November 3, 2015

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

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

AMES, Iowa, Nov. 03, 2015 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company at the forefront of developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, to improve the lives of patients with cancer, today reported consolidated financial results for the third quarter of 2015 and progress in its proprietary and partnered clinical development programs.

"Our dynamic and experienced team has made significant progress in driving our broad clinical development programs," said Charles Link, M.D., Chairman and Chief Executive Officer. "We look forward to reporting on our strong pipeline of clinical data over the coming year."

Dr. Link added, "GDC-0919, the checkpoint inhibitor program partnered with Genentech continues to make great progress. Both companies are putting substantial resources behind this program, and we continue to be excited about the development plan and the progress of our collaboration."

"As we anticipate the data readout for the IMPRESS trial in 2016, NewLink Genetics continues to advance its investment in manufacturing and pre-commercial activities relating to algenpantucel-L, our HyperAcute® Cellular Immunotherapy product candidate for patients with resected pancreatic cancer," said Nicholas Vahanian, M.D., President and Chief Medical Officer. "We await the promise of our cellular immunotherapy agents to educate the immune system to destroy tumor cells in pancreatic and other cancers."

Financial Results for the Three-Month Period Ended September 30, 2015

Cash Position: NewLink Genetics ended the quarter on September 30, 2015, with cash, cash equivalents, and certificates of deposit totaling $200.4 million, compared to $202.8 million for the year ending December 31, 2014 .

R&D Expenses: Research and development expenses in the third quarter of 2015 were $22.5 million, compared to $10.9 million during the comparable period in 2014. The increase is primarily due to clinical trial expenses related to NewLink Genetics' broad pipeline of product candidates, as well as expenses for manufacturing and research related to the Ebola vaccine candidate. The majority of the Ebola-related expenses are subject to reimbursement under government contracts.

G&A Expenses: General and administrative expenses in the third quarter of 2015 were $7.4 million, compared to $4.9 million during the comparable period in 2014. The increase was primarily due to an increase in share-based compensation expense, consulting and legal fees, and medical affairs and pre-commercial activities.

Net Loss: NewLink Genetics reported a net loss of $15.9 million, or ($0.55) per diluted share, for the third quarter of 2015, compared to a net loss of $5.6 million, or ($0.20) per diluted share, for the comparable period in 2014.

NewLink Genetics ended the quarter with 28,774,911 shares outstanding.

Financial Guidance

NewLink Genetics expects to have more than $160 million in cash and equivalents on December 31, 2015.

Conference Call and Program Updates:

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss these results and to provide an update on clinical and business development activities. Dial-in information for the conference call is set forth at the end of this press release. Programs to be discussed include:

IDO Checkpoint Inhibitor Programs

NewLink Genetics entered into an exclusive worldwide license and collaboration agreement with Genentech, a member of the Roche Group, for the development of the IDO checkpoint inhibitor GDC-0919 and an expanded pipeline of potential IDO/TDO inhibitor candidates in 2014. This product candidate is currently in Phase 1 clinical development for patients with advanced solid tumors.

- Key preclinical data is being presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in Bethesda, Maryland on November 6, 2015.
- Phase 1 data on GDC-0919 was presented at the ECC/ESMO meeting in Vienna. Key preliminary data showed that GDC-0919 had a favorable safety profile and preliminary evidence of disease stabilization and peripheral pharmacodynamic modulation. Details from the poster presentation are available in the press release found at http://investors.linkp.com/releasedetail.cfm?ReleaseID=933270
- The collaboration's clinical development team has advanced GDC-0919 into a combination study with atezolizumab that is actively enrolling patients. In addition, the collaboration is planning combination studies of GDC-0919 with OX-40 agonists.
- NewLink will be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech.

Indoximod, NewLink Genetics' proprietary IDO pathway inhibitor, is in multiple Phase 1 and Phase 2 clinical trials for patients with breast, prostate, pancreatic and brain cancers as well as melanoma. We will provide additional details about our trials on the conference call. Additionally, there will be multiple opportunities for the Company to provide further updates during 2015 and 2016 at academic meetings and associated programs.

HyperAcute® Cellular Immunotherapy Programs

NewLink Genetics' proprietary HyperAcute Cellular Immunotherapy programs may prove to have broad potential for patients across a spectrum of cancer indications, including use in combination with checkpoint inhibitors.

Algenpantucel-L is NewLink Genetics' HyperAcute Cellular Immunotherapy product candidate for patients with pancreatic cancer. The product is currently being studied in a Phase 3 clinical trial called IMPRESS, or **IM**munotherapy for **P**ancreatic **RES**ectable Cancer **S**tudy, in patients with surgically resected pancreatic cancer. The study is powered to show an improvement in overall survival after 442 events, and we continue to expect that final results will be reported in 2016.

