



April 28, 2016

## **Intra-Cellular Therapies Reports First Quarter 2016 Financial Results and Provides Corporate Update**

NEW YORK, April 28, 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 March 31, 2016, and provided a corporate update.

### **First Quarter 2016 Financial Results**

Intra-Cellular Therapies (the Company) reported a net loss of \$27.8 million, or \$0.64 per share (basic and diluted), for the first quarter of 2016 compared to a net loss of \$22.3 million, or \$0.72 per share (basic and diluted), for the first quarter of 2015.

Research and development (R&D) expenses for the first quarter of 2016 were \$23.4 million, compared to \$18.6 million for the first quarter of 2015. The increase is primarily due to costs associated with the second Phase 3 clinical trial for ITI-007 in schizophrenia and, to a lesser extent, the Phase 3 trials of ITI-007 in bipolar depression.

General and administrative (G&A) expenses were \$5.1 million for the first quarter of 2016, compared to \$3.8 million for the same period in 2015. The increase is primarily the result of higher stock-based compensation expense and, to a lesser extent, increased salaries and professional fees.

Cash and investments totaled \$456.1 million at March 31, 2016, 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 schizophrenia, bipolar depression, behavioral disturbances in dementia, depressive disorders 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**

- | Clinical conduct in ITI-007-302, the second Phase 3 clinical trial of ITI-007 in schizophrenia, is progressing well. Patient enrollment is expected to be completed in the second quarter of 2016.
- | At the Schizophrenia International Research Society meeting (SIRS), the Company presented additional data from the positive Phase 3 study of ITI-007 and from the Positron Emission Tomography or PET study, in patients with schizophrenia. The Phase 3 data highlighted the positive results demonstrating a statistically significant improvement versus placebo in schizophrenia symptoms and a favorable safety and tolerability profile along with high completion rates seen in patients receiving ITI-007.
- | The Company's Phase 3 bipolar depression program is also progressing well. The bipolar program consists of two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials and includes patients with both bipolar I and bipolar II disorder. One trial will evaluate ITI-007 as a monotherapy and the other trial will evaluate ITI-007 as an adjunctive therapy with either lithium or valproate.
- | The Company plans to initiate its late-stage clinical program evaluating ITI-007 for the treatment of behavioral disturbances in patients with dementia, including Alzheimer's disease, in the second quarter of 2016.
- | 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 humans. ITI-214 has been studied in 4 Phase 1 clinical trials. In these studies, ITI-214 demonstrated a favorable safety profile and was generally well tolerated in both healthy volunteers and patients with schizophrenia. The Company will provide an update on the next steps for this program later this year.

"With the second ITI-007 Phase 3 clinical trial in schizophrenia nearing completion and our other late-stage clinical development programs moving forward, we are proud of our progress towards offering patients and their families new treatment options for those suffering from neuropsychiatric and neurologic diseases," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We believe ITI-007 represents a novel approach for the treatment of schizophrenia and other indications, and we will continue with our mission to address these significant unmet medical needs."

## 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 general business update. The live webcast and subsequent replay may be accessed by visiting the Company's website at [www.intracellulartherapies.com](http://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 91500459. 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 dementia, 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 and bipolar depression. 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 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; 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 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)

	<b>Three Months Ended March 31,</b>	
	<b>2016 (1)</b>	<b>2015 (1)</b>
Revenues	\$ —	\$ 3,315
Costs and expenses:		
Research and development	23,433,620	18,632,427
General and administrative	5,064,233	3,771,628
Total costs and expenses	<u>28,497,853</u>	<u>22,404,055</u>
Loss from operations	(28,497,853)	(22,400,740)
Interest expense	—	—
Interest income	656,404	113,916
Net loss	<u>\$ (27,841,449)</u>	<u>\$ (22,286,824)</u>



Burns McClellan, Inc.  
Lisa Burns  
Justin Jackson (Media)  
jjackson@burnsmc.com  
212-213-0006