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 28, 2016

Intra-Cellular Therapies, Inc.
(Exact name of registrant as specified in its charter)

Commission File Number: 001-36274

Delaware	**36-4742850**
(State or other jurisdiction of incorporation)	**(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 8.01 Other Events.

On September 28, 2016, Intra-Cellular Therapies, Inc. (the "Company") announced the results from its second Phase 3 clinical trial of its lead drug candidate, ITI-007 (ITI 007-302), for the treatment of schizophrenia.

The Company's press release announcing the results from its second Phase 3 clinical trial of ITI-007 for the treatment of 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

Exhibit Number	Description
99.1	Press release dated September 28, 2016

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, Chief Financial Officer, Treasurer and Assistant Secretary

Date: September 28, 2016

Exhibit 99.1

Intra-Cellular Therapies Announces Top-Line Results from the Second Phase 3 Trial of ITI-007 in Patients with Schizophrenia (Study '302)

Intra-Cellular Therapies to Host a Conference Call Today at 4:45 p.m. ET to Discuss Results

NEW YORK, September 28, 2016 (GLOBAL NEWSWIRE) — Intra-Cellular Therapies, Inc. (NASDAQ: ITCI) today announced top-line results from the second Phase 3 clinical trial (Study '302) of ITI-007, an oral, first-in-class investigational medicine for the treatment of schizophrenia. In this trial, neither dose of ITI-007 separated from placebo on the primary endpoint, change from baseline on the Positive and Negative Syndrome Scale (PANSS) total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. In this trial, ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of a previous study (our Phase 2 Study '005) in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar. We believe ITI-007 did not separate from placebo on the pre-specified primary endpoint in Study '302 in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive efficacy studies. Drug development in psychiatry faces numerous challenges and approved antipsychotics have had negative results as part of their clinical development programs. We are committed and adequately resourced to continue the development of ITI-007 for the treatment of schizophrenia. We believe the ITI-007 late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this Study '302, collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia. Across all three of our efficacy trials, ITI-007 60 mg improved symptoms of schizophrenia with the same magnitude of change from baseline in the primary endpoint, the PANSS total score. We plan to request a meeting with the U.S. Food and Drug Administration's (FDA) Division of Psychiatry Products to discuss the regulatory path for this first-in-class investigational agent.

"It is not uncommon in the field of psychiatry for studies to be challenged by high placebo response and there has been great variability in the effects observed from one study to the next," said Christoph Corell, M.D., Professor of Psychiatry at Hofstra Northwell School of Medicine. "Taken together, the ITI-007 schizophrenia program supports ITI-007 as a unique medication with an unprecedented safety and tolerability profile. Moreover, efficacy has been demonstrated in two large-scale schizophrenia studies to date. In one of these studies, ITI-007 and risperidone, the active control, had similar efficacy. In light of the results to date, I believe that ITI-007 represents a unique investigational medication which has the potential to advance the treatment of patients suffering from schizophrenia."

In this study, consistent with our previous schizophrenia studies, ITI-007 was well-tolerated with a safety profile similar to placebo. There were no clinically significant differences with ITI-007 from placebo in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, and lipids. As expected, risperidone demonstrated a statistically significant increase in weight gain, glucose, cholesterol, triglycerides and prolactin compared to placebo. These increases have

a negative impact on patients. In contrast, ITI-007 was statistically significantly better than risperidone on all of these tolerability parameters. There were no significant increases observed with ITI-007 versus placebo on any of these parameters. There continues to be a need for safer and more tolerable medications for patients with schizophrenia, which are not associated with the motoric and cardio-metabolic side effects of many existing treatments, thereby potentially improving compliance and reducing relapse and hospitalizations. We believe ITI-007 has the potential to address this need.

“Based on the strength of the clinical data generated in this program to date, including two positive studies, supportive evidence from Study ‘302 and a consistent, well-tolerated and placebo-like safety profile across all studies, we continue to believe ITI-007 will be an important treatment for patients suffering from schizophrenia. We remain committed to the development of ITI-007 for the treatment of schizophrenia, bipolar depression, agitation associated with dementia, including Alzheimer’s disease and other neuropsychiatric indications,” said Dr. Sharon Mates, Chairman and CEO of ITCI.

