



February 25, 2016

Intra-Cellular Therapies Reports Fourth Quarter and Full-Year 2015 Financial Results and Provides Corporate Update

NEW YORK, Feb. 25, 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 fourth quarter and year ended December 31, 2015, and provided a corporate update.

Selected Fourth Quarter and Year End 2015 Financial Results

Intra-Cellular Therapies (the Company) reported a net loss of \$28.8 million, or \$0.67 per share (basic and diluted), for the fourth quarter of 2015 compared to a net loss of \$15.2 million, or \$0.52 per share (basic and diluted), for the fourth quarter of 2014. The Company reported a net loss of \$104.8 million, or \$2.91 per share (basic and diluted), for the full year ended December 31, 2015 compared with a net loss of \$30.7 million, or \$1.07 per share (basic and diluted), for the full year ended December 31, 2014.

Research and development (R&D) expenses for the fourth quarter of 2015 were \$22.9 million, compared to \$11.6 million for the fourth quarter of 2014. For the full year ended December 31, 2015, R&D expenses were \$87.7 million, compared to \$21.2 million for the full year ended December 31, 2014. The increase year over year is primarily due to costs associated with the Phase 3 clinical development program for ITI-007 in schizophrenia, which was initiated in late 2014.

General and administrative (G&A) expenses were \$6.5 million for the fourth quarter of 2015, compared to \$3.7 million for the same period in 2014. For the full year ended December 31, 2015, G&A expenses were \$18.2 million, compared to \$10.3 million for the prior-year period. The increase is primarily the result of higher stock-based compensation expense and, to a lesser extent, bonuses and labor costs and state and local franchise and capital taxes.

Cash and investments totaled \$475.2 million at December 31, 2015, compared to \$129.6 million at December 31, 2014. During the third quarter of 2015, the Company completed a public offering of its common stock in which the Company raised approximately \$345.2 million in gross proceeds and approximately \$327.4 million in net proceeds. During the first quarter of 2015, the Company completed a public offering of its common stock in which the Company raised approximately \$129.9 million in gross proceeds and approximately \$121.8 million in net proceeds.

Corporate Highlights

ITI-007 Program

In 2015, the Company significantly advanced its ITI-007 development programs across multiple central nervous system disorders including treatments for schizophrenia, bipolar depression and behavioral disturbances in patients with dementia, including Alzheimer's disease.

- | Clinical conduct for the ITI-007-302 Phase 3 clinical trial in schizophrenia is ongoing. The Company expects patient enrollment will be completed in the second quarter of 2016.
- | In 2015, the Company announced positive results from the 450 patient ITI-007-301 Phase 3 clinical trial in schizophrenia. ITI-007, at a once-daily dose of 60 mg, met the primary and key secondary endpoints of the trial, demonstrating a statistically significant improvement versus placebo in schizophrenia symptoms with additional improvements observed in social function. In this Phase 3 trial, ITI-007 had a highly favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo. Additionally, ITI-007 showed an improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose but the effect with 40 mg did not reach statistical significance on the primary endpoint. The 40 mg dose demonstrated a statistically significant improvement versus placebo on secondary measures of efficacy. The results of this study are consistent with those described in the 2015 publication in the journal *Biological Psychiatry* describing the positive data from the Company's double-blind, placebo- and active-controlled Phase 2 clinical trial in 335 patients with schizophrenia (Lieberman et al., *Biological Psychiatry*, epub ahead of print, 2015).
- | In 2015, the Company announced results from an open-label ITI-007 positron emission tomography (PET) study in patients with schizophrenia. In this study, the dose of 60 mg of ITI-007 was associated with a mean peak striatal D2

receptor occupancy of approximately 40%, lower than that observed with most other antipsychotic drugs. We believe this differentiating pharmacological profile of ITI-007 likely contributes to its favorable clinical profile with motoric tolerability similar to placebo and without hyperprolactinemia. This confirms and builds on data from the Company's prior PET study of ITI-007 in healthy volunteers published in the journal *Psychopharmacology* in 2015 (Davis et al. *Psychopharmacology* (Berl). 2015 Aug). These human PET data further the Company's understanding of the unique mechanism of action of ITI-007 beyond data from the pre-clinical models also published in 2015 in *Psychopharmacology* (Snyder et al. *Psychopharmacology* (Berl). 2015 Feb).

