

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): May 5, 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 May 5, 2015, NewLink Genetics Corporation, a Delaware corporation (the "Company"), issued a press release reporting financial results for the first quarter ended March 31, 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 May 5, 2015, entitled "NewLink Genetics Corporation Reports First 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: May 5, 2015

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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|-----------------------|--|
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FOR IMMEDIATE RELEASE

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

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

AMES, Iowa - May 5, 2015 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology medicines to patients with cancer, today reported consolidated financial results for the first quarter of 2015 and progress in its clinical and business development programs.

“NewLink Genetics continued to execute on its immuno-oncology pipeline of products during the first quarter,” said Dr. Charles Link, Chairman and Chief Executive Officer. “On the IDO/TDO front, we have successfully launched both our small molecule research and clinical development teams with Genentech, and we are excited about the progress of this partnership. We also accelerated our hiring and pre-commercial activities relating to algenpantucel-L. Finally, we earned a \$20 million milestone payment from Merck Inc. on our investigational rVSV-EBOV (Ebola) vaccine candidate, originally developed by the Public Health Agency of Canada. This vaccine has emerged as the only vaccine currently being tested in two of the three large-scale trials in West Africa.”

“In addition to working toward the second interim analysis of the IMPRESS clinical trial data, we drove the Company’s other key clinical programs forward,” said Dr. Nicholas Vahanian, President and Chief Medical Officer. “We are accelerating enrollment in key clinical trials, including PILLAR, and expanding our manufacturing capacity of algenpantucel-L.”

Program Updates:

HyperAcute® Cancer Immunotherapy Programs

NewLink Genetics’ proprietary cancer immuno-oncology programs may prove to have broad potential across a spectrum of cancer indications, including in combination with checkpoint inhibitors. NewLink Genetics has multiple HyperAcute immunotherapy programs in various stages of clinical development, including pancreatic cancer, lung cancer and melanoma.

- Algenpantucel-L is NewLink Genetics’ HyperAcute pancreatic cancer immunotherapy candidate in a Phase 3 clinical trial called, **IM**munotherapy for **Pan**creatic **RE**sectable cancer **S**tudy, or IMPRESS. The study, evaluating the addition of algenpantucel-L to standard of care therapy after surgery for pancreatic cancer, is fully enrolled and the second interim analysis is expected to be reported in the second quarter of 2015.
- PILLAR, or **Pan**creatic **IM**munotherapy with algenpantucel-**L** for **L**ocally **A**dvanced non-**R**esectable disease is our Phase 3 clinical trial studying the efficacy of algenpantucel-L in

patients with locally advanced pancreatic cancer. The Company continues to expect to complete enrollment in the second half of 2015.

- Tergenpumatucel-L for patients with lung cancer is NewLink Genetics' HyperAcute lung immunotherapy being tested in a randomized, Phase 2b study in advanced lung cancer. An update on this program will be provided in the second half of 2015.
- Dorgenmeltucel-L for patients with melanoma is being evaluated in a randomized Phase 2 study in combination with ipilimumab vs. ipilimumab alone.

IDO Pathway Inhibitor Program (Proprietary)

We expect to complete enrollment of the following studies with indoximod, our proprietary IDO pathway inhibitor, within the next 12-15 months.

- First is NLG2101, a global randomized Phase 2 trial testing indoximod in combination with docetaxel or paclitaxel in patients with metastatic breast cancer with full enrollment expected by the end of 2015.
- Next is NLG2102, a Phase 1b/2 trial testing indoximod in combination with temozolomide in patients with progressive or refractory glioblastoma. We expect to report results from the Phase 1b portion at a poster presentation (#2070) during the *American Society of Clinical Oncology* meeting on Monday, June 1, 2015 from 1:15 - 4:45 p.m. CT.
- Then there is NLG2103, a Phase 1b/2 trial testing indoximod in combination with ipilimumab in patients with advanced melanoma. We expect to report Phase 1b top-line results by the end of 2015; and
- Finally, we have NLG2104, a Phase 1b/2 trial testing indoximod in combination with gemcitabine plus nab-paclitaxel in patients with metastatic pancreas cancer. Phase 1b top-line results are expected in 2016.

