Intra-Cellular Therapies Reports First Quarter 2019 Financial Results and Provides Corporate Update

May 8, 2019

NEW YORK, May 08, 2019 (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, 2019, and provided a corporate update.

“2018 was an important year for ITCI and our momentum has carried over into 2019,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “Our NDA for lumateperone for the treatment of schizophrenia is under review and we continue to make progress in preparing all areas of the Company for the potential launch of lumateperone and the advancement of our other clinical and preclinical development programs.”

Corporate Update

Lumateperone Programs

Schizophrenia

- Our new drug application (NDA) for lumateperone, an investigational agent for the treatment of schizophrenia, is under review by the U.S. Food and Drug Administration (FDA) and the Prescription Drug User Fee Act (PDUFA) target action date is September 27, 2019.

- We made considerable progress during the first quarter in preparing critical areas of our Company to support the potential commercialization of lumateperone. We have conducted extensive market research to inform our overall go-to-market strategy. We have also significantly advanced the expansion of our internal infrastructure to support our transition from a clinical stage company to a fully-integrated commercial organization, including the implementation of enterprise-wide systems and processes as well as progressing our commercial capabilities in the areas of Sales, Marketing, Managed Care, and Manufacturing & Supply Chain to support a successful launch, pending FDA approval.

- Recently, at the 2019 Congress of the Schizophrenia International Research Society (SIRS), we presented results from our long term safety study of lumateperone in patients with stable symptoms of schizophrenia, Study 303. The results showed that lumateperone, administered for up to one year, was generally well tolerated and exhibited statistically significant improvements from baseline on key safety measures of body weight, cardiometabolic and endocrine parameters, without motor side effects often associated with other antipsychotic medications. Patients treated with lumateperone remained stable with respect to their symptoms of schizophrenia upon switching from standard of care. We presented results on the improvements in symptoms of depression seen over a 1-year treatment duration in patients with stabilized schizophrenia experiencing moderate to severe co-morbid depression. The antidepressant effects of lumateperone (ITI-007 60 mg) were assessed using the Calgary Depression Scale for Schizophrenia (CDSS), a validated scale to assess depression in patients with schizophrenia. In patients with moderate-to-severe depression symptoms at baseline (CDSS≥6; N=55), lumateperone treatment was associated with marked improvement in CDSS scores. Specifically, mean CDSS scores decreased by approximately 60% from 7.4 (baseline) to 3.1 (Day 300). In addition, the majority of patients (60%) improved by at least 50%, meeting responder criteria, by Day 75 and this response rate was maintained through Day 300. Importantly, in this study patients who were taking antidepressant therapy and patients who were not on antidepressant therapy saw improvements in their symptoms of depression while on lumateperone. These data extend results previously reported in patients with acute symptoms of schizophrenia and comorbid depression. We believe lumateperone has the potential to provide antidepressant effects in patients suffering from a range of mood disorders, while offering the advantages of a favorable safety profile.

Bipolar Depression

- We continue to advance our lumateperone bipolar depression Phase 3 clinical program. We have completed patient enrollment in our two monotherapy studies: Study 401 conducted in the U.S. and Study 404 conducted globally. We anticipate reporting topline results from Study 401 and Study 404 simultaneously later this quarter. Subject to the outcome of these trials, we expect to submit for FDA regulatory approval of lumateperone for bipolar depression in the second half of 2019.

Major Depressive Disorder

- We believe lumateperone has the potential to exhibit potent and rapid antidepressant effects and have commenced a program in major depressive disorder (MDD), beginning with a dose-finding trial. In order to explore the effect of different modes of drug administration and the potential for rapid-onset antidepressant activity, our program includes the assessment of novel formulations of lumateperone. Pharmacokinetic studies evaluating these formulations of lumateperone are currently ongoing.

ITI-214 (PDE1 inhibitor) Programs

Parkinson's Disease

- We presented 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 mild-to-moderate Parkinson's disease (PD) at the 2019 American Academy of Neurology Annual Meeting. The primary objective was to evaluate safety and tolerability. Efficacy in improving motor and non-motor symptoms of PD was explored using multiple scales, providing input from both patients and site raters. 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.

Heart Failure

- Our 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 is ongoing. Clinical conduct for the second cohort, 30 mg, is ongoing following completion of the 10 mg dose cohort where no safety concerns were identified.

ITI-333 Program

- We plan to develop ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opioid receptors, for the treatment of opioid and other substance use disorders, pain, and mood disorders. We expect to initiate our clinical program later this year.

