May 9, 2016

Neuralstem Reports Fiscal First Quarter 2016 Results and Business Update

GERMANTOWN, Md., May 9, 2016 /PRNewswire/ -- Neuralstem, Inc. (Nasdaq: CUR), a biopharmaceutical company focused on the development of central nervous system therapies based on its neural stem cell technology, reported its financial results for the three months ended March 31, 2016 and provided a business update.

Business Highlights

- On May 6, 2016, the Company closed a public offering resulting in net proceeds of $7.42 million. The net proceeds will be used for general corporate purposes, including the Phase 2 NSI-189 major depressive disorder (MDD) clinical trial and ongoing research and development activities.
- In March 2016, we commenced the NSI-189 Phase 2 clinical trial for the treatment of Major Depressive Disorder (MDD).
- In February 2016, we strengthened our management team with the appointment of Richard Daly as our President and Chief Executive Officer.
- In January 2016, we announced an initiative to pursue collaborations for our stem cell therapy programs in order to utilize additional expertise, expedite clinical and regulatory pathways and secure alternative funding.

"The Company's ability to raise significant capital from institutional investors provides us a cash runway to continue to fund our clinical development programs, specifically the NSI-189 Phase 2 MDD clinical trial," said Richard Daly, CEO. "We recently commenced our Phase 2 MDD trial which confirms the Company is on track to have results in the second half of 2017. We are committed to continue to execute our clinical and corporate strategy to create additional stakeholder value."

Small Molecule Pharmaceutical Compounds Clinical Development

Lead asset, NSI-189 Phase 2 clinical trial for the treatment of major depressive disorder (MDD)

- In March 2016, we commenced our NSI-189 Phase 2 clinical trial for the treatment of MDD, a double-blind, randomized, placebo-controlled, 220 subject study. For information on the trial please visit https://clinicaltrials.gov/show/NCT02695472.

Cell Therapy Platform Clinical Developments

- In January 2016, Karl Johe, Founder and Chief Scientific Officer, presented at the Phacilitate Cell & Gene Therapy World Conference. He concluded that the collective trial data analysis showed that our proprietary neural stems cells consistently demonstrated biological activity in all three program indications: amyotrophic lateral sclerosis (ALS), chronic spinal cord injury (cSCI), and motor deficits due to ischemic stroke.

NSI-566 Phase 1 safety trial for the treatment of cSCI

- In January 2016, the Company reported preliminary six-month follow-up Phase 1 safety data on all four subjects in the chronic spinal cord injury trial. The stem cell treatment demonstrated feasibility and safety. A self-reported ability to contract some muscles below the level of injury was confirmed via clinical and electrophysiological follow-up examinations in one of the four patients treated. This study was completed with the collaboration of the UCSD School of Medicine, supported by the UCSD Sanford Stem Cell Clinical Center; substantially all of the clinical costs of this study have been funded by grants arranged through the University.

NSI-566 Phase 1 and 2 safety trials for the treatment of amyotrophic lateral sclerosis (ALS)

- In September 2015, nine-month Phase 2 and combined Phase 1 and Phase 2 data on the NSI-566 trial in amyotrophic lateral sclerosis (ALS) was presented at the American Neurological Association Annual Meeting by the principal investigator, Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well tolerated.
- In January 2016, the Company announced that it is in discussions with various governmental, state and non-profit organizations regarding funding grants for the next trial. Initiation of the trial will be dependent upon significant funding from such sources.

NSI-566 Phase 1 safety trial for the treatment of motor deficits in stroke

- During the three months ended March 31, 2016, the company completed dosing the third of three planned cohorts, each cohort included three patients, for a total of nine patients in a Phase 1 open label, dose-escalation trial evaluating safety and the maximum tolerated dose. The trial is being conducted by Neuralstem China, at BaYi Brain Hospital in Beijing, China.

Results of Operations for the Quarter Ended March 31, 2016

Cash, cash equivalents and short-term investments on hand was approximately $7.6 million at March 31, 2015, compared to approximately $12.2 million at December 31, 2015. The decrease was primarily due to our ongoing operating expenses primarily related to preparations for the initiation of our NSI-189 Phase 2 clinical trial for the treatment of MDD.

On May 06, 2016, we closed a public offering of 20,000,000 shares of common stock and 20,000,000 common stock purchase warrants at a public offering price of $0.40 per each share and common stock purchase warrant. We received aggregate gross proceeds of $8.0 million and net proceeds of approximately $7,420,000 from the offering. Based upon our cash at March 31, 2016, and the proceeds from our May public offering, we expect to be able to fund our operations through December 31, 2016.