PILLAR, or **P**ancreatic **I**mmunotherapy with Algenpantucel-**L** for **L**ocally **A**dvanced Non-**R**esectable Disease, is our Phase 3 clinical trial studying the efficacy of algenpantucel-L for patients with borderline resectable or locally advanced unresectable pancreatic cancer. We expect to complete enrollment in this study in 2015.

Tergenpumatucel-L

Tergenpumatucel-L, NewLink Genetics' HyperAcute Cellular Immunotherapy product candidate for patients with non-small cell lung cancer (NSCLC), remains in Phase 2. We are eager to learn more about this product in our recently begun trial evaluating tergenpumatucel-L in combination with indoximod and chemotherapy for patients with advanced NSCLC.

Dorgenmeltucel-L

Dorgenmeltucel-L, NewLink Genetics' HyperAcute Cellular Immunotherapy product candidate for patients with melanoma, continues in a trial evaluating efficacy in combination with the checkpoint inhibitors ipilimumab, nivolumab, and pembrolizumab for patients with advanced melanoma.

Ebola Vaccine

During the third quarter, we announced that NewLink Genetics was awarded an $8.1 million base contract with future options totaling $5.2 million by the Defense Threat Reduction Agency of the United States Department of Defense to support various development activities of the investigational rVSV-ZEBOV (Ebola) vaccine candidate. Additionally, the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services exercised an $18 million option on NewLink Genetics' existing contract.

NewLink has exclusively licensed research, development, manufacturing and commercialization of the rVSV-ZEBOV (Ebola) vaccine to Merck. This vaccine candidate was originally developed by the Public Health Agency of Canada (PHAC).

Conference call details

NewLink Genetics' 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 66888213. 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 immuno-oncology products to improve treatment options for patients with cancer. NewLink Genetics' 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. For more information, please visit http://www.newlinkgenetics.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 Genetics' financial guidance for 2015; enrollment in or results of its clinical trials for product candidates; its timing of release of 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.

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

	Three Months Ended September 30 ,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Grant revenue	$ 13,365	$ 2,801	$ 26,294	$ 3,347
Licensing and collaboration revenue	844	—	34,555	—
Total revenue	14,209	2,801	60,849	3,347
Operating expenses:				
Research and development	22,508	10,896	56,619	23,760
General and administrative	7,384	4,931	23,007	11,044
Loss from operations	(15,683)	(13,026)	(18,777)	(31,457)
Other income (expense), net	(63)	15	(30)	47
Loss before income taxes	(15,746)	(13,011)	(18,807)	(31,410)
Income tax (expense) benefit	(160)	7,413	—	7,413
Net loss	$ (15,906)	$ (5,598)	$ (18,807)	$ (23,997)
Basic and diluted loss per share	$ (0.55)	$ (0.20)	$ (0.66)	$ (0.86)
Basic and diluted average shares outstanding	28,734,768	27,914,782	28,518,503	27,800,246

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets

(unaudited)
(In thousands)

	Year Ended	
	September 30, 2015	**December 31, 2014**
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	$ 200,357	$ 202,797
Prepaid expenses, advance payments to vendors and other current assets	16,758	12,062
Income tax receivable	76	8,775
Total current assets	217,191	223,634
Property and equipment, net	9,628	7,599
Total assets	$ 226,819	$ 231,233
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 9,649	$ 11,779
Unearned revenue	901	12,966
Other current liabilities	665	276
Total current liabilities	11,215	25,021
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	409	941
Deferred rent	1,175	1,238
Unearned revenue, excluding current portion	608	1,085
Total long-term liabilities	8,192	9,264
Total liabilities	19,407	34,285
Stockholders' equity:		
Common stock	288	280
Additional paid-in capital, net	266,454	236,838
Treasury stock, at cost	(551)	(222)
Retained deficit	(58,779)	(39,948)
Total equity	207,412	196,948
Total liabilities and equity	$ 226,819	$ 231,233

Corporate Contact:

Jack Henneman

Chief Financial Officer, NewLink Genetics

515-598-2561

Investor@linkp.com

Investors:

Donna LaVoie

LaVoieHealthScience

617-374-8800, ext. 107

dlavoie@lavoiehealthscience.com

Media:

David Connolly

LaVoieHealthScience

617-374-8800, ext. 108

dconnolly@lavoiehealthscience.com

Primary Logo

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