



March 25, 2014

## **Intra-Cellular Therapies Reports Fourth Quarter and Full-Year 2013 Financial Results**

**– Conference Call and Webcast Today, March 25, at 4:30 p.m. ET –**

NEW YORK, March 25, 2014 /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 fourth quarter and year ended December 31, 2013, and provided an update on corporate developments and upcoming events.

### **2013 Fourth Quarter and Full Year Financial Results**

The Company reported a net loss of \$8.0 million, or \$(0.36) per share (basic and diluted), for the fourth quarter of 2013 compared with a net loss of \$1.2 million, or \$(0.21) per share (basic and diluted), for the fourth quarter of 2012. The Company reported a net loss of \$26.9 million, or \$(1.56) per share (basic and diluted), for the full year ended December 31, 2013 compared with a net loss of \$16.6 million, or \$(2.96) per share (basic and diluted), for the same period in 2012.

Research and development (R&D) expenses for the fourth quarter of 2013 were \$6.1 million, compared to \$517,000 for fourth quarter of 2012. For the full year ended December 31, 2013, R&D expenses were \$23.0 million, compared to \$15.5 million for 2012. The increase in R&D costs year over year is primarily due to the expenses associated with the completion of the ITI-007 Phase 2 study in schizophrenia.

General and administrative (G&A) expenses were \$2.7 million for the fourth quarter of 2013, compared to \$1.1 million for the same period in 2012. For the full year ended December 31, 2013, G&A expenses were \$6.0 million, compared to \$4.0 million for the prior-year period. The increase in G&A expenses in both cases were primarily due to being a public reporting entity and to a lesser extent increases in salaries and bonuses.

Cash and cash equivalents and investments totaled \$37.2 million at December 31, 2013 compared to \$19.1 million at December 31, 2012.

### **Financing Highlights and Use of Proceeds**

- During the third quarter of 2013, the Company raised net proceeds of approximately \$40.0 million in a private placement of its common stock and completed a reverse merger which closed on August 29, 2013. In addition, the Company's common stock began trading on the OTCQB on December 20, 2013 under the symbol "ITCI".
- During the first quarter of 2014, the Company raised net proceeds of approximately \$115.4 million in a public offering of its common stock, and on January 31, 2014, its common stock began trading on The NASDAQ Global Select Market under the symbol "ITCI".
- The Company expects that existing cash and cash equivalents and investments will be dedicated primarily to ITI-007's clinical trials in schizophrenia and bipolar disorder, earlier stage ITI-007 clinical trials in dementia, and other ITI-007 clinical and preclinical activities. To a much lesser extent, funds will be used for other pre-clinical programs the Company is undertaking.

### **Clinical Highlights**

#### ITI-007

• In December 2013, the Company announced positive topline results from the 335 patient ITI-007 28 day Phase 2 clinical trial in patients with acutely exacerbated schizophrenia. The study randomized patients to ITI-007 at a dose of 60 mg or 120 mg, risperidone 4 mg (positive control) or placebo. ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis ( $p = 0.017$ ; MMRM-ITT) on the trial's pre-specified primary endpoint, which was change from baseline on the PANSS total score, compared to placebo. In the Phase 2 trial, ITI-007 was well-tolerated and the most frequent adverse event was sedation. There were no serious adverse events related to ITI-007.

• In March 2014, the Company initiated ITI-007-200, a Phase 1/2 randomized, double blind placebo controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007, in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease.

### ITI-214

• In February 2013, the Company announced topline safety and pharmacokinetic data for a Phase 1 study of ITI-214, a first-in-class selective phosphodiesterase 1 (PDE1) inhibitor. ITI-214 is the lead drug candidate in the Company's PDE1 collaboration with Takeda Pharmaceutical Company and is being developed for the treatment of cognitive impairment associated with schizophrenia, or CIAS, and other disorders.

### Pre-clinical Pipeline

• Intra-Cellular Therapies continues to advance its pre-clinical programs, which include pre-clinical studies to explore additional indications and a follow-on program to ITI-007. The Company also continues its drug discovery efforts for PDE2 and PDE9 inhibitors as well as other drug discovery programs aimed at generating drug candidates for the treatment of Alzheimer's disease and related disorders.

### **Upcoming Events and Clinical Development Plans**

- Intra-Cellular Therapies plans to present additional analyses of the ITI-007 Phase 2 study in patients with acutely exacerbated schizophrenia and other ITI-007 related presentations at upcoming scientific and medical conferences.
- In Q2 2014, Intra-Cellular Therapies plans to request a meeting with the FDA to discuss the existing ITI-007 safety and efficacy data and future clinical development plans for ITI-007.
- Subject to discussions with the FDA Intra-Cellular Therapies plans to initiate Phase 3 trials of ITI-007 in schizophrenia in 2H 2014 and clinical studies in bipolar disorder in 2015.
- Intra-Cellular Therapies expects initial data from the ITI-007-200 trial, in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease, to be available in 2H 2014.

"Following the completion of the ITI-007 Phase 2 study in patients with acutely exacerbated schizophrenia coupled with successful financings, we believe that the Company is in a strong position to complete the development of ITI-007 for patients with schizophrenia and to explore additional neuropsychiatric conditions, including the use of low doses of ITI-007 for behavioral disturbances in patients with dementia and other neuropsychiatric and neurological indications," said Sharon Mates, Ph.D., Chief Executive Officer and Chairman.

### **Conference Call and Webcast Details**

The Company will host a live conference call and webcast today at 4:30 p.m. 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.intracellularterapies.com](http://www.intracellularterapies.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 877-375-1350 (U.S.) or 315-625-3229 (international) to listen to the live conference call. The conference ID number for the live call is 15579533. Please dial in approximately 10 minutes prior to the call. The webcast will be available on the Company's website for 7 days.

### **About Intra-Cellular Therapies**

Intra-Cellular Therapies (the "Company") is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative disease and other disorders of the central nervous system ("CNS"). The Company is developing its lead drug candidate, ITI-007, for the treatment of schizophrenia, behavioral disturbances in dementia, bipolar disorder and other neuropsychiatric and neurological disorders. In December 2013, the Company announced positive topline results from the Company's randomized, placebo- and active-controlled Phase II clinical trial of ITI-007 in patients with acutely exacerbated schizophrenia. This study showed a statistically significant improvement in symptoms associated with schizophrenia at the 60 mg dose on the trial's pre-specified primary endpoint and a favorable safety profile. The Company is also utilizing its phosphodiesterase (PDE) platform and other proprietary chemistry platforms to develop drugs for the treatment of cognitive deficits in schizophrenia and other CNS disorders. The Company has partnered its lead PDE1 compound, ITI-214, and backups from this platform with the Takeda Pharmaceutical Company. ITI-214 has finished the first Phase 1 clinical trial and is now in subsequent Phase 1 trials. The Company is also developing inhibitors against additional targets for CNS indications such as Alzheimer's disease, Parkinson's disease and depression and non-CNS indications such as cardiovascular disease.

### **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 investments; our pre-clinical and drug discovery programs under the caption "Pre-Clinical Pipeline;" our clinical development plans for ITI-007 and our other programs under the caption "Upcoming Events and Clinical Development Plans;" 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 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 and commercialization of our product candidates; and the other risk factors discussed under the heading "Risk Factors" contained in our Current Report on Form 8-K filed with the Securities and Exchange Commission (SEC) on October 31, 2013, as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with the SEC, including our Annual Report on Form 10-K for the year ended December 31, 2013 to be 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.

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