

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): April 17, 2012 (April 17, 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 April 17, 2012, the NewLink Genetics Corporation issued a press release reporting that the Japan Patent Office has issued a notice of allowance for a patent entitled "Antitumor Vaccination Using Allogeneic Tumor Cells Expressing Alpha (1,3)-Galactosyltransferase," which contains broad pharmaceutical composition claims covering NewLink's HyperAcute products for the treatment of cancer.

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 April 17, 2012, entitled "NewLink Genetics receives notice of allowance from the Japan Patent Office for new patent broadly covering its HyperAcute® cancer immunotherapy products"

**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: April 17, 2011

**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 April 17, 2012, entitled "NewLink Genetics receives notice of allowance from the Japan Patent Office for new patent broadly covering its HyperAcute® cancer immunotherapy products"



Today's Discoveries . . . Tomorrow's Medicines

**Contact:**

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FOR IMMEDIATE RELEASE

**NewLink Genetics receives notice of allowance from the Japan Patent Office for new patent broadly covering its HyperAcute® cancer immunotherapy products**

AMES, Iowa, April 17, 2012 - NewLink Genetics Corporation today announced that the Japan Patent Office has issued a notice of allowance for a patent entitled “Antitumor Vaccination Using Allogeneic Tumor Cells Expressing Alpha (1,3)-Galactosyltransferase,” which contains broad pharmaceutical composition claims covering NewLink’s HyperAcute products for the treatment of cancer. NewLink holds exclusive rights to the allowed application as well as to previously issued counterpart patents in the United States, Canada, Mexico, and Europe.

“These patents are valuable additions to our intellectual property portfolio in the immunotherapy arena,” commented Dr. Charles Link, NewLink’s Chairman and CEO, “We expect them to facilitate our partnering efforts.”

**About HyperAcute cancer immunotherapies**

NewLink’s lead product candidate, HyperAcute Pancreas cancer immunotherapy, 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>) that is being performed under a Special Protocol Assessment with the United States Food and Drug Administration. Pancreatic cancer is the fifth most common cause of death by malignant neoplasm in Japan, where the incidence of the disease has increased rapidly since the early 1960s, resulting in a relative risk that is almost forty percent greater in Japan than the United States. It has been estimated that approximately 26,000 patients with pancreatic cancer die per year in Japan.

NewLink is also currently engaged in clinical development of HyperAcute immunotherapies specific for pancreatic cancer, lung cancer, and melanoma, has initiated clinical development of product candidates for prostate cancer and breast cancer, and is actively developing the HyperAcute technology for other indications.

NewLink’s HyperAcute cancer immunotherapy product candidates are composed of live, irradiated, allogeneic (non-patient specific) human cancer cells that have been modified to express alpha (1,3)-Galactosyl (alpha Gal) carbohydrates, a non-human form of carbohydrate, on the surface of the affected cells. The company believes its HyperAcute immunotherapy technology offers several advantages over other cancer immunotherapy approaches. Specifically, our HyperAcute products are designed to:

- harness the human body’s innate immune response to alpha-Gal to fight cancer;
- utilize a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- use allogeneic (non-patient specific) cells from previously-established cell lines, enabling a simpler, more consistent and scalable manufacturing process than therapies based on autologous (patient-specific) tissues or cells.

## **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. In addition to its HyperAcute product candidates, NewLink also is developing 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 D-1MT in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. For more information please visit [www.linkp.com](http://www.linkp.com).

## **Safe Harbor Statement**

This press release contains "forward-looking statements" for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the issuance of, and protection provided by, the patent entitled "Antitumor Vaccination Using Allogeneic Tumor Cells Expressing Alpha (1,3)-Galactosyltransferase" in Japan and statements regarding the potential for the patent to facilitate partnering efforts. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with: the protection and market exclusivity provided by the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; and, the impact of competitive products and technological changes. These and other factors are identified and described in more detail in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2011, as amended, and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.