March 1, 2017

Intra-Cellular Therapies Reports Fourth Quarter and Full-Year 2016 Financial Results and Provides Corporate Update

NEW YORK, March 01, 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 fourth quarter and year ended December 31, 2016, and provided a corporate update.

Selected Fourth Quarter and Year End 2016 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $27.5 million, or $0.64 per share (basic and diluted), for the fourth quarter of 2016 compared to a net loss of $28.8 million, or $0.67 per share (basic and diluted), for the fourth quarter of 2015. The Company reported a net loss of $116.4 million, or $2.69 per share (basic and diluted), for the full year ended December 31, 2016 compared with a net loss of $104.8 million, or $2.91 per share (basic and diluted), for the full year ended December 31, 2015.

Research and development (R&D) expenses for the fourth quarter of 2016 were $21.2 million, compared to $22.9 million for the fourth quarter of 2015. For the full year ended December 31, 2016, R&D expenses were $93.8 million, compared to $87.7 million for the full year ended December 31, 2015. The decrease for the quarter is primarily due to lower costs associated with the completion of the second Phase 3 clinical trial for lumateperone (also known as ITI-007) in patients with schizophrenia in the third quarter of 2016, offset in part by the costs of the Phase 3 clinical trials of lumateperone for the treatment of bipolar depression and agitation associated with dementia, including Alzheimer's disease, and other clinical trials and increased manufacturing costs for lumateperone. The increase for the year is primarily due to an increase in manufacturing and labor related costs, offset in part by lower clinical trial related costs. There were decreased costs in 2016 for the first Phase 3 clinical trial for lumateperone in patients with schizophrenia that was completed in 2015. These lower costs were offset primarily by increased costs for the second Phase 3 clinical trial for lumateperone in patients with schizophrenia completed in the third quarter of 2016, along with the costs associated with the Phase 3 clinical trials of lumateperone for the treatment of bipolar depression and agitation associated with dementia, including Alzheimer's disease, and other clinical trials.

General and administrative (G&A) expenses were $7.0 million for the fourth quarter of 2016, compared to $6.5 million for the same period in 2015. For the full year ended December 31, 2016, G&A expenses were $24.8 million, compared to $18.2 million for the prior-year period. The increase in both periods is primarily the result of higher stock-based compensation expense and, to a lesser extent, professional fees, pre-commercialization activities and increased salaries.

Cash and investments totaled $384.1 million at December 31, 2016, compared to $475.2 million at December 31, 2015.

The Company expects that existing cash and investments of $384.1 million 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, if lumateperone 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 lumateperone. Funds will also be used for other clinical and pre-clinical programs, including the Company's phosphodiesterase (PDE) development activities.

Corporate Update

- We have a meeting scheduled with the FDA in late March 2017 to discuss the submission of a New Drug Application (NDA) for lumateperone for the treatment of schizophrenia. We expect to provide an update on the status of our discussions following this meeting.
- We had a positive pre-NDA meeting with the FDA regarding the Chemistry, Manufacturing and Controls (CMC) data package. Additionally, we have signed a long-term agreement with a third party manufacturer for the supply of lumateperone in commercial quantities.
- We presented the results from the lumateperone clinical development program in schizophrenia at the 55th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) and at CNS Summit.
- We plan to present additional data on our development programs at several upcoming scientific and medical conferences including the International Congress on Schizophrenia Research (ICOSR), the Society of Biological

Psychiatry (SOBP), the American Psychiatric Association (APA), the International Society for Bipolar Disorders (ISBD) and the International College of Neuropsychopharmacology (CINP).

