

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 29, 2012 (March 27, 2012)

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 29, 2012, 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, 2011.

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 8 - Other Events

Item 8.01. Other Events.

On March 27, 2012, the Company issued a press release reporting that it had entered into an agreement with the Iowa Economic Development Authority (“IEDA”) under which the IEDA (i) forgave the \$6.0 million Iowa Values Fund loan to the Company and (ii) released its security interest in the Company's business assets in return for a future royalty obligation. Under this agreement, the Company will pay IEDA a 0.5% capped royalty on future product sales.

The press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

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 29, 2012, entitled "NewLink Genetics Corporation Reports Fourth Quarter and Full-Year 2011 Financial Results." |
| 99.2 | Press Release, dated March 27, 2012, entitled "NewLink Enters Into an Agreement Converting Its \$6 Million Forgivable Loan to a Royalty Interest." |

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 29, 2011

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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Contact:
 Gordon Link
 Chief Financial Officer
 515-598-2925
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FOR IMMEDIATE RELEASE

NewLink Genetics Corporation Reports Fourth Quarter and Full-Year 2011 Financial Results

Conference call scheduled for 5:00 pm EDT March 29, 2012

AMES, Iowa, March 29, 2012 - NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today reported financial results for its quarter and year ended December 31, 2011, and provided an update on the progress of its clinical development programs.

“2011 was a pivotal year for NewLink,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. “By successfully completing our initial public offering and raising additional private money we raised adequate capital to allow us to complete patient enrollment in our pivotal Phase three pancreatic cancer clinical trial as well as advancing four other cancer immunotherapies into or further into clinical trials addressing patients with significant unmet medical needs.”

Full Year 2011 Financial Results

- Cash, cash equivalents and certificates of deposit totaled \$42.0 million.
- Total grant revenues for 2011 were \$1.9 million compared with \$2.1 million for 2010. Grant revenues will vary depending on the level of research funded under grants as well as changes in the overhead rates and profit factors agreed to under the grants. On September 21, 2011, NewLink entered into an amendment to a contract with the United States Department of Defense extending the contract period to September 24, 2013 and increasing the aggregate amounts for which BioProtection Systems Corporation, NewLink's wholly-owned subsidiary, may receive reimbursements by \$3.4 million to a total of up to approximately \$7.1 million.
- Research and development (R&D) expense for 2011 was \$14.3 million compared with \$12.7 million in 2010. The increase was primarily due to increases in personnel-related expenses and clinical trial expense. We expect R&D expense to increase as we expand our clinical trials.
- General and administrative (G&A) expense for 2011 was \$5.7 million compared with \$6.1 million in 2010. The decrease was primarily due to a decrease in legal fees and licensing fees, offset by an increase in personnel expenses. We expect increases in G&A expense in 2012 associated with the cost of being a public company.
- Net loss for 2011 was \$18.1 million or \$2.98 per common share (based on 6.1 million weighted average shares outstanding), compared with \$16.2 million, or \$4.84 per common share, for 2010 (based on 3.4 million weighted average shares outstanding). The difference in the number of weighted average shares outstanding primarily resulted from NewLink's initial public offering in November 2011, as well as the conversion of all preferred stock to common stock in connection with the initial public offering.

Financial Guidance

NewLink expects to end 2012 with about \$20 million in cash, cash equivalents and marketable securities. NewLink anticipates that this capital should allow it to fund its operations through 2013 based on its current operating plans.

