# 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): August 5, 2014 (August 5, 2014)

#### **NewLink Genetics Corporation**

(Exact name of registrant as specified in its charter)

Delaware001-3534242-1491350(State or other jurisdiction<br/>of incorporation)(Commission<br/>File Number)(IRS Employer<br/>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 2 - Financial Information**

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

On August 5, 2014, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release reporting financial results for the second quarter ended June 30, 2014.

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.

Exhibit Number	Description						
	Press Release, dated August 5, 2014, entitled "NewLink Genetics Corporation Reports Second Quarter 2014 Financial						
99.1	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: August 5, 2014

# **NewLink Genetics Corporation**

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

# INDEX TO EXHIBITS

Exhibit Number	Description						
	Press Release, dated August 5, 2014, entitled "NewLink Genetics Corporation Reports Second Quarter 2014 Financial						
99.1	Results"						



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

FOR IMMEDIATE RELEASE

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

AMES, IA -- 08/05/14 -- NewLink Genetics Corporation (NASDAQ: NLNK), today reported consolidated financial results for the second quarter of 2014 and progress in its development programs.

"We continue to expand our clinical development efforts with additional promising HyperAcute and IDO pathway inhibitor product candidates from our pipeline. This includes additional studies combining our IDO pathway product candidates with treatment modalities including other checkpoint inhibitors, chemotherapy, and our own HyperAcute immunotherapies. Furthermore, we are in the early stages of building our commercial footprint in our new facility in Austin, Texas as we approach the events required to trigger the second interim analysis of our IMPRESS study. Importantly, we are accomplishing this without a significant increase in our rate of spending," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink.

"The diversity of our clinical development program was highlighted at the recent 50<sup>th</sup> annual ASCO meeting by a series of nine presentations demonstrating progress with our IDO pathway inhibitors, indoximod and NLG919, as well as our HyperAcute product candidates," commented Dr. Nicholas Vahanian, President and Chief Medical Officer of NewLink.

"We were particularly pleased to present additional demographic data for all 722 patients from our IMPRESS study demonstrating a high level of comparability to historical data from other large U.S.-based phase 3 resected pancreatic cancer studies. We also presented data that nearly half (31/64) of the patients in our phase 2 trial of algenpantucel-L had increased expression of anti-calreticulin antibody that correlated with an increase in overall survival. This was particularly important because the increase in overall survival was statistically significant even though the study only evaluated anti-calreticulin expression in a limited number of patients."

NewLink reported a net loss of \$9.2 million or \$.33 per share for the second quarter of 2014 compared to a net loss of \$7.1 million or \$.28 per share for the comparable period in 2013.

Research and development expense in the second quarter of 2014 was \$6.5 million compared to \$5.0 million during the comparable period in 2013. The increase was primarily due to an increase in personnel-related expenses, offset by a decrease in contract research, manufacturing and consulting fees.

General and administrative expense in the second quarter of 2014 was \$2.9 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.

NewLink ended the quarter on June 30, 2014, with cash, cash equivalents, and certificates of deposit totaling \$77.1 million and expects to end the year with at least \$40 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 February. NewLink ended the second quarter of 2014 with 27,903,705 shares outstanding.

#### **Recent Accomplishments**

- Entered into a Development and Manufacturing Agreement with a contractor to, among other things, increase the potential commercial manufacturing capacity of HyperAcute® product candidates.
- <u>HyperAcute Platform.</u> Presented data at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting in the following poster presentations or discussions:

Correlation of anti-calreticulin antibody titers with improved overall survival in a phase 2 clinical trial of algenpantucel-L immunotherapy for patients with resected pancreatic cancer.

A phase 2b study of ipilimumab with or without dorgenmeltucel-L (HyperAcute-Melanoma) immunotherapy for patients with stage IV melanoma.

An open-label, randomized phase 2b active control study of second-line tergenpumatucel-L immunotherapy versus docetaxel in patients with progressive or relapsed non-small cell lung cancer (NSCLC).

• <u>IDO Inhibitors.</u> Presented data at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting in the following poster presentations or discussions:

Phase 1/2 trial of the indoleamine 2,3-dioxygenase pathway (IDO) inhibitor indoximod plus ipilimumab for the treatment of unresectable stage 3 or 4 melanoma.

