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

November 7, 2018

NEW YORK, Nov. 07, 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 provided a corporate update and announced its financial results for the third quarter ended September 30, 2018.

"This is a very exciting time for our company," said Dr. Sharon Mates, Chairman and CEO of ITCI. "We are pleased with the progress we have made in numerous areas including the completion of our new drug application submission to the FDA for lumateperone for the treatment of schizophrenia, the completion of patient enrollment in our lumateperone bipolar depression trial (Study 401 – U.S. monotherapy) and the favorable results in our Phase 1/2 trial of our phosphodiesterase 1 inhibitor, ITI-214, in patients with Parkinson's disease. In addition, we have strengthened our management team, including the appointment of a Chief Commercial Officer as we prepare for the commercialization of lumateperone if it is approved for sale in the U.S."

Corporate Update

Lumateperone Programs

Schizophrenia

- We completed the submission of our new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for lumateperone for the treatment of schizophrenia.

- Later this quarter, we plan to present results from the second part of our lumateperone open-label safety switching study in patients with stable symptoms in schizophrenia. This portion of the study follows patients for up to 1-year of treatment with lumateperone after a switch from standard-of-care antipsychotic therapy. Last year we presented results from the first part of this study in which we demonstrated improved safety when patients were switched to a 6-week treatment duration with lumateperone, followed by a loss of this benefit when switched back to standard-of-care.

- We continue to build our team and expand our infrastructure in preparation for the commercialization of lumateperone if it is approved for sale in the U.S. and for the further advancement of our pipeline. We believe the recent appointments of Mark Neumann as Executive Vice President, Chief Commercial Officer, Suresh Durgam, MD, as Senior Vice President, Late Stage Clinical Development and Medical Affairs, and Michael Olchaskey, PharmD, as Senior Vice President, Head of Regulatory Affairs, strengthen and complement our growing organization.

Bipolar Depression

- We continue to advance our lumateperone bipolar depression Phase 3 clinical program. This program consists of two monotherapy studies and one adjunctive study. We have completed patient enrollment in our first monotherapy study (Study 401) being conducted in the U.S. and we expect to complete patient enrollment in Q1 2019 in the second monotherapy study (Study 404) being conducted globally. Given the relative timing of these two events and to avoid introducing potential expectation bias in the ongoing Study 404, we anticipate reporting topline results from Study 401 and Study 404 simultaneously in Q2 2019. The Study 401 dataset will remain locked and blinded until the Study 404 dataset is available and then both datasets will be analyzed concurrently. Subject to the outcome of these trials, we expect to submit in 2H 2019 for FDA regulatory approval for bipolar depression.

Dementia

- Our lumateperone program in patients with agitation associated with dementia, including Alzheimer's disease, currently consists of one Phase 3 clinical trial and clinical conduct is ongoing. We expect that the outcome of the interim analysis for this trial will be available in Q4 2018.

ITI-214 (PDE1 inhibitor) Programs

Parkinson's Disease (PD)

- We have progressed our ITI-214 development program for Parkinson's disease. We recently presented top-line results from our Phase 1/2 randomized, double-blind, placebo-controlled, multiple ascending dose clinical trial to evaluate ITI-214, our phosphodiesterase 1 (PDE1) inhibitor, in patients with PD at the American Neurological Association Annual Meeting. The primary objective was to evaluate the safety and tolerability of ITI-214 in patients with mild to moderate PD. Topline results demonstrate ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. No serious adverse events were reported in the trial, and no clinically significant effects of ITI-214 compared to placebo were observed on vital signs, or cardiovascular or laboratory parameters. The efficacy of ITI-214 in improving motor and non-motor symptoms of PD was measured using multiple scales, providing

input from both subjects and site raters. Motor performance was improved in the “On” state by ITI-214 relative to placebo treatment as assessed by the Movement Disorder Society Unified Parkinson’s Disease Rating Scale (MDS-UPDRS). ITI-214 reduced scores on the MDS-UPDRS total scale and 2 subscales: Part III - clinician ratings of the motor manifestations of PD, and Part IV- motor complications including dyskinesias. In addition, ITI-214 reduced dyskinesia symptoms as measured by the Unified Dyskinesia Rating Scale (UDysRS) and increased total On time and On time without dyskinesias as rated by subjects using the Hauser Patient Motor Diary. We plan to advance this program with a Phase 2 clinical trial of ITI-214 for the treatment of PD in 2019.

Heart Failure

- Earlier this year we initiated our ITI-214 program for the treatment of heart failure. Clinical conduct is ongoing in a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate hemodynamic effects and safety in patients with systolic heart failure. Preclinical data, reported in a recently published article in the journal *Circulation* with an accompanying editorial, indicate ITI-214 acts by a novel mechanism of action via modulation of the adenosine A2B receptor signaling pathway and increases cardiac contractility without increasing intracellular calcium. The pharmacological profile of ITI-214 introduces a new mechanism of action for the treatment of heart failure that is different from ß-adrenergic agonism and PDE3 inhibition and offers a potential new treatment for heart failure with a novel mechanism of action that may provide an effective and safer alternative to existing therapies.

