July 29, 2016

NewLink Genetics Reports Second Quarter 2016 Financial Results

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

- Analyst Day to be held on October 25 in New York

AMES, Iowa , July 29, 2016 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company focused on bringing novel immuno-oncology medicines to patients, today reported consolidated financial results for the second quarter of 2016 and provided updates on its clinical development programs and operational restructuring.

"We have streamlined our operations and focused development efforts on the clinical validation of indoximod, our proprietary IDO pathway inhibitor program, which is being studied in multiple cancers," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer and Chief Scientific Officer. "Additionally, we continue the clinical advancement of GDC-0919, with our partner Genentech, and look forward to progress in this program."

"We have the financial resources to realize the potential of our product development pipeline as well as opportunities for the development of other potentially synergistic therapies that could provide benefit to patients with cancer," commented Nicholas N. Vahanian, M.D., President and Chief Medical Officer.

Program Updates

Indoleamine 2,3-Dioxgenase (IDO) Checkpoint Inhibitor Programs

The IDO pathway regulates immune response by suppressing T cell function and enabling local tumor immune escape. NewLink Genetics is developing two distinct IDO pathway inhibitors, indoximod and GDC-0919, which are small-molecule product candidates having the potential to disrupt mechanisms by which tumors evade the immune system. Indoximod and GDC-0919 have different mechanisms of action within the IDO pathway and are in Phase 1 or 2 clinical trials for a range of cancers, including breast cancer, melanoma, pancreatic cancer, and other malignancies.

Indoximod

NewLink Genetics reported on two clinical studies in two posters highlighting the combination therapeutic potential of indoximod at the 2016 American Society of Clinical Oncology Annual Meeting in June. Data reported included:

- Updates on Phase 1b/2 trial of the IDO pathway inhibitor, indoximod, plus checkpoint inhibitors for the treatment of unresectable stage 3 or 4 melanoma. The trial design allows for the combination of indoximod with either ipilimumab or one of the PD-1 checkpoint inhibitors, pembrolizumab or nivolumab. The combination of indoximod with other checkpoint inhibitors has been well tolerated thus far with no increase in toxicity noted in this Phase 1b/2 study. Overall, 40 patients had been enrolled in the combined Phase 1b/2 study long enough to have response data available at the time of data cut off. The poster data presented at ASCO were based on data via site reported RECIST criteria available from 28 subjects, the objective response rate, comprised of complete response plus partial response, for these patients is 36 percent (10 of 28) with three complete responses. Interestingly, the subset of 15 patients who received indoximod in combination with pembrolizumab had an objective response rate of 53 percent (8 of 15) with two complete responses (13 percent). The trial continues to enroll, with 55 patients currently enrolled in Phase 2.

- Interim analysis on a Phase 2 trial of the IDO pathway inhibitor, indoximod, plus gemcitabine/nab-paclitaxel for the treatment of metastatic pancreatic cancer. The combination of indoximod and gemcitabine/nab-paclitaxel continues to be well tolerated by patients with metastatic pancreatic cancer. These data come from the Phase 1/2 trial in which treatment-naïve patients with metastatic pancreatic cancer were treated with the combination therapy in continuous four week cycles. As of the data cut off for the analysis, a total of 45 patients (Phase 1 and 2) were enrolled in the trial long enough to potentially have cycle 4 imaging available by the ASCO presentation. Data via site reported RECIST criteria were available on 31 patients. At the time of this analysis, objective response rate was 45 percent (14 of 31) and multiple durable responses ≥6 months were observed. Two patients achieved a complete response (6 percent), both at Cycle 8, showing delayed kinetics that may indicate an immune based mechanism. The trial

continues to enroll patients and a biopsy cohort expansion is underway.

"These promising data continue to demonstrate the potential of combination therapies with other checkpoint inhibitors and with chemotherapies for different cancers," added Dr. Vahanian. "We believe that these data further support the IDO pathway as one of the key immune checkpoint targets."

Restructuring

The company also announced that it has implemented a significant restructuring program following the May results of the IMPRESS Phase 3 study of algenpantucel-L. The objective of the restructuring is to focus the company's financial resources on the following priorities:

- Progress and accelerate the development of indoximod;
- Continue the alliances with Genentech (GDC-0919) and Merck (Ebola vaccine candidate);
- Advancing other drug discovery programs, including both PTEN and Zika virus; and
- Evaluate external opportunities to expand our pipeline.