- | In 2015, the Company initiated its Phase 3 clinical development program for ITI-007 in bipolar depression. The program consists of two Phase 3 clinical trials: ITI-007-401 to evaluate ITI-007 as a monotherapy and ITI-007-402 to evaluate ITI-007 as an adjunctive therapy to lithium or valproate. Both trials include patients with bipolar I or bipolar II disorder.
- | The Company plans to commence its clinical program evaluating ITI-007 for the treatment of behavioral disturbances in patients with dementia, including Alzheimer's disease in the first half of 2016.
- | In December 2015, the Company presented the positive results from the ITI-007-301 Phase 3 clinical trial and the PET study in patients with schizophrenia at the 54th Annual Meeting of the American College of Neuropsychopharmacology (ACNP).
- | The Company continues to advance its pre-clinical programs including its long acting injectable formulation of ITI-007.

PDE Program

- | The Company continues to advance its innovative, clinical stage, phosphodiesterase (PDE) platform. The lead compound in the PDE portfolio, ITI-214, is the first selective PDE type 1 inhibitor to be studied in humans. ITI-214 demonstrated a favorable safety profile and was generally well-tolerated in normal healthy volunteers and patients with schizophrenia across a broad range of doses in four completed Phase 1 clinical trials. The Company intends to pursue the development of its PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson's disease, cognition in Alzheimer's disease, cognition in schizophrenia and in other non-CNS indications.

Financial

- | In 2015, the Company received gross proceeds of approximately \$475 million and net proceeds of approximately \$449 million from two separate follow on offerings of its common stock. With the net proceeds from these offerings, the Company plans to fund primarily the ITI-007 late stage clinical development programs; pre-launch and, if regulatory approval is received, early commercial activities for ITI-007 for the treatment of schizophrenia; other clinical trials of ITI-007; the pre-clinical and clinical development of the ITI-007 long acting injectable program; and the continued clinical development of the PDE program, including ITI-214.

"The past year was very exciting for ITCI. With the positive Phase 3 data building on our previous Phase 2 study, the clinical profile of ITI-007 to date suggests broad efficacy for schizophrenia along with pro-social benefits and a placebo-like safety and tolerability profile. We also initiated our Phase 3 bipolar depression program for which we believe ITI-007 holds great value," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We look forward to announcing top-line data from our second Phase 3 clinical trial in schizophrenia later this year, and continue to advance our programs with the aim of improving the lives of patients suffering from neuropsychiatric and neurologic conditions, and the lives of 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 general business update. The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellularterapies.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 45850524. 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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015 (1)	2014 (1)
Revenues	\$ 30,659	\$ 65,862	\$ 91,364	\$ 577,301
Costs and expenses:				
Research and development	22,865,498	11,641,009	87,718,074	21,226,345
General and administrative	6,538,117	3,721,923	18,187,286	10,337,679
Total costs and expenses	<u>29,403,615</u>	<u>15,362,932</u>	<u>105,905,360</u>	<u>31,564,024</u>
Loss from operations	(29,372,956)	(15,297,070)	(105,813,996)	(30,986,723)
Interest income	540,040	99,540	1,022,455	303,936
Interest expense	—	—	—	(7,073)
Income taxes	(1,600)	(1,600)	(1,600)	(1,600)
Net loss	<u>\$ (28,834,516)</u>	<u>\$ (15,199,130)</u>	<u>\$ (104,793,141)</u>	<u>\$ (30,691,460)</u>
Net loss per common share:				
Basic & Diluted	\$ (0.67)	\$ (0.52)	\$ (2.91)	\$ (1.07)
Weighted average number of common shares:				
Basic & Diluted	43,052,117	29,431,302	36,069,237	28,650,067

(1) The condensed consolidated statements of operations for the years ended December 31, 2015 and 2014 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.

INTRA-CELLULAR THERAPIES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2015 (1)	December 31, 2014 (1)
	(Audited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 47,159,303	\$ 61,325,044
Investment securities, available-for-sale	428,041,021	68,320,672
Accounts receivable	30,660	51,603
Prepaid expenses and other current assets	8,025,147	1,288,953
Total current assets	483,256,131	130,986,272
Property and equipment, net	775,522	54,553
Other assets	71,875	70,944
Total assets	\$ 484,103,528	\$ 131,111,769
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,632,905	\$ 2,052,765
Accrued and other current liabilities	3,423,464	7,529,241
Accrued employee benefits	1,207,143	975,058
Total current liabilities	6,263,512	10,557,064
Long-term deferred rent	1,597,105	—
Total liabilities	7,860,617	10,557,064
Stockholders' equity:		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 43,155,875 and 29,499,059 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	4,316	2,950
Additional paid-in capital	669,878,103	208,912,345
Accumulated deficit	(193,049,098)	(88,255,957)
Accumulated comprehensive loss	(590,410)	(104,633)
Total stockholders' equity	476,242,911	120,554,705
Total liabilities and stockholders' equity	\$ 484,103,528	\$ 131,111,769

(1) The condensed consolidated balance sheets at December 31, 2015 and 2014 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.

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