Intra-Cellular Therapies Reports Third Quarter 2017 Financial Results and Provides Corporate Update

November 8, 2017

NEW YORK, Nov. 08, 2017 (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 third quarter ended September 30, 2017, and provided a corporate update.

Third Quarter 2017 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $22.9 million, or $0.53 per share (basic and diluted), for the third quarter of 2017 compared to a net loss of $30.3 million, or $0.70 per share (basic and diluted), for the third quarter of 2016.

Research and development (R&D) expenses for the third quarter of 2017 were $18.5 million, compared to $23.9 million for the third quarter of 2016. The decrease for the third quarter of 2017 is primarily due to lower costs associated with outside clinical and non-clinical activities in the 2017 period. In the third quarter of 2016, outside costs were incurred primarily for the second Phase 3 clinical trial of lumateperone in patients with schizophrenia, which was completed in 2016. In the third quarter of 2017, outside costs were incurred primarily for the Phase 3 clinical trials of lumateperone in patients with bipolar depression and dementia and other lumateperone related trials.

General and administrative (G&A) expenses were $5.3 million for the third quarter of 2017, compared to $6.3 million for the same period in 2016. The decrease is primarily the result of decreased stock option expense incurred in the third quarter of 2017 and legal fees incurred in the third quarter of 2016 for costs relating to the license of certain intellectual property by us to our wholly-owned subsidiary ITI Limited.

Cash, cash equivalents and investment securities totaled $328.1 million at September 30, 2017, compared to $384.1 million at December 31, 2016. In October 2017, the Company raised gross proceeds of approximately $172.5 million with net proceeds of $162 million in a public offering of its common stock.

The Company expects that cash, cash equivalents and investment securities of $328.1 million at September 30, 2017 along with the $162 million of net proceeds from the public offering of its common stock in October 2017 will be used primarily to advance the lumateperone development program, including to fund clinical trials of lumateperone in bipolar depression, behavioral disturbances in patients with dementia, depressive disorders and other lumateperone clinical trials and related clinical and non-clinical activities; to fund pre-commercial activities for lumateperone for the treatment of schizophrenia and bipolar disorder and, if lumateperone receives regulatory approval, initial commercialization efforts; to fund pre-commercial activities for lumateperone for the treatment of behavioral disturbances in patients with dementia, including Alzheimer's disease; 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 lumateperone. Funds will also be used for other clinical and pre-clinical programs, including the Company's phosphodiesterase (PDE) development activities.

Corporate Update

- We announced positive topline data from our 6-week open-label safety switching study with lumateperone in patients with schizophrenia. This trial evaluated stable patients with schizophrenia in an outpatient setting similar to common clinical practice and assessed both the impact of switching to lumateperone from standard-of-care (SOC) antipsychotics as well as the impact of switching back to SOC from lumateperone. Unlike many other antipsychotic drugs, patients were switched from SOC without the need for dose titration for lumateperone; patients received the active dose on the first day of treatment. In this trial, statistically significant improvements from SOC were observed in body weight, cardiometabolic and endocrine parameters in patients with stable symptoms of schizophrenia when switched to lumateperone and worsened again when switched back to SOC medication. These data are consistent with previous study results reflecting a safety profile similar to placebo in placebo-controlled trials with lumateperone in patients with acutely exacerbated schizophrenia and extend this favorable safety profile to this stable patient population. In this study, symptoms of schizophrenia did not worsen upon switch to lumateperone from SOC. Rather, statistically significant improvement from baseline was observed in the Positive and Negative Syndrome Scale (PANSS) mean total score. Notably, greater improvements were observed in subgroups of patients with elevated symptomatology such as those with comorbid symptoms of depression and those with prominent negative symptoms.

- We announced that following U.S. Food and Drug Administration (FDA) guidance received earlier this year regarding our planned new drug application (NDA), we intend to submit an NDA for lumateperone for the treatment of schizophrenia by mid-2018.

- We continue to advance our Phase 3 programs of lumateperone in bipolar depression and in agitation associated with dementia, including Alzheimer's disease. Our lumateperone bipolar depression program consists of three Phase 3 clinical trials: a monotherapy study conducted in the United States, an adjunctive study conducted in the United States and a global monotherapy study. We expect to complete patient enrollment in our bipolar studies in 2018.

