

NewLink Genetics Reports Fourth Quarter, Year-End 2017 Financial Results and Provides Update for Indoximod Programs

March 1, 2018

Management to Host Conference Call Today at 4:30 p.m. ET

AMES, Iowa, March 01, 2018 (GLOBE NEWSWIRE) -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today reported consolidated financial results for the fourth quarter and year ended 2017, as well as progress in its clinical development programs. The Company also outlined key 2018 business priorities related to the clinical programs for indoximod, its IDO pathway inhibitor drug candidate.

"NewLink Genetics has produced encouraging data supporting indoximod in several indications and looks forward to presenting additional data in 2018, further validating IDO pathway inhibition as a key target in immuno-oncology," said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. "In addition, Indigo301, our pivotal trial for patients with metastatic melanoma, and Indigo201, our randomized Phase 2 trial in collaboration with AstraZeneca for patients with metastatic pancreatic cancer, are our core clinical priorities for 2018."

Anticipated 2018 Highlights

- Initiate randomization portion of Indigo301, a pivotal Phase 3 trial for patients with advanced melanoma, in Q2-Q3 2018
- Full Phase 2 results of indoximod plus checkpoint inhibitors in metastatic melanoma in 1H:2018
- Initiate Indigo201, a randomized Phase 2 trial for patients with metastatic pancreatic cancer, in 1H:2018
- Full Phase 2 results from the single-arm trial of indoximod plus gemcitabine nab-paclitaxel in metastatic pancreatic cancer in 1H:2018
- Two abstract presentations at AACR Annual Meeting 2018 include data from a Phase 1 study of indoximod for pediatric patients with malignant brain tumors and data providing additional characterization of the differentiated mechanism of action of indoximod
- Continued evaluation of indoximod in additional oncology indications

2017 Highlights

- Presented updated Phase 2 data of indoximod plus pembrolizumab in advanced melanoma at the Third Annual International Cancer Immunotherapy Conference with encouraging overall and complete response rates and progression-free survival
- Commenced dose determination portion of Indigo301
- Entered into a collaboration with AstraZeneca on Indigo201
- Presented Phase 2 data from a randomized, double-blind study of indoximod plus cancer vaccine for patients with metastatic castration-resistant prostate cancer at ASCO Annual Meeting, indicating statistically significant improvement in median progression-free survival compared to monotherapy
- Presented Phase 1b data of indoximod plus chemotherapy in newly diagnosed AML suggesting the potential for indoximod in treatment regimens beyond PD-1
- Successfully raised \$74.3 million, net of offering costs, and ended 2017 with \$158.7 million cash and equivalents

Update on Current Clinical Timeline and Financial Guidance

NewLink Genetics reported an update of its clinical timeline and now expects to initiate Indigo301 randomization in Q2 to Q3 2018 and complete enrollment in 2019. The Company expects to end this year with approximately \$75 million in cash. The shift in the timeline arises from an increased number of trial sites planned for Indigo301 and additional work related to manufacturing.

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2017, with cash and cash equivalents totaling \$158.7 million compared to \$131.5 million for the year ending December 31, 2016. The Company's cash position is sufficient to fund operations in the near and medium term.

R&D Expenses: Research and development expenses were \$17.5 million and \$69.9 million in the fourth quarter and year ended December 31, 2017 compared to \$19.5 million and \$93.3 million during the comparable periods in 2016. The decrease year-over-year was due primarily to higher restructuring charges of \$11.1 million incurred in 2016, including a non-cash charge of \$4.0 million related to impaired assets, as compared to \$600,000 of charges incurred in 2017. Remainder of the decrease was due to decreases of \$6.2 million in clinical trial costs, \$4.4 million in supplies, equipment and licensing, \$3.6 million in personnel-related expense, and \$200,000 in manufacturing expense. Decreases were offset by increases of \$1.0 million in stock compensation expense and \$600,000 in legal and consulting.

G&A Expenses: General and administrative expenses in the fourth quarter and year ended December 31, 2017 were \$6.7 million and \$31.7 million compared to \$7.2 million and \$33.2 million during the comparable periods in 2016. The decrease was primarily due to a \$2.3 million reduction in personnel-related spend and \$1.2 million reduction in legal and consulting, offset by increases of \$700,000 in stock compensation expense, \$700,000 in supplies and equipment, and \$600,000 in restructuring charges incurred in 2017.

Net Loss: NewLink Genetics reported a net loss of \$13.7 million or \$0.37 per diluted share for the fourth quarter of 2017 and a net loss of \$72.0 million or \$2.30 per diluted share for the year ended December 31, 2017, compared to a net loss of \$13.5 million or \$0.46 per diluted share for the fourth quarter of 2016 and a net loss of \$85.2 million or \$2.94 per diluted share for the year ended December 31, 2016.

NewLink Genetics ended 2017 with 37,109,556 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 4:30 p.m. ET today to discuss the results and to give an update on clinical and business development activities. 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 to the webcast can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in the "Investors & Media" section under "Events and Presentations" or by clicking [here](#). To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast. 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 9466627. The replay will be available for two weeks from the date of the call.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target involved in regulating the tumor microenvironment and immune escape. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies.

About NewLink Genetics Corporation

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune system to combat cancer. For more information, please visit www.NewLinkGenetics.com and follow us on Twitter [@NLNKGenetics](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," 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 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; 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, 2016 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.

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Source: NewLink Genetics Corporation

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Condensed Consolidated Statements of Operations (unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Grant revenue	\$ 10,042	\$ 12,185	\$ 28,321	\$ 32,242
Licensing and collaboration revenue	56	518	390	3,526
Total operating revenues	10,098	12,703	28,711	35,768

Operating expenses:				
Research and development	17,461	19,490	69,866	93,300
General and administrative	6,688	7,183	31,726	33,226
Loss from operations	(14,051) (13,970) (72,881) (90,758
Other income, net	235	129	371	247
Net loss before taxes	(13,816) (13,841) (72,510) (90,511
Income tax benefit	130	335	559	5,356
Net loss	\$ (13,686) \$ (13,506) \$ (71,951) \$ (85,155
Basic and diluted loss per share	\$ (0.37) \$ (0.46) \$ (2.30) \$ (2.94
Basic and diluted average shares outstanding	36,770,490	29,147,247	31,304,309	28,979,327

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands)

	Year Ended	
	December 31,	December 31,
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 158,708	\$ 131,490
Prepaid expenses and other current assets	6,226	5,921
Income tax receivable	356	5,975
Other receivables	10,176	24,526
Total current assets	175,466	167,912
Non-current Assets		
Property and equipment, net	5,091	6,835
Income Tax Receivable	140	—
Total non-current assets	5,231	6,835
Total assets	\$ 180,697	\$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,723	\$ 37,192
Unearned revenue	56	391
Other current liabilities	252	322
Total current liabilities	22,031	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	111	285
Deferred rent	998	1,091
Total long-term liabilities	7,109	7,376
Total liabilities	29,140	45,281
Stockholders' equity:		
Common stock	372	292
Additional paid-in capital	389,786	295,535
Treasury stock, at cost	(1,142) (853
Accumulated deficit	(237,459) (165,508
Total stockholders' equity	151,557	129,466
Total liabilities and stockholders' equity	\$ 180,697	\$ 174,747

 [Primary Logo](#)