
**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): **June 23, 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))

ITEM 8.01 Other Events.

On June 23, 2015, Intra-Cellular Therapies, Inc. (the “Company”) announced initiation of enrollment for the second Phase 3 clinical trial (ITI-007-302) of the Company’s lead product candidate ITI-007 for the treatment of schizophrenia.

The Company’s press release announcing the initiation of enrollment for the second Phase 3 clinical trial 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 June 23, 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: June 24, 2015

Intra-Cellular Therapies Reports Initiation of Randomization for ITI-007-302 Phase 3 Trial in Schizophrenia

NEW YORK, June 23, 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 initiation of enrollment for the second Phase 3 clinical trial (ITI-007-302) of the Company's lead product candidate ITI-007. The Company anticipates top-line results from this trial will be available in 2016.

The first phase 3 clinical trial (ITI-007-301) completed enrollment earlier this month and the Company anticipates topline data from this trial will be available in the second half of 2015. This Phase 3 program follows positive results from an earlier positive Phase 2 clinical trial (ITI-007-005) demonstrating antipsychotic efficacy and a favorable safety and tolerability profile of ITI-007.

"I am pleased with the progress in our Phase 3 program of ITI-007 for the treatment of schizophrenia as this week we randomized the first patients in our second Phase 3 clinical trial," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "ITI-007 is a first-in-class approach to the treatment of schizophrenia that we believe will improve the lives of patients by allowing them to interact more fully with their family, friends and society as a whole."

The Company plans to initiate clinical trials for ITI-007 in bipolar depression and behavioral disturbances in patients with dementia later this year. Based on the existing ITI-007 safety and efficacy data and its unique pharmacology, the Company intends to expand the development of ITI-007 in different neuropsychiatric indications.

About the ITI-007-302 Phase 3 Trial

The Phase 3 clinical trial, ITI-007-302, is a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, over 500 patients will be randomized to receive one of four treatments: 60 mg ITI-007, 20 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. Patients will receive study treatment orally once daily in the morning for 6 weeks. Clinical conduct includes a 1-week screening period before randomization followed by the 6 week study treatment period. Prior to discharge from the study patients are switched to a standard-of-care antipsychotic treatment during a 5 day inpatient stabilization period. Patients are instructed to return for an outpatient safety follow-up visit approximately two weeks following the last dose of study treatment (study day 54). Topline results from this Phase 3 trial are anticipated to be available in 2016.

The primary endpoint for this clinical trial is change from baseline at Day 42 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. Secondary endpoints include the subscales on the PANSS and other measures to highlight differentiating features of ITI-007 among antipsychotic drugs. Safety and tolerability are also assessed.

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 Bipolar Depression

According to the National Institute of Mental Health the twelve-month prevalence of bipolar disorder in the US adult population is 2.6%. Bipolar disorder is characterized by changes in mood, with episodes of depression interposed with manic or hypomanic episodes along with changes in activity and energy. Depressive symptoms represent the predominant clinical presentation in patients with bipolar disorder. These depressive episodes can last longer, recur more often, and are associated with a worse prognosis than manic or hypomanic episodes. Bipolar depression remains an underserved medical need, with only a few FDA approved treatment options available. Therefore, there is a need for efficacious well-tolerated therapies with high patient compliance and without metabolic, motor and cardiovascular adverse events.

About Behavioral Disturbances in Dementia, Including Alzheimer's Disease

It has been estimated that 44.4 million people worldwide were living with dementia in 2013 including over five million patients with Alzheimer's disease in the United States. This number is expected to nearly double to 75.6 million by 2030 and to 135.5 million by 2050. While the diagnostic criteria for Alzheimer's disease and other dementias mostly focus on the related cognitive deficits, it is often the behavioral and psychiatric symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. Several behavioral symptoms are quite prevalent in patients with dementia, including patients with Alzheimer's disease. Rates of depression in Alzheimer's disease are estimated to be up to 87%, although most estimates are between 30% and 50%. Agitation and aggression are present in approximately 60% of patients. Sleep disturbances, particularly an increased likelihood of day-night reversal, are present in up to approximately 60% of patients. In view of the potential benefits of ITI-007 for aggression, agitation, sleep disorders and depression, and its safety profile to date, we believe that ITI-007 may provide a novel therapy for treating the behavioral disturbances accompanying dementia, including Alzheimer's disease.

The FDA has not approved any drug to treat the behavioral symptoms of dementia, including Alzheimer's disease. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. Current antipsychotic drugs are associated with a number of side effects, which can be problematic for elderly patients with dementia. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with dementia. There is a large unmet medical need for a safe and effective therapy to treat the behavioral symptoms in patients with dementia, including Alzheimer's disease.

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, behavioral disturbances in dementia, bipolar disorder, depression and other neuropsychiatric and neurological disorders. ITI-007, a first-in-class molecule, is in Phase 3 clinical trials 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 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.

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