

Intra-Cellular Therapies Reports First Quarter 2018 Financial Results and Provides Corporate Update

May 3, 2018

NEW YORK, May 03, 2018 (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, 2018 and provided a corporate update.

First Quarter 2018 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of \$35.5 million, or \$0.65 per share (basic and diluted), for the first quarter of 2018 compared to a net loss of \$26.9 million, or \$0.62 per share (basic and diluted), for the first quarter of 2017.

Research and development (R&D) expenses for the first quarter of 2018 were \$30.7 million, compared to \$21.5 million for the first quarter of 2017. The increase for the first quarter of 2018 is primarily due to an increase of approximately \$5.9 million of outside clinical and non-clinical costs. 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. In the first quarter of 2018, outside costs were incurred for the Phase 3 clinical trials of lumateperone in patients with bipolar depression and dementia and other lumateperone related trials, manufacturing costs and development costs for our phosphodiesterase (PDE) program.

General and administrative (G&A) expenses were \$6.4 million for the first quarter of 2018, compared to \$6.3 million for the same period in 2017. The comparative increase is primarily due to a minimal increase in labor and pre-commercialization costs, offset in part by lower stock compensation expense.

Cash, cash equivalents and investment securities totaled \$437.0 million at March 31, 2018, compared to \$464.3 million at December 31, 2017.

The Company expects that its cash, cash equivalents and investment securities of \$437.0 million as of March 31, 2018 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 preclinical 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. The Company expects funds will also be used for other clinical and preclinical programs, including the Company's PDE development activities including its PDE-1 inhibitor, ITI-214 for the treatment of Parkinson's disease (PD) and other disorders.

"We are pleased with our progress in preparing our NDA submission for lumateperone for the treatment of schizophrenia. We remain on track and expect to complete our submission in mid-2018. We also continue to advance pre-commercial activities for lumateperone as well as our programs in bipolar depression and agitation in patients with dementia," said Dr. Sharon Mates, Chairman and CEO of ITCI. "Moreover, our development pipeline continues to be strengthened with the planned expansion of the lumateperone development program into additional therapeutic areas, such as depressive disorders, and the advancement of ITI-214 in PD and other disorders and ITI-333 for the treatment of substance use disorders as we strive to improve the lives of patients and their families."

Corporate Update

Lumateperone Programs

- We had a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in late Q1 2018 and reached agreement on the timing and content of a rolling NDA submission for lumateperone for the treatment of schizophrenia. We expect to complete the NDA submission in mid-2018.
- We presented data on lumateperone at the Schizophrenia International Research Society meeting (SIRS); our presentations included additional data from our open-label safety switching study for lumateperone in patients with stable schizophrenia and a review of our lumateperone schizophrenia program. We also presented supporting data for our lumateperone program in agitation in patients with dementia at the Advances in Alzheimer's and Parkinson's Therapies Focus Meeting.
- We will present additional data on lumateperone and other development programs at several upcoming scientific and medical conferences, including the American Psychiatric Association (APA), the Society of Biological Psychiatry (SOBP), the American Society of Clinical Psychopharmacology (ASCP), and the International College of Neuropsychopharmacology (CINP).
- We continue to progress our lumateperone bipolar depression Phase 3 clinical program. This program consists of two monotherapy studies and one adjunctive study. We anticipate top-line results from the first monotherapy study (Study 401, which is being conducted in the United States) will be available in 2H 2018 and the top-line results from our global monotherapy study (Study 404) will be available in 2019. Subject to the outcomes of these trials, we expect to submit an NDA for bipolar depression in 2H 2019. Our adjunctive study (Study 402), which is being conducted globally, is ongoing.
- Our lumateperone program in agitation associated with dementia, including Alzheimer's disease, currently consists of one

Phase 3 clinical trial and clinical conduct is ongoing. Subject to timely patient enrollment, we expect that the outcome of the interim analysis for this trial will be available in 2H 2018.

- We plan to initiate our late stage clinical program of lumateperone in depressive disorders in 2018.