- Clinical conduct in our Phase 3 programs in bipolar depression and in agitation associated with dementia, including Alzheimer's disease, is ongoing. We continue to employ a number of strategies designed to ensure we recruit appropriately diagnosed patients in an effort to reduce the risk of a high placebo response. Patient enrollment in our Phase 3 bipolar depression monotherapy study, or Study ‘401, is expected to be completed in the first half of 2018. Patient enrollment in our Phase 3 bipolar depression adjunctive study, or Study ‘402, is expected to be completed in the second half of 2018. One of our strategies to optimize potential success in this program is to initiate a third trial in bipolar depression conducted globally. We anticipate patient enrollment in our global study to complete by the end of 2018.
- We continue to advance our innovative PDE platform. ITI-214, the lead molecule in our PDE-1 program, has been shown to be safe and well-tolerated in four Phase 1 clinical trials to date in healthy volunteers as well as patients with schizophrenia. In the first half of 2017, we expect to initiate a Phase 1/2 clinical trial with ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population as well as motor and non-motor exploratory endpoints. We continue to explore additional indications for our PDE1 inhibitors, including opportunities to advance the program into other CNS and non-CNS therapeutic areas, including cardiovascular diseases.
- We continue to advance our pre-clinical programs including our ITI-007 long acting injectable program and we expect this program to enter clinical development in 2018.

"Patients who suffer from neuropsychiatric and neurodegenerative disorders continue to be underserved by existing medications and we remain committed to developing innovative treatments that can provide broad efficacy without many of the safety and tolerability issues associated with current therapies," said Dr. Sharon Mates, Chairman and CEO of ITCI.

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 72927263. 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 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 lumateperone 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 initiation, 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 lumateperone; our plans to present additional data on our development programs; 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 and other studies for lumateperone and for 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016(1)**	**2015(1)**
Revenues	**$ 97,895**	$ 30,659	**$ 330,702**	$ 91,364
Costs and expenses:				
Research and development	**21,179,010**	22,865,498	**93,831,530**	87,718,074
General and administrative	**6,951,498**	6,538,117	**24,758,063**	18,187,286
Total costs and expenses	**28,130,508**	29,403,615	**118,589,593**	105,905,360
Loss from operations	**(28,032,613)**	(29,372,956)	**(118,258,891)**	(105,813,996)
Interest income	**(805,150)**	(540,040)	**(2,935,077)**	(1,022,455)
Interest expense	**24,521**	—	**36,781**	—
Income taxes	**233,055**	1,600	**1,065,673**	1,600
Net loss	**$ (27,485,039)**	$(28,834,516)	**$ (116,426,268)**	$(104,793,141)
Net loss per common share:				
Basic & Diluted	**$ (0.64)**	$ (0.67)	**$ (2.69)**	$ (2.91)
Weighted average number of common shares:				
Basic & Diluted	**43,272,233**	43,052,117	**43,240,188**	36,069,237

(1) The condensed consolidated statements of operations for the years ended December 31, 2016 and 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.

INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2016 (1)	**December 31, 2015** (1)
	(Audited)	**(Audited)**
Assets		

Current assets:		
Cash and cash equivalents	**$ 48,642,225**	$ 47,159,303
Investment securities, available-for-sale	**335,458,459**	428,041,021
Accounts receivable	**94,339**	30,660
Prepaid expenses and other current assets	**4,005,093**	8,025,147
Total current assets	**388,200,116**	483,256,131
Property and equipment, net	**627,614**	775,522
Other assets	**75,765**	71,875
Total assets	**$ 388,903,495**	$ 484,103,528
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**3,754,647**	1,632,905
Accrued and other current liabilities	**5,329,293**	3,423,464
Accrued employee benefits	**1,448,394**	1,207,143
Total current liabilities	**10,532,334**	6,263,512
Long-term deferred rent	**2,868,622**	1,597,105
Total liabilities	**13,400,956**	7,860,617
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 43,292,906 and 43,155,875 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	**4,329**	4,316
Additional paid-in capital	**685,290,815**	669,878,103
Accumulated deficit	**(309,475,366)**	(193,049,098)
Accumulated comprehensive loss	**(317,239)**	(590,410)
Total stockholders' equity	**375,502,539**	476,242,911
Total liabilities and stockholders' equity	**$ 388,903,495**	$ 484,103,528

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