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Intra-Cellular Therapies Reports First Quarter 2014 Financial Results

NEW YORK, May 5, 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 first quarter ended March 31, 2014, and provided a corporate update.

First Quarter 2014 Financial Results

The Company reported a net loss of $4.5 million, or $(0.17) per share (basic and diluted), for the first quarter of 2014 compared with a net loss of $5.6 million, or $(0.39) per share (basic and diluted), for the first quarter of 2013.

Research and development (R&D) expenses for the first quarter of 2014 were $2.8 million, compared to $5.0 million for the first quarter of 2013. The decrease is due almost exclusively to costs associated with outside clinical testing for our Phase 2 clinical trials of ITI-007 that was completed in late 2013, with no related costs incurred in 2014. Partially offsetting this decrease are expenses relating to manufacturing of drug material for our ITI-007 product candidate of approximately $635,000 and the initiation of our Phase 1/2 clinical trial of ITI-007 in healthy geriatric volunteers and dementia patients totaling approximately $1.0 million.

General and administrative (G&A) expenses were $1.9 million for the first quarter of 2014, compared to $1.0 million for the same period in 2013. The increase is primarily the result of professional fees and directors' and officers' insurance costs due to the activities associated with being a public company, with the remainder comprised primarily of higher salary and benefits expenses.

Cash and cash equivalents totaled $145.6 million at March 31, 2014, compared to $37.2 million at December 31, 2013.

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 in connection with the closing of that offering, its common stock began trading on The NASDAQ Global Select Market under the symbol "ITCI" on January 31, 2014.

The Company expects that existing cash and cash equivalents will be dedicated primarily to clinical trials of ITI-007 in schizophrenia and bipolar disorder, earlier stage clinical trials of ITI-007 in dementia, and other clinical and preclinical activities for ITI-007. To a much lesser extent, funds will be used for other pre-clinical programs.

Recent and Upcoming Corporate Highlights

• The Company presented additional analyses of the Phase 2 clinical trial of ITI-007 in patients with acutely exacerbated schizophrenia and other related presentations at the 4th Biennial Schizophrenia International Research Society Conference held in Florence, Italy, April 5-9, 2014.

• The Company announced that IC200131, the major circulating active metabolite of ITI-007, is in preclinical development as a candidate for the treatment of mood disorders and other neurological and psychiatric conditions.

• Additional presentations on ITI-007 will be featured later this week at the 167th Annual Meeting of the American Psychiatric Association (APA) and the 69th Annual Meeting of the Society of Biological Psychiatry (SOBP). The APA annual meeting will be held May 3-7, 2014, in New York, NY. The SOBP annual meeting will be held May 8-10, 2014 in New York, NY.

• In Q2 2014, the Company plans to request a meeting with the FDA to discuss the existing safety and efficacy data for ITI-007 and future clinical development plans for ITI-007.

• The Company plans to initiate Phase 3 trials of ITI-007 in schizophrenia in the second half of 2014 and clinical studies in bipolar disorder in 2015.

• The Company 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 the second half of 2014.

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 and cash equivalents; our clinical development plans for ITI-007 under the caption “Recent and Upcoming Corporate Highlights;” 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 most recent Annual Report on Form 10-K 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.

Contact:
Juan Sanchez, M.D.
Vice President
Corporate Communications and Investor Relations
Intra-Cellular Therapies, Inc.
212-923-3344

Burns McClellan, Inc.
Lisa Burns/Angeli Kolhatkar (Investors)
Justin Jackson (Media)
jjackson@burnsmc.com
212-213-0006

View Condenced Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

View Condenced Consolidated Balance Sheets