



August 12, 2014

Intra-Cellular Therapies Reports Financial Results for Second Quarter Ended June 30, 2014

Company Announces Successful End-of-Phase 2 Meeting With the FDA and Phase 3 Plans for ITI-007 for Schizophrenia

NEW YORK, Aug. 12, 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 second quarter ended June 30, 2014, and provided a corporate update, including that it has successfully completed an End-of-Phase 2 meeting with the United States Food and Drug Administration ("FDA") for its lead drug candidate ITI-007 for the treatment of schizophrenia. ITI-007 is the Company's first-in-class new molecular entity in development for the treatment of schizophrenia and other neuropsychiatric disorders.

End-of-Phase 2 Meeting with the FDA for ITI-007 and Phase 3 Plans

The Company recently met with the FDA following the successful conclusion of a Phase 2 clinical trial in 335 patients with acutely exacerbated schizophrenia. The FDA reviewed the current data package and provided input regarding the Company's proposed Phase 3 development plan for ITI-007 in schizophrenia.

Following this meeting with the FDA, the Company is proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. The Company plans to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. Subject to finalizing the trial protocols and arrangements with clinical trial sites, the Company intends to initiate the first Phase 3 clinical trial in schizophrenia in the second half of 2014 and a second Phase 3 clinical trial in early 2015. In the first Phase 3 trial, the Company plans to randomize patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration. The Company currently expects that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to initiation of these trials as planned and timely enrollment, the Company anticipates that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015.

"We are very pleased with the outcome of the End-of-Phase 2 meeting and the input we received from the FDA," said Dr. Sharon Mates, Chief Executive Officer and Chairman. "The meeting was an important milestone in the clinical development of ITI-007, and we are now focused on initiating the ITI-007 Phase 3 program in schizophrenia with the first clinical trial starting in the second half of this year."

ITI-007 Program in Healthy Geriatric Subjects and in Patients with Dementia, Including Alzheimer's Disease

The Company continues to make progress in the ITI-007-200 Phase 1/2 trial testing low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease. Patient enrollment has been completed in this trial. The Company expects initial data from the ITI-007-200 trial to be available in the second half of 2014. Subject to successful completion of the Phase 1/2 trial and finalization of clinical trial protocols, the Company intends to initiate a Phase 2 clinical trial in 2015 evaluating ITI-007 in patients with behavioral disturbances associated with dementia, including Alzheimer's disease.

Selected Financial Results for the Second Quarter Ended June 30, 2014

The Company reported a net loss of \$4.5 million, or \$(0.15) per share (basic and diluted), for the second quarter of 2014, compared with a net loss of \$8.3 million, or \$(0.56) per share (basic and diluted), for the second quarter of 2013.

Research and development (R&D) expenses for the second quarter of 2014 were \$2.7 million, compared to \$7.8 million for the second quarter of 2013. The decrease of \$5.1 million 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 were expenses of approximately \$1.0 million relating to manufacturing and other clinical and non-clinical testing of our ITI-007 product candidate.

General and administrative (G&A) expenses were \$2.1 million for the second quarter of 2014, compared to \$0.9 million for the second quarter 2013. The increase of \$1.2 million is primarily due to professional fees, directors' and officers' insurance costs and board of director compensation fees, which are primarily related to the activities associated with being a public company, with the remainder comprised primarily of higher salary and benefits expenses.

Cash and cash equivalents and investments totaled \$140.5 million at June 30, 2014, compared to \$37.2 million at December 31, 2013. The increase is due to the Company raising net proceeds of approximately \$115.4 million in a public offering of common stock during the first quarter of 2014.

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

Conference Call and Webcast Details

The Company will host a live conference call and webcast today at 8:30 a.m. Eastern Time to discuss the Company's financial results and provide a general business update, including its proposed Phase 3 development plan for ITI-007 in schizophrenia. 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 80195906. Please dial in approximately 10 minutes prior to the call. The webcast will be available on the Company's website for 7 days.

