

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): March 11, 2014 (March 11, 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 March 11, 2014, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release reporting financial results for the fourth quarter and full year ended December 31, 2013.

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 March 11, 2014, entitled "NewLink Genetics Reports Fourth Quarter and Full-Year 2013 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: March 11, 2014

### **NewLink Genetics Corporation**

By: /s/ Gordon H. Link, Jr.  
Gordon H. Link, Jr.  
Its: Chief Financial Officer

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release, dated March 11, 2014, entitled "NewLink Genetics Reports Fourth Quarter and Full-Year 2013 Financial Results."



## NewLink Genetics Corporation Reports Fourth Quarter and Year End 2013 Financial Results

*Conference Call Scheduled for Tuesday, March 11, 2014 at 4:30 EST*

Ames, IA - March 11, 2014- NewLink Genetics Corporation (NASDAQ: NLNK), today reported consolidated financial results for the fourth quarter and year end 2013 and reviewed key 2013 accomplishments.

“We achieved a major milestone in 2013 with the completion of patient enrollment in the algenpantucel-L pivotal Phase 3 IMPRESS study, which we believe to be the largest corporate-sponsored, post-resection pancreatic cancer trial ever conducted. Algenpantucel-L is our most advanced HyperAcute product candidate for pancreatic cancer, and, assuming positive data, we plan to file a BLA for this product in 2015,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink.

“During 2014, we will continue our strategy of advancing product development efforts across both our HyperAcute and IDO pathway inhibitor platforms,” commented Dr. Nick Vahanian, President and Chief Medical Officer of NewLink. “We now have six HyperAcute vaccines in various stages of clinical development for multiple indications (pancreas, lung, melanoma, breast, prostate, and renal). We also are expanding the breadth and depth of our IDO pathway inhibitor program by aggressively pursuing clinical development of our lead product candidate, Indoximod, as well as initiating first in human clinical studies of NLG-919, our second compound from this platform. In addition, we hope to evaluate our IDO pathway inhibitors combined with other checkpoint inhibitors and to assess potential synergy between our HyperAcute Vaccines and our IDO Pathway Inhibitors in combination studies.”

NewLink reported a net loss of \$8.0 million or (\$.31) per share for the fourth quarter of 2013 and \$31.2 million or (\$1.23) per share for the year ended December 31, 2013 compared to a net loss of \$6.3 million or (\$.30) per share and \$23.3 million or (\$1.12) per share for the comparable periods in 2012.

Research and development expense in the fourth quarter of 2013 was \$5.2 million and \$22.7 million for the year ended December 31, 2013 compared to \$4.5 million and \$17.8 million during the comparable periods in 2012. The increase was primarily due to increases in outside clinical and other expenses including contract development costs for NLG-919, contract manufacturing costs for indoximod, accompanied by an increase in personnel-related expenses due to increased staffing levels and compensation increases to support our expanding clinical trials.

General and administrative expense in the fourth quarter of 2013 was \$3.0 million and \$9.5 million for the year ended December 31, 2013 compared to \$2.1 million and \$7.1 million during the comparable periods in 2012. The increase was primarily due to an increase in other costs including legal and consulting fees, travel, dues, subscriptions and licensing fees, accompanied by an increase in personnel-related expenses due to increased staffing levels and compensation increases.

NewLink ended the year on December 31, 2013 with cash, cash equivalents and certificates of deposit totaling \$61.5 million and expects to end the year ending December 31, 2014 with approximately \$40 million in cash, cash equivalents and other securities. NewLink received gross proceeds from sales under its at-the-market offering (ATM) of approximately \$17.8 million in 2013 and has received an additional \$28.3 million in gross

proceeds from sales under the ATM through March 10, 2014. NewLink ended 2013 with 26,573,023 shares of common stock outstanding.

### **Recent Accomplishments**

- *Algenpantucel-L*. Completed the first interim analysis in the Phase 3 IMPRESS clinical study of algenpantucel-L for patients with surgically resected pancreatic cancer. As part of the planned interim analysis, scheduled to occur following 222 patient events, the independent data safety monitoring committee (DSMC) met to review available patient data. Following their review, the DSMC recommended that the study should proceed as planned, without modification. A second interim analysis is planned upon reaching 333 patient events and, if needed, a final analysis is planned at 444 patient events.
- *HyperAcute Renal*. Launched a first in human Phase 1 clinical trial of HyperAcute Renal immunotherapy in patients with metastatic renal cell cancer. HyperAcute Renal, NewLink's most recent HyperAcute immunotherapy product candidate, is a novel biologic designed to stimulate the patient's immune system to recognize and attack cancer cells. This platform includes algenpantucel-L, NewLink's most advanced HyperAcute immunotherapy, which is currently in Phase 3 clinical development for the treatment of pancreatic cancer, tergenpumatumucel-L for the treatment of non-small cell lung cancer, dorgenmeltucel-L for the treatment of melanoma and HyperAcute Prostate for the treatment of prostate cancer.
- *NLG919*. Initiated a first in human Phase 1 clinical trial of NLG919 in patients with recurrent advanced solid tumors. NLG919, NewLink's second IDO (*indoleamine-(2,3)-dioxygenase*) pathway inhibitor, is a small-molecule, orally bioavailable, checkpoint inhibitor designed to counteract a fundamental mechanism by which tumors evade immune-mediated destruction. NLG919 represents a novel class of compounds from NewLink's IDO pathway platform. This platform includes indoximod, NewLink's most advanced IDO pathway inhibitor, which is currently in Phase 2 clinical development for the treatment of breast cancer.