2011 Key Accomplishments and 2012 Goals:

- Completed Series E preferred stock private round and a \$43.4 million initial public offering of common stock to capitalize the company.
- Advanced the HyperAcute Pancreas Phase 3 clinical trial by enrolling over 200 patients during 2011. Patient enrollment remains robust and we are matching our anticipated enrollment rates. We still expect that our first interval look will occur at the end of 2012 or early 2013. We anticipate presenting further clinical data on our Phase 2 dose finding study as well in the first half of 2012.
- Completed final HyperAcute Lung Phase 2 clinical trial in patients with metastatic lung cancer at the National Cancer Institute. Data was presented at the American Society for Clinical Oncology (ASCO) Annual Meeting in 2011 and we anticipate presenting updated clinical data mid-2012 at a clinical meeting.
- Completed a HyperAcute Melanoma Phase 2 clinical trial in patients with Stage III and IV malignant melanoma. Initial data was presented at the ASCO Annual Meeting in 2011.
- Initiated studies of D-1MT, our IDO pathway inhibitor, in combination with a dendritic cell vaccine or Taxotere in 2011. We anticipate clinical data from these studies will be presented in the first half of 2012.
- Completed settlement agreement with the State of Iowa converting our current \$6 million loan into a future royalty obligation and removed any future encumbrance of our growing intellectual property portfolio.
- Advanced studies of HyperAcute technology for the enhancement of Influenza and other viral vaccines that is under a contract with the United States Department of Defense.
- Expanded into a new 25,000 square foot facility, the majority of which is cGMP manufacturing and testing space, during 2011 and we have just begun to occupy another 25,000 square foot facility that further supports our clinical trial and chemistry division.
- We converted our letter of intent with the National Cancer Institute into cooperative research and development agreement (CRADA).

Upcoming Activities

NewLink expects to present at the following investor conferences:

- 2012 Needham Life Sciences Conference, April 3-4, 2012, in New York, NY.
- Canaccord 2012 Health Care Conference, August 14-16, 2012, in Boston, MA.
- SNW Health Care Conference, September 4-7, 2012, in Boston, MA.
- Robert W Baird Healthcare Conference, September 2012, in New York, NY.

NewLink expects to present at the following oncology and pharmacology meetings:

- 53rd Annual Meeting of the American Gastroenterological Association in conjunction with Digestive Disease Week at the San Diego Convention Center, May 19-22, 2012, in San Diego, CA.
- 2012 ASCO Annual Meeting, June 1-5, 2012, in Chicago, IL.

Today's Conference Call and Webcast Reminder

The NewLink management team will host a conference call discussing the company's financial results, recent developments and 2012 expectations on Thursday, March 29, 2012 at 5:00 p.m. (EDT). The call can be accessed by dialing 1-(877) 303-6919 (domestic) or 1-(253) 237-1194 (international) five minutes prior to the start of the call and providing the passcode 62462759. 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 (domestic) or 1-(404) 537-3406 (international), providing the passcode 62462759. The replay will be available for two weeks from the date of the live call.

The live, listen-only webcast of the conference call can be accessed by visiting the investors section of the NewLink website at <http://investors.linkp.com/>. A replay of the webcast will be archived on the company's website for two weeks following the call.

About NewLink Genetics Corporation

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and

commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. 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 with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. NewLink's lead product candidate, HyperAcute Pancreas cancer immunotherapy is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients (patient information is available at <http://www.pancreaticcancer-clinicaltrials.com>). This clinical trial is being performed under a Special Protocol Assessment with the U.S. Food and Drug Administration. NewLink and its collaborators have completed patient enrollment for a Phase 1/2 clinical trial evaluating its HyperAcute Lung cancer immunotherapy product candidate for non-small cell lung cancer and a Phase 2 clinical trial for its HyperAcute Melanoma cancer immunotherapy product candidate. NewLink also is developing d-1-methyltryptophan, or D-1MT, a small-molecule, orally bioavailable product candidate from NewLink's proprietary indoleamine-(2, 3)-dioxygenase, or IDO, pathway inhibitor technology. Through NewLink's collaboration with the National Cancer Institute, NewLink is studying D-1MT in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. For more information please visit 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 2012; the timing for completion of enrollment of our Phase 3 clinical trial for our HyperAcute Pancreas cancer immunotherapy; the timing of release of clinical data from ongoing clinical studies; NewLink's future financial performance, results of operations or 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, 2011 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

