

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 15, 2014 (May 15, 2014)

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 15, 2014, NewLink Genetics (NASDAQ:NLNK) announced presentations highlighting its HyperAcute® and IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor programs at the upcoming American Society of Clinical Oncology (ASCO) 50th Annual meeting, May 30-June 3, 2014 in Chicago, IL.

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 May 15, 2014, entitled "NewLink Genetics to Present at the ASCO 2014 Annual Meeting"

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 15, 2014

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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99.1	Press Release, dated May 15, 2014, entitled "NewLink Genetics to Present at the ASCO 2014 Annual Meeting"



NewLink Genetics to Present at the ASCO 2014 Annual Meeting

Hosting Special Program with Immuno-Oncology Thought Leaders

Ames, IA - May 15, 2014 -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutics to improve treatment options for patients with cancer, today announced presentations highlighting its HyperAcute® and IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor programs at the upcoming American Society of Clinical Oncology (ASCO) 50th Annual meeting, May 30-June 3, 2014 in Chicago, IL.

In addition to these presentations, NewLink Genetics will host a special program entitled “Points to Consider in Future Cancer Treatment: Chemotherapy, Checkpoint Inhibitors and Novel Synergistic Combinations” on Sunday evening, June 1st from 6-7:30 p.m. CT. This panel discussion with key opinion leaders in the field of immuno-oncology will explore the potential benefits of combining multiple therapies, including checkpoint inhibitors, chemotherapy, and immunotherapy, for effective immune-based cancer treatments.

NewLink is also planning to exhibit at the meeting. Please plan to visit us at booth #10163.

Details of the poster presentations at ASCO:

- **Monday, June 2, 2014, 1:15 p.m. - 4:15 p.m. CDT (Poster Discussion, 4:30 p.m. - 6:00 p.m.)**
Title: Correlation of anti-calreticulin antibody titers with improved overall survival in a phase 2 clinical trial of algenpantucel-L immunotherapy for patients with resected pancreatic cancer. (Abstract #3029)
Presenter: G.R. Rossi
Session: Poster Highlights Session: Developmental Therapeutics: Immunotherapy
Location: S405, Poster Board #21

- **Saturday, May 31, 2014, 8:00 a.m. - 11:45 a.m. CDT**
Title: Phase 1/2 trial of the indoleamine 2,3-dioxygenase pathway (IDO) inhibitor indoximod plus ipilimumab for the treatment of unresectable stage 3 or 4 melanoma. (Abstract #TPS9117)
Presenter: E. Kennedy
Session: General Poster Session: Melanoma/Skin Cancers
Location: S Hall A2, Poster Board #313B

- **Saturday May 31, 2014, 8:00 a.m. - 11:45 a.m. CDT**
Title: Abstract Title: NLG-0304: A phase 2b study of ipilimumab with or without dorgenmeltucel-L (HyperAcute-Melanoma) immunotherapy for patients with stage IV melanoma. (Abstract # TPS9115)
Presenter: A. I. Riker
Session: General Poster Session: Melanoma/Skin Cancers
Location: S Hall A2, Poster Board #: 312B

- **Saturday, May 31, 2014, 1:15 p.m. - 5:00 p.m. CDT**
Title: NLG-0301: An open-label, randomized phase 2b active control study of second-line tergenpumatucel-L immunotherapy versus docetaxel in patients with progressive or relapsed non-small cell lung cancer (NSCLC). (Abstract #TPS8133)
Presenter: R. Govindan
Session: General Poster Session: Lung Cancer - Non-Small Cell Metastatic
Location: S Hall A2, Poster Board #306
- **Saturday, May 31, 2014, 1:15 p.m. - 5:00 p.m. CDT**
Title: A phase 1/2 study of the combination of indoximod and temozolomide for adult patients with temozolomide-refractory primary malignant brain tumors. (Abstract #TPS2107)
Presenter: Y. Zakharia
Session: General Poster Session: Central Nervous System Tumors
Location: S Hall A2, Poster Board #69A
- **Sunday, June 1, 2014, 8:00 a.m. - 11:45 a.m. CDT**
Title: First in human phase 1 study of the novel indoleamine-2,3-dioxygenase (IDO) inhibitor NLG919. (Abstract #TPS3121)
Presenter: S. Khleif
Session: General Poster Session: Developmental Therapeutics: Immunotherapy
Location: S Hall A2, Poster Board #183A
- **Sunday, June 1, 2014, 8:00 a.m. - 11:45 a.m. CDT**
Title: A phase 2 study of docetaxel in combination with indoximod in metastatic breast cancer. (Abstract #TPS3124)
Presenter: H. H. Soliman
Session: General Poster Session: Developmental Therapeutics: Immunotherapy
Location: S Hall A2, Poster Board #184B
- **Sunday, June 1, 2014, 8:00 a.m. - 11:45 a.m. CDT**
Title: A phase 2 study of Ad.p53 DC vaccine in combination with indoximod in metastatic solid tumors. (Abstract #TPS3125)
Presenter: H. H. Soliman
Session: General Poster Session: Developmental Therapeutics: Immunotherapy
Location: S Hall A2, Poster Board #185A
- **Monday, June 2, 2014, 1:15 p.m. - 5:00 p.m. CDT**
Title: A randomized, double-blind phase 2 study of sipuleucel-T followed by indoximod or placebo in the treatment of patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. (Abstract #TPS5111)
Presenter: G. G. Jha
Session: General Poster Session: Genitourinary (Prostate) Cancer
Location: S Hall A2, Poster Board #231B

About NewLink Genetics' IDO Pathway Inhibitors

NewLink is developing two distinct IDO (indoleamine-(2,3)-dioxygenase) pathway inhibitor product candidates, indoximod and NLG919, with different and potentially complementary mechanisms of action. IDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. These small molecule drug candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. In many different cancers, IDO can be overexpressed either directly by cancer cells or by antigen-presenting cells in the tumor microenvironment

and draining lymph nodes, representing a substantial drug development opportunity. When IDO is expressed by cancers, IDO pathway activity creates an immunosuppressive environment that shifts the immune response from anti-cancer to cancer tolerance. Multiple elements of the immune system are affected by this shift, including effector T-cells, regulatory T-cells, and dendritic cells, resulting in the survival of cancers that might otherwise be recognized and attacked by the immune system. Inhibiting the IDO pathway allows reprogramming of the immune response from tolerance back to an active anti-cancer response.

NewLink's most advanced IDO pathway inhibitor, indoximod, is in multiple Phase 1 and Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreas, melanoma and brain cancers. Additionally, NLG919 is currently in Phase 1 clinical development in patients with recurrent advanced solid tumors. In addition to these two clinical drug candidates, NewLink has an active drug discovery program which focuses on IDO and a related target, tryptophan-(2,3)-dioxygenase or TDO.

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 immuno-oncology 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>.

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 and efficacy of algenpantucel-L, tergenpumatumucel-L, indoximod, NLG919, and our other HyperAcute and/or IDO pathway product candidates and related clinical trials, plans to develop and

commercialize our product candidates; ongoing and planned preclinical studies and clinical trials, the timing for completion of enrollment and outcomes of our other ongoing clinical studies; 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, 2013, Quarterly Report on Form 10-Q for the period ended March 31, 2014, 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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