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): July 8, 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 July 8, 2019, Intra-Cellular Therapies, Inc. (the "Company") announced top-line results from two Phase 3 clinical trials of lumateperone in patients with bipolar depression.

The Company's press release announcing top-line results from two Phase 3 clinical trials of lumateperone in patients with bipolar depression 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 July 8, 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: July 8, 2019

Intra-Cellular Therapies Announces Positive Top-line Results from a Phase 3 Trial of Lumateperone in Patients with Bipolar Depression

Study 404 met its primary endpoint of change from baseline at Week 6 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo (p<0.001; effect size = 0.56).

Study 404 also met its key secondary objective on the Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score (p<0.001; effect size = 0.46); lumateperone also positive on the CGI component that specifically assesses depression (CGI-BP-S Depression Score; p<0.001; effect size = 0.50).

Study 404 benefits were statistically significant in both Bipolar I and Bipolar II patients.

In Study 401, lumateperone did not separate from placebo. A high placebo response was observed in the trial.

Favorable safety and tolerability profile observed in both trials, consistent with prior lumateperone trials. Rates of akathisia, restlessness and extrapyramidal symptoms combined were less than 1% and similar to placebo in both studies.

Conference call scheduled today at 8:00 a.m. ET

NEW YORK, July 8, 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 top-line results from two Phase 3 clinical trials (Study 401 and Study 404) evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 404, lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the MADRS total score (p<0.001; effect size = 0.56). Study 404 also met its key secondary endpoint, Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score (p<0.001; effect size = 0.46). In both trials, lumateperone demonstrated a favorable safety profile and was generally well-tolerated.

“We consider today’s positive results to be a significant milestone in our bipolar depression program. The distinct pharmacological profile of lumateperone and positive clinical results in schizophrenia and bipolar depression further support the potential for benefits in a broad range of neuropsychiatric conditions, including major depressive disorder,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “It is an exciting time at ITCI as we prepare for the launch of lumateperone for the treatment of schizophrenia, pending FDA approval.”

“Bipolar depression is a severe and difficult to treat mental health condition where few effective treatments are available. Depressive episodes associated with bipolar disorder are disabling and affect millions of people,” said Joseph Calabrese, MD, Director, Mood Disorders Program, Department of Psychiatry, University Hospitals Cleveland Medical Center. “Today’s results with lumateperone are exciting and represent a potential advancement for the treatment of patients with bipolar depression as there is a need for well-tolerated treatment options.”

Study 404 topline results

Study 404 was conducted globally including in the U.S. A total of 381 patients were randomized 1:1 to lumateperone 42 mg or placebo. In this trial, once-daily lumateperone 42 mg met the primary endpoint with statistically significant greater improvement over placebo at week 6 (trial endpoint), as measured by change from baseline on the MADRS total score. In the intent-to-treat (ITT) study population, the least squares (LS) mean reduction from baseline for lumateperone 42 mg was 16.7 points, versus 12.1 points for placebo (LS mean difference = 4.6 points; effect size = 0.56, $p<0.001$). Moreover, lumateperone 42 mg showed statistically significant separation from placebo as early as week 1, which was maintained at every time point throughout the trial.

Lumateperone 42 mg also met the key secondary endpoint of statistically significant improvement on the CGI-BP-S Total Score ($p<0.001$; effect size = 0.46) and on the CGI component that specifically assesses depression (CGI-BP-S Depression Score; $p<0.001$; effect size = 0.50).

These results were supported by statistically significant benefits on responder rates and remission rates, demonstrating the clinical meaningfulness of the primary outcome. In addition, in subgroup analyses of patients with Bipolar I and patients with Bipolar II disorder lumateperone 42 mg demonstrated statistically significant improvement versus placebo on the MADRS total score in both subgroups.

