



August 4, 2016

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

NEW YORK, Aug. 04, 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 June 30, 2016, and provided a corporate update.

Second Quarter 2016 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of \$30.8 million, or \$0.71 per share (basic and diluted), for the second quarter of 2016 compared to a net loss of \$21.5 million, or \$0.61 per share (basic and diluted), for the second quarter of 2015.

Research and development (R&D) expenses for the second quarter of 2016 were \$25.3 million, compared to \$17.8 million for the second quarter of 2015. The increase is primarily due to costs associated with the second Phase 3 clinical trial for ITI-007 in patients with schizophrenia and, to a lesser extent, the Phase 3 clinical trials of ITI-007 in bipolar depression.

General and administrative (G&A) expenses were \$6.5 million for the second quarter of 2016, compared to \$4.0 million for the same period in 2015. The increase is primarily the result of higher stock-based compensation expense and, to a lesser extent, pre-commercialization activities, increased salaries and professional fees.

Cash and investments totaled \$442.7 million at June 30, 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

- | Patient enrollment in ITI-007-302, the second Phase 3 clinical trial of ITI-007 in schizophrenia, was completed in the second quarter of 2016. The Company anticipates topline data from this trial will be available later this year.
- | The Company announced the advancement of ITI-007 into Phase 3 development for the treatment of agitation in patients with dementia, including Alzheimer's disease (AD). The ITI-007-201 trial is a Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation. In this trial, approximately 360 patients are planned to be randomized in a 1:1 ratio to receive ITI-007 9 mg or placebo orally once daily for four weeks.
- | Clinical conduct of the Company's Phase 3 bipolar depression program is ongoing. The bipolar program consists of two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials and includes patients with either bipolar I or 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 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 more details regarding its clinical development plans for this program later this year.
- | In the second quarter of 2016, the Company had a strong presence at scientific and medical conferences. The Company presented data from its two positive, previously-completed, late-stage clinical studies in schizophrenia, data from the ITI-007 Positron Emission Tomography, or PET study, in patients with schizophrenia and an overview of ITI-007's unique pharmacology. The data were highlighted at various scientific and medical conferences, including

meetings of the Schizophrenia International Research Society, or SIRS; the American Psychiatric Association, or APA; the Society of Biological Psychiatry, or SOBP; and the American Society of Clinical Psychopharmacology, or ASCP.

"It has been an exciting quarter with the completion of enrollment of our second ITI-007 Phase 3 clinical trial in patients with schizophrenia and the initiation of our Phase 3 clinical trial for the treatment of agitation in patients with dementia, including Alzheimer's disease," said Dr. Sharon Mates, Chairman and CEO of ITCI. "These major milestones mark another step forward in our mission to provide safer and better tolerated treatment options for patients suffering from neuropsychiatric and neurologic diseases. We believe ITI-007 represents an innovative therapeutic approach in the treatment of CNS disorders that has the potential to provide significant benefits to patients, caregivers and clinicians."

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 46135510. 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, 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 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 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 June 30,	
	2016 (1)	2015 (1)
Revenues	\$ 228,445	\$ 57,390
Costs and expenses:		
Research and development	25,300,668	17,762,518
General and administrative	6,471,804	3,985,797
Total costs and expenses	31,772,472	21,748,315

Loss from operations	(31,544,027)	(21,690,925)
Interest income	709,573	179,607
Net loss	<u>\$ (30,834,454)</u>	<u>\$ (21,511,318)</u>

Net loss per common share:

Basic & Diluted	\$ (0.71)	\$ (0.61)
Weighted average number of common shares:		
Basic & Diluted	43,239,708	35,002,819

(1) The condensed consolidated statements of operations for the quarters ended June 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

	June 30, 2016 (1)	December 31, 2015 (1)
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,972,773	\$ 47,159,303
Investment securities, available-for-sale	390,717,316	428,041,021
Accounts receivable	98,240	30,660
Prepaid expenses and other current assets	4,020,092	8,025,147
Total current assets	446,808,421	483,256,131
Property and equipment, net	718,659	775,522
Other assets	75,765	71,875
Total assets	<u>\$ 447,602,845</u>	<u>\$ 484,103,528</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,889,566	\$ 1,632,905
Accrued and other current liabilities	12,981,891	3,423,464
Accrued employee benefits	2,509,611	1,207,143
Total current liabilities	19,381,068	6,263,512
Long-term deferred rent	2,258,996	1,597,105
Total liabilities	21,640,064	7,860,617
Stockholders' equity:		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 43,250,266 and 43,155,875 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	4,325	4,316
Additional paid-in capital	677,623,643	669,878,103
Accumulated deficit	(251,725,000)	(193,049,098)
Accumulated comprehensive gain (loss)	59,813	(590,410)
Total stockholders' equity	425,962,781	476,242,911
Total liabilities and stockholders' equity	<u>\$ 447,602,845</u>	<u>\$ 484,103,528</u>

(1) The condensed consolidated balance sheets at June 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.

Contact:

Intra-Cellular Therapies, Inc.

Juan Sanchez, M.D.

Vice President, Corporate Communications and Investor Relations

646-440-9333

Burns McClellan, Inc.

Lisa Burns

Justin Jackson (Media)

jjackson@burnsmc.com

212-213-0006