May 10, 2017

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

NEW YORK, May 10, 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 first quarter ended March 31, 2017, and provided a corporate update.

First Quarter 2017 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $26.9 million, or $0.62 per share (basic and diluted), for the first quarter of 2017 compared to a net loss of $27.8 million, or $0.64 per share (basic and diluted), for the first quarter of 2016.

Research and development (R&D) expenses for the first quarter of 2017 were $21.5 million, compared to $23.4 million for the first quarter of 2016. The decrease for the first quarter of 2017 is primarily due to lower costs associated with outside clinical and non-clinical costs. In the first 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 first quarter of 2017, outside costs were incurred 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 first quarter of 2017, compared to $5.1 million for the same period in 2016. The increase is primarily the result of state franchise tax expense and, to a lesser extent, increased stock-based compensation expense, salaries and professional fees.

Cash, cash equivalents and and investment securities totaled $367.8 million at March 31, 2017, compared to $384.1 million at December 31, 2016.

The Company expects that existing cash, cash equivalents and investment securities of $367.8 million at March 31, 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 requested guidance from the U.S. Food and Drug Administration (FDA) on the acceptability of our two positive, large well-controlled schizophrenia efficacy trials (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from our third trial, Study ITI-007-302, as the basis for the submission of a new drug application (NDA) for the treatment of schizophrenia. We are pleased that the FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date. The FDA has raised questions, however, relating to certain findings observed in nonclinical animal toxicology studies of lumateperone and has requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. We and our expert consultants believe these findings are not indicative of a safety risk for humans due to species differences in the metabolism of lumateperone. We are preparing responses to the FDA's request for additional information.
- We presented the scientific basis for the ongoing Phase 3 clinical investigation of lumateperone as a treatment for bipolar depression at the 19th Annual Conference of the International Society for Bipolar Disorders (ISBD). Our presentations at ISBD focused on the unique pharmacology of lumateperone and included both preclinical and clinical data, supporting its development for the treatment of bipolar depression. New preclinical data demonstrate that lumateperone as a standalone agent uniquely potentiates neurotransmission through both AMPA and NMDA channels — mechanisms thought to predict potent and rapid antidepressant effect. We also recently demonstrated that lumateperone regulates phosphorylation of key proteins in the mTOR pathway, similar to ketamine which has shown rapid antidepressant effects, yet lumateperone has not been associated with ketamine-like safety concerns. These exciting 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 including bipolar depression, major depressive disorder (MDD) and treatment-resistant depression (TRD).

- We will present additional data on our development programs at several upcoming scientific and medical conferences including the Society of Biological Psychiatry (SOBP), the American Psychiatric Association (APA), the American Society of Clinical Psychopharmacology (ASCP), and the International College of Neuropsychopharmacology (CINP).
- Clinical conduct in our Phase 3 programs of lumateperone in bipolar depression and in agitation associated with dementia, including Alzheimer's disease, is ongoing. 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. We also plan to initiate a global bipolar depression trial.
- 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 in healthy volunteers as well as patients with schizophrenia. We are initiating a Phase 1/2 clinical trial 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.

"We, at ITCI, are committed to developing innovative treatments that can provide broad efficacy without many of the safety and tolerability issues associated with current therapies thereby reducing the burden on 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 an 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 plans for the completion of enrollment of our ongoing Phase 3 trials in bipolar depression and our plans to initiate a global bipolar depression trial; our development plans for our PDE program, including ITI-214, and our ITI-007 long acting injectable program; 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 March 31,	
	2017 (1)	**2016** (1)
Revenues	**$ 95,287**	$ —
Costs and expenses:		
Research and development	**21,538,958**	23,433,620
General and administrative	**6,310,486**	5,064,233
Total costs and expenses	**27,849,444**	28,497,853
Loss from operations	**(27,754,157)**	(28,497,853)
Interest income	**822,175**	656,404
Loss before provision for income taxes	**(26,931,982)**	(27,841,449)
Income tax expense	**1,600**	—
Net loss	**$ (26,933,582)**	$ (27,841,449)
Net loss per common share:		
Basic & Diluted	**$ (0.62)**	$ (0.64)
Weighted average number of common shares:		
Basic & Diluted	**43,385,605**	43,193,857

(1) The condensed consolidated statements of operations for the quarters ended March 31, 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

	March 31, 2017 (1)	December 31, 2016 (1)
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 23,598,325**	$ 48,642,225
Investment securities, available-for-sale	**344,183,051**	335,458,459
Accounts receivable	**68,200**	94,339
Prepaid expenses and other current assets	**3,761,282**	4,005,093
Total current assets	**371,610,858**	388,200,116
Property and equipment, net	**605,683**	627,614
Other assets	**75,765**	75,765
Total assets	**$ 372,292,306**	$ 388,903,495
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**7,157,746**	3,754,647
Accrued and other current liabilities	**7,039,115**	5,329,293
Accrued employee benefits	**2,121,795**	1,448,394
Total current liabilities	**16,318,656**	10,532,334
Long-term deferred rent	**2,946,573**	2,868,622
Total liabilities	**19,265,229**	13,400,956
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized;		

43,415,728 and 43,292,906 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	**4,342**	4,329
Additional paid-in capital	**689,723,391**	685,290,815
Accumulated deficit	**(336,408,948)**	(309,475,366)
Accumulated comprehensive loss	**(291,708)**	(317,239)
Total stockholders' equity	**353,027,077**	375,502,539
Total liabilities and stockholders' equity	**$ 372,292,306**	$ 388,903,495

(1) The condensed consolidated balance sheets at March 31, 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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