### **Key 2014 Milestones**

- *HyperAcute Platform*. We will continue to enroll patients in ongoing studies with algenpantucel-L in our Phase 3 study in locally advanced pancreatic cancer, with tergenpumatumucel-L in our Phase 2b/3 study in advanced NSCLC and our Phase 1 study in metastatic renal cancer with our new HyperAcute renal product candidate. We also plan to advance dorgenmeltucel-L, our HyperAcute melanoma product candidate into a Phase 1b/2 combination immunotherapy trial for advanced melanoma and to initiate a Phase 1b/2 study evaluating a combination of one of our HyperAcute product candidates with one of our IDO pathway inhibitor candidates.
- *IDO Pathway Inhibitor Platform*. We will continue to enroll patients in our ongoing Phase 2 studies combining indoximod with docetaxel in advanced breast cancer and with sipuleucel-T in metastatic castration resistant prostate cancer and in our Phase 1b/2 study combining indoximod with temozolomide in advanced brain tumors. Beyond this, we plan to initiate a Phase 1b/2 study in advanced melanoma combining indoximod and ipilimumab as well as a Phase 1b/2 study in metastatic pancreatic cancer combining indoximod with gemcitabine and nab-paclitaxel. We expect to evaluate the synergy between our two IDO pathway inhibitors and upon completion of Phase 1 to advance NLG 919 into a variety of combination studies.

### **Today's Conference Call and Webcast Reminder**

The NewLink management team will host a conference call discussing the company's financial results and recent corporate developments on (Tuesday, March 11, 2014, at 4:30 pm EST). The call can be accessed by dialing 1-

(855) 469-0612 (domestic) or 1-(484) 756-4268 (international) five minutes prior to the start of the call. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-(855) 859-2056 or 1-(404) 537-3406 (international), providing the passcode 11958508. The replay will be available for two weeks from the date of the live call.

### **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. By leveraging its dual cancer immunotherapy platforms, NewLink has established itself as a leader in cancer immunotherapy. 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 Quarterly Report on Form 10-Q for the period ended September 30, 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.*

Contact:

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NewLink Genetics Corporation  
Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Quarter Ended		Year Ended	
	December 31, 2013	December 31, 2012	December 31, 2013	December 31, 2012
Grant revenue	\$ 294	\$ 299	\$ 1,093	\$ 1,687
Operating expenses:				
Research and development	5,208	4,489	22,713	17,838
General and administrative	2,999	2,103	9,521	7,108
Loss from operations	(7,913)	(6,293)	(31,141)	(23,259)
Other income (expense), net	(3)	(26)	91	(62)
Net loss before taxes	(7,916)	(6,319)	(31,050)	(23,321)
Income tax expense	(130)	—	(130)	—
Net loss	\$ (8,046)	\$ (6,319)	\$ (31,180)	\$ (23,321)
Net loss per common share, basic and diluted	\$ (0.31)	\$ (0.30)	\$ (1.23)	\$ (1.12)
Weighted average number of common shares outstanding	25,890,638	20,929,184	25,275,179	20,779,450

NewLink Genetics Corporation  
Condensed Consolidated Balance Sheets (unaudited)

(In thousands, except share and per share data)

	Year Ended	
	December 31, 2013	December 31, 2012
Assets:		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 61,540	\$ 21,744
Prepaid expenses, other receivables and other current assets	2,430	1,645
Total current assets	<u>63,970</u>	<u>23,389</u>
Property and equipment, net	<u>6,587</u>	<u>6,040</u>
Total assets	<u>\$ 70,557</u>	<u>\$ 29,429</u>
	December 31, 2013	December 31, 2012
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,473	\$ 2,631
Deferred rent	84	84
Income tax payable and other current liabilities	319	204
Total current liabilities	<u>3,876</u>	<u>2,919</u>
Long term liabilities:		
Notes payable	6,987	7,140
Obligations under capital leases	46	38
Deferred rent, excluding current portion	1,321	1,405
Total long term liabilities	<u>8,354</u>	<u>8,583</u>
Total liabilities	<u>12,230</u>	<u>11,502</u>
Stockholders' Equity:		
Common stock	266	210
Additional paid-in capital, net	194,038	122,514
Deficit accumulated during the development stage	(135,977)	(104,797)
Total stockholders' equity	<u>58,327</u>	<u>17,927</u>
Commitments		
Total liabilities and stockholders' equity	<u>\$ 70,557</u>	<u>\$ 29,429</u>