In the quarter ended March 31, 2016, we reported a net loss of approximately $6.6 million or $0.07 per share, compared to a loss of approximately $5.1 million or $0.06 per share in the first quarter of 2015. Our operating loss in the quarter ended March 31, 2016 was approximately $6.2 million compared to a loss of $4.6 million in the same quarter of 2015. The increase in operating loss was primarily attributable to the severance accrual and acceleration of stock based compensation expense related to the departure of our previous CEO. A decrease of approximately $0.1 million in research and development expense was offset by an increase of approximately $1.7 million in general and administrative expenses.

Research and development expenses decreased approximately $117,000 or 4% for the period ended March 31, 2016 compared to the comparable period of 2015 primarily as a result of a decrease in pre-clinical and clinical costs partially offset by an increase in headcount and stock based compensation.

General and administrative expenses increased approximately $1,737,000 or 121% for the period ended March 31, 2016 compared to the comparable period of 2015 primarily due to a severance accrual and increased stock based compensation resulting from the accelerated vesting of options, both related to the termination of our former Chief Executive Officer.

In addition, in the first quarter of 2016 we recognized approximately $0.4 million of other expenses primarily comprised of interest expenses related to our long-term debt.

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

	March 31, 2016	December 31, 2015

ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$7,620,746	$4,716,533
Short-term investments	-	7,517,453
Trade and other receivables	39,167	37,316
Prepaid expenses	1,077,762	1,159,782
Total current assets	8,737,675	13,431,084
Property and equipment, net	336,974	343,200
Patents, net	1,066,577	1,103,467
Other assets	57,692	71,797
Total assets	$10,198,918	$14,949,548
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$2,627,137	$1,455,826
Accrued bonuses	287,046	161,362
Current portion of long term debt, net of fees and discount	4,466,081	4,634,742
Other current liabilities	241,008	173,542
Total current liabilities	7,621,272	6,425,472
Long term debt, net of fees, discount and current portion	2,546,296	3,391,808
Other long term liabilities	200,739	164,990
Total liabilities	10,368,307	9,982,270

STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, $0.01 par value; 300 million shares authorized, 92,044,042 and 92,005,705 shares outstanding in 2016 and 2015, respectively	920,440	920,057
Additional paid-in capital	177,473,335	176,002,832
Accumulated other comprehensive income	1,298	3,071
Accumulated deficit	(178,564,462)	(171,958,682)
Total stockholders' equity (deficit)	(169,389)	4,967,278
Total liabilities and stockholders' equity (deficit)	$10,198,918	$14,949,548

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended March 31,	
	2016	**2015**
Revenues	$2,500	$2,917
Operating expenses:		
Research and development expenses	3,065,590	3,182,823
General and administrative expenses	3,170,522	1,433,074
Total operating expenses	6,236,112	4,615,897
Operating loss	(6,233,612)	(4,612,980)

Other income (expense):		
Interest income	11,136	13,569
Interest expense	(386,506)	(453,734)
Other income	3,199	-
Total other income (expense)	(372,171)	(440,165)
Net loss	$ (6,605,783)	$ (5,053,145)
Net loss per share - basic and diluted	$ (0.07)	$ (0.06)
Weighted average common shares outstanding - basic and diluted	92,009,782	89,654,634
Comprehensive loss:		
Net loss	$ (6,605,783)	$ (5,053,145)
Foreign currency translation adjustment	(1,773)	13
Comprehensive loss	$ (6,607,556)	$ (5,053,132)

About Neuralstem

Neuralstem's patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are being developed as potential therapies for multiple central nervous system diseases and conditions.

Neuralstem's ability to generate neural stem cell lines from human hippocampus, which were used for systematic chemical screening for neurogenesis effect, led to the discovery and patenting of molecules that Neuralstem believes may stimulate the brain's capacity to generate new neurons, potentially reversing pathophysiologies associated with certain central nervous system (CNS) conditions.

The Company has completed Phase 1a and 1b trials evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder (MDD), and is currently conducting a Phase 2 efficacy study for MDD.

Neuralstem's first stem cell product candidate, NSI-566, a spinal cord-derived neural stem cell line, is under

development for treatment of amyotrophic lateral sclerosis (ALS). Neuralstem has completed two clinical studies, in a total of 30 patients, which met primary safety endpoints.

In addition to ALS, NSI-566 is also in a Phase 1 study to treat paralysis due to chronic spinal cord injury, as well as in a Phase 1 study to treat paralysis from ischemic stroke.

Cautionary Statement Regarding Forward Looking Information:

This news release contains "forward-looking statements" made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements relate to future, not past, events and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include risks inherent in the development and commercialization of potential products, uncertainty of clinical trial results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of our intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in Neuralstem's periodic reports, including the Annual Report on Form 10-K for the year ended December 31, 2015, and filed with the Securities and Exchange Commission (SEC) on March 14, 2016, Form 10-Q for the period ended March 31, 2016, and in other reports filed with the SEC.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neuralstem-reports-fiscal-first-quarter-2016-results-and-business-update-300264839.html

SOURCE Neuralstem, Inc.