# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 28, 2016

# Intra-Cellular Therapies, Inc.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-36274

Delaware (State or other jurisdiction of incorporation) 36-4742850 (IRS Employer Identification No.)

430 East 29th Street New York, New York 10016 (Address of principal executive offices, including zip code)

(646) 440-9333 (Registrant's telephone number, including area code)

Not applicable (Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### ITEM 2.02 Results of Operations and Financial Condition.

On April 28, 2016, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the first quarter ended March 31, 2016, and provided a corporate update.

A copy of the Company's press release containing such announcements is attached hereto as Exhibit 99.1. The information in the press release under the caption "First Quarter 2016 Financial Results," together with the condensed consolidated financial information included in the press release, are incorporated by reference into this Item 2.02 of this Current Report on Form 8-K.

#### ITEM 8.01 Other Events.

In the press release dated April 28, 2016, the Company also provided a corporate update. The information set forth under the headings "Recent and Upcoming Corporate Highlights" and "About Intra-Cellular Therapies," together with the forward-looking statement disclaimer at the end of the press release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

#### ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

## Exhibit Number Description

99.1 Press release dated April 28, 2016.

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## INTRA-CELLULAR THERAPIES, INC.

By: /s/ Lawrence J. Hineline

Lawrence J. Hineline Vice President of Finance and Chief Financial Officer

Date: April 28, 2016

#### Intra-Cellular Therapies Reports First Quarter 2016 Financial Results and Provides Corporate Update

NEW YORK, April 28, 2016 /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 March 31, 2016, and provided a corporate update.

#### First Quarter 2016 Financial Results

Intra-Cellular Therapies (the Company) reported a net loss of \$27.8 million, or \$0.64 per share (basic and diluted), for the first quarter of 2016 compared to a net loss of \$22.3 million, or \$0.72 per share (basic and diluted), for the first quarter of 2015.

Research and development (R&D) expenses for the first quarter of 2016 were \$23.4 million, compared to \$18.6 million for the first quarter of 2015. The increase is primarily due to costs associated with the second Phase 3 clinical trial for ITI-007 in schizophrenia and, to a lesser extent, the Phase 3 trials of ITI-007 in bipolar depression.

General and administrative (G&A) expenses were \$5.1 million for the first quarter of 2016, compared to \$3.8 million for the same period in 2015. The increase is primarily the result of higher stock-based compensation expense and, to a lesser extent, increased salaries and professional fees.

Cash and investments totaled \$456.1 million at March 31, 2016, compared to \$475.2 million at December 31, 2015.

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-commercial 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

program; 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**

- Clinical conduct in ITI-007-302, the second Phase 3 clinical trial of ITI-007 in schizophrenia, is progressing well. Patient enrollment is expected to be completed in the second quarter of 2016.
- At the Schizophrenia International Research Society meeting (SIRS), the Company presented additional data from the positive Phase 3 study of ITI-007 and from the Positron Emission Tomography or PET study, in patients with schizophrenia. The Phase 3 data highlighted the positive results demonstrating a statistically significant improvement versus placebo in schizophrenia symptoms and a favorable safety and tolerability profile along with high completion rates seen in patients receiving ITI-007.
- The Company's Phase 3 bipolar depression program is also progressing well. The bipolar program consists of two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials and includes patients with both bipolar I and bipolar II disorder. One trial will evaluate ITI-007 as a monotherapy and the other trial will evaluate ITI-007 as an adjunctive therapy with either lithium or valproate.
- The Company plans to initiate its late-stage clinical program evaluating ITI-007 for the treatment of behavioral disturbances in patients with dementia, including Alzheimer's disease, in the second quarter of 2016.
- The Company continues to advance its innovative phosphodiesterase (PDE) platform. The Company believes ITI-214, the lead compound in the PDE 1 portfolio, is the first selective PDE type 1 inhibitor to be tested in humans. ITI-214 has been studied in 4 Phase 1 clinical trials. In these studies, ITI-214 demonstrated a favorable safety profile and was generally well tolerated in both healthy volunteers and patients with schizophrenia. The Company will provide an update on the next steps for this program later this year.

"With the second ITI-007 Phase 3 clinical trial in schizophrenia nearing completion and our other late-stage clinical development programs moving forward, we are proud of our progress towards offering patients and their families new treatment options for those suffering from

neuropsychiatric and neurologic diseases," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We believe ITI-007 represents a novel approach for the treatment of schizophrenia and other indications, and we will continue with our mission to address these significant unmet medical needs."

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

The Company will host a live conference call and webcast today at 8:30 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 <u>www.intracellulartherapies.com</u>. 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 91500459. Please dial in approximately 10 minutes prior to the call.

#### 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 and bipolar depression. 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, cash equivalents and investment securities; 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 detailed in our public filings with the Securities and Exchange Commission. 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:**

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#### INTRA-CELLULAR THERAPIES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	<b>Three Months F</b> <b>2016</b> (1)	Ended March 31, 2015 (1)
Revenues	<del>\$</del> —	\$ 3,315
Costs and expenses:		
Research and development	23,433,620	18,632,427
General and administrative	5,064,233	3,771,628
Total costs and expenses	28,497,853	22,404,055
Loss from operations	(28,497,853)	(22,400,740)
Interest expense		
Interest income	656,404	113,916
Net loss	<u>\$(27,841,449)</u>	\$(22,286,824)
Net loss per common share:		
Basic & Diluted	\$ (0.64)	\$ (0.72)
Weighted average number of common shares:		
Basic & Diluted	43,193,857	30,775,287

(1) The condensed consolidated statements of operations for the quarters ended March 31, 2016 and 2015 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

	March 31, 2016 (1) (Unaudited)	December 31, 2015 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,240,565	\$ 47,159,303
Investment securities, available-for-sale	418,827,867	428,041,021
Accounts receivable	—	30,660
Prepaid expenses and other current assets	6,790,104	8,025,147
Total current assets	462,858,536	483,256,131
Property and equipment, net	731,429	775,522
Other assets	71,875	71,875
Total assets	\$ 463,661,840	\$ 484,103,528
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,959,272	\$ 1,632,905
Accrued and other current liabilities	5,241,839	3,423,464
Accrued employee benefits	1,745,561	1,207,143
Total current liabilities	8,946,672	6,263,512
Long-term deferred rent	1,970,747	1,597,105
Total liabilities	10,917,419	7,860,617
Stockholders' equity:		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 43,232,652 and 43,155,875 shares issued		
and outstanding at March 31, 2016 and December 31, 2015, respectively	4,323	4,316
Additional paid-in capital	673,679,915	669,878,103
Accumulated deficit	(220,890,547)	(193,049,098)
Accumulated comprehensive loss	(49,270)	(590,410)
Total stockholders' equity	452,744,421	476,242,911
Total liabilities and stockholders' equity	\$ 463,661,840	\$ 484,103,528

(1) The condensed consolidated balance sheets at March 31, 2016 and December 31, 2015 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.