About the ITI-007-005 Phase 2 Clinical Trial

The Phase 2 clinical trial, ITI-007-005, was a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, 335 patients were randomized to receive one of four treatments: 60 mg ITI-007, 120 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. Patients received study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the intent-to-treat primary analysis. The primary endpoint for this clinical trial was change from baseline to Day 28 on the Positive and Negative Syndrome Scale ("PANSS") total score. The PANSS is a well-validated, 30-item rating scale that measures the ability of a drug to reduce schizophrenia symptom severity (Kay et al., 1987, *Schizophrenia Bulletin* 13:261-276). The PANSS measures positive symptoms such as delusions, suspiciousness, and hallucinations; negative symptoms, such as blunted affect, social and emotional withdrawal, and stereotyped thinking; and general psychopathology, such as anxiety, tension, depression, and active social avoidance. The study also evaluated key secondary endpoints including the PANSS positive and negative subscales and co-morbid schizophrenia and depression. These results are listed below.

In December 2013, the Company announced positive topline results from the Company's randomized, placebo- and active-controlled Phase 2 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 presented additional data from the Phase 2 trial in April 2014 in a poster and a live presentation at the 4th Biennial Schizophrenia International Research Society (SIRS) held in Florence, Italy, as summarized below, and in May 2014 at the 167th Annual Meeting of the American Psychiatric Association (APA) held in New York City.

Primary endpoint: ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis on the trial's pre-specified primary endpoint, which was a change from baseline on the PANSS total score, compared to placebo on Study Day 28 ($p = 0.017$; MMRM-ITT).

Secondary endpoints: ITI-007 demonstrated differentiation across several pre-specified secondary analyses, including the PANSS positive symptom subscale, PANSS negative symptom subscale and subgroup analysis in patients with prominent negative symptoms at baseline, PANSS individual item response, the Calgary Depression Scale for Schizophrenia (CDSS) and a subgroup analysis in patients with schizophrenia and co-morbid depression at baseline, and safety measures. For example, ITI-007 at a dose of 60 mg significantly reduced the PANSS positive symptom subscale score over four weeks of treatment ($p \leq 0.05$ versus placebo at day 15, 22 and 28). Moreover, ITI-007 improved the PANSS negative symptom subscale score with an effect size of 0.34 in a subgroup of patients with prominent negative symptoms at baseline. Unlike risperidone, ITI-007 at 60 mg did not worsen certain negative symptoms such as blunted affect. The Company believes that these data suggest that ITI-007 differentiates from risperidone in two ways, by improving some negative symptoms that risperidone does not improve, and by not worsening other negative symptoms that risperidone worsens.

Co-morbid schizophrenia and depression: Patients were evaluated for depression using the Calgary Depression Scale for Schizophrenia (CDSS) and were included in the subgroup analysis if they exhibited a score of greater than 6 at baseline. In these patients with schizophrenia and co-morbid depression, at a dose of 60 mg, ITI-007 significantly reduced depression as measured by the CDSS ($p=0.044$) and significantly improved psychosis as measured by the PANSS total score ($p=0.018$).

Social function: ITI-007, at a dose of 60 mg, significantly improved certain individual symptom items on the PANSS across the positive symptom, negative symptom and general psychopathology subscales consistent with improved social function. Specifically, patients on ITI-007 at 60 mg experienced significant improvements in the Pro-social PANSS Factor (PPF),

separating from placebo as early as the first week of treatment ($p \leq 0.05$ versus placebo at day 8) and continuing to improve over time with a robust effect size of 0.6 at the completion of 4 weeks of treatment ($p < 0.001$).

Safety and tolerability: ITI-007 was well tolerated and the most frequent adverse event was sedation. At 60 mg and 120 mg ITI-007 showed a favorable side effect profile compared to risperidone in the present study. For example, ITI-007 demonstrated a favorable metabolic profile on blood glucose levels, insulin, cholesterol and triglycerides. There were no serious adverse events related to ITI-007.

About ITI-007

ITI-007 is the Company's lead product candidate, whose mechanisms of action, the Company believes, have the potential to yield a first-in-class antipsychotic therapy and, at lower doses, a first-in-class therapy for the behavioral disturbances associated with dementia including Alzheimer's disease. In pre-clinical and clinical trials to date, the Company has demonstrated that ITI-007 combines potent serotonin 5-HT_{2A} receptor antagonism, dopamine receptor phosphoprotein modulation (DPPM), glutamatergic modulation and serotonin reuptake inhibition into a single drug candidate. These trials also demonstrated that, at dopamine D₂ receptors, ITI-007 has dual properties, acting as both a post-synaptic antagonist and a pre-synaptic partial agonist. ITI-007 has also been demonstrated to stimulate phosphorylation of glutamatergic NMDA NR2B, or GluN2B, receptors in a mesolimbic specific manner.

