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 21, 2012 (September 21, 2012)

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2503 South Loop Drive **Ames, IA**	**50010**
(Address of principal executive offices)	(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 21, 2012, NewLink Genetics (NASDAQ:NLNK) announced that it will begin an investigator initiated, randomized, double blind placebo controlled Phase 2 study entitled “Phase II Study of sipuleucel-T (PROVENGE®) plus indoximod (D-1MT/NLG8189) in the treatment of patients with asymptomatic or minimally symptomatic metastatic hormone refractory prostate cancer”**.** This study is done in collaboration with Dendreon Corporation (DNDN) and the Masonic Cancer Center, University of Minnesota.

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.

Exhibit Number	Description
99.1	Press Release, dated September 21, 2012, entitled “NewLink announces an Investigator initiated Phase 2 Study of Sipuleucel-T plus Indoximod in the Treatment of Certain Men with Advanced Prostate Cancer”

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 21, 2012

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 21, 2012, entitled “NewLink announces an Investigator initiated Phase 2 Study of Sipuleucel-T plus Indoximod in the Treatment of Certain Men with Advanced Prostate Cancer”

Exhibit 99.1

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

FOR IMMEDIATE RELEASE
Date: September 21, 2012

NewLink announces an Investigator initiated Phase 2 Study of Sipuleucel-T plus Indoximod in the Treatment of Certain Men with Advanced Prostate Cancer

AMES, Iowa, September 21, 2012 -- NewLink Genetics (NASDAQ:NLNK) announced today that it will begin an investigator initiated, randomized, double blind placebo controlled Phase 2 study entitled “Phase II Study of sipuleucel-T (PROVENGE®) plus indoximod (D-1MT/NLG8189) in the treatment of patients with asymptomatic or minimally symptomatic metastatic hormone refractory prostate cancer”**.** This study is done in collaboration with Dendreon Corporation (DNDN) and the Masonic Cancer Center, University of Minnesota.

Dr. Gautam Jha, assistant professor of medicine at the University of Minnesota will lead this multicenter study with a planned enrollment of 50 patients. Men with hormone refractory metastatic prostate cancer, eligible for therapy with sipuleucel-T (PROVENGE) will be enrolled to evaluate the safety and efficacy of the combination of NewLink's indoximod with Dendreon's PROVENGE.

“We are excited with the opportunity to explore potential benefits of combining our indoximod immuno-modulatory product candidate with PROVENGE, the first FDA-approved active cellular immunotherapy product for cancer” said Dr. Nick Vahanian, President and Chief Medical Officer of NewLink Genetics.

About indoximod and inhibition of the IDO pathway

IDO pathway inhibitors, including indoximod, represent a potential breakthrough approach to cancer therapy using small-molecule, anti-toleragenic product candidates intended to counteract a key mechanism by which tumors evade immune-mediated destruction. IDO is an enzyme that regulates immune response by suppressing T-cell function and enabling local tumor immune escape. Recent studies have demonstrated that IDO is overexpressed in many cancers, within both tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor draining lymph nodes whereby IDO promotes peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, IDO may facilitate the survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system as foreign. Indoximod is currently in multiple Phase 1B/2 studies evaluating the addition of indoximod to

Taxotere in the treatment of breast cancer and the addition of indoximod to an autologous P-53 Denritic Cell vaccine, also in the treatment of breast cancer patients. In addition to its clinical indoximod product candidate, NewLink has an active program directed at synthesizing other IDO pathway inhibitors.

PROVENGE Indication and Safety

PROVENGE is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

PROVENGE is intended solely for autologous use and is not routinely tested for transmissible infectious diseases.

The safety evaluation of PROVENGE was based on 601 prostate cancer patients in four randomized clinical trials who underwent at least one leukapheresis. The most common adverse events (incidence greater-than or equal to 15%) were chills, fatigue, fever, back pain, nausea, joint ache, and headache. Serious adverse events reported in the PROVENGE group included acute infusion reactions (occurring within 1 day of infusion) and cerebrovascular events. In controlled clinical trials, severe (Grade 3) acute infusion reactions were reported in 3.5% of patients in the PROVENGE group. Reactions included chills, fever, fatigue, asthenia, dyspnea, hypoxia, bronchospasm, dizziness, headache, hypertension, muscle ache, nausea, and vomiting. No Grade 4 or 5 acute infusion reactions were reported in patients in the PROVENGE group.

To fulfill a post marketing requirement and as a part of the company's ongoing commitment to patients, Dendreon will conduct a registry of approximately 1500 patients to further evaluate a small potential safety signal of cerebrovascular events. In four randomized clinical trials of PROVENGE in prostate cancer patients, cerebrovascular events were observed in 3.5% of patients in the PROVENGE group compared with 2.6% of patients in the control group.

For more information on PROVENGE, please see the full prescribing information at http://www.provenge.com or call 1-877-336-3736.

About NewLink Genetics Corporation

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. 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 with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. NewLink's lead product candidate, HyperAcute® Pancreas cancer immunotherapy (algenpantucel-L) is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients (patient information is available at http://www.pancreaticcancer-clinicaltrials.com). This clinical trial is being performed under a Special Protocol Assessment with the U.S. Food and Drug Administration. NewLink and its collaborators have completed patient enrollment for a Phase 1/2 clinical trial evaluating its HyperAcute® Lung cancer immunotherapy (tergenpumatucel-L) product candidate for non-small cell lung cancer and a Phase 2 clinical trial for its HyperAcute® Melanoma cancer immunotherapy product candidate. NewLink also 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. Through NewLink's collaboration with the National Cancer Institute, NewLink is studying indoximod in various

chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. For more information please visit www.linkp.com.

About the Masonic Cancer Center at the University of Minnesota:

The Masonic Cancer Center at the University of Minnesota is part of the University's Academic Health Center and has been a designated a Comprehensive Cancer Center by the National Cancer Institute for cancer research, treatment, and education since 1998. Over 500 faculty and staff support the mission of advancing knowledge and enhancing care.

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 for indoximod (NLG8189); potential implications of data from this collaborative study; 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 risks relating to: the study itself; application of indoximod (NLG8189); collaboration with sipuleucel-T (PROVENGE); adverse general economic and industry conditions; and those risks discussed in "Risk Factors" and elsewhere in NewLink's's Quarterly Report on Form 10-Q for the period ended June 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.