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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): July 23, 2019**

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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)

**(646) 440-9333**  
(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))

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.

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**ITEM 8.01 Other Events.**

On July 23, 2019, Intra-Cellular Therapies, Inc. (the “Company”) announced that the U.S. Food and Drug Administration (“FDA”) has cancelled the Psychopharmacologic Drugs Advisory Committee meeting scheduled for July 31, 2019 to discuss the New Drug Application (“NDA”) for lumateperone for the treatment of schizophrenia.

The Company’s press release announcing that the FDA has cancelled the Psychopharmacologic Drugs Advisory Committee meeting scheduled for July 31, 2019 to discuss the NDA for 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press release dated July 23, 2019</a>

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

Date: July 24, 2019

**Intra-Cellular Therapies Provides Update on FDA Advisory Committee Meeting for Lumateperone for the Treatment of Schizophrenia**

NEW YORK, July 23, 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 the U.S. Food and Drug Administration (FDA) has cancelled the Psychopharmacologic Drugs Advisory Committee meeting scheduled for July 31, 2019 to discuss the New Drug Application (NDA) for lumateperone for the treatment of schizophrenia.

The Company recently provided additional information to the FDA in response to information requests relating to non-clinical studies. The FDA cancelled the Advisory Committee meeting to allow sufficient time to review this new and any forthcoming information as they continue the NDA review. This information may result in an extension of the September 27, 2019 Prescription Drug User Fee Act (PDUFA) target action date for the lumateperone NDA.

The Company has a meeting scheduled with the FDA shortly and will provide an update following the meeting.

**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-HT<sub>2A</sub> receptor antagonist, a dopamine receptor phosphoprotein modulator (DPPM) acting as a presynaptic partial agonist and postsynaptic antagonist at dopamine D<sub>2</sub> receptors, a dopamine D<sub>1</sub> receptor-dependent indirect modulator of glutamate (both NMDA 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 U.S. Food and Drug Administration (FDA) or any other regulatory authority in any other jurisdiction.

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## **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 target action date for the FDA's review of the lumateperone NDA; our plans to provide an update following our meeting with the FDA; 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 any new PDUFA target action date; the risk that the NDA will not be approved despite the FDA's acceptance of the NDA for review; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; 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:

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Burns McClellan, Inc.  
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