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 11, 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 11, 2018, Intra-Cellular Therapies, Inc. (the "Company") announced favorable results from the second part of its open-label safety switching study (Study 303) assessing the effects of long-term administration of lumateperone in patients with stable symptoms of schizophrenia at the 57th Annual Meeting of the American College of Neuropsychopharmacology (the "ACNP").

The Company's press release announcing the favorable results from the second part of its open-label safety switching study (Study 303) assessing the effects of long-term administration of lumateperone in patients with stable symptoms of schizophrenia at the ACNP 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 11, 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 and Chief Financial Officer

Date: December 12, 2018

Exhibit 99.1

Intra-Cellular Therapies Announces Favorable Results From Long-Term Open-Label Safety Switching Study With Lumateperone in Patients with Schizophrenia at the 57th Annual Meeting of the American College of Neuropsychopharmacology

Favorable safety results following administration of lumateperone for up to one year treatment duration are consistent with and extend the safety and tolerability profile previously reported in short-term trials

Intra-Cellular Therapies to Host a Conference Call Wednesday, December 12, 2018 at 8:30 a.m. ET

NEW YORK, December 11, 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 favorable results from the second part of its open-label safety switching study (Study 303) assessing the effects of long-term administration of lumateperone in patients with stable symptoms of schizophrenia at the 57th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) held in Hollywood, FL, December 9-13, 2018.

Poster T184 entitled “Long-Term Safety for Lumateperone (ITI-007) in the Treatment of Schizophrenia” is being presented today from 5:30 pm - 7:30 pm during Poster Session II.

The poster presented data demonstrating that lumateperone, administered for up to one year, was generally well tolerated and exhibited statistically significant improvements from baseline on key safety measures of body weight, cardiometabolic and endocrine parameters, without motor side effects often associated with other antipsychotic medications.

Last year, we presented results from Part I of Study 303, which demonstrated an improved safety profile when patients were switched to a 6-week treatment duration with lumateperone, followed

by a loss of this benefit when switched back to standard-of-care (SOC). In the second part (Part II) of Study 303, 603 patients with stable symptoms of schizophrenia were switched from SOC antipsychotic medications to lumateperone (ITI-007 60 mg) for up to one year with no dose titration of lumateperone required.

The data from Part II of Study 303 presented at ACNP reflect a planned interim data analysis that included at least 300 patients who completed at least six months of treatment and at least 100 patients who completed one year of treatment, consistent with Food and Drug Administration (FDA) and International Council for Harmonisation (ICH) safety database guidelines.

In contrast to many other antipsychotics that are associated with weight gain, in this study, mean body weight significantly decreased after switch from SOC antipsychotic treatment at six months (-1.82 kg at Day 175, $p < 0.001$) and one year (-3.16 kg at Day 350, $p < 0.001$) of treatment with lumateperone. Of the 603 patients in the trial, 24% experienced a decrease of ³7% from their SOC baseline body weight over the course of the study, whereas only 8% experienced a body weight increase of ³7%. Long-term treatment with lumateperone also demonstrated a favorable cardiometabolic and endocrine safety profile with stable blood levels of glucose, insulin, and HDL cholesterol and statistically significant ($p < 0.001$) reductions from SOC baseline in total cholesterol, LDL cholesterol and prolactin.

With long-term administration, the most frequent (occurring in ³5% of patients) treatment-emergent adverse events, regardless of whether such adverse event was related to treatment, were decrease in weight (9.5%), dry mouth (7.6%), diarrhea (7.0%), and headache (5.1%). The proportion of patients experiencing motor side effects while on lumateperone was low: any adverse event related to extrapyramidal side effects combined including akathisia (5.3%); and akathisia specifically (0.5%). There were no signs of treatment-emergent extrapyramidal side effects, akathisia, or dyskinesia as measured by the Simpson Angus Scale (SAS), the Barnes Akathisia Rating Scale (BARS), or the Abnormal Involuntary Movement Scale (AIMS), respectively. In addition, there were no signs of treatment-emergent suicidal ideation or behavior as measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).

As observed in Part I of the study (6 weeks of treatment), patients treated with lumateperone in Part II (up to one year of treatment) did not worsen with respect to their symptoms of schizophrenia upon switch from SOC. Rather, statistically significant ($p < 0.001$) improvements

from a baseline score of 62.9 were observed on the Positive and Negative Syndrome Scale total score (PANSS).

Given the favorable safety profile of lumateperone observed to date, the study has been extended to allow patients to stay on lumateperone for more than one year and study conduct is ongoing.