At the lowest doses studied to date, ITI-007 acts primarily as a potent 5-HT_{2A} serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. The Company believes that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT_{2A} antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer's disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of ITI-007 is further increased, leading to moderate dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT_{2A} serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating symptoms associated with schizophrenia. The Company believes this and other doses may be useful in treating the symptoms associated with schizophrenia, bipolar disorder, major depressive disorder and other neuropsychiatric diseases.

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. 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 proposed Phase 3 plans for ITI-007 in schizophrenia and our expected timing for the initiation of trials and receipt of initial data; our beliefs about the potential uses and benefits of ITI-007 compared to existing treatments; the timing of results of our Phase 1/2 trial of ITI-007 in healthy geriatric patients and in patients with dementia, including Alzheimer's disease; our expected timing for the initiation of Phase 2 clinical trials for ITI-007 in patients with behavioral disturbances associated with dementia; our expected use of our cash and cash equivalents; and our research and development efforts and plans under the caption "About Intra-Cellular Therapies, Inc." 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 Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our periodic and current reports. 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues	\$ 219,238	\$ 643,264	\$ 387,025	\$ 1,241,516
Costs and expenses:				
Research and development	2,709,702	7,787,901	5,539,001	12,740,161
General and administrative	2,121,120	903,406	4,034,071	1,950,014
Total costs and expenses	4,830,822	8,691,307	9,573,072	14,690,175
Loss from operations	(4,611,584)	(8,048,043)	(9,186,047)	(13,448,659)
Interest expense	(2,032)	(231,756)	(7,073)	(473,072)
Interest income	80,077	2,408	116,297	5,963
Net loss	<u>(4,533,539)</u>	<u>(8,277,391)</u>	<u>(9,076,823)</u>	<u>(13,915,768)</u>
Net loss per common share:				
Basic & Diluted	\$ (0.15)	\$ (0.56)	\$ (0.33)	\$ (0.95)
Weighted average number of common shares:				
Basic & Diluted	29,273,357	14,690,942	27,882,360	14,645,529

The condensed consolidated statements of operations for the three and six months ended June 30, 2014 and 2013 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

	June 30, 2014	December 31, 2013
	<i>(Unaudited)</i>	<i>(Audited)</i>
Assets		
Current assets:		
Cash and cash equivalents	\$ 91,140,138	\$ 35,150,924
Investment securities, available-for-sale	49,355,284	2,000,000
Accounts receivable	219,238	336,318
Prepaid expenses and other current assets	493,356	762,243
Total current assets	141,208,016	38,249,485

Property and equipment, net	63,850	68,272
Other assets	<u>70,944</u>	<u>131,555</u>
Total assets	<u>\$ 141,342,810</u>	<u>\$ 38,449,312</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 415,791	\$ 3,395,067
Accrued and other current liabilities	1,434,875	2,611,091
Accrued employee benefits	<u>888,588</u>	<u>827,879</u>
Total current liabilities	2,739,254	6,834,037

Stockholders' equity:

Common stock, \$.0001 par value: 100,000,000 shares authorized; 29,344,020 and 22,159,446 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	2,934	2,216
Additional paid-in capital	205,289,691	89,177,556
Accumulated deficit	(66,641,320)	(57,564,497)
Accumulated other comprehensive loss	<u>(47,749)</u>	<u>—</u>
Total stockholders' equity	<u>138,603,556</u>	<u>31,615,275</u>
Total liabilities and stockholders' equity	<u>\$ 141,342,810</u>	<u>\$ 38,449,312</u>

The condensed consolidated balance sheet at June 30, 2014 has not been audited and this schedule does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

CONTACT: Intra-Cellular Therapies, Inc.

Juan Sanchez, M.D.

Vice President,

Corporate Communications and Investor Relations

212-923-3344

Burns McClellan, Inc.

Lisa Burns/Angeli Kolhatkar (Investors)

Justin Jackson (Media)

jjackson@burnsmc.com

212-213-0006