

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): July 31, 2015

**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 July 31, 2015, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting financial results for the second quarter ended June 30, 2015 ("Press Release").

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 July 31, 2015, entitled "NewLink Genetics Corporation Provides Operational Update and Reports Second Quarter 2015 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: July 31, 2015

**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 July 31, 2015, entitled “NewLink Genetics Corporation Provides Operational Update and Reports Second Quarter 2015 Financial Results”



FOR IMMEDIATE RELEASE

## **NewLink Genetics Corporation Provides Operational Update and Reports Second Quarter 2015 Financial Results**

-Management to Host Conference Call Today at 8:30 a.m. ET-

AMES, Iowa - July 31, 2015 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company at the forefront of developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer, today reported consolidated financial results for the second quarter of 2015 and progress in its clinical and business development programs.

“NewLink Genetics continues to drive forward, and to execute on, its strategy of developing treatment options for patients with cancer using targeted immune response and disruptive checkpoint blockade,” said Dr. Charles Link, Chairman and Chief Executive Officer. “We have seven product candidates across multiple cancer types in clinical development from Phase 1 to Phase 3. Our combined platform of product candidates positions us well to execute on our vision of combining cancer vaccines and checkpoint blockade inhibitors through our HyperAcute® Immunotherapy and indoleamine 2,3-dioxygenase (IDO) pathway inhibitor platforms.”

“During the second quarter, we continued our planned hiring and pre-commercial activities relating to our HyperAcute Immunotherapy algenpantucel-L, which is being studied for adjuvant treatment of patients with surgically resected pancreatic cancer,” said Dr. Nicholas Vahanian, President and Chief Medical Officer.

The Company continued to build its presence with key opinion leaders by having a booth and poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. The poster (#2070) highlighted encouraging results of the Phase 1b portion of a study showing that the combination of indoximod and temozolomide in temozolomide-refractory patients with progressive or refractory glioblastoma was well tolerated, with preliminary evidence of efficacy. Enrollment of the Phase 2 portion of the study is underway.

In addition, the Company hosted its first-ever analyst day on July 14, outlining its vision and execution plans surrounding its clinical programs. A webcast of the Company’s presentations can be found at <http://media.rampard.com/20150714/reg.jsp>.

### **Program Updates:**

#### **HyperAcute® Immunotherapy Cancer Programs**

NewLink Genetics’ proprietary HyperAcute Immunotherapy programs may prove to have broad potential for patients across a spectrum of cancer indications, including use in combination with checkpoint inhibitors.

NewLink Genetics has multiple HyperAcute Immunotherapy programs in various stages of clinical development, including for pancreatic cancer, lung cancer, melanoma, renal cell cancer and prostate cancer.

- Algenpantucel-L is NewLink Genetics' HyperAcute Immunotherapy pancreatic cancer candidate in a Phase 3 clinical trial called IMPRESS, or **IM**munotherapy for **P**ancreatic **RES**ectable Cancer Study. During the second quarter, following the second interim analysis of the study, the Company announced the recommendation of the data safety monitoring committee to proceed without modification to final analysis. The Company has announced that at the time of the second interim analysis, the estimated blended median overall survival in the trial from the time of randomization was 28.5 months for all patients. Median time from surgery to randomization was approximately 1.5 months. Therefore median survival from surgery was estimated to be approximately 30 months for all patients in our study. We believe that the median months of overall survival from randomization in the control arm is in the low twenties. The study is powered to show an improvement in overall survival after 442 events.
- PILLAR, or **P**ancreatic **IM**munotherapy with Algenpantucel-L for **L**ocally **A**dvanced **N**on-**R**esectable Disease, is our Phase 3 clinical trial studying the efficacy of algenpantucel-L in patients with borderline resectable or locally advanced pancreatic cancer. We expect to complete enrollment in this study during 2015.
- NewLink Genetics' HyperAcute Immunotherapy product candidate tergenpumatumucel-L is being tested versus docetaxel in a randomized Phase 2b study in patients with advanced lung cancer. We are currently enrolling patients in this study.
- HyperAcute Immunotherapy product candidate dorgenmeltucel-L for patients with melanoma is being evaluated in a randomized Phase 2 study in combination with the checkpoint inhibitors ipilimumab, nivolumab, and pembrolizumab versus these checkpoint inhibitors alone.

### **IDO Pathway Inhibitor Programs**

NewLink Genetics' proprietary IDO pathway inhibitor, indoximod, is in multiple Phase 1 and Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic and brain cancers as well as melanoma. We expect to complete enrollment of the following studies with indoximod within the next 12-15 months.

- NLG2101, a global randomized Phase 2 trial testing indoximod in combination with docetaxel or paclitaxel in patients with metastatic breast cancer, is expected to fully enroll by the end of 2015. NewLink Genetics intends to present preliminary data from this study at an upcoming medical meeting in 2015.
- NLG2102 is a Phase 2 trial of the combination of indoximod and temozolomide in refractory or relapsed glioblastoma multiforme patients.
- NLG2103 is a Phase 2 trial testing indoximod in combination with the checkpoint inhibitors ipilimumab, nivolumab or pembrolizumab in patients with advanced melanoma. We expect to report top-line Phase 1b results at the Immunotherapy in Cancer Poster Session of the ESMO/ECC meeting in Vienna on Saturday, September 26 (#248, abstract 514).
- NLG2104 is in a Phase 1b/2 trial testing indoximod in combination with gemcitabine plus nab-paclitaxel in patients with metastatic pancreatic cancer. Top-line Phase 1b results are expected in 2016.

