November 5, 2015

# Intra-Cellular Therapies Reports Third Quarter 2015 Financial Results and Provides Corporate Update

NEW YORK, Nov. 5, 2015 (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 quarter ended September 30, 2015, and provided a corporate update.

**Third Quarter 2015 Financial Results**

Intra-Cellular Therapies (the Company) reported a net loss of $32.2 million, or $(0.91) per share (basic and diluted), for the third quarter of 2015 compared to a net loss of $6.4 million, or $(0.22) per share (basic and diluted), for the third quarter of 2014.

Research and development (R&D) expenses for the third quarter of 2015 were $28.5 million, compared to $4.0 million for the third quarter of 2014. The increase is primarily due to costs associated with the Phase 3 clinical development program for ITI-007 in schizophrenia, which was initiated in late 2014.

General and administrative (G&A) expenses were $3.9 million for the third quarter of 2015, compared to $2.6 million for the same period in 2014. The increase is primarily the result of higher stock-based compensation expense and, to a lesser extent, salaries and professional fees and costs due to the activities associated with being a public company.

Cash and investments totaled $510.7 million at September 30, 2015, compared to $129.6 million at December 31, 2014. During the third quarter of 2015, the Company completed a public offering of its common stock in which the Company raised approximately $345.2 million in gross proceeds and approximately $327.4 million in net proceeds.

The Company expects that existing cash and investments will be dedicated primarily to the ITI-007 development program, including to fund clinical trials of ITI-007 in schizophrenia, bipolar depression, behavioral disturbances in dementia, depressive disorders and related clinical and non-clinical activities; to fund pre-launch activities for ITI-007 for the treatment of schizophrenia and, if ITI-007 receives regulatory approval, initial commercialization efforts; to fund pre-clinical and clinical development of the Company's ITI-007 long-acting injectable; and to fund non-clinical activities including the continuation of manufacturing activities in connection with the development of ITI-007. Funds will also be used for other clinical and pre-clinical programs, including the Company's phosphodiesterase (PDE) development activities.

**Recent and Upcoming Corporate Highlights**

- In September 2015, the Company announced positive top-line results from the 450 patient ITI-007-301 Phase 3 clinical trial in schizophrenia. ITI-007, at a dose of 60 mg, demonstrated a statistically significant improvement over placebo on the trial's pre-specified primary endpoint, which was change from baseline versus placebo at study endpoint (4 weeks) on the Positive and Negative Syndrome Scale (PANSS) total score. ITI-007 60 mg also met the key secondary endpoint of demonstrating a statistically significant improvement versus placebo on the Clinical Global Impression Scale for Severity of Illness (CGI-S). In the Phase 3 trial, ITI-007 had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, or lipids. ITI-007 showed a dose-related improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the primary endpoint. ITI-007 40 mg also demonstrated a statistically significant improvement versus placebo on the CGI-S.

- In September 2015, the Company also announced top-line results from an open-label ITI-007 positron emission tomography (PET) study in patients with schizophrenia. In this study, the 60 mg dose of ITI-007 was associated with a mean peak striatal D2 receptor occupancy of approximately 40% with a range of peak occupancy up to 51%. The Company believes this range of occupancy is lower than that required by most other antipsychotic drugs for efficacy, and likely contributes to the favorable safety profile of ITI‑007 with reduced risk for akathisia, extrapyramidal side effects and other motoric side effects, and hyperprolactinemia.

- The Company continues clinical conduct in ITI-007-302, the second Phase 3 clinical trial of ITI-007 in schizophrenia. This randomized, placebo- and active-controlled Phase 3 study is ongoing and the Company anticipates that top-line results will be available in mid-2016.

- The Company has commenced start-up activities for its Phase 3 clinical trials of ITI-007 in bipolar depression. The bipolar program consists of two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials: one to evaluate ITI-007 as a monotherapy and the other to evaluate ITI-007 as an adjunctive therapy with lithium or valproate.

