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 23, 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, NY 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 December 23, 2019, Intra-Cellular Therapies, Inc. (the "Company") announced the approval by the U.S. Food and Drug Administration of the Company's novel antipsychotic, CAPLYTA® (lumateperone) for the treatment of schizophrenia in adults.

The Company's press release announcing the approval 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 23, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: December 23, 2019

Exhibit 99.1

FDA Approves Intra-Cellular Therapies' Novel Antipsychotic, CAPLYTA® (lumateperone) for the Treatment of Schizophrenia in Adults

NEW YORK, Dec. 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 CAPLYTA® (lumateperone) has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia in adults. The Company expects to initiate the commercial launch of CAPLYTA in late Q1 2020.

The efficacy of CAPLYTA 42 mg was demonstrated in two placebo-controlled trials, showing a statistically significant separation from placebo on the primary endpoint, the Positive and Negative Syndrome Scale (PANSS) total score. The most common adverse reactions (³5% and twice the rate of placebo) for the recommended dose of CAPLYTA vs placebo were somnolence/sedation (24% vs.10%) and dry mouth (6% vs. 2%).

In pooled data from short term studies, mean changes from baseline in weight gain, fasting glucose, triglycerides and total cholesterol were similar between CAPLYTA and placebo. The incidence of extrapyramidal symptoms was 6.7% for CAPLYTA and 6.3% for placebo.

"We believe CAPLYTA provides healthcare providers a new, safe and effective treatment option to help the millions of adult patients with schizophrenia," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "This approval represents the culmination of years of scientific research. We are especially grateful to the patients, their caregivers, and the healthcare professionals who have contributed to the development of CAPLYTA."

Schizophrenia is a serious mental illness impacting approximately 2.4 million adults in the United States. The clinical presentation of schizophrenia is diverse. Acute episodes are characterized by psychotic symptoms, including hallucinations and delusions, often requiring hospitalization. The disease is chronic and lifelong, often accompanied by depression and gradual deterioration of social functioning and cognitive ability. Patients with schizophrenia often discontinue treatment as a result of side effects such as weight gain and movement disorders.

"Schizophrenia is a complex disease that severely impacts patients and their families," said Jeffrey A. Lieberman, M.D., Lawrence C. Kolb Professor and Chairman of Psychiatry, Columbia University, College of Physicians and Surgeons and Director, New York State Psychiatric Institute. "Effective treatment provided in a timely fashion can be game-changing for people living with schizophrenia. The efficacy and safety profile of CAPLYTA approved by the FDA, offers healthcare providers an important new option for treating people living with schizophrenia."

Please also see full Prescribing Information including **Boxed Warning**.

Important Safety Information

Boxed Warning: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA.

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis**, including stroke and transient ischemic attack. See BOXED WARNING above.
- **Neuroleptic Malignant Syndrome**, which is a potentially fatal reaction. Signs and symptoms include: hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and close monitoring.
- **Tardive Dyskinesia**, a syndrome of potentially irreversible, dyskinetic, and involuntary movements which may increase as the duration of treatment and total cumulative dose increases. Discontinue CAPLYTA if clinically appropriate.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases)**. Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Discontinue CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors.
- **Orthostatic Hypotension and Syncope**. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease.
- **Falls**. CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for risk when using CAPLYTA.
- **Seizures**. Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment**. Advise patients to use caution when operating machinery or motor vehicles until they are reasonably certain CAPLYTA therapy does not affect them adversely.
- **Body Temperature Dysregulation**. Use CAPLYTA with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- **Dysphagia**. Use CAPLYTA with caution in patients at risk for aspiration.

Drug Interactions: Avoid concomitant use with CYP3A4 inducers and moderate or strong CYP3A4 inhibitors.

Special Populations: Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Breastfeeding is not recommended. Avoid use in patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation (24% vs. 10%) and dry mouth (6% vs. 2%).

About CAPLYTA (lumateperone)

CAPLYTA is an oral, once daily medicine approved for the treatment of schizophrenia of adults (42mg/day).

The mechanism of action of CAPLYTA in the treatment of schizophrenia is unknown. However, the efficacy of CAPLYTA could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

CAPLYTA is being developed for the treatment of bipolar depression, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. CAPLYTA has not been demonstrated to be safe and effective in these other areas. CAPLYTA was approved for the treatment of schizophrenia in adults by the U.S. Food and Drug Administration in December 2019.

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's first product, CAPLYTA, has received FDA approval for the treatment of schizophrenia in adults and is in development for the treatment of bipolar depression, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. 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 initiation of the commercial launch of CAPLYTA, including the timing thereof, our belief that CAPLYTA provides healthcare providers a new, safe and effective treatment option to help the millions of adult patients with schizophrenia, our estimates of the number of adults in the United States impacted by schizophrenia, the safety and efficacy of CAPLYTA and our other product candidates; the potential for CAPLYTA to benefit patients suffering from a range of neuropsychiatric and neurodegenerative diseases 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: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in launching or commercializing CAPLYTA; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indication; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia once we have launched the product may be different than observed in clinical trials, and may vary among patients; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or 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.

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