NewLink Genetics has also entered into an exclusive worldwide license and collaboration agreement with Genentech, a member of the Roche Group, for the development of the IDO inhibitor GDC-0919.

Based on pre-clinical data presented at ASCO by our partner, GDC-0919 demonstrated decreases in plasma kynurenine levels and regulatory T-cells as well as an anti-tumor efficacy when combined with anti-PD-L1 and anti-CTLA4. This product candidate is currently in Phase 1 clinical development in patients with advanced solid tumors, and Phase 1 data on GDC-0919 is expected to be presented in a poster presentation at the ESMO/ECC meeting in Vienna on Sunday, September 27 (#157, abstract 346). In addition, a Phase 1 clinical trial, with a planned enrollment target of 224 patients, will study GDC-0919 in combination with Genentech's PD-L1 inhibitor MPDL3280A for patients with locally advanced or metastatic solid tumors. An additional study is planned for GDC-0919 in combination with an OX40 inhibitor.

### **Financial Results for the Three-Month Period Ended June 30, 2015**

**Cash Position:** NewLink Genetics ended the quarter on June 30, 2015, with cash and equivalents totaling \$207.6 million, compared to \$202.8 million for the year ending December 31, 2014.

**R&D Expenses:** Research and development expenses in the second quarter of 2015 were \$16.1 million, compared to \$6.5 million during the comparable period in 2014. The increase is primarily due to clinical trial expenses related to NewLink Genetics' broad pipeline of product candidates, as well as expenses for manufacturing and research related to the Ebola vaccine candidate. Most of the Ebola-related expenses are subject to reimbursement under government contracts.

**Net Income/Loss:** NewLink Genetics reported a net loss of \$14.1 million, or (\$0.49) per diluted share, for the second quarter of 2015, compared to a net loss of \$9.2 million, or (\$0.33) per diluted share, for the comparable period in 2014.

NewLink Genetics ended the quarter with 28,661,588 shares outstanding.

### **Financial Guidance**

NewLink Genetics expects to have more than \$160 million in cash and equivalents on December 31, 2015.

"Our research and development expenses and capital expenditures continue to reflect our commitment to developing a broad pipeline of drug candidates and to ensure that we have the infrastructure in place to support the commercialization and manufacturing of algenpantucel-L," said Jack Henneman, Executive Vice President and Chief Financial Officer. "We will continue to make significant investments for the remainder of 2015 to support these efforts."

### **Conference Call**

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss these results and to provide an update on clinical and business development activities. NewLink Genetics' 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 (U.S.) or (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 (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 94565879. The replay will be available for two weeks from the date of the call.

### **[About NewLink Genetics Corporation](#)**

NewLink Genetics is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. NewLink Genetics'



portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink Genetics' 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.

### **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 Genetics' financial guidance for 2015; enrollment in or results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink Genetics' 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 Genetics' Annual Report on Form 10-K for the year ended December 31, 2014 and other reports filed with the U.S. Securities and Exchange Commission (SEC). 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 Genetics' views as of any date subsequent to the date of this press release.*

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#### Corporate Contact:

Jack Henneman

Chief Financial Officer, NewLink Genetics

515-598-2561

[Investor@linkp.com](mailto:Investor@linkp.com)

#### Investors:

Donna LaVoie

LaVoieHealthScience

617-374-8800, ext. 107

[dlavoie@lavoiehealthscience.com](mailto:dlavoie@lavoiehealthscience.com)

#### Media:

David Connolly

LaVoieHealthScience

617-374-8800, ext. 108

[dconnolly@lavoiehealthscience.com](mailto:dconnolly@lavoiehealthscience.com)

**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,	
	2015	2014	2015	2014
Grant revenue	\$ 3,280	\$ 212	\$ 12,929	\$ 546
Licensing and collaboration revenue	4,165	—	33,711	—
Total revenue	7,445	212	46,640	546
Operating expenses:				
Research and development	16,130	6,475	34,111	12,863
General and administrative	7,257	2,863	15,623	6,114
Loss from operations	(15,942)	(9,126)	(3,094)	(18,431)
Other income (expense), net	22	(38)	33	32
Loss before income taxes	(15,920)	(9,164)	(3,061)	(18,399)
Income tax benefit	1,829	—	160	—
Net loss	\$ (14,091)	\$ (9,164)	\$ (2,901)	\$ (18,399)
Basic and diluted loss per share	\$ (0.49)	\$ (0.33)	\$ (0.10)	\$ (0.66)
Basic and diluted average shares outstanding	28,661,588	27,876,652	28,408,474	27,742,029

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

	Year Ended	
	June 30, 2015	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 207,579	\$ 202,797
Prepaid expenses, advance payments to vendors and other current assets	24,354	12,062
Income tax receivable	2,519	15,604
Total current assets	234,452	230,463
Property and equipment, net	8,798	7,599
Total assets	\$ 243,250	\$ 238,062
<b>Liabilities and Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,428	\$ 11,779
Unearned revenue	936	12,966
Other current liabilities	672	276
Total current liabilities	9,036	25,021
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	450	941
Deferred rent	1,196	1,238
Unearned revenue, excluding current portion	809	1,085
Total long-term liabilities	8,455	9,264
Total liabilities	17,491	34,285
Stockholder's equity:		
Common stock	287	280
Additional paid-in capital, net	262,055	236,838
Treasury stock, at cost	(551)	(222)
Retained deficit	(36,032)	(33,119)
Total equity	225,759	203,777
Total liabilities and equity	\$ 243,250	\$ 238,062