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 13, 2018

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 March 13, 2018, Intra-Cellular Therapies, Inc. (the "Company") announced that it had a positive pre-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration (the "FDA") regarding lumateperone for the treatment of schizophrenia.

The Company's press release announcing that it had a positive pre-NDA meeting with the FDA regarding 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 March 13, 2018

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: March 13, 2018

Exhibit 99.1

Intra-Cellular Therapies Announces Positive Pre-NDA Meeting with FDA for Lumateperone for the Treatment of Schizophrenia

NEW YORK, March 13, 2018 (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 that the Company had a positive pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding lumateperone for the treatment of schizophrenia. At the meeting, the Company and the FDA agreed on the proposed content and timing of a rolling NDA submission. As previously announced, the Company plans to complete its NDA submission by mid-2018.

In 2017 the FDA granted Fast Track designation for lumateperone for the treatment of schizophrenia. The Company requested Fast Track designation for lumateperone based on clinical evidence that lumateperone has the potential to address unmet medical needs for the treatment of schizophrenia. The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drug candidates to treat serious and life-threatening conditions.

"We are pleased with the outcome of our pre-NDA meeting and look forward to initiating our rolling NDA submission. We have made significant progress in the advancement of lumateperone and our mission to provide better treatment options for patients suffering from neuropsychiatric conditions," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

About Lumateperone for the Treatment of Schizophrenia

Lumateperone, our lead product candidate, is a first-in-class molecule that provides selective and simultaneous modulation of serotonin, dopamine, and glutamate—three neurotransmitter pathways implicated in severe mental illness. Unlike existing schizophrenia treatments, lumateperone is a dopamine receptor phosphoprotein modulation, or DPPM, acting as a pre-synaptic partial agonist and post-synaptic antagonist at D2 receptors. We believe this mechanism, along with potent interactions at 5-HT2A receptors, serotonin transporters, and D1 receptors with indirect glutamatergic modulation, may contribute to the efficacy of lumateperone across a broad array of symptoms, with improved psychosocial function and favorable tolerability. This compound has the potential to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases.

Our clinical development program for the treatment of schizophrenia with lumateperone includes three large randomized, double-blind, placebo-controlled trials. In two studies, ITI-007 60 mg showed a statistically significant separation from placebo on the primary endpoint, the Positive and Negative Syndrome Scale, or PANSS, total score. Across all three studies, ITI-007 was found to be well tolerated with a safety profile similar to placebo.

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 (PDE) platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders. The lead molecule in the Company's PDE1 portfolio, ITI-214, is in development for the treatment of symptoms associated with Parkinson's disease.

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 plans to initiate a rolling NDA for lumateperone for the treatment of schizophrenia and our expectations about the timing of the completion of such NDA submission by mid-2018; our belief that lumateperone has the potential to address unmet medical needs for the treatment of schizophrenia; the potential benefits of Fast Track designation to facilitate or accelerate the regulatory approval of lumateperone for the treatment of schizophrenia; 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: risks associated with our current and planned clinical trials, we may encounter unexpected safety or tolerability issues with lumateperone in ongoing or future trials and other development activities, 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; fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process; 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.