# 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): March 31, 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)

k 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 sions:
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 March 31, 2015, Intra-Cellular Therapies, Inc. announced that it presented data regarding the ITI-007 development program and described the rationale supporting the strategy for the advancement of ITI-007 in multiple clinical indications at the 15th International Congress on Schizophrenia Research (ICOSR) in Colorado Springs, Colorado.

The Company's press release announcing these presentations 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 March 31, 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. Hineline

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

Date: March 31, 2015

#### Intra-Cellular Therapies Presents the ITI-007 Clinical Development Program at the 15th International Congress on Schizophrenia Research

NEW YORK, March 31, 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 data regarding the ITI-007 development program and described the rationale supporting the strategy for the advancement of ITI-007 in multiple clinical indications at the 15th International Congress on Schizophrenia Research (ICOSR) in Colorado Springs.

In a poster the Company described the rationale for dose selection in the ongoing Phase 3 clinical trial in schizophrenia. Preclinical data predicted antipsychotic efficacy at human equivalent doses as low as 20-40 mg of ITI-007. Positron emission tomography (PET) data in healthy volunteers demonstrated striatal D2 receptor occupancy of ~20% and ~40% at doses of 20 mg and 40 mg, respectively. Striatal D2 receptor occupancy at 60 mg was projected to be approximately 50%. In a Phase 2 clinical trial in patients with schizophrenia, ITI-007 at a dose of 60 mg demonstrated a statistically significant and clinically meaningful improvement in psychosis with a favorable metabolic, cardiovascular and motor adverse event profile.

Based on the preclinical and clinical results described above the Company selected doses of 60 mg and 40 mg of ITI-007 for the ongoing Phase 3 clinical trial in schizophrenia. This study, ITI-007-301, is a randomized, double-blind, placebo-controlled, inpatient clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, over 400 patients are expected to be randomized to receive one of three treatments: 60 mg ITI-007, 40 mg ITI-007 or placebo in a 1:1:1 ratio. The Company anticipates topline results from this trial will be available in the second half of 2015.

In an oral presentation the Company summarized the clinical progress of ITI-007 to date and emphasized its rationale supporting the development of ITI-007 for other indications. ITI-007 has a unique pharmacological profile acting as a serotonergic, dopaminergic, and glutamatergic modulator. In addition, ITI-007 has a dose-dependent pharmacology. At low doses, ITI-007 acts mainly as a potent 5-HT2A receptor antagonist, with modest interaction with other drug targets. As the dose is increased, additional pharmacological interactions play a greater role, i.e., dopamine and glutamate receptor modulation and inhibition of SERT are gradually increased. The Company emphasized the pharmacological, pharmacodynamic and safety profile of ITI-007, which supports its development in other indications beyond schizophrenia, including bipolar disorder and major depressive disorder as well as behavioral disturbances in patients with dementia.

ITI-007's unique pharmacology, including its activity at the serotonergic, dopaminergic, and glutamatergic systems, is associated with reduction in symptoms associated with depression. In the Phase 2 schizophrenia trial, a 60 mg dose of ITI-007 resulted in

marked antidepressant effects in patients with schizophrenia and co-morbid depression. The drug's unique pharmacological activity also supports potential efficacy for the treatment of bipolar disorder and major depressive disorder.

In addition, low doses of ITI-007 have the potential to reduce behavioral disturbances in patients with dementia (including Alzheimer's disease) such as a reduction in agitation and irritability, improvements in mood and emotional stress as well as improvement in sleep. Low doses of ITI-007, up to and including 30 mg were demonstrated to be safe and well tolerated in a clinical trial of healthy geriatric subjects and elderly patients with dementia. The Company believes that these characteristics, when coupled with the drug's favorable safety and tolerability profile and the pro-social profile of ITI-007's clinical effects, result in a differentiated profile across multiple indications.

"We are undertaking a robust clinical development program for ITI-007. The key aspects of our ITI-007 program have been designed based on our understanding of the unique pharmacology of ITI-007, the strong existing clinical evidence and the supporting preclinical data. As a result, ITI-007 is being developed as a differentiated treatment in several CNS indications in which important medical needs exist" said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

#### **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.

#### Contact:

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

Burns McClellan, Inc. Lisa Burns/Nancy Yu (Investors) Justin Jackson (Media) <u>jjackson@burnsmc.com</u> 212-213-0006