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): August 5, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**ITCI**	**The Nasdaq Global Select Market**

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 August 5, 2019, Intra-Cellular Therapies, Inc. (the "Company") provided a regulatory update following its recent meeting with the U.S. Food and Drug Administration ("FDA") in connection with the FDA's ongoing review of the Company's New Drug application ("NDA") for lumateperone for the treatment of schizophrenia.

The Company's press release providing a regulatory update 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 August 5, 2019

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
Senior Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary

Date: August 5, 2019

Exhibit 99.1

Intra-Cellular Therapies to Host Conference Call to Provide Regulatory Update Following Recent Meeting with FDA

- Agreement reached with FDA on submission of additional non-clinical information for NDA review of lumateperone for the treatment of schizophrenia
- Lumateperone PDUFA goal date extended three months to December 27, 2019

Conference call scheduled today at 8:30 am ET

NEW YORK, August 5, 2019 (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 it recently met with the U.S. Food and Drug Administration (FDA) and reached agreement to submit additional non-clinical information in connection with the FDA's ongoing review of the Company's New Drug application (NDA) for lumateperone for the treatment of schizophrenia. The FDA has informed the Company that the planned submission of this additional information constitutes a major amendment to the NDA, resulting in a three-month extension of the Prescription Drug User Fee Act (PDUFA) goal date to December 27, 2019 in order to provide time for a full review of the submission.

"We are pleased with the productive dialogue we have had with the FDA," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We intend to provide the FDA with the requested information in the coming weeks and we believe this information will be sufficient to address the FDA's requests."

The Company has agreed with the FDA to provide additional information related to toxicology findings in previous animal studies with the objective to further substantiate the Company's position that those findings are not relevant to humans due to species specific differences in the metabolism of lumateperone. The Company is performing a limited number of in-vitro analyses, including the analysis of animal and human plasma samples from previous studies to confirm that the metabolic pathway, and the metabolites formed, are different in animals and humans. The Company has commenced the requested analyses and expects to complete them shortly and provide the information to the FDA.

Conference Call and Webcast Details

The Company will host a live conference call and webcast today at 8:30 AM Eastern Time to provide a corporate update following its recent meeting with the FDA. 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 9883468. Please dial in approximately 10 minutes prior to the call.

About Lumateperone

Lumateperone, our lead product candidate, is a molecule that provides selective and simultaneous modulation of serotonin, dopamine, and glutamate - three neurotransmitter pathways implicated in severe mental illness. Lumateperone is a potent serotonin 5-HT2A receptor antagonist, a dopamine receptor phosphoprotein modulator (DPPM) acting as a presynaptic partial agonist and postsynaptic antagonist at dopamine D2 receptors, a dopamine D1 receptor-dependent indirect modulator of glutamate (both NDMA and AMPA), and a serotonin reuptake inhibitor. Lumateperone is an investigational new drug and has not been approved for marketing for any use by the FDA or any other regulatory authority in any other jurisdiction.

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 is under review by the FDA for the treatment of schizophrenia and is in Phase 3 clinical development for the treatment of bipolar depression. Intra-Cellular Therapies 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 and for the treatment of heart failure.

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, the safety, tolerability and efficacy of our product candidates; the PDUFA goal date for the FDA’s review of the lumateperone NDA; our expectation that we will complete the non-clinical studies shortly and provide the results to the FDA; our intent to provide the FDA with requested information in the coming weeks and our belief that the information will be sufficient to address the FDA’s requests; the potential for lumateperone to provide benefits in a broad range of neuropsychiatric conditions; 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: whether the NDA for lumateperone for the treatment of schizophrenia will be approved by the FDA and whether the FDA will complete its review within the target timelines, including the new PDUFA goal date; the risk that the NDA will not be approved despite the FDA’s acceptance of the NDA for review; whether we will be able to provide in a timely manner the additional information that the FDA requests, whether such additional information will be satisfactory to the FDA, and whether the FDA will require further additional information; the risk that a future Advisory Committee meeting will negatively impact the approval of the NDA for lumateperone; 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; 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
jgrimaldi@burnsmc.com
212-213-0006

MEDIA INQUIRIES:

Jennifer Paganelli
Corporate Media Relations, W2Owcg
jpaganelli@wcgworld.com
347-658-8290