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): March 23, 2020

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 March 23, 2020, Intra-Cellular Therapies, Inc. (the "Company") announced that CAPLYTA (lumateperone) is now available to pharmacies in the U.S. CAPLYTA is an oral, once daily medicine approved 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.

In addition, the global spread of a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), as well as the Company's actions to protect the health of its employees and the healthcare providers and patients it serves, and their families and communities, create a number of risks and uncertainties to the Company's business which could have a material adverse effect on its business, results of operations and financial condition, described further below:

The outbreak of the novel strain of coronavirus, SARS-CoV-2, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials and preclinical studies.

Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to multiple countries, including the United States. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the spread of SARS-CoV-2 and COVID-19, we have instructed the majority of our office-based employees to work from home. In connection with our commercial launch of CAPLYTA, which is approved by U.S. Food and Drug Administration for the treatment of schizophrenia in adults, our commercial organization and sales force and medical organization may have significantly reduced personal interactions with physicians and customers and increasingly conduct promotional activities virtually, and we may elect to cease in-person interactions with physicians and customers entirely for some period of time in the interest of employee and community safety. As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, including our ability to successfully commercialize our only commercial product, CAPLYTA, in the U.S., and these disruptions could negatively impact our sales of CAPLYTA. Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture CAPYLTA and to produce our product candidates in quantities we require, which may impair the commercialization and our research and development activities.

We are currently conducting clinical trials for our product candidates in many countries, including the United States, Europe and Russia and may expand to other geographies. Timely enrollment of, completion of and reporting on our clinical trials is dependent upon these global clinical trial sites which are, or in the future may be, adversely affected by the COVID-19 outbreak or other pandemics. Some factors from the COVID-19 outbreak that may adversely affect the timing and conduct of our clinical trials and adversely impact our business generally, include but are not limited to delays or difficulties in clinical site initiation, diversion of healthcare resources away from clinical trials to pandemic concerns, limitations on travel, regulatory delays and supply chain disruptions.

The COVID-19 outbreak continues to rapidly evolve, and the extent to which the outbreak impacts our business, including our commercial results, clinical trials, and preclinical studies will depend on future developments, which are highly uncertain.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated March 23, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

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: March 23, 2020

Exhibit 99.1

Intra-Cellular Therapies Announces Availability of CAPLYTA™ (lumateperone) for Adult Patients with Schizophrenia

NEW YORK, March 23, 2020 (GLOBE NEWSWIRE) — Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, today announced that CAPLYTA (lumateperone) is now available to pharmacies in the U.S. CAPLYTA is an oral, once daily medicine approved for the treatment of schizophrenia in adults.

“At Intra-Cellular Therapies, we understand the lifelong debilitating struggle people with schizophrenia experience. The need for new treatment options for this community has driven our efforts to bring CAPLYTA to market,” said Mark Neumann, Chief Commercial Officer of Intra-Cellular Therapies. “We have an experienced commercial team and have developed a comprehensive strategy with a multi-channel promotional plan to support the launch of CAPLYTA in light of the ongoing COVID-19 pandemic. In addition, affordability support programs are available to eligible CAPLYTA patients.”

The efficacy of CAPLYTA 42 mg was demonstrated in two placebo-controlled trials, showing a statistically significant benefit over 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 recognize this is an extraordinary and challenging time with COVID-19; we are monitoring developments closely and we will adapt our approach as appropriate. To complement our current launch plan, we have developed remote capabilities for detailing, sampling and peer to peer interactions designed to ensure physicians are properly educated on CAPLYTA. We will also rely more heavily on digital promotion to augment the remote interactions of our sales colleagues.

We have substantial product supply in the U.S. with long expiry dating to support expected demand. Each 30-capsule pack of CAPLYTA covers once daily dosing for one month. Sample packs of 10 capsules are available for healthcare professionals. More information about CAPLYTA is available at 888-252-ITCI or at CAPLYTA.com.

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%).

Please click here to see full Prescribing Information including **Boxed Warning**.

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.

About Intra-Cellular Therapies

Intra-Cellular Therapies is a biopharmaceutical company founded on Nobel prize-winning research that allows us to understand how therapies affect the inner-workings of cells in the body. The company leverages this intracellular approach to develop innovative treatments for people living with complex psychiatric and neurologic diseases. For more information, please visit www.intracellulartherapies.com.

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 expectations regarding our commercialization of CAPLYTA, including the impact of COVID-19 on the commercialization of CAPLYTA and our ability to adapt our approach as appropriate, the sales force that we expect to deploy and the promotional efforts we expect to utilize in support of the product; the supply and availability of and demand for our product, and our beliefs about the potential utility of our product candidates; 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; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials, 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; any other impacts on our business as a result of or related to the COVID-19 pandemic; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA 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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