

March 29, 2012

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

## Conference Call Scheduled for 5:00 pm EDT March 29, 2012

AMES, lowa, March 29, 2012 (GLOBE NEWSWIRE) -- 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 <a href="http://investors.linkp.com/">http://investors.linkp.com/</a>. 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 <a href="http://www.pancreaticcancer-clinicaltrials.com">http://www.pancreaticcancer-clinicaltrials.com</a>). 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 <a href="https://www.linkp.com">www.linkp.com</a>.

#### **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,	December 31,	December 31,	December 31,
	2011	2010	2011	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
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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, December 31,

2011 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	42,788	14,642

Property and equipment, net	5,591	5,436
Total assets	\$ 48,379	\$ 20,078
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	10,664	3,265
Long-term liabilities:		
Notes payable	848	6,942
Obligations under capital lease	94	145
Total long-term liabilities	942	7,087
Total liabilities	11,606	10,352
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	36,773	(54,962)
Equity attributable to noncontrolling interests	_	2,943
Total (deficit) equity	36,773	(52,019)
Commitments	_	_
Total liabilities and equity	\$ 48,379	\$ 20,078

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