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): November 14, 2012 (November 14, 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 November 14, 2012, NewLink Genetics (NASDAQ:NLNK) announced that the European Commission (EC) has designated HyperAcute-Pancreas® Immunotherapy (algenpantucel-L) as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on Orphan Medicinal Products. NewLink filed the application for orphan designation in June 2012. A positive opinion was adopted by the Committee for Orphan Medicinal Products (COMP) and was formally accepted by the EC. Finalization of the Public Summary is projected for November, 2012. Algenpantucel-L is an "off-the-shelf" product candidate currently being studied in IMPRESS (Immunotherapy Pancreas Resected Survival Study), an open-label, randomized, controlled, multi-center, Phase 3 clinical trial of approximately 700 Stage I and Stage II surgically-resected pancreatic cancer patients, which is being performed under a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA).

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 November 14, 2012, entitled "NewLink Genetics Receives European Orphan Designation for Algenpantucel-L Immunotherapy to Treat Pancreatic 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: November 14, 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 November 14, 2012, entitled "NewLink Genetics Receives European Orphan Designation for Algenpantucel-L Immunotherapy to Treat Pancreatic Cancer"

Exhibit 99.1

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

FOR IMMEDIATE RELEASE
Date: November 14, 2012

NewLink Genetics Receives European Orphan Designation for Algenpantucel-L Immunotherapy to Treat Pancreatic Cancer

AMES, Iowa, Nov. 14, 2012 /PRNewswire/ -- NewLink Genetics Corporation (Nasdaq: NLNK) today announced that the European Commission (EC) has designated HyperAcute-Pancreas® Immunotherapy (algenpantucel-L) as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on Orphan Medicinal Products. NewLink filed the application for orphan designation in June 2012. A positive opinion was adopted by the Committee for Orphan Medicinal Products (COMP) and was formally accepted by the EC. Finalization of the Public Summary is projected for November, 2012. Algenpantucel-L is an "off-the-shelf" product candidate currently being studied in IMPRESS (Immunotherapy Pancreas Resected Survival Study), an open-label, randomized, controlled, multi-center, Phase 3 clinical trial of approximately 700 Stage I and Stage II surgically-resected pancreatic cancer patients, which is being performed under a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA).

As a result of the orphan designation NewLink will have access to multiple incentives for the development of the drug in the EU, including reduced fees during development, access to the centralized authorization procedure (a single application for all EU countries), ten years of market exclusivity, and reduced fees for marketing authorization applications, pre-marketing inspections and multiple post-approval fees. Currently, algenpantucel-L has both orphan drug designation and Fast-track status in the United States.

"As emphasized during National Pancreatic Cancer Awareness Month in November, there is a desperate need for new treatment options for this disease and the European Commission's decision to grant orphan drug designation to algenpantucel-L should help us to address this unmet medical need," said Dr. Charles Link, CEO and Chairman of NewLink Genetics. "We believe that orphan designation in the European Union will significantly enhance our ability to bring this product globally to patients who have pancreatic cancer."

"Orphan drug designation provides significant incentives for us to accelerate clinical development in the EU," said Dr. Nick Vahanian. "We believe that this designation, in combination with data from our ongoing 700 patient IMPRESS Phase 3 study of algenpantucel-L, will expedite advancement of this product through the approval process in Europe.

About Orphan Drug Status in Europe

As established by the European Medicines Agency (EMA), orphan designation is granted to product candidates intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in the EU and for whom satisfactory alternative therapies are not available or where they do exist, the orphan product will be of significant benefit to those affected by that condition. Applications are reviewed by the COMP and encompass evaluations of the underlying science and clinical experience with the product.

About algenpantucel-L

NewLink's algenpantucel-L is an "off-the-shelf" immunotherapy product candidate that consists of a group of two allogeneic pancreatic cancer tumor cell lines that were genetically modified to express Alpha-Gal. These cell lines were chosen to provide a broad coverage of pancreatic cancer antigens. Each of the modified cell lines is grown in large cultures, harvested, irradiated and packaged. Approximately 150 million cells of each HyperAcute Pancreas cell line are given by intradermal injection with each treatment.

About Pancreatic Cancer

The American Cancer Society estimates that approximately 44,030 new cases of pancreatic cancer were diagnosed in the United States in 2011. In the EU, there are about 66,000 similar patients. Pancreatic cancer has generally been recognized as an aggressive form of cancer with non-specific initial symptoms, making it difficult to diagnose at an early stage. Due to the difficulty in diagnosis and the aggressive nature of this cancer, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer Society estimates one-year and five-year overall survival rates of about 24% and 5%, respectively.

Pancreatic cancer can generally be divided into three broad categories: (1) local disease, in which the cancer is confined to the pancreas and can be removed surgically, which is called resection; (2) locally advanced disease, in which the cancer has spread locally and may or may not be eligible for resection because it has invaded tissues that should not be removed, such as key nerves and arteries; and (3) metastatic disease, in which the tumor has spread beyond the region of the pancreas. NewLink's algenpantucel-L is being studied in phase 3 studies in both local disease and locally advanced disease.

About NewLink Genetics Corporation

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for cancer patients. 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. NewLink's lead product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in a Phase 3 clinical trial in surgically resected pancreatic cancer patients (under a Special Protocol Assessment with the U.S. FDA) as well as in a separate study in locally advanced pancreatic cancer patients. NewLink has recently launched an adaptive design Phase 2B/3 clinical trial of tergenpumatucel-L (HyperAcute Lung) in patients with non-small cell lung cancer. NewLink 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. NewLink is studying indoximod in various chemotherapy and immunotherapy combination studies independently and in collaboration with the National Cancer Institute. For more information please visit http://www.linkp.com. Patient information is available at http://www.pancreaticcancer-clinicaltrials.com

Safe Harbor Statement

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 and the prospects of NewLink's Phase 3 clinical 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, 2011, in its Quarterly Report on Form 10-Q for the period ended September 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.