August 9, 2017

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

NEW YORK, Aug. 09, 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 second quarter ended June 30, 2017, and provided a corporate update.

Second Quarter 2017 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $17.8 million, or $0.41 per share (basic and diluted), for the second quarter of 2017 compared to a net loss of $30.8 million, or $0.71 per share (basic and diluted), for the second quarter of 2016.

Research and development (R&D) expenses for the second quarter of 2017 were $12.5 million, compared to $25.3 million for the second quarter of 2016. The decrease for the second quarter of 2017 is primarily due to lower costs associated with outside clinical and non-clinical costs. In the second quarter of 2016, outside costs were incurred primarily for the ITI-007-302 clinical trial of lumateperone in patients with schizophrenia, which was completed in 2016. In the second 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 $6.3 million for the second quarter of 2017, compared to $6.5 million for the same period in 2016. The decrease is primarily the result of higher professional fees in the second quarter of 2016.

Cash, cash equivalents and investment securities totaled $342.6 million at June 30, 2017, compared to $384.1 million at December 31, 2016.

The Company expects that existing cash, cash equivalents and investment securities of $342.6 million at June 30, 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, 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 submitted responses to the U.S. Food and Drug Administration (FDA) following its request for additional information related to nonclinical toxicology findings in certain animal studies with lumateperone. Discussions with the FDA are ongoing. We and our expert consultants believe these nonclinical findings are not indicative of a safety risk for humans due to species differences in the metabolism of lumateperone.

- Lumateperone's potential as a potent and rapid antidepressant in a range of mood disorders including bipolar depression was elaborated in presentations at the 19th Annual Conference of the International Society for Bipolar Disorders (ISBD) and at the International College of Neuropsychopharmacology (CINP) thematic meeting on treatment resistant depression. At these meetings, we shared data demonstrating that lumateperone, as a standalone agent, indirectly enhances glutamatergic neurotransmission through both AMPA and NMDA channels in the prefrontal cortex. Additionally, we presented data demonstrating that lumateperone increases protein phosphorylation of key proteins in the mTOR pathway. These findings, in addition to the potent SERT activity previously described with lumateperone, suggest the potential for lumateperone to exhibit potent and rapid antidepressant effects in patients suffering from a range of mood disorders.

- Additional data on our development programs were presented at other scientific and medical conferences including the American Psychiatric Association (APA), the American Society of Clinical Psychopharmacology (ASCP), and the Alzheimer's Association International Conference (AAIC). At these conferences, we presented an overview of the clinical development program for lumateperone, including safety and efficacy data. In addition, we presented pre-clinical and Phase 1 clinical data supporting the development of ITI-214 and the rationale behind ITI-214's potential

for the treatment of CNS indications. Pre-clinical data has demonstrated anti-inflammatory properties of ITI-214, and as such, ITI-214 may be disease modifying in neurodegenerative disorders, including Parkinson's and Alzheimer's disease. We also presented our novel preclinical compound ITI-333, or ‘triple three', which has exhibited a three-pronged mechanism of action with high affinity at serotonin 5-HT2A, dopamine D1 and mu opiate receptors. This unique pharmacological profile is predicted to translate into clinical utility to address symptoms associated with mood disorders and substance abuse, with particular potential importance for patients with both substance use disorders and psychiatric comorbidities including depression and anxiety.

- In the upcoming months, we will present on our development programs at scientific and medical conferences including the 30th European College of Neuropsychopharmacology (ECNP) Congress, the World Psychiatric Association (WPA) Congress, and the 10th Clinical Trials on Alzheimer's Disease (CTAD) Meeting.

- We continue to advance our Phase 3 programs of lumateperone in bipolar depression and in agitation associated with dementia, including Alzheimer's disease. Patient enrollment in these studies is ongoing. We are initiating a second bipolar depression monotherapy trial, Study ‘404, to be conducted globally.

- We continue to advance our innovative PDE platform. Following the positive safety and tolerability results in our Phase 1 program, we have initiated our development program for ITI-214 for Parkinson's disease. We expect to commence patient enrollment shortly in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as explore motor and non-motor symptom benefit.

"We are committed to developing novel treatments for patients suffering from neuropsychiatric and neurodegenerative diseases. We continue to advance lumateperone and our diverse drug development pipeline to better meet the needs of patients and their caregivers," said Dr. Sharon Mates, Chairman and CEO of ITCI.

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 a new drug application (NDA) filing for lumateperone for the treatment of schizophrenia; our belief that the toxicity findings observed in nonclinical animal toxicology studies of lumateperone are not indicative of a safety risk for humans; our ability to address the FDA's questions about the toxicity findings observed in nonclinical animal toxicology studies of lumateperone and provide evidence satisfactory to the FDA that the toxicities observed in these nonclinical animal toxicology studies of lumateperone are not indicative of a safety risk for humans; our ability to proceed with our long-term safety study and to file an NDA with the FDA; our beliefs about lumateperone's potential as a potent and rapid antidepressant in a range of mood disorders; our beliefs and predictions about the clinical utility of ITI-333; our plans to continue to advance our ongoing Phase 3 trials of lumateperone in bipolar depression, including the initiation of Study ‘404, and in agitation associated with dementia, including Alzheimer's disease,; our development plans for our PDE program, including our plans to commence patient enrollment in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease; our plans to present additional data on our development programs at several upcoming scientific and medical conferences; 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: the FDA may place our long-term safety study on a clinical hold, which would delay or prevent us from completing the safety study and from filing an NDA; 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; 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.

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

	Three Months Ended June 30,	
	2017 (1)	**2016** (1)
Revenues	**$ 114,741**	$ 228,445
Costs and expenses:		
Research and development	**12,478,638**	25,300,668
General and administrative	**6,254,616**	6,471,804
Total costs and expenses	**18,733,254**	31,772,472
Loss from operations	**(18,618,513)**	(31,544,027)
Interest income	**857,809**	709,573
Loss before provision for income taxes	**(17,760,704)**	(30,834,454)
Income tax expense	**—**	—
Net loss	**$ (17,760,704)**	$ (30,834,454)
Net loss per common share:		
Basic & Diluted	**$ (0.41)**	$ (0.71)
Weighted average number of common shares:		
Basic & Diluted	**43,419,798**	43,239,708

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

	June 30, 2017 (1)	December 31, 2016 (1)
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 29,590,446**	$ 48,642,225
Investment securities, available-for-sale	**313,037,669**	335,458,459
Accounts receivable	**61,935**	94,339
Prepaid expenses and other current assets	**6,144,819**	4,005,093
Total current assets	**348,834,869**	388,200,116
Property and equipment, net	**628,901**	627,614
Other assets	**75,765**	75,765
Total assets	**$ 349,539,535**	$ 388,903,495
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**1,775,252**	3,754,647
Accrued and other current liabilities	**2,781,198**	5,329,293
Accrued employee benefits	**2,406,269**	1,448,394
Total current liabilities	**6,962,719**	10,532,334
Long-term deferred rent	**2,911,092**	2,868,622

Total liabilities	**9,873,811**	13,400,956
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 43,424,321 and 43,292,906 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	**4,342**	4,329
Additional paid-in capital	**694,146,861**	685,290,815
Accumulated deficit	**(354,169,652)**	(309,475,366)
Accumulated comprehensive loss	**(315,827)**	(317,239)
Total stockholders' equity	**339,665,724**	375,502,539
Total liabilities and stockholders' equity	**$ 349,539,535**	$ 388,903,495

(1) The condensed consolidated balance sheets at June 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.

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