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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**Form 8-K**

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

**Date of Report (Date of earliest event reported): May 18, 2015**

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

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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)

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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 May 18, 2015, Intra-Cellular Therapies, Inc. announced that it presented further analyses regarding the Phase 2 clinical trial of ITI-007 in schizophrenia at the 168<sup>th</sup> Annual Meeting of the American Psychiatric Association.

The Company's press release announcing this presentation 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 May 18, 2015

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**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 and Chief Financial Officer

Date: May 19, 2015

**Intra-Cellular Therapies Announces Further Analyses of the Phase 2 Clinical Trial of ITI-007 in Schizophrenia at the 168th Annual Meeting of the American Psychiatric Association**

NEW YORK, May 18, 2015 (GLOBE NEWSWIRE) — Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders presented further analyses of the Phase 2 clinical trial of ITI-007 in schizophrenia at the American Psychiatric Association (APA) 168th Annual Meeting being held in Toronto, Canada.

The oral presentation titled “ITI-007 for the Treatment of Schizophrenia: Further Analyses of the Randomized ITI-007-005 Trial” was presented by Kimberly E. Vanover, Ph.D., Vice President of Clinical Development. The presentation provided further analyses of the Phase 2 clinical trial of ITI-007, whose topline results and secondary analyses were previously presented at scientific and medical meetings.

A summary of the information contained in the oral presentation is set forth below.

Primary endpoint and secondary efficacy analyses:

As previously reported, ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis on the trial’s pre-specified primary endpoint, which was a change from baseline on the PANSS total score, compared to placebo on Study day 28 ( $p = 0.017$ ; MMRM-ITT).

At 60 mg, ITI-007 demonstrated a differentiated efficacy response profile including improvements in negative symptoms, depression and prosocial behavior.

- Specifically, 60 mg ITI-007 improved negative symptoms in both the overall intent-to-treat (ITT) population and in the pre-specified subgroup of patients with prominent negative symptoms at baseline. These effects were not seen with risperidone.
- In a subgroup of schizophrenia patients who had co-morbid depression, ITI-007 60mg showed a rapid, robust and statistically significant anti-psychotic effect not observed with risperidone. Furthermore, ITI-007 60mg consistently and significantly improved depressive symptoms in this subgroup.

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#### Safety and Tolerability:

ITI-007 demonstrated a favorable tolerability profile with little or no weight gain, a favorable effect on metabolic parameters, and a reduced risk for akathisia and hyperprolactinemia.

- ITI-007 had little or no effect on weight gain analyses including placebo-adjusted mean weight gain by clinical site. In contrast, risperidone resulted in weight gain of approximately 2 kg after adjusting for placebo response.
- In the '005 trial patients received blinded study medication for 28 days and were switched to standard of care (SOC) for a 5-day stabilization period prior to hospital discharge. Insulin, glucose and triglyceride levels remained low during the treatment period for patients randomized to either dose of ITI-007, but increased when patients were switched to SOC. In contrast, glucose, insulin and triglyceride levels were increased during risperidone therapy during the 28-day treatment period.
- Similarly, prolactin levels were low for patients randomized to either dose of ITI-007, but increased after patients were switched to SOC. In contrast, patients on risperidone experienced a significant increase in prolactin levels during the study period.
- ITI-007 demonstrated a low relative risk of akathisia, with rates of akathisia similar to placebo, in contrast to risperidone which showed a relative risk 3X that of placebo.

Patients treated with conventional or newer second generation antipsychotic drugs (SGAs) for schizophrenia have an increased risk of diabetes and other associated diseases including cardiovascular disease, resulting in a significant burden on our healthcare system. Altered metabolic parameters are known to increase disease risk following certain antipsychotic drug use. Prominent among these metabolic risk factors are elevations in plasma glucose, insulin and triglyceride levels. Existing data suggests that ITI-007 does not impact these metabolic parameters in patients with schizophrenia and may have a substantial potential benefit for this patient population.

“The additional analyses presented at APA continue to demonstrate ITI-007’s unique safety profile. We believe the finding that patients’ metabolic parameters and prolactin are low while on ITI-007, then worsen after being switched to standard of care antipsychotic therapy, speaks to the beneficial profile of ITI-007,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “We believe these analyses continue to support the unique potential benefits of ITI-007 for patients, their families, and the healthcare system. Existing data provide evidence for the positioning of ITI-007 as a potential single stand-alone therapy for the treatment of multiple symptoms associated with schizophrenia including positive symptoms and negative symptoms and symptoms of impaired social function.”

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### **About the ITI-007-005 Phase 2 Clinical Trial Design**

The Phase 2 clinical trial, ITI-007-005, was a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, 335 patients were randomized to receive one of four treatments: 60 mg ITI-007, 120 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. Patients received study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the ITT primary analysis.

The primary endpoint for this clinical trial was change from baseline to Day 28 on the 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. Safety and tolerability were also assessed.

### **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 progress and timing of our drug discovery and development programs; 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

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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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