ITI-333 Program

- ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opioid 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.

Third Quarter 2018 Financial Results

The Company reported a net loss of $41.5 million, or $0.76 per share (basic and diluted), for the third quarter of 2018 compared to a net loss of $22.9 million, or $0.53 per share (basic and diluted), for the third quarter of 2017.

Research and development (R&D) expenses for the third quarter of 2018 were $35.4 million, compared to $18.5 million for the second quarter of 2017. This increase is primarily due to increases of approximately $7.3 million of lumateperone clinical costs, $2.0 million of costs for lumateperone non-clinical efforts, $2.6 million of manufacturing expense, $1.1 million of stock compensation expense, and $4.0 million of costs related to other projects and overhead expenses. General and administrative (G&A) expenses were $8.0 million for the third quarter of 2018, compared to $5.3 million for the same period in 2017. The comparative increase is primarily due to increased labor, stock compensation and pre-commercialization costs.

Cash, cash equivalents, and investment securities totaled $376.0 million at September 30, 2018, compared to $464.3 million at December 31, 2017.

The Company expects that its cash, cash equivalents, and investment securities of $376.0 million as of September 30, 2018 will be used primarily to advance the lumateperone development program, including to fund clinical trials of lumateperone in patients with bipolar depression, in patients with agitation associated with dementia, including Alzheimer’s disease, 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 preclinical and clinical development of the Company’s ITI-007 long-acting injectable program; to fund non-clinical activities, including the continuation of manufacturing activities, in connection with lumateperone; and to fund other clinical and preclinical programs, including the Company’s PDE development activities including ITI-214, for the treatment of PD, heart failure and other disorders.

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 4966996. 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 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 our NDA submission for lumateperone for the treatment of schizophrenia; our plans and the expected timing for the completion of enrollment in and the availability and reporting 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 expectations that the Study 401 dataset will remain locked and blinded until the Study 404 dataset is available; the expected timing for conducting an interim analysis of the Phase 3 trial in agitation in patients with dementia, including Alzheimer's disease, and the expected timing for the availability of the outcome of this analysis; the expected timing for the availability of data from the second part of our lumateperone open-label safety switching study; our expectations about presenting data at upcoming scientific and medical conferences; our development plans for our PDE program, including ITI-214 and our expected timing of the initiation of additional clinical trials for ITI-214; 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 September 30	
	2018 (1)	**2017** (1)
Revenues	**$ -**	$ 30,754
Costs and expenses:		
Research and development	**35,419,016**	18,472,372
General and administrative	**7,972,329**	5,317,577
Total costs and expenses	**43,391,345**	23,789,949
Loss from operations	**(43,391,345)**	(23,759,195)
Interest income	**1,868,431**	884,763
Loss before provision for income taxes	**(41,522,914)**	(22,874,432)
Income tax benefit	**-**	(4,016)
Net loss	**$ (41,522,914)**	$ (22,870,416)
Net loss per common share:		
Basic & Diluted	**(0.76)**	(0.53)
Weighted average number of common shares:		
Basic & Diluted	**54,708,065**	43,424,387

1. The condensed consolidated statements of operations for the quarters ended September 30, 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

	September 30, 2018 (1) (Unaudited)	December 31, 2017 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 69,776,956**	$ 37,790,114
Investment securities, available-for-sale	**306,211,066**	426,540,921
Prepaid expenses and other current assets	**7,265,428**	4,884,293
Total current assets	**383,253,450**	469,215,328
Property and equipment, net	**1,196,480**	1,137,171
Long term deferred tax asset, net	**1,058,435**	1,058,435
Other assets	**78,833**	75,765
Total assets	**$ 385,587,198**	$ 471,486,699
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**10,453,186**	6,173,539
Accrued and other current liabilities	**14,168,130**	6,424,221
Accrued employee benefits	**4,507,580**	1,611,846
Total current liabilities	**29,128,896**	14,209,606
Long-term deferred rent	**2,832,906**	2,840,132
Total liabilities	**31,961,802**	17,049,738
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 54,713,831 and 54,597,679 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	**5,471**	5,460
Additional paid-in capital	**876,094,265**	862,479,505
Accumulated deficit	**(521,628,155**	(407,248,780)
Accumulated comprehensive loss	**(846,185**	(799,224)
Total stockholders' equity	**353,625,396**	454,436,961
Total liabilities and stockholders' equity	**$ 385,587,198**	$ 471,486,699

(1)The condensed consolidated balance sheets at September 30, 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.

Source: Intra-Cellular Therapies Inc.