A phase 1/2 study of the combination of indoximod and temozolomide for adult patients with temozolomide-refractory primary malignant brain tumors.

First in human phase 1 study of the novel indoleamine-2,3-dioxygenase (IDO) inhibitor NLG919.

A phase 2 study of docetaxel in combination with indoximod in metastatic breast cancer.

A phase 2 study of Ad.p53 DC vaccine in combination with indoximod in metastatic solid tumors.

A randomized, double-blind phase 2 study of sipuleucel-T followed by indoximod or placebo in the treatment of patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer.

• <u>TDO Inhibitors.</u> Continued preclinical testing directed at selection of a clinical candidate from a novel class of compounds that mediate TDO (*tryptophan-2,3-dioxygenase*).

#### **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 <a href="http://www.linkp.com">http://www.linkp.com</a>.

By leveraging its dual cancer immunotherapy platforms, which are designed to harness multiple components of the immune system to combat cancer, NewLink is well positioned to establish a leadership position in immuno-oncology. NewLink's HyperAcute immunotherapy platform uniquely stimulates the patient's immune system to recognize and attack cancer cells, while its IDO pathway inhibitor platform technology targets a key immune checkpoint and disrupts mechanisms by which tumors evade the patient's immune system. NewLink's broad product pipeline includes biologic and small molecule immunotherapy product candidates designed to treat a wide range of oncology indications either as monotherapy or in combination with other treatment regimens. NewLink's most advanced product candidates include algenpantucel-L and tergenpumatucel-L HyperAcute immunotherapies, currently in Phase 3 clinical development for pancreatic cancer and Phase 2b/3 for non-small cell lung cancer, respectively. The IDO pathway inhibitor platform has two drug candidates currently in development. The first, indoximod, is currently in Phase 2 development for a range of solid tumor cancers. NewLink's second IDO pathway inhibitor, NLG919, is currently in Phase 1 development for advanced solid tumors. By targeting multiple immune system deficits, NewLink's product pipeline offers a broad approach to immuno-oncology.

#### 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 quidance 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 June 30,			Six Months Ended June 30,				
	2014		2013		2014		2013	
Grant revenue	\$	212	\$	232	\$	546	\$	534
Operating expenses:								
Research and development		6,475		5,037		12,863		11,380
General and administrative		2,863		2,264		6,114		4,265
Loss from operations		(9,126)		(7,069)		(18,431)		(15,111)
Other (expense) income, net		(38)		(8)		32		100
Net loss	\$	(9,164)	\$	(7,077)	\$	(18,399)	\$	(15,011)
Net loss per common share, basic and diluted	\$	(0.33)	\$	(0.28)	\$	(0.66)	\$	(0.61)
Weighted average number of common shares outstanding		27,876,652		25,620,566		27,742,029		24,745,380

# NewLink Genetics Corporation Condensed Consolidated Balance Sheets (unaudited)

(In thousands, except share and per share data)

	June 30, 2014	December 31, 2013		
Assets				
Current assets:				
Cash, cash equivalents and certificates of deposit	\$ 77,110	\$	61,540	
Prepaid expenses and other current assets	 1,104		2,430	
Total current assets	78,214		63,970	
Property and equipment, net	 6,456		6,587	
Total assets	\$ 84,670	\$	70,557	
Liabilities and Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$ 3,578	\$	3,473	
Other current liabilities	279		403	
Total current liabilities	 3,857		3,876	
Long-term liabilities:	 			
Royalty obligation payable	6,000		6,000	
Notes payable and obligations under capital leases	937		1,033	
Deferred rent	 1,279		1,321	
Total long-term liabilities	8,216		8,354	
Total liabilities	 12,073		12,230	
Stockholder's equity:				
Common stock	279		266	
Additional paid-in capital, net	226,876		194,038	
Treasury Stock, at cost	(182)		_	
Retained Deficit	(154,376)		(135,977)	
Total equity	72,597		58,327	
Total liabilities and equity	\$ 84,670	\$	70,557	