- We recently initiated a Phase 1/2 randomized, double-blind, placebo-controlled, multiple rising dose clinical trial to evaluate ITI-214, our PDE1 inhibitor, in patients with Parkinson's disease (PD). The primary objective is to evaluate the safety and tolerability of ITI-214 in patients with mild to moderate PD who are maintained on stable PD therapy. Secondary objectives are to evaluate the pharmacokinetic profile of ITI-214 and explore its potential utility to control motor fluctuations and to evaluate treatment of non-motor symptoms (daytime sleepiness, dysautonomia) associated with PD. Biomarkers of disease progression (inflammation) will be assessed. We expect to complete patient enrollment in this trial by mid-2018.

"During the past few months, we made significant progress in our mission to provide better treatment options for patients suffering from neuropsychiatric and neurodegenerative conditions," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We look forward to continuing our efforts to develop lumateperone for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia and additional indications and to advance our PDE1 inhibitor platform."

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 13757899. 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, lumateperone (also known as 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. Lumateperone, 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 (PDE) platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders. The lead molecule in the Company's PDE1 portfolio, ITI-214, is in development for the treatment of symptoms associated with Parkinson's disease.

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 a new drug application (NDA) filing for lumateperone for the treatment of schizophrenia and our expectations about the timing of such NDA filing; our plans and the expected timing for the completion of enrollment of our ongoing Phase 3 trials in bipolar depression; our development plans for our PDE program, including ITI-214, and our ITI-007 long acting injectable program, including the expected timing for completion of patient enrollment in our Phase 1/2 trial of ITI-214; 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 lumateperone, and our other product candidates may not be successful or may take longer and be more costly than anticipated; if we are unable to complete our long-term safety study or the results of our long-term safety study do not demonstrate the safety and tolerability of long-term use of lumateperone, we would not be able to file an NDA for lumateperone for a chronic condition such as schizophrenia; 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.

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INTRA-CELLULAR THERAPIES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,			
	2017 (1)		**2016** (1)	
Revenues	**$ 30,754**		$ 4,362	
Costs and expenses:				
Research and development	**18,472,372**		23,918,232	
General and administrative	**5,317,577**		6,270,528	
Total costs and expenses	**23,789,949**		30,188,760	
Loss from operations	**(23,759,195**	**)**	(30,184,398	)
Interest expense	**—**		(12,260	)
Interest income	**884,763**		763,949	
Loss before provision for income taxes	**(22,874,432**	**)**	(29,432,709	)
Income tax benefit (expense)	**4,016**		(832,618	)
Net loss	**$ (22,870,416**	**)**	$ (30,265,327	)
Net loss per common share:				
Basic & Diluted	**$ (0.53**	**)**	$ (0.70	)

Weighted average number of common shares:		
Basic & Diluted	**43,424,387**	43,253,429

(1) The condensed consolidated statements of operations for the quarters ended September 30, 2017 and 2016 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, 2017 (1)	December 31, 2016 (1)
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 52,340,519**	$ 48,642,225
Investment securities, available-for-sale	**275,781,285**	335,458,459
Accounts receivable	**6,309**	94,339
Prepaid expenses and other current assets	**5,307,357**	4,005,093
Total current assets	**333,435,470**	388,200,116
Property and equipment, net	**679,606**	627,614
Other assets	**75,765**	75,765
Total assets	**$ 334,190,841**	$ 388,903,495
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**4,407,655**	3,754,647
Accrued and other current liabilities	**4,151,120**	5,329,293
Accrued employee benefits	**3,316,378**	1,448,394
Total current liabilities	**11,875,153**	10,532,334
Long-term deferred rent	**2,875,612**	2,868,622
Total liabilities	**14,750,765**	13,400,956
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 43,427,344 and 43,292,906 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	**4,342**	4,329
Additional paid-in capital	**696,695,317**	685,290,815
Accumulated deficit	**(377,040,068)**	(309,475,366)
Accumulated comprehensive loss	**(219,515)**	(317,239)
Total stockholders' equity	**319,440,076**	375,502,539
Total liabilities and stockholders' equity	**$ 334,190,841**	$ 388,903,495

(1) The condensed consolidated balance sheets at September 30, 2017 and December 31, 2016 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.

Source: Intra-Cellular Therapies Inc.