(in thousands, except share and per share amounts)

| | Quarter Ended | | Year Ended | |
|--|----------------------|----------------------|----------------------|----------------------|
| | December 31, 2011 | December 31, 2010 | December 31, 2011 | December 31, 2010 |
| Grant revenue | \$ 301 | \$ 974 | \$ 1,872 | \$ 2,079 |
| Operating expenses: | | | | |
| Research and development | 3,979 | 3,022 | 14,255 | 12,666 |
| General and administrative | 2,126 | 2,251 | 5,679 | 6,074 |
| Loss from operations | (5,804) | (4,299) | (18,062) | (16,661) |
| Other (expense) income, net | (6) | 41 | (26) | 99 |
| Net loss | \$ (5,810) | \$ (4,258) | \$ (18,088) | \$ (16,562) |
| Net loss attributable to NewLink | \$ (5,810) | \$ (4,095) | \$ (18,087) | \$ (16,213) |
| Net loss per common share, basic and diluted | \$ 0.44 | \$ (112) | \$ (2.98) | \$ (4.84) |
| Weighted average number of common shares outstanding | 13,237,960 | 3,641,830 | 6,064,542 | 3,352,331 |

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

| | Year Ended | |
|---|----------------------|----------------------|
| | December 31, 2011 | December 31, 2010 |
| Assets | | |
| Current assets: | | |
| Cash, cash equivalents and certificates of deposit | \$ 41,980 | \$ 12,841 |
| Prepaid expenses and other current assets | 808 | 1,801 |
| Total current assets | <u>42,788</u> | <u>14,642</u> |
| Property and equipment, net | <u>5,591</u> | <u>5,436</u> |
| Total assets | <u>\$ 48,379</u> | <u>\$ 20,078</u> |
| Liabilities and Equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 3,537 | \$ 2,106 |
| Deferred rent | 913 | 951 |
| Other current liabilities | 6,214 | 208 |
| Total current liabilities | <u>10,664</u> | <u>3,265</u> |
| Long-term liabilities: | | |
| Notes payable | 848 | 6,942 |
| Obligations under capital lease | 94 | 145 |
| Total long-term liabilities | <u>942</u> | <u>7,087</u> |
| Total liabilities | <u>11,606</u> | <u>10,352</u> |
| Redeemable preferred stock | — | 61,745 |
| Stockholders' equity: | | |
| Preferred Stock | — | 1,030 |
| Common stock | 206 | 36 |
| Additional paid-in capital, net | 118,043 | 7,374 |
| Deficit accumulated during the development stage | (81,476) | (63,389) |
| Notes receivable for common stock | — | (13) |
| Total NewLink Genetics stockholders' (deficit) equity | <u>36,773</u> | <u>(54,962)</u> |
| Equity attributable to noncontrolling interests | — | 2,943 |
| Total (deficit) equity | <u>36,773</u> | <u>(52,019)</u> |
| Commitments | — | — |
| Total liabilities and equity | <u>\$ 48,379</u> | <u>\$ 20,078</u> |

NewLink Enters Into an Agreement Converting Its \$6 Million Forgivable Loan to a Royalty Interest

AMES, Iowa, March 27, 2012 (GLOBE NEWSWIRE) -- NewLink Genetics (Nasdaq:NLNK) announced today that it has entered into an agreement with the Iowa Economic Development Authority (“IEDA”). After reviewing NewLink’s accomplishments on its milestones and its significant contributions to the State of Iowa, the \$6.0 million Iowa Values Fund loan to NewLink was forgiven by the IEDA, and it released its security interest in the business assets of NewLink in return for a future royalty obligation. Under this agreement, NewLink will pay IEDA a 0.5% capped royalty on future product sales.

“This agreement strengthens our balance sheet and improves our flexibility when dealing with possible large cap pharmaceutical development and marketing partners,” said Dr. Charles Link, Chairman and CEO of NewLink. “We continue to have a strong commitment to and an excellent working relationship with the state of Iowa. In the near future, we will be moving into our second new facility in Iowa in the last two years and we continue to house substantially all our staff in our facilities here in Ames, Iowa.”

NewLink’s President and Chief Medical Officer, Dr. Nicholas Vahanian, added, “We believe that being based in the Midwest has provided us with a strategic cost advantage over many of our peers and we are very pleased with the quality of our Iowa based employees.”

About NewLink Genetics Corporation

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