ITI-214 (PDE1 inhibitor) Programs

Parkinson's Disease

- In 2017, we 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 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. Clinical conduct has been completed for the first three cohorts (1, 3, and 10 mg). At these doses, ITI-214 was safe and generally well tolerated. Based on this favorable safety and tolerability profile, the study has been expanded to include a 30 mg dose cohort and clinical conduct is ongoing. We anticipate top-line results from this trial will be available in 2H 2018.
- We presented preclinical and Phase I clinical data supporting the clinical development of ITI-214 in PD, including preclinical data showing ITI-214's anti-neuroinflammatory and neuroprotective effects at the Advances in Alzheimer's and Parkinson's Therapies Focus Meeting and recently at the Annual Meeting of the American Academy of Neurology.

Heart Failure

- In Q1 of 2018, the Investigational New Drug (IND) application went into effect for ITI-214 for the treatment of heart failure. Preparations are underway to initiate clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure.

ITI-333 Program

- ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opiate receptors continues to advance in preclinical development. We plan to develop ITI-333 for the treatment of opioid and other substance use disorders, pain, and mood disorders. We expect to initiate clinical trials in 2019.

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 and for the treatment of heart failure.

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 submission for lumateperone for the treatment of schizophrenia and our expectations about the timing of such NDA submission; our plans and the expected timing for the availability of data from our ongoing Phase 3 trials in bipolar depression and agitation associated with dementia, including Alzheimer's disease, and our expectations about the timing of our NDA submission for bipolar depression; our plans and the expected timing to initiate a late stage program in depression; our expectations about presenting additional data at upcoming scientific and medical conferences; our development plans for our PDE program, including ITI-214, including the anticipated timing for the availability of data from our ongoing Phase 1/2 trial of ITI-214 and the expected timing of the initiation of a trial of ITI-214 in patients with systolic heart failure; our development plans for our ITI-333 program and our expected timing of the initiation of clinical trials for ITI-333 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; 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 March 31,	
	2018 (1)	2017 (1)
Revenues	\$ —	\$ 95,287
Costs and expenses:		
Research and development	30,702,998	21,538,958
General and administrative	6,381,228	6,310,486
Total costs and expenses	37,084,226	27,849,444
Loss from operations	(37,084,226)	(27,754,157)
Interest income	1,604,148	822,175
Loss before provision for income taxes	(35,480,078)	(26,931,982)
Income tax expense	—	1,600
Net loss	\$ (35,480,078)	\$ (26,933,582)
Net loss per common share:		
Basic & Diluted	\$ (0.65)	\$ (0.62)
Weighted average number of common shares:		
Basic & Diluted	54,676,175	43,385,605

(1) The condensed consolidated statements of operations for the quarters ended March 31, 2018 and 2017 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,	December 31,
	2018 (1)	2017 (1)
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 74,421,386	\$ 37,790,114
Investment securities, available-for-sale	362,584,126	426,540,921
Prepaid expenses and other current assets	6,148,067	4,884,293
Total current assets	443,153,579	469,215,328
Property and equipment, net	1,349,765	1,137,171
Long term deferred tax asset, net	1,058,435	1,058,435
Other assets	77,293	75,765
Total assets	\$ 445,639,072	\$ 471,486,699
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	10,038,850	6,173,539
Accrued and other current liabilities	7,355,955	6,424,221
Accrued employee benefits	2,257,963	1,611,846
Total current liabilities	19,652,768	14,209,606
Long-term deferred rent	2,797,349	2,840,132
Total liabilities	22,450,117	17,049,738
Stockholders' equity:		

Common stock, \$.0001 par value: 100,000,000 shares authorized; 54,694,718 and 54,597,679 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	5,469		5,460	
Additional paid-in capital	867,152,094		862,479,505	
Accumulated deficit	(442,728,858))	(407,248,780)
Accumulated comprehensive loss	(1,239,750))	(799,224)
Total stockholders' equity	423,188,955		454,436,961	
Total liabilities and stockholders' equity	\$ 445,639,072		\$ 471,486,699	

(1) The condensed consolidated balance sheets at March 31, 2018 and December 31, 2017 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.

 [Primary Logo](#)

Source: Intra-Cellular Therapies Inc.