**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 3, 2015

**NewLink Genetics Corporation**
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-35342** | **42-1491350** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **2503 South Loop Drive**<br>**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 November 3, 2015, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release providing an operational update and reporting financial results for the third quarter ended September 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.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated November 3, 2015, entitled “NewLink Genetics Corporation Provides Operational Update and Reports Third 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: November 3, 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 November 3, 2015, entitled “NewLink Genetics Corporation Provides Operational Update and Reports Third Quarter 2015 Financial Results” |

FOR IMMEDIATE RELEASE

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

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

AMES, Iowa - November 3, 2015 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company at the forefront of developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, to improve the lives of patients with cancer, today reported consolidated financial results for the third quarter of 2015 and progress in its proprietary and partnered clinical development programs.

“Our dynamic and experienced team has made significant progress in driving our broad clinical development programs,” said Charles Link, M.D., Chairman and Chief Executive Officer. “We look forward to reporting on our strong pipeline of clinical data over the coming year.”

Dr. Link added, “GDC-0919, the checkpoint inhibitor program partnered with Genentech continues to make great progress. Both companies are putting substantial resources behind this program, and we continue to be excited about the development plan and the progress of our collaboration.”

“As we anticipate the data readout for the IMPRESS trial in 2016, NewLink Genetics continues to advance its investment in manufacturing and pre-commercial activities relating to algenpantucel-L, our HyperAcute® Cellular Immunotherapy product candidate for patients with resected pancreatic cancer,” said Nicholas Vahanian, M.D., President and Chief Medical Officer. “We await the promise of our cellular immunotherapy agents to educate the immune system to destroy tumor cells in pancreatic and other cancers.”

**Financial Results for the Three-Month Period Ended September 30, 2015**
Cash Position: NewLink Genetics ended the quarter on September 30, 2015, with cash, cash equivalents, and certificates of deposit totaling $200.4 million, compared to $202.8 million for the year ending December 31, 2014.

R&D Expenses: Research and development expenses in the third quarter of 2015 were $22.5 million, compared to $10.9 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. The majority of the Ebola-related expenses are subject to reimbursement under government contracts.

G&A Expenses: General and administrative expenses in the third quarter of 2015 were $7.4 million, compared to $4.9 million during the comparable period in 2014. The increase was primarily due to an increase in share-based compensation expense, consulting and legal fees, and medical affairs and pre-commercial activities.

Net Loss: NewLink Genetics reported a net loss of $15.9 million, or ($0.55) per diluted share, for the third quarter of 2015, compared to a net loss of $5.6 million, or ($0.20) per diluted share, for the comparable period in 2014.

NewLink Genetics ended the quarter with 28,774,911 shares outstanding.

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

**Conference Call and Program Updates:**
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. Dial-in information for the conference call is set forth at the end of this press release. Programs to be discussed include:

**IDO Checkpoint Inhibitor Programs**
NewLink Genetics entered into an exclusive worldwide license and collaboration agreement with Genentech, a member of the Roche Group, for the development of the IDO checkpoint inhibitor GDC-0919 and an expanded pipeline of potential IDO/TDO inhibitor candidates in 2014. This product candidate is currently in Phase 1 clinical development for patients with advanced solid tumors.

- Key preclinical data is being presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in Bethesda, Maryland on November 6, 2015.
- Phase 1 data on GDC-0919 was presented at the ECC/ESMO meeting in Vienna. Key preliminary data showed that GDC-0919 had a favorable safety profile and preliminary evidence of disease stabilization and peripheral pharmacodynamic modulation. Details from the poster presentation are available in the press release found at http://investors.linkp.com/releasedetail.cfm?ReleaseID=933270
- The collaboration's clinical development team has advanced GDC-0919 into a combination study with atezolizumab that is actively enrolling patients. In addition, the collaboration is planning combination studies of GDC-0919 with OX-40 agonists.
- NewLink will be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech.

Indoximod, NewLink Genetics' proprietary IDO pathway inhibitor, is in multiple Phase 1 and Phase 2 clinical trials for patients with breast, prostate, pancreatic and brain cancers as well as melanoma. We will provide additional details about our trials on the conference call. Additionally, there will be multiple opportunities for the Company to provide further updates during 2015 and 2016 at academic meetings and associated programs.

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

Algenpantucel-L is NewLink Genetics' HyperAcute Cellular Immunotherapy product candidate for patients with pancreatic cancer. The product is currently being studied in a Phase 3 clinical trial called IMPRESS, or **IM**munotherapy for **P**ancreatic **RES**sectable Cancer **S**tudy, in patients with surgically resected pancreatic cancer. The study is powered to show an improvement in overall survival after 442 events, and we continue to expect that final results will be reported in 2016.

