

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 14, 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 August 14, 2012, NewLink Genetics Corporation, a Delaware corporation (the “Company”), issued a press release reporting financial results for the second quarter ended June 30, 2012.

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 August 14, 2012, entitled "NewLink Genetics Corporation Reports Second Quarter 2012 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: August 14, 2012

NewLink Genetics Corporation

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

INDEX TO EXHIBITS

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

FOR IMMEDIATE RELEASE

NewLink Genetics Corporation Reports Second Quarter 2012 Financial Results

AMES, Iowa, August 8, 2012 - NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today reported consolidated financial results for the second quarter of 2012, and provided an update on the progress of its clinical development programs.

“Data from the Phase 2 study of our HyperAcute pancreatic cancer immunotherapy was successfully presented at two major conferences and continues to support our Phase 3 study design,” commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. “We are well past the halfway point in our pivotal trial in pancreatic cancer and we expect to reach the triggering point for our first interim analysis in the first quarter of 2013 and to complete patient enrollment in 2013.”

Dr. Nicholas Vahanian NewLink’s President and Chief Medical Officer added; “Recent positive data from Phase 2 studies in three different HyperAcute cancer immunotherapies have given us confidence to move forward aggressively in the clinical development of multiple therapies derived from this platform.”

The second quarter 2012 Financial Results

- Cash, cash equivalents and certificates of deposit totaled \$31.1 million at June 30, 2012.
- Total grant revenues for the second quarter 2012 were \$590,000 compared with \$537,000 for the second quarter 2011. 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. The increase in revenue was due to increased research under various Department of Defense contracts and National Institutes of Health grants.
- Research and development (R&D) expense for the second quarter 2012 was \$4.7 million compared with \$3.8 million for the second quarter 2011. The increase was primarily due to increases in personnel-related expenses associated with both increased headcounts and increased compensation levels in addition to increased clinical trial expense associated with an increase in the number of patients enrolled in clinical trials.
- General and administrative (G&A) expense for the second quarter 2012 was \$2.2 million compared with \$1.1 million for the second quarter 2011. The increase was primarily due to increases in personnel-related expenses as well as increases in professional and Board fees and Directors and Officers insurance premiums associated with our new public company status.
- Net loss for the second quarter 2012 was \$6.3 million or \$.31 per common share (based on 20.7 million weighted average shares outstanding), compared with \$4.4 million, or \$1.20 per common share, for the second quarter 2011 (based on 3.6 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 is maintaining its financial guidance and continues to expect to end 2012 with about \$20 million in cash, cash equivalents and marketable securities.

Recap of Data From Phase-2 HyperAcute® Pancreas (algenpantucel-L) Immunotherapy Trial:

Treated patients demonstrated statistically significant improvement in 12-month disease free survival and there was a strong suggestion of improvements in 12 month overall survival (OS) (observed 86% v. predicted 63% indicating a 37% improvement). Kaplan-Meier analysis suggests the improvement in OS increases over time with the 2-year and 3-year observed survival rates of 51% and 42% suggesting relative improvement of 59% and 121% in comparison to expected survival of 32% and 19% predicted by nomogram analysis.

Upcoming Activities

NewLink expects to present at the following investor conferences:

- 2nd Annual Canaccord Global Growth Conference, August 14-16, in Boston, MA.
- Stifel Nicolaus Weisel Healthcare Conference 2012, September 4-7, in Boston, MA.
- Robert W. Baird Health Care Conference, September 5-6, in New York City.
- 9th Annual Lazard Capital Markets Healthcare Conference, November 13-14, in New York City.

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 (algenpantucel-L) 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 (tergenpumatumucel-L) 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 indoximod (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 indoximod 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; its plans related to moving additional indications into clinical development;

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 Annual Report on Form 10-K for the period ended December 31, 2011, in its Quarterly Report on Form 10-Q for the period ended June 30, 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 | | Six Months Ended | |
|--|--------------------|------------------|------------------|------------------|
| | June 30, 2012 | June 30, 2011 | June 30, 2012 | June 30, 2011 |
| Grant revenue | \$ 590 | \$ 537 | \$ 1,061 | \$ 1,141 |
| Operating expenses: | | | | |
| Research and development | 4,740 | 3,795 | 8,570 | 6,975 |
| General and administrative | 2,151 | 1,136 | 3,609 | 2,452 |
| Loss from operations | (6,301) | (4,394) | (11,118) | (8,286) |
| Other (expense) income, net | (8) | — | (33) | (6) |
| Net loss | \$ (6,309) | \$ (4,394) | \$ (11,151) | \$ (8,292) |
| Net loss attributable to NewLink | \$ (6,309) | \$ (4,394) | \$ (11,151) | \$ (8,291) |
| Net loss per common share, basic and diluted | \$ (0.31) | \$ (1.20) | \$ (0.54) | \$ (2.28) |
| Weighted average number of common shares outstanding | 20,684,944 | 3,646,973 | 20,649,045 | 3,641,539 |

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

| | June 30, 2012 | December 31, 2011 |
|---|------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash, cash equivalents and certificates of deposit | \$ 31,074 | \$ 41,980 |
| Prepaid expenses and other current assets | 1,797 | 808 |
| Total current assets | <u>32,871</u> | <u>42,788</u> |
| Property and equipment, net | <u>6,265</u> | <u>5,591</u> |
| Total assets | <u>\$ 39,136</u> | <u>\$ 48,379</u> |
| Liabilities and Equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 2,341 | \$ 3,537 |
| Deferred rent | 71 | 913 |
| Other current liabilities | 204 | 6,214 |
| Total current liabilities | <u>2,616</u> | <u>10,664</u> |
| Long-term liabilities: | | |
| Royalty obligation payable | 6,000 | — |
| Notes payable and obligations under capital leases, excluding current portion | 854 | 942 |
| Deferred rent, excluding current portion | 1,434 | — |
| Total long-term liabilities | <u>8,288</u> | <u>942</u> |
| Total liabilities | <u>10,904</u> | <u>11,606</u> |
| Stockholders' equity: | | |
| Preferred Stock | — | — |
| Common stock | 208 | 206 |
| Additional paid-in capital | 120,651 | 118,043 |
| Deficit accumulated during the development stage | (92,627) | (81,476) |
| Total NewLink Genetics stockholders' equity | <u>28,232</u> | <u>36,773</u> |
| Total equity | <u>28,232</u> | <u>36,773</u> |
| Commitments | — | — |
| Total liabilities and equity | <u>\$ 39,136</u> | <u>\$ 48,379</u> |