Financial Results for the Three Month Period Ended March 31, 2015

Cash Position: NewLink Genetics ended the quarter on March 31, 2015, with cash, cash equivalents, and certificates of deposit totaling \$214.4 million compared to \$202.8 million for the year ending December 31, 2014. The increase was attributable primarily to net proceeds received from the milestone payment from Merck & Co., sales under the Company's "at the market" facility (ATM), which was completed in the quarter, and amounts received under government contracts.

R&D Expenses: Research and development expenses in the first quarter of 2015 were \$18 million compared to \$6.4 million during the comparable period in 2014. The increase is primarily due to clinical trial expenses and the manufacturing and research related to the Ebola vaccine candidate.

G&A Expenses: General and administrative expenses in the first quarter of 2015 were \$8.4 million compared to \$3.3 million during the comparable period in 2014. The increase was primarily due to an increase in share-based compensation expense, as well as increases in consulting and legal fees, and medical affairs and pre-commercial activities.

Net Income/Loss: NewLink Genetics reported net income of \$11.2 million or \$0.35 per diluted share for the first 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 received approximately \$13.5 million in net proceeds from sales under its ATM during the three months ended March 31, 2015 and ended the quarter with 28,517,195 shares outstanding.

Financial Guidance

NewLink Genetics expects to end the year on December 31, 2015, with approximately \$160 million in cash, cash equivalents and certificates of deposit. This guidance recognizes that an early halt in the IMPRESS trial for effectiveness would require the need to accelerate organizational development and spending levels.

“We finished the quarter with a strong cash position and the capacity to make the necessary investments to become a commercial biopharmaceutical company,” said Jack Henneman, Executive Vice President and Chief Financial Officer. “Significant investments for the remainder of 2015 will include developing our manufacturing capacity, building our commercialization team, and investments in broadening our pipeline of drug candidates.”

Conference Call

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to provide 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 (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 31502548. 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's 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 clinical 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 March 31, | |
|------------------------------------|------------------------------|------------|
| | 2015 | 2014 |
| Grant revenue | \$ 9,649 | \$ 334 |
| Licensing revenue | 29,546 | — |
| Total revenue | 39,195 | 334 |
| Operating expenses: | | |
| Research and development | 17,981 | 6,387 |
| General and administrative | 8,366 | 3,251 |
| Income (loss) from operations | 12,848 | (9,304) |
| Other income (expense), net | 11 | 68 |
| Income (loss) before income taxes | 12,859 | (9,236) |
| Income tax expense | (1,669) | — |
| Net income (loss) | \$ 11,190 | \$ (9,236) |
| Basic earnings per share | \$ 0.40 | \$ (0.33) |
| Diluted earnings per share | \$ 0.35 | \$ (0.33) |
| Basic average shares outstanding | 28,218,631 | 27,605,910 |
| Diluted average shares outstanding | 31,919,318 | 27,605,910 |

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

| | Year Ended | |
|--|-------------------|----------------------|
| | March 31, 2015 | December 31, 2014 |
| Assets | | |
| Current assets: | | |
| Cash, cash equivalents and certificates of deposit | \$ 214,369 | \$ 202,797 |
| Prepaid expenses, advance payments to vendors and other current assets | 22,540 | 12,062 |
| Income tax receivable | 14,190 | 15,604 |
| Total current assets | 251,099 | 230,463 |
| Property and equipment, net | 8,028 | 7,599 |
| Total assets | \$ 259,127 | \$ 238,062 |
| Liabilities and Equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 13,408 | \$ 11,779 |
| Unearned revenue | 3,478 | 12,966 |
| Other current liabilities | 676 | 276 |
| Total current liabilities | 17,562 | 25,021 |
| Long-term liabilities: | | |
| Royalty obligation payable | 6,000 | 6,000 |
| Notes payable and obligations under capital leases | 494 | 941 |
| Deferred rent | 1,216 | 1,238 |
| Unearned revenue, excluding current portion | 1,024 | 1,085 |
| Total long-term liabilities | 8,734 | 9,264 |
| Total liabilities | 26,296 | 34,285 |
| Stockholder's equity: | | |
| Common stock | 285 | 280 |
| Additional paid-in capital, net | 254,966 | 236,838 |
| Treasury stock, at cost | (491) | (222) |
| Retained deficit | (21,929) | (33,119) |
| Total equity | 232,831 | 203,777 |
| Total liabilities and equity | \$ 259,127 | \$ 238,062 |