Selected First Quarter 2019 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $34.8 million, or $0.63 per share (basic and diluted), for the first quarter of 2019 compared to a net loss of $35.5 million, or $0.65 per share (basic and diluted), for the first quarter of 2018.

Research and development (R&D) expenses for the first quarter of 2019 were $25.0 million, compared to $30.7 million for the first quarter of 2018. This decrease of $5.7 million is due primarily to a decrease of approximately $4.8 million of costs associated with the lumateperone development programs and a decrease of approximately $1.7 million of non ITI-007 projects and overhead expenses, which is partially offset by an increase in labor and stock compensation expense.

General and administrative (G&A) expenses were $11.7 million for the first quarter of 2019, compared to $6.4 million for the same period in 2018. The increase of $5.3 million is primarily the result of an increase in pre-commercialization costs of approximately $3.2 million, and to a lesser extent, labor costs, stock compensation expense, and rent expense.

Cash, cash equivalents and investment securities totaled $312.8 million at March 31, 2019, compared to $347.5 million at December 31, 2018.

We expect these existing funds will be used primarily for pre-commercialization preparation, initial commercialization activities and related infrastructure expansion in connection with the commercialization of lumateperone, if approved, for the treatment of schizophrenia; the development of lumateperone in our late stage clinical programs; the development of our other product candidates, including ITI-214; the continuation of manufacturing activities in connection with the development of lumateperone; and general operations.

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 3993733. 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 is under review by the FDA for the treatment of schizophrenia and is in Phase 3 clinical development for the treatment of bipolar depression. 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 belief that lumateperone has the potential to provide antidepressant effects in patients suffering from a range of mood disorders, while offering the advantages of a favorable safety profile; our plans and the expected timing for the availability and reporting of data from our ongoing Phase 3 trials in bipolar depression, and our expectations about the timing of our NDA submission for bipolar depression; 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; the potential for ITI-214 to provide an effective and safer alternative to existing therapies; 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: whether the NDA for lumateperone for the treatment of schizophrenia will be approved by the FDA; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with lumateperone in ongoing or future trials and other development activities; 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; fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process; 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

	Three Months Ended March 31,	
	2019	**2018**
	(Unaudited)	(Unaudited)
Revenues	**$ —**	$ —
Costs and expenses:		
Research and development	**24,990,856**	30,702,998
General and administrative	**11,704,984**	6,381,228
Total costs and expenses	**36,695,840**	37,084,226
Loss from operations	**(36,695,840)**	(37,084,226)
Interest income	**(1,860,077)**	(1,604,148)
Net loss	**$ (34,835,763)**	$ (35,480,078)
Net loss per common share:		
Basic & Diluted	**$ (0.63)**	$ (0.65)
Weighted average number of common shares:		
Basic & Diluted	**55,113,226**	54,676,175

1. The condensed consolidated statements of operations for the quarters ended March 31, 2019 and 2018 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

	March 31, 2019 (1)	December 31, 2018 (1)
	(Unaudited)	(Audited)
Assets		

Current assets:		
Cash and cash equivalents	**$ 64,091,080**	$ 54,947,502
Investment securities, available-for-sale	**248,731,291**	292,583,046
Prepaid expenses and other current assets	**8,305,259**	7,908,133
Total current assets	**321,127,630**	355,438,681
Property and equipment, net	**1,125,606**	1,159,766
Right to use assets, net	**20,104,280**	—
Long term deferred tax asset, net	**529,218**	529,218
Other assets	**86,083**	78,833
Total assets	**$ 342,972,817**	$ 357,206,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**8,574,433**	13,961,060
Accrued and other current liabilities	**18,700,638**	20,044,866
Lease liabilities, short-term	**2,873,022**	—
Accrued employee benefits	**3,351,208**	2,293,259
Total current liabilities	**33,499,301**	36,299,185
Long-term deferred rent	**—**	3,192,432
Long-term lease liabilities	**20,859,089**	—
Total liabilities	**54,358,390**	39,491,617
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 55,131,125 and 54,895,295 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	**5,513**	5,490
Additional paid-in capital	**885,888,318**	880,753,339
Accumulated deficit	**(597,211,954)**	(562,376,191)
Accumulated comprehensive loss	**(67,450)**	(667,757)
Total stockholders' equity	**288,614,427**	317,714,881
Total liabilities and stockholders' equity	**$ 342,972,817**	$ 357,206,498

(1) The condensed consolidated balance sheets at March 31, 2019 and December 31, 2018 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

Source: Intra-Cellular Therapies Inc.