

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): October 31, 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 2 - Financial Information**

### **Item 2.02. Results of Operations and Financial Condition.**

On October 31, 2012, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release reporting financial results for the third quarter ended September 30, 2012.

The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

**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 October 31, 2012, entitled "NewLink Genetics Corporation Reports Third Quarter 2012 Financial Results"

## 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: October 31, 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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99.1	Press Release, dated October 31, 2012, entitled "NewLink Genetics Corporation Reports Third Quarter 2012 Financial Results"



Contact:  
 Gordon Link  
 Chief Financial Officer  
 515-598-2925  
[glink@linkp.com](mailto:glink@linkp.com)

FOR IMMEDIATE RELEASE

## **NewLink Genetics Corporation Reports Third Quarter 2012 Financial Results**

AMES, Iowa, October 31, 2012 - NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today reported consolidated financial results for the third quarter of 2012. NewLink updated the status of its clinical development programs including its HyperAcute® Pancreas Immunotherapy Phase 3 trial (Immunotherapy for Pancreatic Resectable cancer Survival Study or "IMPRESS").

"As we approach the trigger event for the first interim analysis in our IMPRESS pivotal study, we have continued to execute our plan within the financial guidance we provided at the beginning of this year," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink.

"In addition to our IMPRESS pivotal study for resected pancreatic patients, we have initiated a separate Phase 3 study for patients with locally advanced disease," said Dr. Nicholas Vahanian, NewLink's President and Chief Medical Officer. "If approved this new indication potentially doubles the number of patients who could be treated with algenpantucel-L. We are also expanding our HyperAcute immunotherapy platform by opening a major Phase 2B/3 study in non-small cell lung cancer."

### **The third quarter 2012 Financial Results**

- Cash, cash equivalents and certificates of deposit totaled \$28.3 million at September 30, 2012.
- Total grant revenues for the third quarter 2012 were \$327,000 compared with \$430,000 for the third quarter 2011. Grant revenues will vary depending on the level of research funded under grants as well as changes in the overhead rates and profit factors agreed to under the grants. The decrease in revenue was due to a decrease in research by BPS under various Department of Defense contracts and National Institutes of Health grants as amended.
- Research and development (R&D) expense for the third quarter 2012 was \$4.8 million compared with \$3.3 million for the third quarter 2011. The increase was primarily due to increases in clinical trial expense associated with an increase in the number of patients enrolled in clinical trials and personnel-related expenses associated with both increased headcounts and increased compensation levels.
- General and administrative (G&A) expense for the third quarter 2012 was \$1.4 million compared with \$1.1 million for the third quarter 2011. The increase was primarily due to increases in professional and Board fees and Directors and Officers insurance premiums associated with our new public company status.
- Net loss for the third quarter 2012 was \$5.9 million or \$.28 per common share (based on 20.9 million weighted average shares outstanding), compared with \$4.0 million, or \$1.09 per common share, for the third quarter 2011 (based on 3.7 million weighted average shares outstanding). The difference in the number of weighted average shares outstanding primarily resulted from NewLink's initial public offering in November 2011, as well as the conversion of all preferred stock to common stock in connection with the initial public offering.

### **Financial Guidance**

NewLink expects to end 2012 with \$20 million to \$23 million in cash, cash equivalents and marketable securities.

**Significant recent events:**

- We have continued to rapidly accrue patients in our 700 patient IMPRESS study of algenpantucel-L. We continue to believe this Phase 3 pivotal study will be fully enrolled in 2013.
- We launched a Phase 3 clinical trial of algenpantucel-L (HyperAcute Pancreas) immunotherapy in patients with borderline resectable or locally advanced unresectable pancreatic cancer.
- We launched an adaptive design Phase 2B/3 clinical trial of tergenpumatumucel-L (HyperAcute Lung) immunotherapy in patients with non-small cell lung cancer.
- We announced an investigator initiated, randomized, double blind placebo controlled Phase 2 study titled "Phase II Study of sipuleucel-T (PROVENGE®) plus indoximod (D-1MT) 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.

**Upcoming Activities**

NewLink expects to present at the following investor conferences:

- Jefferies Global Healthcare Conference, November 14-15, in London;
- 9<sup>th</sup> Annual Lazard Capital Markets Healthcare Conference, November 13-14, in New York City;
- Piper Jaffray 24th Annual Healthcare Conference, November 27-28, in New York City.

**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 tergenpumatumucel-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>.

**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: NewLink's financial guidance for 2012; the timing for completion of enrollment of our Phase 3 clinical trial for our HyperAcute Pancreas cancer immunotherapy; the timing of release of clinical data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink's future financial performance, results of operations or sufficiency of capital resources to fund its operating requirements; 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.*

**NewLink Genetics Corporation**  
**Condensed Consolidated Statements of Operations**  
(unaudited)  
(In thousands, except share and per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
Grant revenue	\$ 327	\$ 430	\$ 1,388	\$ 1,571
Operating expenses:				
Research and development	4,779	3,301	13,349	10,276
General and administrative	1,396	1,101	5,005	3,553
Loss from operations	(5,848)	(3,972)	(16,966)	(12,258)
Other (expense) income, net	(3)	(14)	(36)	(20)
Net loss	\$ (5,851)	\$ (3,986)	\$ (17,002)	\$ (12,278)
Net loss attributable to NewLink	\$ (5,851)	\$ (3,986)	\$ (17,002)	\$ (12,277)
Net loss per common share, basic and diluted	\$ (0.28)	\$ (1.09)	\$ (0.82)	\$ (3.37)
Weighted average number of common shares outstanding	20,887,689	3,658,122	20,729,174	3,647,127

**NewLink Genetics Corporation**  
**Condensed Consolidated Balance Sheets**  
(unaudited)  
(In thousands, except share and per share amounts)

	<u>September 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 28,296	\$ 41,980
Prepaid expenses and other current assets	625	808
Total current assets	<u>28,921</u>	<u>42,788</u>
Property and equipment, net	<u>6,087</u>	<u>5,591</u>
Total assets	<u>\$ 35,008</u>	<u>\$ 48,379</u>
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,844	\$ 3,537
Deferred rent	76	913
Other current liabilities	230	6,214
Total current liabilities	<u>3,150</u>	<u>10,664</u>
Long-term liabilities:		
Royalty obligation payable	6,000	—
Notes payable and obligations under capital leases, excluding current portion	1,221	942
Deferred rent, excluding current portion	1,414	—
Total long-term liabilities	<u>8,635</u>	<u>942</u>
Total liabilities	<u>11,785</u>	<u>11,606</u>
Stockholders' equity:		
Preferred Stock	—	—
Common stock	209	206
Additional paid-in capital	121,492	118,043
Deficit accumulated during the development stage	(98,478)	(81,476)
Total NewLink Genetics stockholders' equity	<u>23,223</u>	<u>36,773</u>
Total equity	<u>23,223</u>	<u>36,773</u>
Commitments	—	—
Total liabilities and equity	<u>\$ 35,008</u>	<u>\$ 48,379</u>