Study 401 topline results

Study 401 was conducted solely in the U.S. A total of 554 patients were randomized 1:1:1 to lumateperone 42 mg, lumateperone 28 mg, or placebo. In this trial, neither dose of lumateperone met the primary endpoint of statistical separation from placebo as measured by change from baseline on the MADRS total score. There was a high placebo response in this trial. Lumateperone 42 mg and 28 mg demonstrated a LS mean reduction from baseline on the MADRS total score of 20.7 points and 18.9 points, respectively, versus 19.7 points on placebo.

Safety and Tolerability Results

Consistent with previous studies in schizophrenia, lumateperone was well-tolerated in both bipolar depression studies, with a favorable safety profile. The rates of discontinuation due to treatment emergent adverse events for both doses of lumateperone were low.

In Study 404, the most commonly reported adverse events that were observed at a rate greater than 5% and higher than placebo were headache, somnolence and nausea.

In Study 401, the most commonly reported adverse events that were observed at rates greater than 5% and higher than placebo for either dose were somnolence, headache, nausea, dry mouth, dizziness, diarrhea, vomiting and fatigue.

Importantly, the rates of akathisia, restlessness and extrapyramidal symptoms combined were less than 1% and similar to placebo in both studies. These findings are consistent with previous lumateperone trials in patients with schizophrenia and provide further evidence supporting lumateperone's favorable safety and tolerability profile across different patient populations.

The Company will report on additional endpoints including subgroup analyses and provide more details on the outcomes presented today in the near future.

Conference Call and Webcast Details

Intra-Cellular Therapies will host a live conference call and webcast today at 8:00 a.m. ET, during which management will discuss the top-line results of Studies 401 and 404. 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 3671478. Please dial in approximately 10 minutes prior to the call.

About Lumateperone Bipolar Depression Program

The lumateperone clinical trial program in bipolar depression includes three Phase 3 trials. Two trials, Study 401 and Study 404, evaluated lumateperone as monotherapy and the third trial, Study 402, is evaluating lumateperone as an adjunctive therapy to lithium or valproate.

Bipolar Depression Monotherapy Studies (Study 404 and Study 401)

Both studies are randomized, double-blind, fixed-dose, placebo-controlled outpatient clinical trials designed to evaluate lumateperone as a monotherapy in patients with major depressive episodes associated with either Bipolar I or II disorder.

Study 404 was conducted globally, including in the U.S., in 57 sites and included 381 patients randomized (1:1) to receive lumateperone 42 mg or placebo once daily for six weeks. Study 401 was conducted in 58 sites in the U.S. and included 554 patients randomized (1:1:1) to receive lumateperone 42 mg or 28 mg, or placebo once daily for six weeks.

Both studies evaluated patients with a clinical diagnosis of Bipolar I or Bipolar II disorder, who were experiencing a major depressive episode. The pre-specified primary endpoint for both clinical trials is change from baseline at week 6 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo. The MADRS is a well-validated, 10-item checklist that measures the ability of a drug to reduce overall severity of depressive symptoms. Individual items are rated by an expert clinician on a scale of 0 to 6 in which a score of 6 represents the greatest severity for each item assessed. The total score ranges from 0 to 60.

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 U.S. Food and Drug Administration (FDA) or any other regulatory authority in any other jurisdiction.

About Bipolar Depression

Bipolar disorder is a serious psychiatric condition characterized by episodes of mania or hypomania interposed with episodes of depression. Bipolar disorder affects approximately 6 million adult Americans, or about 2.8% of the U.S. population age 18 and older, according to the National Institute of Mental Health. Bipolar depression is the most common clinical presentation of bipolar disorder. These episodes tend to last longer, recur more often, and are associated with a worse prognosis than the manic/hypomanic episodes. Bipolar depression remains a significantly underserved medical need, with only a few FDA-approved treatment options available.

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 potential for lumateperone to represent an advancement for the treatment of bipolar depression; the potential for lumateperone to provide benefits in a broad range of neuropsychiatric conditions, including major depressive disorder; 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; the risk that the NDA will not be approved despite the FDA's acceptance of the NDA for review or that the FDA will require additional information; 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