November 9, 2016

Intra-Cellular Therapies Reports Third Quarter 2016 Financial Results and Provides Corporate Update

NEW YORK, Nov. 09, 2016 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (NASDAQ:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today announced its financial results for the quarter ended September 30, 2016, and provided a corporate update.

Third Quarter 2016 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $30.3 million, or $0.70 per share (basic and diluted), for the third quarter of 2016 compared to a net loss of $32.2 million, or $0.91 per share (basic and diluted), for the third quarter of 2015.

Research and development (R&D) expenses for the third quarter of 2016 were $23.9 million, compared to $28.5 million for the third quarter of 2015. The decrease is primarily due to lower costs associated with the Company's second Phase 3 clinical trial for ITI-007 in patients with schizophrenia, which was completed during the third quarter of 2016, offset in part by costs associated with the Company's Phase 3 clinical trials of ITI-007 in patients with bipolar depression and dementia and increased manufacturing costs for ITI-007.

General and administrative (G&A) expenses were $6.3 million for the third quarter of 2016, compared to $3.9 million for the same period in 2015. The increase is primarily the result of higher stock-based compensation expense, and to a lesser extent, increases in professional fees, cost associated with pre-commercialization activities and salaries.

Cash and investments totaled $537.8 million at September 30, 2016. This amount included short-term borrowing of $125 million that was repaid in October 2016. The resulting net cash available for operations at September 30, 2016 was $412.8 million, compared to $475.2 million at December 31, 2015.

The Company expects that existing cash and investments will be dedicated primarily to the ITI-007 development program, including to fund clinical trials of ITI-007 in bipolar depression, behavioral disturbances in dementia, depressive disorders and other ITI-007 clinical trials, and related clinical and non-clinical activities; to fund pre-commercial activities for ITI-007 for the treatment of schizophrenia and, if ITI-007 receives regulatory approval, initial commercialization efforts; to fund pre-clinical and clinical development of the Company's ITI-007 long-acting injectable program; and to fund non-clinical activities including the continuation of manufacturing activities in connection with the development of ITI-007. Funds will also be used for other clinical and pre-clinical programs, including the Company's phosphodiesterase (PDE) development activities.

Recent and Upcoming Corporate Highlights

- In September 2016, the Company announced topline results from the 696 patient ITI-007-302 Phase 3 clinical trial in schizophrenia (Study ‘302). Recently, the Company presented data from its ITI-007 clinical development program in schizophrenia at the CNS Summit annual conference, including results from the recently completed Study ‘302. Presentations highlighted the findings from the overall clinical program in which the efficacy of ITI-007 60 mg has been replicated in two large, well-controlled clinical studies, ITI-007-005 (Study ‘005) and ITI-007-301 (Study ‘301), and found ITI-007 to be safe and well-tolerated in all three studies: Studies ‘005, ‘301, and ‘302. While ITI-007 60 mg did not separate from placebo in Study ‘302, the trajectory and the magnitude of improvement on the Positive and Negative Syndrome Scale (PANSS) total score from baseline was the same across all three trials, demonstrating a robust and consistent response. The difference was the placebo response, increasing in each successive trial, going from an approximate 7 point change from baseline to a 10 point change, to over 15 points in Study ‘302. In all three of these studies, ITI-007 was well-tolerated and exhibited a safety profile similar to placebo. In addition, in the studies where risperidone was used as an active control (Studies ‘005 and ‘302), ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters, including cholesterol, triglycerides, glucose, and prolactin.
- The Company believes that the two large, well-controlled positive studies (Studies ‘005 & ‘301) and supportive results from the third study (Study ‘302) collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia. We have requested a meeting with the FDA to discuss the submission of a New Drug Application (NDA) for the treatment of schizophrenia. We expect to provide an update on the status of our discussions with the FDA in the first quarter of 2017.
- Clinical conduct of the Company's Phase 3 programs in bipolar depression and in agitation and aggression associated with dementia, including Alzheimer's disease, is ongoing.

- The Company continues to advance its innovative phosphodiesterase (PDE) platform. The Company believes ITI-214, the lead compound in the PDE 1 portfolio, is the first selective PDE type 1 inhibitor to be tested in four Phase 1 clinical trials. We expect to advance ITI-214 into additional clinical development trials later this year or in early 2017 in both CNS and non-CNS indications.