About the ITI-007 Schizophrenia Program

The ITI-007 clinical program in schizophrenia includes three randomized, double-blind, placebo-controlled trials. The Phase 2 trial (Study ‘005) was positive and was completed in 2013 with 335 patients. The first Phase 3 trial (Study ‘301) was positive and was completed in September 2015 with 450 patients. Today, we are reporting top-line results from our second Phase 3 trial (Study ‘302) with 696 patients.

About the ITI-007-302 Trial: This randomized, double-blind, fixed-dose, placebo- and active-controlled inpatient clinical trial was conducted at 13 sites in the United States consisting of 696 patients randomized (1:1:1:1) to receive ITI-007 60 or 20 mg, risperidone 4 mg as the active control, or placebo once daily in the morning for six weeks. Risperidone required a dose titration from 2 mg to 4 mg while no dose titration was required for ITI-007. Patients were diagnosed with schizophrenia (using DSM-5 criteria) and were required to have an acute exacerbation of psychotic symptoms. The pre-specified primary efficacy measure was change from baseline versus placebo at study endpoint (6 weeks) on the centrally rated 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.

In this study, approximately 79% of patients on placebo completed treatment compared to approximately 75% with 60 mg, 68% with 20 mg and only 63% for risperidone.

ITI-007 60 mg and 20 mg demonstrated a change from baseline on the PANSS total score of -14.6 points and -15.0 points respectively versus a -15.1 point change in placebo. Risperidone, the active control, demonstrated a change from baseline on the PANSS total score of -20.5 points.

In the context of the ITI-007 development program, ITI-007 60 mg improved symptoms of schizophrenia with the same magnitude of change from baseline on the PANSS total score across all three studies (-13.2 points in Study ‘005, -14.5 points in Study ‘301 as compared with -13.2

points at week 4 and -14.6 points at week 6 in Study ‘302). The magnitude of change for ITI-007 60 mg was similar to the active control, risperidone (-13.4 points) in Study ‘005. The trajectory of improvement with ITI-007 60 mg was similar across all three studies.

An unusually high placebo response was observed in this study compared with previous studies (-15.1 point change from baseline on PANSS total score in Study ‘302 in contrast to -7.4 points in Study ‘005 and -10.3 points in Study ‘301).

Conference Call and Webcast Details

Intra-Cellular Therapies will host a live conference call and webcast today at 4:45 p.m. ET, during which management will discuss the top-line results of our Phase 3 trial. 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 88711286. Please dial in approximately 10 minutes prior to the call.

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.

About ITI-007

ITI-007 is our lead drug development candidate with mechanisms of action that, we believe, have the potential to yield a first-in-class therapy for multiple therapeutic indications. In our pre-clinical and clinical trials to date, ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation (DPPM), glutamatergic modulation, and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia, as well as for the treatment of bipolar disorder, including bipolar

depression, and the treatment of agitation associated with dementia, including Alzheimer's disease. At dopamine D2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a post-synaptic antagonist and a pre-synaptic partial agonist. ITI-007 has also been demonstrated to have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA GluN2B receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases.

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, bipolar depression and agitation associated with dementia, including Alzheimer's disease. 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 beliefs about the potential uses and benefits of ITI-007; our clinical and non-clinical development plans; our plans to request a meeting with the FDA; the progress, timing and results of our clinical trials; the safety and efficacy of our product development candidates; our beliefs about unmet medical needs; the adequacy of our resources; 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 proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; 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:

Juan Sanchez, M.D.
Vice President
Corporate Communications and Investor Relations of Intra-Cellular Therapies, Inc.
Phone: 212-923-3344

Burns McClellan, Inc.
Lisa Burns
Justin Jackson (Media)
Email: jjackson@burnsmc.com
Phone: 212-213-0006