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

November 5, 2019

NEW YORK, Nov. 05, 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 provided a corporate update and announced its financial results for the third quarter ended September 30, 2019.

“I am pleased with the significant progress we have made in the third quarter across our commercial, regulatory, and clinical initiatives,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “We are preparing for a potential launch of lumateperone in the first quarter of 2020, and continue to advance our clinical programs, including our PDE1 program and our Phase 3 trial evaluating lumateperone as an adjunctive therapy in bipolar depression.”

**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) goal date is December 27, 2019.

- We continue to make progress on our commercial preparedness to support the potential launch of lumateperone in the first quarter of 2020. Our sales leadership team including Area Sales Directors are on board and hiring is ongoing for the Regional Business Managers. Our market access team is in place and engagement with payors has commenced. Manufacturing and supply chain related activities remain on track to support commercial supply.

- At the 2019 European College of Neuropsychopharmacology (ECNP) annual meeting and at the 32nd Annual Psych Congress, we made presentations highlighting lumateperone’s efficacy results and favorable safety and tolerability profile in schizophrenia clinical studies including the long-term safety study, which is extending beyond one year of treatment.

**Bipolar Depression**

- In July 2019, we announced positive topline results in our bipolar depression program from Study ‘404, a Phase 3 trial of lumateperone in patients with bipolar depression associated with either Bipolar I or Bipolar II disorder. Study ‘404 met its primary endpoint of change from baseline at Week 6 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo ($p<0.0001$; effect size = 0.56). These benefits were statistically significant in both Bipolar I and Bipolar II patients. The study also met its key secondary objective on the Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score. In a second Phase 3 trial, Study ‘401, lumateperone did not separate from placebo; the placebo response was very high in this trial. In these two trials, which enrolled an aggregate of 935 patients with over 550 patients receiving lumateperone, lumateperone demonstrated a favorable safety profile and was generally well-tolerated. The safety profile is consistent with favorable results observed in the schizophrenia program. Importantly, the rates of akathisia, restlessness and extrapyramidal symptoms combined were less than 1% and similar to placebo in both trials. We plan to present additional details of the results from these trials at a major medical conference later this year.

- Our global adjunctive bipolar depression Phase 3 trial, Study ‘402, is ongoing. We anticipate reporting topline results from this trial in mid-2020.

**Major Depressive Disorder**

- We believe lumateperone has the potential to exhibit potent and rapid antidepressant effects and have an ongoing program in major depressive disorder. 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. We are continuing to explore the pharmacokinetics of these formulations and anticipate initiating a Phase 2 clinical trial in major depressive disorder in 2020.

**Other Programs**

**ITI-214 Program**

- We intend to pursue the development of our phosphodiesterase program for the treatment of several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is

an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases such as Parkinson's disease, and other non-CNS disorders.

- Our Phase 1/2 clinical trial of escalating single doses of ITI-214, our phosphodiesterase 1 (PDE1) inhibitor, evaluating hemodynamic effects and safety in patients with systolic heart failure, is ongoing. Specifically, assessment of vital signs, left ventricular contractility and power using echocardiography, and ectopic arrythmias using continuous ECG monitoring are being made following the administration of ITI-214. Clinical conduct for the third and last cohort, 90 mg, is ongoing following completion of the 10 mg and 30 mg dose cohorts where no safety concerns were identified. We anticipate reporting topline results from this trial in the first half of 2020.

- Our Phase 1 clinical trial of ITI-214 to determine CNS engagement in healthy volunteers completed clinical conduct in the third quarter of 2019. This trial is a single site, randomized, double-blind, placebo-controlled within-subject trial evaluating doses of 1 mg and 10 mg ITI-214 compared to placebo using functional magnetic resonance imaging (fMRI) for changes in brain activation during behavioral tasks related to learning and attention. This trial was designed to provide data supporting proof-of mechanism for indirect modulation of dopaminergic systems in the brain during complex behavioral tasks consistent with PDE1 inhibition and inform the development of ITI-214 in a variety of CNS disorders. We anticipate reporting topline results from this trial later this year.

**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 plan to present preclinical data from this program at a medical conference later this year and expect to initiate our clinical program in the first half of 2020.

**Selected Third Quarter 2019 Financial Results**

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $34.9 million, or $0.63 per share (basic and diluted), for the third quarter of 2019 compared to a net loss of $41.5 million, or $0.76 per share (basic and diluted), for the third quarter of 2018.