The restructuring includes the following initiatives:

- Winding down HyperAcute Cellular Immunotherapy clinical trials that do not include a checkpoint inhibitor combination;
- Winding down commercial manufacturing capacity for algenpantucel-L;
- Consolidating the Company's facilities footprint from 133,000 square feet to approximately 66,000 square feet;
- Reducing headcount from approximately 230 to approximately 130; and
- Focusing capital spending to primarily support drug discovery and development.

We recorded $12.3 million in restructuring expenses in Q2, including severance expense, the impairment of fixed assets, and the costs of terminating certain contracts. In Q3, the Company expects to record small additional charges relating to the closing or reduction of leased facilities.

Financial Results for the Three-Month Period Ended June 30, 2016

Cash Position: NewLink Genetics ended the quarter on June 30, 2016, with cash and cash equivalents totaling $160.5 million compared to $197.8 million for the year ending December 31, 2015.

R&D Expenses: Research and development expenses in the second quarter of 2016 were $27.4 million compared to $16.1 million during the comparable period in 2015. The increase was primarily due to the R&D expenses related to the restructuring initiatives of $11.8 million.

G&A Expenses: General and administrative expenses in the second quarter of 2016 were $9.1 million compared to $7.3 million during the comparable period in 2015. The increase was primarily due to an increase in medical affairs and marketing expenses along with G&A expenses incurred due to the restructuring initiatives of $0.5 million.

Net Loss: NewLink Genetics reported a net loss of $32.4 million or ($1.12) per diluted share for the second quarter of 2016 compared to a net loss of $14.1 million or ($0.49) per diluted share for the comparable period in 2015.

NewLink Genetics ended the quarter with 28,962,296 shares outstanding.

Financial Guidance and Upcoming Investor Meetings

NewLink Genetics' goal and expectation remains to finish 2016 with two years of cash on hand and the capacity to make incremental investments.

We expect to present at the Baird Healthcare Conference on September 7 and we look forward to hosting our Analyst Day on Tuesday, October 25 in New York.

Conference Call Details

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to give an update. NewLink Genetics' senior management team will host the 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 conference call is available by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) five minutes prior to the start of the call. The conference call will be webcast live and a link can be accessed through the NewLink Genetics website at http://investors.linkp.com/events.cfm. A replay of the call will be available for two weeks from the date of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 46406260.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' portfolio includes 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. For more information, please visit http://www.newlinkgenetics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics 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 2016; results of its clinical trials for product candidates; 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 Genetics 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, 2015 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink' Genetics' views as of the date of this press release. NewLink Genetics 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.

NewLink Genetics Corporation
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Grant revenue	$ 1,262	$ 3,280	$ 5,600	$ 12,929
Licensing and collaboration revenue	750	4,165	2,120	33,711
Total revenue	2,012	7,445	7,720	46,640
Operating expenses:				
Research and development	27,410	16,130	49,347	34,111
General and administrative	9,130	7,257	18,294	15,623
Loss from operations	(34,528)	(15,942)	(59,921)	(3,094)
Other income, net	60	22	99	33
Net loss before taxes	(34,468)	(15,920)	(59,822)	(3,061)
Income tax benefit	2,079	1,829	3,713	160
Net loss	$ (32,389)	$ (14,091)	$ (56,109)	$ (2,901)
Basic and diluted loss per share	$ (1.12)	$ (0.49)	$ (1.94)	$ (0.10)
Basic and diluted average shares outstanding	28,891,827	28,661,588	28,874,385	28,408,474

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)

(In thousands)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	$ 160,527	$ 197,800
Prepaid expenses and other current assets	7,228	10,342
Income tax receivable	4,259	—
Total current assets	172,014	208,142
Property and equipment, net	7,435	10,400
Total assets	$ 179,449	$ 218,542
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,380	$ 12,422
Unearned revenue	838	892
Other current liabilities	327	667
Income taxes payable	—	859
Total current liabilities	22,545	14,840
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	395	368
Deferred rent	1,109	1,153
Unearned revenue	56	407
Total long-term liabilities	7,560	7,928
Total liabilities	30,105	22,768
Stockholders' equity:		
Common stock	290	288
Additional paid-in capital	286,300	276,610
Treasury stock, at cost	(784)	(771)
Accumulated deficit	(136,462)	(80,353)
Total stockholders' equity	149,344	195,774
Total liabilities and stockholders' equity	$ 179,449	$ 218,542

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