
**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): September 1, 2015

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)

(212) 923-3344
(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))
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ITEM 8.01 Other Events.

On September 1, 2015, Intra-Cellular Therapies, Inc. (the “Company”) announced the publication of results from its ITI-007 Phase 2 clinical trial (ITI-007-005) in patients with schizophrenia in the journal *Biological Psychiatry*.

The Company’s press release announcing the publication of results from its ITI-007 Phase 2 clinical trial (ITI-007-005) in patients with schizophrenia is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated September 1, 2015

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. Hinline

Lawrence J. Hinline

Vice President of Finance, Chief Financial Officer,
Treasurer and Assistant Secretary

Date: September 2, 2015

INTRA-CELLULAR THERAPIES ANNOUNCES PUBLICATION OF POSITIVE PHASE 2 SCHIZOPHRENIA STUDY IN THE JOURNAL *BIOLOGICAL PSYCHIATRY*

NEW YORK, Sept. 1, 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 the publication of positive results from its ITI-007 Phase 2 clinical trial (ITI-007-005) in patients with schizophrenia. The article, “ITI-007 for the Treatment of Schizophrenia: A 4-Week Randomized, Double-Blind, Controlled Trial” (Lieberman et al. 2015), was published online on September 1st, 2015 in *Biological Psychiatry* and is available at [http://www.biologicalpsychiatryjournal.com/article/S0006-3223\(15\)00694-0/abstract](http://www.biologicalpsychiatryjournal.com/article/S0006-3223(15)00694-0/abstract).

In the trial, ITI-007 significantly improved symptoms in patients experiencing an acute exacerbation of schizophrenia at a dose of 60 mg daily, as demonstrated by a statistically significant separation from placebo on the PANSS total score at 4 weeks, the primary endpoint. Additionally, ITI-007 was found to be comparable to placebo on measures of safety and tolerability.

Secondary analyses indicated improved negative symptoms and symptoms of depression, particularly in the pre-specified subgroups who had these symptoms prominent at baseline. Additionally, ITI-007 significantly improved symptoms measured by the subscale for General Psychopathology compared to placebo, in addition to the previously presented improvements in positive symptoms and the Positive and Negative Syndrome Scale total score. Moreover, a significantly higher proportion of patients randomized to 60 mg ITI-007 experienced an improvement of 30% or greater than those randomized to placebo, meeting a pre-specified ‘responder’ criterion at a level that is considered to be clinically meaningful. ITI-007 was well-tolerated in patients with schizophrenia as evidenced by low discontinuation and adverse event rates, and was associated with a benign metabolic profile with significantly lower levels of prolactin, fasting glucose, total cholesterol, and triglycerides than risperidone. Based on these positive Phase 2 results, the Company initiated the Phase 3 ITI-007 program in schizophrenia in late 2014 and data from the first Phase 3 trial (ITI-007-301) are expected late in the third quarter or early in the fourth quarter of this year. A second phase 3 schizophrenia trial (ITI-007-302) is ongoing.

“Schizophrenia continues to place a substantial burden in suffering, disability, and cost on patients, caregivers, and society; existing antipsychotic medications, though effective, have significant limitations in their ability to alleviate symptoms in the different domains of the illness and can cause many side effects,” said Dr. Jeffrey Lieberman, Lawrence C. Kolb Professor and Chairman of Psychiatry at the Columbia University College of Physicians and Surgeons, and Director of the New York State Psychiatric Institute, Psychiatrist-in-Chief, Columbia University Medical Center of the New York-Presbyterian Hospital and lead author. “The results from this Phase 2 study of ITI-007, in light of its unique pharmacology, indicate that this novel drug represents a potential advance in the treatment of patients with schizophrenia.”

About the ITI-007 Phase 3 program

The ITI-007 Phase 3 program in schizophrenia includes two randomized, double-blind, placebo-controlled clinical trials in patients with an acutely exacerbated episode of schizophrenia. The primary measure is change from baseline on the Positive and Negative Syndrome Scale (PANSS) total score. Additional measures, along with safety and tolerability, include the subscales on the PANSS and other measures that may highlight differentiating features of ITI-007 among antipsychotic drugs.

The first Phase 3 clinical trial, ITI-007-301, is a randomized, double-blind, placebo-controlled clinical trial in patients with schizophrenia. In this trial, 450 patients were randomized to receive one of three treatments: 60 mg ITI-007, 40 mg ITI-007, or placebo in a 1:1:1 ratio. Patients received study treatment orally once daily in the morning for 4 weeks. Clinical conduct included a 1-week screening period before randomization followed by the 4 week study treatment period. Prior to discharge from the study, patients were switched to a standard-of-care antipsychotic treatment during a 5-day inpatient stabilization period. Patients were instructed to return for an outpatient safety follow-up visit approximately two weeks following the last dose of study treatment (study day 54). The clinical conduct for the ITI-007-301 trial is complete, and data are expected late in the third quarter or early in the fourth quarter of this year.

The second Phase 3 trial, or ITI-007-302, is evaluating 60 mg and 20 mg of ITI-007 compared to placebo after six weeks of once daily treatment, with risperidone as an active control. The Company plans to randomize approximately 580 patients in this trial. The Company anticipates topline results will be available in mid-2016.

Intra-Cellular Therapies has also recently announced that following communications with the FDA, the Company plans to initiate registration trials in bipolar depression later this year. Bipolar depression represents a significant unmet medical need.

About Schizophrenia

Schizophrenia is a disabling and chronic mental illness affecting over 1% of the world's population. Schizophrenia is characterized by multiple symptoms during an acute phase of the disorder that can include so-called "positive" symptoms, such as hearing voices, grandiose beliefs and suspiciousness or paranoia. These symptoms can be accompanied by additional, harder-to-treat symptoms, such as social withdrawal, blunted emotional response and speech deficits, collectively referred to as "negative" symptoms, difficulty concentrating and disorganized thoughts, or cognitive impairment, depression and insomnia. Such residual symptoms often persist even after the acute positive symptoms subside, and contribute substantially to the social and employment disability associated with schizophrenia. Current antipsychotic medications provide some relief for the symptoms associated with the acute phase of the disorder, but they do not effectively treat the residual phase symptoms associated with chronic schizophrenia. Currently available medications used to treat acute schizophrenia are limited in their use due to side effects that can include movement disorders, weight gain, metabolic disturbances, and cardiovascular disorders. There is an unmet medical need for new therapies that have improved side effect and efficacy profiles.

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 clinical and nonclinical development plans, including the design of our Phase 3 programs for ITI-007; 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.

Contact:

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