"We are committed to bringing ITI-007 to patients suffering from schizophrenia, bipolar depression, dementia, and other neuropsychiatric and neurodegenerative conditions," said Dr. Sharon Mates, Chairman and CEO of ITCI. "Patients suffering from these conditions are in urgent need of new medications that are effective, safer, and better tolerated over standard of care. We are excited about the potential of ITI-007 to improve the lives of patients and their caregivers."

Conference Call and Webcast Details

The Company will host a live conference call and webcast today at 8:30 AM Eastern Time to discuss the Company's financial results and provide a corporate update. The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellulartherapies.com. Please connect to the Company's website at least 5-10 minutes prior to the live webcast to ensure adequate time for any necessary software download. Alternatively, please call 1-(844) 835-6563. (U.S.) or 1-(970) 315-3916 (international) to listen to the live conference call. The conference ID number for the live call is 2128890. Please dial in approximately 10 minutes prior to the call.

About Intra-Cellular Therapies

Intra-Cellular Therapies is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative diseases and diseases of the elderly, including Parkinson's and Alzheimer's disease. The Company is developing its lead drug candidate, ITI-007, for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. ITI-007, a first-in-class molecule, is in Phase 3 clinical development for the treatment of schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer's disease. The Company is also utilizing its phosphodiesterase platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders.

Forward-Looking Statements

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, our expected use of our cash, cash equivalents and investment securities; our beliefs about the extent to which the results of our clinical trials to date support an NDA filing for ITI-007 for the treatment of schizophrenia; the time period in which we expect to provide an update on the status of our discussions with the FDA; our clinical and non-clinical development plans; the progress, timing and results of our clinical trials; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of ITI-007; our beliefs about unmet medical needs and our research and development efforts and plans under the caption "About Intra-Cellular Therapies." All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include but are not limited to the following: our current and planned clinical trials, other studies for ITI-007, and our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,	
	2016 (1)	**2015** (1)
Revenues	**$ 4,362**	$ -

Costs and expenses:		
Research and development	**23,918,232**	28,457,631
General and administrative	**6,270,528**	3,891,744
Total costs and expenses	**30,188,760**	32,249,375
Loss from operations	**(30,184,398)**	32,349,375
Interest income, net	**751,689**	188,892
Net loss before income taxes	**(29,432,709)**	(32,160,483)
Income taxes	**(832,618)**	-
Net loss	**$ (30,265,327)**	$ (32,160,483)
Net loss per common share:		
Basic & Diluted	**$ (0.70)**	$ (0.91)
Weighted average number of common shares:		
Basic & Diluted	**43,253,429**	35,320,046

(1) The condensed consolidated statements of operations for the quarters ended September 30, 2016 and 2015 have not been audited and do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2016 (1) (Unaudited)	**December 31, 2015** (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 200,388,020**	$ 47,159,303
Investment securities, available-for-sale	**337,405,780**	428,041,021
Accounts receivable	**1,309**	30,660
Prepaid expenses and other current assets	**4,023,405**	8,025,147
Total current assets	**541,818,514**	483,256,131
Property and equipment, net	**677,703**	775,522
Other assets	**75,765**	71,875
Total assets	**$ 542,571,982**	$ 484,103,528
Liabilities and stockholders' equity		
Current liabilities:		
Borrowing under secured line of credit (2)	**$ 125,000,000**	$ --
Accounts payable	**5,417,451**	1,632,905
Accrued and other current liabilities	**7,520,073**	3,423,464
Accrued employee benefits	**2,752,381**	1,207,143
Total current liabilities	**140,689,905**	6,263,512
Long-term deferred rent	**2,563,809**	1,597,105
Total liabilities	**143,253,714**	7,860,617
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 43,268,243 and 43,155,875 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	**4,327**	4,316
Additional paid-in capital	**681,475,390**	669,878,103

Accumulated deficit	**(281,990,327)**	(193,049,098)
Accumulated comprehensive loss	**(171,122)**	(590,410)
Total stockholders' equity	**399,318,268**	476,242,911
Total liabilities and stockholders' equity	**$ 542,571,982**	$ 484,103,528

(1) The condensed consolidated balance sheets at September 30, 2016 and December 31, 2015 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

(2) This short term borrowing occurred during September 2016 and was repaid in full in October 2016.

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