

NEWLINK GENETICS CORP

Form 8-K

November 14, 2012

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 (State or other jurisdiction of incorporation)	001-35342 (Commission File Number)	42-1491350 (IRS Employer Identification No.)
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2503 South Loop Drive Ames, IA (Address of principal executive offices)	50010 (Zip Code)
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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))
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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

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