PILLAR, or **P**ancreatic **I**mmunotherapy with Algenpantucel-**L** for **L**ocally **A**dvanced Non-**R**esectable Disease, is our Phase 3 clinical trial studying the efficacy of algenpantucel-L for patients with borderline resectable or locally advanced unresectable pancreatic cancer. We expect to complete enrollment in this study in 2015.

**Tergenpumatucel-L**
Tergenpumatucel-L, NewLink Genetics' HyperAcute Cellular Immunotherapy product candidate for patients with non-small cell lung cancer (NSCLC), remains in Phase 2. We are eager to learn more about this product in our recently begun trial evaluating tergenpumatucel-L in combination with indoximod and chemotherapy for patients with advanced NSCLC.

**Dorgenmeltucel-L**
Dorgenmeltucel-L, NewLink Genetics' HyperAcute Cellular Immunotherapy product candidate for patients with melanoma, continues in a trial evaluating efficacy in combination with the checkpoint inhibitors ipilimumab, nivolumab, and pembrolizumab for patients with advanced melanoma.

**Ebola Vaccine**
During the third quarter, we announced that NewLink Genetics was awarded an $8.1 million base contract with future options totaling $5.2 million by the Defense Threat Reduction Agency of the United States Department of Defense to support various development activities of the investigational rVSV-ZEBOV (Ebola) vaccine candidate. Additionally, the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services exercised an $18 million option on NewLink Genetics' existing contract.

NewLink has exclusively licensed research, development, manufacturing and commercialization of the rVSV-ZEBOV (Ebola) vaccine to Merck. This vaccine candidate was originally developed by the Public Health Agency of Canada (PHAC).

**Conference call details**
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 66888213. 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 immuno-oncology 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. For more information, please visit http://www.newlinkgenetics.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 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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**NewLink Genetics Corporation**
**Condensed Consolidated Statements of Operations**
**(unaudited)**
**(In thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Grant revenue | $ 13,365 | $ 2,801 | $ 26,294 | $ 3,347 |
| Licensing and collaboration revenue | 844 | — | 34,555 | — |
| Total revenue | 14,209 | 2,801 | 60,849 | 3,347 |
| Operating expenses: | | | | |
| Research and development | 22,508 | 10,896 | 56,619 | 23,760 |
| General and administrative | 7,384 | 4,931 | 23,007 | 11,044 |
| Loss from operations | (15,683) | (13,026) | (18,777) | (31,457) |
| Other income (expense), net | (63) | 15 | (30) | 47 |
| Loss before income taxes | (15,746) | (13,011) | (18,807) | (31,410) |
| Income tax (expense) benefit | (160) | 7,413 | — | 7,413 |
| Net loss | $ (15,906) | $ (5,598) | $ (18,807) | $ (23,997) |
| Basic and diluted loss per share | $ (0.55) | $ (0.20) | $ (0.66) | $ (0.86) |
| Basic and diluted average shares outstanding | 28,734,768 | 27,914,782 | 28,518,503 | 27,800,246 |

**NewLink Genetics Corporation**
**Condensed Consolidated Balance Sheets**
**(unaudited)**
**(In thousands)**

| | Year Ended | |
|---|---|---|
| | **September 30, 2015** | **December 31, 2014** |
| Assets | | |
| Current assets: | | |
| Cash, cash equivalents and certificates of deposit | $ 200,357 | $ 202,797 |
| Prepaid expenses, advance payments to vendors and other current assets | 16,758 | 12,062 |
| Income tax receivable | 76 | 8,775 |
| Total current assets | 217,191 | 223,634 |
| Property and equipment, net | 9,628 | 7,599 |
| Total assets | $ 226,819 | $ 231,233 |
| | | |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 9,649 | $ 11,779 |
| Unearned revenue | 901 | 12,966 |
| Other current liabilities | 665 | 276 |
| Total current liabilities | 11,215 | 25,021 |
| Long-term liabilities: | | |
| Royalty obligation payable | 6,000 | 6,000 |
| Notes payable and obligations under capital leases | 409 | 941 |
| Deferred rent | 1,175 | 1,238 |
| Unearned revenue, excluding current portion | 608 | 1,085 |
| Total long-term liabilities | 8,192 | 9,264 |
| Total liabilities | 19,407 | 34,285 |
| Stockholders' equity: | | |
| Common stock | 288 | 280 |
| Additional paid-in capital, net | 266,454 | 236,838 |
| Treasury stock, at cost | (551) | (222) |
| Retained deficit | (58,779) | (39,948) |
| Total equity | 207,412 | 196,948 |
| Total liabilities and equity | $ 226,819 | $ 231,233 |