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): May 1, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 8.01 Other Events.

On May 1, 2017, Intra-Cellular Therapies, Inc. (the "Company") provided an update on its clinical program of its lead drug candidate, lumateperone (ITI-007), for the treatment of schizophrenia.

The Company's press release providing an update on its clinical program of lumateperone 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 May 1, 2017

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: May 1, 2017

Exhibit 99.1

May 1, 2017

Intra-Cellular Therapies Provides Corporate Update On Schizophrenia Program

Intra-Cellular Therapies to Host a Conference Call Today at 8:30 a.m. ET

NEW YORK, May 1, 2017 (GLOBE NEWSWIRE) — Intra-Cellular Therapies, Inc. (NASDAQ:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today provided a corporate update.

As part of our ongoing dialogue with the U.S. Food and Drug Administration (FDA) regarding our lumateperone (also known as ITI-007) development program in schizophrenia, we requested guidance from the FDA on the acceptability of the two positive well controlled clinical trials we have conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, as the basis for the submission of a new drug application (NDA) for the treatment of schizophrenia. In connection with this request we provided extensive information and data analyses to the FDA relating to the three studies. The FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date. We are pleased with this response from the FDA and we believe our schizophrenia clinical development program collectively provides evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia.

The FDA has raised questions, however, relating to certain findings observed in nonclinical animal toxicology studies of lumateperone and has requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. These findings only occurred in one of the nonclinical toxicology species and only after high exposure to drug related material. We and our expert consultants believe these findings are not indicative of a safety risk for humans due to species differences in the metabolism of lumateperone. In humans, lumateperone and its metabolites are rapidly eliminated from the body and there is no retention of drug or drug related material. In the animal species in question, a substantial amount of drug related metabolites are retained for an extended period of time and metabolites are formed in this species that are not detected in humans.

As we have previously disclosed, in our clinical trials of lumateperone in schizophrenia up to and including 6 weeks treatment duration in humans, lumateperone has a favorable safety and tolerability profile with the incidence of movement disorders and cardiometabolic adverse events similar to placebo and statistically significantly better on several key safety and tolerability parameters than risperidone, the most frequently prescribed antipsychotic for the treatment of

schizophrenia. The FDA has not raised any safety concerns regarding the study of lumateperone in short term treatment trials in humans, including our completed schizophrenia clinical trials and our ongoing Phase 3 clinical trials in bipolar depression and agitation associated with dementia, including Alzheimer's disease. With over 1500 people exposed to date, lumateperone has been well-tolerated with a safety profile similar to placebo.

We are preparing responses to the FDA's request for additional information and intend to proceed with our long-term safety study of lumateperone in patients with schizophrenia. If the FDA deems our responses regarding the nonclinical findings to be sufficient, we intend to submit an NDA for lumateperone for the treatment of schizophrenia by mid-year 2018 supported by the efficacy studies we have conducted to date. If the FDA deems our responses insufficient, they may place our long-term safety study on a clinical hold. The results of the long-term safety study will be required to support an NDA approval for a chronic condition such as schizophrenia.

Conference Call and Webcast Details

Intra-Cellular Therapies will host a live conference call and webcast today at 8:30 a.m. ET, during which management will discuss the corporate update on the schizophrenia program. 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 16993694. Please dial in approximately 10 minutes prior to the call.

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, lumateperone (also known as ITI-007), for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. Lumateperone, 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 extent to which the results of our clinical trials to date support an NDA filing for lumateperone for the treatment of schizophrenia; our belief that the toxicity findings observed in nonclinical animal toxicology

studies of lumateperone are not indicative of a safety risk for humans; our ability to address the FDA's questions about the toxicity findings observed in nonclinical animal toxicology studies of lumateperone and provide evidence satisfactory to the FDA that the toxicities observed in these nonclinical animal toxicology studies of lumateperone are not indicative of a safety risk for humans; our ability to proceed with our long-term safety study and to file an NDA with the FDA; 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: the FDA may place our long-term safety study on a clinical hold, which would delay or prevent us from completing the safety study and from filing an NDA; our current and planned clinical trials, other studies for lumateperone, 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:

Intra-Cellular Therapies, Inc.
Juan Sanchez, M.D.
Vice President, Corporate Communications and Investor Relations
646-440-9333

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