial as we enthusiastically look forward to the clinical results.”

“We are increasingly confident in the progress made with the clinical development of algenpantucel-L,” said Nicholas N. Vahanian, M.D., President, Chief Medical Officer of NewLink Genetics. “As we enter a critical data collection and analysis phase of the study we are encouraged by the progress made in such a short period of time. Completion of study enrollment is a critical step towards our mission of bringing better treatment options to pancreatic cancer patients who are in desperate need of more promising alternatives.”

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 tergenpumatumucel-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, tergenpumatumucel-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.

Contact:

Media:
Gina Nugent
The Yates Network
gina@theyatesnetwork.com

Investors:
Gordon Link
Chief Financial Officer
515-598-2925
glink@linkp.com