“These data contribute to the growing body of clinical evidence of the favorable safety and tolerability profile of lumateperone in patients with acute and stable symptoms of schizophrenia over short and long-term treatment periods. We believe lumateperone, if approved, would represent an important new treatment option for patients suffering from schizophrenia,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

“Schizophrenia places a substantial burden on patients, caregivers, and society. Existing antipsychotic medications, though effective, have significant limitations, including their association with weight gain, other cardiometabolic side effects and motor side effects,” said Dr. Christoph Correll, M.D., Professor of Psychiatry and Molecular Medicine, Hofstra Northwell School of Medicine. “An improvement in symptoms of schizophrenia without compromising the overall health of patients would represent a crucial advance in the treatment of patients with schizophrenia.”

In addition, at ACNP, the Company presented a poster on ITI-333, a novel compound that possesses a three-pronged mechanism of action with high affinity at serotonin 5-HT2A, dopamine D1 and mu opioid (MOP) receptors. Poster M270 entitled “ITI-333 for the Treatment of Pain and Psychiatric Co-Morbidities Accompanying a Broad Spectrum of Substance Use Disorders: Pharmacologic and Safety Profile” was presented on Monday, December 10, 2018, 5:30 pm - 7:30 pm during Poster Session I.

The poster provided preclinical data detailing the unique pharmacology of ITI-333, acting simultaneously as a 5-HT2A and D1 receptor antagonist and a μ-opioid partial agonist. ITI-333 exhibits potent analgesia in animal models of acute and inflammatory pain but is not associated with dependence and abuse liability, effects commonly associated with opioid use in animals. ITI-333 also dose-dependently reduces symptoms associated with naloxone-precipitated opioid withdrawal in mice and suppresses cue-induced heroin reinstatement responding in rats, a model predictive of relapse behavior at doses that do not decrease gastrointestinal motility or depress respiratory function. Preclinical development of ITI-333 is

currently ongoing. ITI-333 is designed as a potential treatment for substance-use disorders, pain and psychiatric comorbidities, including depression and anxiety.

About the Lumateperone Long-Term Open-label Safety Switching Study (Study 303)

Study 303 was conducted to assess the long-term effects of treatment with lumateperone on weight and other safety parameters and to observe the impact of switching from SOC antipsychotic medications. This study has two parts. Positive results from Part I of the study were reported last year for 302 patients who were switched from SOC antipsychotic medications to a 6-week treatment duration with lumateperone followed by a 2-week period in which they were switched back to SOC. Part II of the study, the Company's long-term safety study in schizophrenia, enrolled 603 patients for a planned treatment duration up to one year with lumateperone following switch from SOC; 137 patients had previous exposure either from another previous study or from Part I, though none directly rolled over from Part I to Part II as all were returned to SOC; and 466 patients were newly exposed to lumateperone. The data from Part II of the study reflect a planned interim data analysis that includes observed cases for those subjects who have completed each visit, but not all subjects have had an opportunity to complete. At the time of this interim analysis, 329 patients had completed six months of treatment and 108 patients had completed one year of treatment. Given the favorable safety profile of lumateperone observed to date, the study has been extended and is continuing to allow patients to stay on lumateperone past one year.

In Part II of the open-label safety switching study, 603 patients with schizophrenia were enrolled and included in the safety analyses with planned treatment duration of up to one year with lumateperone administered orally once daily in the evening. To be eligible for inclusion in the study, patients must have had a clinical diagnosis of schizophrenia according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and be stable with respect to their schizophrenia symptoms. The primary objective was to determine the safety of lumateperone. Safety is measured by treatment-emergent adverse events, vital signs including body weight, electrocardiograms, clinical laboratory values, physical and neurological exams and standardized clinical assessments such as the SAS, BARS, AIMS, and C-SSRS. Secondary objectives were to determine the effectiveness of lumateperone as measured by change from baseline on the PANSS and other measures. Analyses in pre-specified subgroups were performed.

No dose titration was needed for the administration of lumateperone when patients were switched from SOC antipsychotics to lumateperone. Patients could be started on an active dose of ITI-007 60 mg from Day 1. Consistent with good clinical care, patients were tapered down from their previous antipsychotic medication during the screening period or switched to lumateperone from one day to the next if no tapering of the previous antipsychotic medication was clinically indicated. In this study, the most recent antipsychotic taken prior to screening, in descending order of frequency, included risperidone, quetiapine, aripiprazole, olanzapine, lurasidone, ziprasidone, haloperidol, paliperidone, perphenazine, asenapine, iloperidone, brexpiprazole and loxapine.

Conference Call and Webcast Details

Intra-Cellular Therapies will host a live conference call and webcast December 12, 2018 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 5289652. 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, is under review by the FDA for the treatment of schizophrenia and is in Phase 3 clinical development for the treatment of 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 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 data supporting the new drug application (NDA) for lumateperone for the treatment of schizophrenia; further clinical conduct in this switching study; our belief that lumateperone has the potential to represent an important new treatment option for patients with 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: 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; 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.

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