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): December 18, 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 December 18, 2018, Intra-Cellular Therapies, Inc. (the "Company") announced that an independent data monitoring committee (DMC) had completed a pre-specified interim analysis of the Company's ongoing clinical trial with low-dose lumateperone (9 mg ITI-007) for the treatment of agitation in patients with probable Alzheimer's disease (Study 201).

The Company's press release announcing that an independent data monitoring committee (DMC) had completed a pre-specified interim analysis of the Company's ongoing clinical trial with low-dose lumateperone (9 mg ITI-007) for the treatment of agitation in patients with probable Alzheimer's disease (Study 201) 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 December 18, 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: December 18, 2018

Exhibit 99.1

Intra-Cellular Therapies Announces Update on ITI-007-201 Clinical Trial for Treatment of Agitation in Patients with Probable Alzheimer's Disease

NEW YORK, December 18, 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 an independent data monitoring committee (DMC) has completed a pre-specified interim analysis of the Company's ongoing clinical trial with low-dose lumateperone (9 mg ITI-007) for the treatment of agitation in patients with probable Alzheimer's disease (Study 201). The DMC concluded that Study 201 is not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result of this recommendation, the Company has determined to discontinue Study 201. Lumateperone was generally well tolerated in Study 201 and the decision to discontinue the study was not related to safety. The Company does not expect that these results will impact any of its other ongoing development programs.

"We are disappointed for patients suffering from Alzheimer's disease that the interim analysis did not detect a signal that would warrant continuation of this study. Effective clinical study design is a challenge, especially for a therapeutic indication for which there are no approved treatments," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We intend to analyze the full data set when it is available to determine the next steps in our program for patients with probable Alzheimer's disease and agitation. On behalf of everyone at Intra-Cellular Therapies, I would like to thank all of the patients, caregivers, investigators and clinical research personnel involved with this study."

About Study 201

Study 201 was a Phase 3 multicenter, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable Alzheimer's disease and clinically significant symptoms of agitation. In this trial, patients were randomized to receive 9 mg ITI-007 or placebo in a 1:1 ratio orally once daily for four weeks. The primary efficacy measure utilized the Cohen-Mansfield Agitation Inventory — Community version (CMAI-C). Other efficacy measures included a Clinical Global Impression scale for Severity (CGI-S) of illness. Safety and tolerability were also assessed in the trial.

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. 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 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, our clinical and non-clinical development plans; the progress, timing and results of our clinical trials; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of lumateperone; our expectation that the results of this interim analysis and the decision to discontinue Study 201 will not impact any of our other ongoing development programs; 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 accepted and approved by the FDA; 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
agray@burnsmc.com
212-213-0006

MEDIA INQUIRIES:

Patrick Ryan, Esq.
Corporate Media Relations, W2Owcg
pryan@wcgworld.com