

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

NEW YORK, Aug. 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 June 30, 2015, and provided a corporate update.

Second Quarter 2015 Financial Results

Intra-Cellular Therapies (the Company) reported a net loss of \$21.5 million, or \$(0.61) per share (basic and diluted), for the second quarter of 2015 compared to a net loss of \$4.5 million, or \$(0.15) per share (basic and diluted), for the second quarter of 2014.

Research and development (R&D) expenses for the second quarter of 2015 were \$17.8 million, compared to \$2.7 million for the second 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 \$4.0 million for the second quarter of 2015, compared to \$2.1 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, cash equivalents and investments totaled \$204.0 million at June 30, 2015, compared to \$129.6 million at December 31, 2014.

The Company expects that existing cash and investments will be dedicated primarily to the ITI-007 development program including clinical trials of ITI-007 in schizophrenia, bipolar depression, behavioral disturbances in dementia, depressive disorders and related clinical and non-clinical activities including manufacturing. 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 June 2015, the Company completed enrollment of 450 patients in the ITI-007-301 Phase 3 clinical trial in schizophrenia. Clinical conduct for this study has been completed. The Company expects topline results from this trial late in the third quarter or early in the fourth quarter of this year.
- The Company initiated patient enrollment in a second Phase 3 clinical trial of ITI-007 in schizophrenia, ITI-007-302, in June 2015. Approximately 580 patients with schizophrenia are expected to be enrolled in this randomized, placebo- and active-controlled study. The second Phase 3 trial is ongoing and the Company anticipates topline results will be available in mid-2016.
- In May 2015, the Company presented additional analyses from the Phase 2 ITI-007 clinical trial in schizophrenia, ITI-007-005, at the 168th Annual Meeting of the American Psychiatric Association. The analyses showed patients' metabolic parameters remained consistently low during the 28 day ITI-007 treatment period, and increased within 5 days when patients were switched from ITI-007 to standard-of-care antipsychotic treatment in preparation for discharge from the clinic. The Company believes these data highlight the favorable metabolic profile of ITI-007 and the potential benefits of staying on treatment.
- In July 2015, following communications with the FDA, the Company announced its plans for the ITI-007 Phase 3 clinical program in bipolar depression. The program consists of two Phase 3 multicenter, randomized, double-blind, placebo-controlled clinical trials: one to evaluate ITI-007 as a monotherapy and the other as an adjunctive therapy to lithium or valproate. The Company plans to commence these studies later this year.
- 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 the second half of 2015.
- As previously communicated, the Company expects results from the ITI-007 positron emission tomography (PET) study in
 patients with schizophrenia, in the second half of 2015. The objective of this study is to further characterize the
 mechanism of action of ITI-007 in the brain.

"We are dedicated to advancing ITI-007 for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia and additional indications," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We are pleased with our progress in our mission to provide better treatment options for patients, enabling them to lead better lives.

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 94982004. Please dial in approximately 10 minutes prior to the call. The webcast will be available on the Company's website until August 12, 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 nonclinical development plans, including the design of our Phase 3 program for ITI-007 for the treatment of depressive episodes associated with bipolar disorder; our expectations concerning the timing of trials and studies and the availability of data; 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 June 30,	
	2015 (1)	2014 (1)
Revenues	\$57,390	\$219,238
Costs and expenses:		
Research and development	17,762,518	2,709,702
General and administrative	3,985,797	2,121,120
Total costs and expenses	21,748,315	4,830,822
Loss from operations	(21,690,925)	(4,611,584)
Interest expense	_	(2,032)

Interest income	179,607	80,077
Net loss	<u>\$(21,511,318)</u>	\$(4,533,539)
Net loss per common share: Basic & Diluted	\$(0.61)	\$(0.15)
Weighted average number of common shares: Basic & Diluted	35,002,819	29,273,357

⁽¹⁾ The condensed consolidated statements of operations for the quarters ended June 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 (Unaudited)

	June 30, 2015 (1)	December 31, 2014 (1)
Assets		
Current assets:	\$74_440_00C	C4 225 044
Cash and cash equivalents	\$71,418,286	\$61,325,044
Investment securities, available-for-sale Accounts receivable	132,570,900	68,320,672
	9,118	51,603
Prepaid expenses and other current assets	8,612,651	1,288,953
Total current assets	212,610,955	130,986,272
Property and equipment, net	722,131	54,553
Other assets	70,944	70,944
Total assets	\$213,404,030	\$131,111,769
Liabilities and stockholders' equity Current liabilities:		
Accounts payable	\$4,911,065	\$2,052,765
Accrued and other current liabilities	3,340,399	7,529,241
Accrued employee benefits	1,066,629	975,058
Total current liabilities	9,318,093	10,557,064
Long-term deferred rent	520,628	
Total liabilities	9,838,721	10,557,064
Stockholders' equity:		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 35,041,746 and 29,499,059 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	3,504	2,950
Additional paid-in capital	335,668,581	208,912,345
Accumulated deficit	(132,054,099)	(88,255,957)
Accumulated comprehensive loss	(52,677)	(104,633)
Total stockholders' equity	203,565,309	120,554,705
Total liabilities and stockholders' equity	\$213,404,030	\$131,111,769
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