

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 6, 2014 (November 6, 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 2 - Financial Information**

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

On November 6, 2014, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release reporting financial results for the third quarter ended September 30, 2014 (the "Press Release"). A copy of the Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item. In the financial statements portion of the Press Release, the Company has included a reconciliation of GAAP general and administrative expense to adjusted general and administrative expense for the three months ended September 30, 2014 and 2013 and the twelve months ended September 30, 2014 and 2013.

The Press Release, 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.

#### **Discussion of Adjusted Financial Measure**

In addition to our GAAP results, we provide adjusted general and administrative expense consisting of total general and administrative expense excluding the expense associated with our chief financial officer transition.

The Company believes that the presentation of adjusted general and administrative expense provides important supplemental information to management and investors relating to the Company's results of operations. Management uses this non-GAAP financial measure when evaluating operating performance because we believe that the inclusion of the expense surrounding the chief financial officer transition was an extraordinary occurrence that varies significantly from projected expense and providing this supplemental information facilitates comparability of our results of operations from period to period. We have chosen to provide this information to investors so they can analyze our results of operations in the same way as management and use this information in their assessment and valuation of the Company.

**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 November 6, 2014, entitled "NewLink Genetics Corporation Reports Third Quarter 2014 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: November 6, 2014

### **NewLink Genetics Corporation**

By: /s/ John B. Henneman III  
John B. Henneman III  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated November 6, 2014, entitled “NewLink Genetics Corporation Reports Third Quarter 2014 Financial Results”



Contact:  
Jack Henneman  
Chief Financial Officer  
515-598-2561  
[Investor@linkp.com](mailto:Investor@linkp.com)

FOR IMMEDIATE RELEASE

### **NewLink Genetics Corporation Reports Third Quarter 2014 Financial Results**

AMES, IA -- 11/06/14 -- NewLink Genetics Corporation (NASDAQ: NLNK), today reported consolidated financial results for the third quarter of 2014 and progress in its clinical and business development programs.

“As we announced in August, we continue to develop the science around combining our IDO pathway product candidates with treatment modalities including other checkpoint inhibitors, chemotherapy, and our own HyperAcute immunotherapies,” said Dr. Charles Link, Chairman and Chief Executive Officer. “The license and collaboration agreement with Genentech, which we announced a few weeks ago, is the most important recent step in realizing that vision, in addition to providing us with substantial new capital to develop further our HyperAcute vaccine technology.”

NewLink reported a net loss of \$5.6 million or \$.20 per share for the third quarter of 2014 compared to a net loss of \$8.1 million or \$.32 per share for the comparable period in 2013.

Research and development expense in the third quarter of 2014 was \$10.9 million compared to \$6.1 million during the comparable period in 2013. The increase was primarily due to increases in compensation including share based compensation, as well as increases in contract research and manufacturing, clinical trial expense, and other expenses.

“We continue to look forward to seeing the second interim look on the IMPRESS trial in the first quarter of 2015,” said Dr. Nicholas Vahanian, President and Chief Medical Officer of NewLink.

General and administrative expense in the third quarter of 2014 was \$4.9 million compared to \$2.3 million during the comparable period in 2013. The increase was primarily due to an increase in share-based compensation expense, as well as increases in consulting and legal fees, travel expense, and medical affairs and marketing. Excluding costs associated with the transition in the chief financial officer function, general and administrative expense for the quarter would have been \$2.8 million, as set forth in the attached reconciliation.

NewLink ended the quarter on September 30, 2014, with cash, cash equivalents, and certificates of deposit totaling \$67.7 million and, if the Hart-Scott-Rodino waiting period with respect to the Genentech collaboration expires as anticipated, expects to end the year with approximately \$180 million in cash, cash equivalents and certificates of deposit.

NewLink has an additional \$13.9 million of shares available for sale under its at-the-market offering (ATM) and has sold no shares under the ATM since March 31, 2014. NewLink ended the third quarter of 2014 with 27,929,874 shares outstanding.

**Conference call**

The company has scheduled a conference call for 8:30 AM ET today to discuss the results and to give an update on clinical and business development activities.

NewLink's senior management team will host the conference call, which will be open to all listeners. There will also be a question and answer session following the prepared remarks.

Access to the live call is available by dialing (855) 469-0612 (domestic) or (484) 756-4268 (international) five minutes prior to the start of the call. The call can also be accessed through a webcast via a link provided on the Investors and Media homepage of NewLink's website at [www.linkp.com](http://www.linkp.com). A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and using the passcode 25598868. The replay will be available for two weeks from the date of the call and the webcast will also be archived on the website.

**About NewLink Genetics Corporation**

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic 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: NewLink's financial guidance for 2014; enrollment in its clinical trials for product candidates based on NewLink's HyperAcute® and IDO platform technologies; its 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, cash position and 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 year ended December 31, 2013, 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.*

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

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2014	2013	2014	2013
Grant revenue	\$ 2,801	\$ 265	\$ 3,347	\$ 799
Operating expenses:				
Research and development	10,896	6,125	23,760	17,505
General and administrative	4,931	2,257	11,044	6,522
Loss from operations	(13,026)	(8,117)	(31,457)	(23,228)
Other income (expense), net	15	(6)	47	94
Income tax benefit	7,413	—	7,413	—
Net loss	\$ (5,598)	\$ (8,123)	\$ (23,997)	\$ (23,134)
Net loss per common share, basic and diluted	\$ (0.20)	\$ (0.32)	\$ (0.86)	\$ (0.92)
Weighted average number of common shares outstanding	27,914,782	25,702,043	27,800,246	25,067,772

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

	Sept. 30, 2014	December 31, 2013
<b>Assets</b>		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 67,706	\$ 61,540
Prepaid expenses and other current assets	3,552	2,430
Income tax receivable	7,502	—
Total current assets	78,760	63,970
Property and equipment, net	7,117	6,587
Total assets	\$ 85,877	\$ 70,557
<b>Liabilities and Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,961	\$ 3,473
Other current liabilities	277	403
Total current liabilities	7,238	3,876
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	989	1,033
Deferred rent	1,259	1,321
Total long-term liabilities	8,248	8,354
Total liabilities	15,486	12,230
Stockholder's equity:		
Common stock	279	266
Additional paid-in capital, net	230,308	194,038
Treasury stock, at cost	(222)	—
Retained deficit	(159,974)	(135,977)
Total equity	70,391	58,327
Total liabilities and equity	\$ 85,877	\$ 70,557

## NewLink Genetics Corporation

**Reconciliation of Non-GAAP Adjustments - GAAP General and Administrative Expense to Measures of Adjusted General and Administrative Expense**  
(unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2014	2013	2014	2013
GAAP general and administrative expense	\$ 4,931	\$ 2,257	\$ 11,044	\$ 6,522
Non-GAAP adjustments:				
Cost associated with chief financial officer transition	2,158	—	2,158	—
Total of non-GAAP adjustments	2,158	—	2,158	—
Adjusted general and administrative expense	\$ 2,773	\$ 2,257	\$ 8,886	\$ 6,522