- The Company plans to commence its late phase clinical program evaluating ITI-007 for the treatment of behavioral disturbances in patients with dementia, including Alzheimer's disease, in late 2015 or during the first half of 2016.

- In September 2015, the Company announced the completion of multiple clinical Phase 1 studies with ITI-214, a novel, potent phosphodiesterase type 1 (PDE1) inhibitor. The Company is currently evaluating the development strategy for its PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in patients with Parkinson's disease, cognition in patients with Alzheimer's disease, cognition in schizophrenia and other CNS and non-CNS indications.

"This past quarter was one of the most exciting quarters for ITI, as we made significant progress in our mission to provide better treatment options for patients suffering from neuropsychiatric conditions," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "Following the success of our first Phase 3 study in schizophrenia, we are energized to continue our efforts to develop ITI-007 for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia and additional indications."

**Conference Call and Webcast Details**

The Company will host a live conference call and webcast today at 8:00 AM Eastern Time to discuss the Company's financial results and provide a general business 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 67764396. Please dial in approximately 10 minutes prior to the call. The webcast will be available on the Company's website until November 10, 2015.

**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, ITI-007, for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in dementia, depression and other neuropsychiatric and neurological disorders. ITI-007, a first-in-class molecule, is in Phase 3 clinical development for the treatment of schizophrenia. 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 and cash investments; our clinical and non-clinical development plans; the progress, timing and results of our clinical trials; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of ITI-007; and our research 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 ITI-007, 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 reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors discussed under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC), as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with the SEC. 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 September 30, | |
|---|---|---|
| | **2015** (1) | **2014** (1) |
| Revenues | **$ —** | $124,414 |
| Costs and expenses: | | |
| Research and development | **28,457,631** | 4,046,335 |
| General and administrative | **3,891,744** | 2,581,685 |
| Total costs and expenses | **32,349,375** | 6,628,020 |
| Loss from operations | **(32,349,375)** | (6,503,606) |
| Interest expense | — | — |
| Interest income | **188,892** | 88,099 |
| Net loss | **$ (32,160,483)** | $ (6,415,507) |
| Net loss per common share: | | |
| Basic & Diluted | **$ (0.91)** | $ (0.22) |
| Weighted average number of common shares: | | |
| Basic & Diluted | **35,320,046** | 29,379,156 |

(1) The condensed consolidated statements of operations for the quarters ended September 30, 2015 and 2014 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, 2015 (1)** | **December 31, 2014** (1) |
|---|---|---|
| | **(Unaudited)** | **(Audited)** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | **$332,828,289** | $61,325,044 |
| Investment securities, available-for-sale | **177,903,693** | 68,320,672 |
| Accounts receivable | — | 51,603 |
| Prepaid expenses and other current assets | **1,532,908** | 1,288,953 |
| Total current assets | **512,264,890** | 130,986,272 |
| Property and equipment, net | **785,544** | 54,553 |
| Other assets | **71,875** | 70,944 |
| Total assets | **$513,122,309** | $131,111,769 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | **$705,043** | $2,052,765 |

| | | |
|---|---|---|
| Accrued and other current liabilities | **8,575,333** | 7,529,241 |
| Accrued employee benefits | **1,106,620** | 975,058 |
| Total current liabilities | **10,386,996** | 10,557,064 |
| Long-term deferred rent | **881,143** | — |
| Total liabilities | **11,268,139** | 10,557,064 |
| Stockholders' equity: | | |
| Common stock, $.0001 par value: 100,000,000 shares authorized; 43,009,886 and 29,499,059 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively | **4,301** | 2,950 |
| Additional paid-in capital | **666,083,825** | 208,912,345 |
| Accumulated deficit | **(164,214,582)** | (88,255,957) |
| Accumulated comprehensive loss | **(19,374)** | (104,633) |
| Total stockholders' equity | **501,854,170** | 120,554,705 |
| Total liabilities and stockholders' equity | **$513,122,309** | $131,111,769 |

(1) The condensed consolidated balance sheets at September 30, 2015 and December 31, 2014 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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