Research and development (R&D) expenses for the third quarter of 2019 were $21.3 million, compared to $35.4 million for the third quarter of 2018. This decrease of $14.1 million is due primarily to a decrease of approximately $10.7 million associated with the completion of certain lumateperone clinical trials, a decrease of approximately $1.4 million of costs for lumateperone non-clinical efforts and a decrease of approximately $1.8 million of manufacturing costs.

General and administrative (G&A) expenses were $15.0 million for the third quarter of 2019, compared to $8.0 million for the same period in 2018. The increase of $7.0 million is the result of an increase in pre-commercialization costs of approximately $3.8 million, and to approximately $1.9 million of higher labor costs, and an increase in stock compensation and rent expense.

Cash, cash equivalents and investment securities totaled $255.4 million at September 30, 2019, compared to $347.5 million at December 31, 2018.

We expect these existing funds will be used primarily for pre-commercialization activities, initial commercialization activities including developing a national sales force 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; 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 5756327. 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; the safety, tolerability and efficacy of our product candidates; our plans for the commercial launch of lumateperone in the first quarter of 2020; our expectations about presenting data at upcoming scientific and medical conferences; our expected timing of reporting topline results from our global adjunctive bipolar depression trial; our development plans for our PDE program, including ITI-214 and our

expected timing of reporting the results of our ITI-214 trial evaluating hemodynamic effects and safety 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: whether the NDA for lumateperone for the treatment of schizophrenia will be approved by the FDA and whether the FDA will complete its review within the target timelines, including the new PDUFA goal date; whether, during its review of our applications for regulatory approval of our product candidates, we will be able to provide in a timely manner all information requested by the FDA and whether the FDA will determine information we submit in the course of such reviews is satisfactory; 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**
**(Unaudited)**

| | Three Months Ended September 30, | |
|---|---|---|
| | **2019** (1) | **2018** (1) |
| Revenues | **$ —** | $ — |
| Costs and expenses: | | |
| Research and development | **21,339,792** | 35,419,016 |
| General and administrative | **15,036,444** | 7,972,329 |
| Total costs and expenses | **36,376,236** | 43,391,345 |
| Loss from operations | **(36,376,236)** | (43,391,345) |
| Interest income | **1,513,837** | 1,868,431 |
| Loss before provision for income taxes | **(34,862,399)** | (41,522,914) |
| Income tax expense | **—** | **—** |
| Net loss | **$ (34,862,399)** | $ (41,522,914) |
| Net loss per common share: | | |
| Basic & Diluted | **$ (0.63)** | $ (0.76) |
| Weighted average number of common shares: | | |
| Basic & Diluted | **55,207,400** | 54,708,065 |

(1) The condensed consolidated statements of operations for the quarters ended September 30, 2019 and 2018 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, 2019 (1) (Unaudited) | December 31, 2018 (1) (Audited) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | **$ 102,162,982** | $ 54,947,502 |
| Investment securities, available-for-sale | **153,270,596** | 292,583,046 |
| Prepaid expenses and other current assets | **4,023,348** | 7,908,133 |
| Total current assets | **259,456,926** | 355,438,681 |
| Property and equipment, net | **2,174,993** | 1,159,766 |
| Right of use assets, net | **18,540,418** | — |
| Deferred tax asset, net | **264,609** | 529,218 |
| Other assets | **86,084** | 78,833 |
| Total assets | **$ 280,523,030** | $ 357,206,498 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | **6,230,923** | 13,961,060 |
| Accrued and other current liabilities | **17,323,632** | 20,044,866 |
| Lease liabilities, short-term | **2,286,885** | — |
| Accrued employee benefits | **7,531,659** | 2,293,259 |
| Total current liabilities | **33,373,099** | 36,299,185 |
| Deferred rent | **—** | 3,192,432 |
| Lease liabilities | **20,269,646** | — |
| Total liabilities | **53,642,745** | 39,491,617 |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value: 100,000,000 shares authorized; 55,247,579 and 54,895,295 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively | **5,525** | 5,490 |
| Additional paid-in capital | **896,191,230** | 880,753,339 |
| Accumulated deficit | **(669,515,518)** | (562,376,191) |
| Accumulated comprehensive gain/(loss) | **199,048** | (667,757) |
| Total stockholders' equity | **226,880,285** | 317,714,881 |
| Total liabilities and stockholders' equity | **$ 280,523,030** | $ 357,206,498 |

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


Source: Intra-Cellular Therapies Inc.