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): August 10, 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, 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 2.02 Results of Operations and Financial Condition.

On August 10, 2020, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2020, and provided a corporate update.

A copy of the Company's press release containing such announcements is attached hereto as Exhibit 99.1. The information in the press release set forth under the heading "Selected Second Quarter 2020 Financial Results," together with the condensed consolidated financial information included in the press release, are incorporated by reference into this Item 2.02 of this Current Report on Form 8-K.

ITEM 8.01 Other Events.

In the press release dated August 10, 2020, the Company also provided a corporate update. The information set forth under the headings "Corporate Update" and "About Intra-Cellular Therapies," together with the forward-looking statement disclaimer at the end of the press release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated August 10, 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.

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

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: August 10, 2020

INTRA-CELLULAR THERAPIES REPORTS SECOND QUARTER 2020 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

NEW YORK, August 10, 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 its financial results for the second quarter ended June 30, 2020, and provided a corporate update.

“We have completed our first full quarter of commercial activities, adapting to the unprecedented challenges of the COVID-19 pandemic, and I am encouraged by CAPLYTA’s week over week prescription growth and increasing prescriber base,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “I am pleased with our team’s performance in the current environment, the positive physician response to CAPLYTA and the impact we are making in the lives of patients suffering from schizophrenia. We are also excited about advancements in our pipeline, including the upcoming announcement of results from our Phase 3 clinical trial evaluating lumateperone as an adjunctive treatment in bipolar depression (Study 402) and the continued progress in our other pipeline programs.”

CORPORATE UPDATE

COMMERCIAL HIGHLIGHTS

- CAPLYTA promotional activities for the treatment of schizophrenia in adults commenced the week of March 30, 2020. Our commercial organization quickly adapted to the challenges to the healthcare industry and patient care brought by COVID-19.
- Following a successful virtual launch, our neuroscience sales specialists are actively engaging with healthcare providers educating on CAPLYTA. We have been effectively engaging with our prescribing audience through a mix of personal and non-personal promotion including both remote, and more recently, live in-person interactions with our sales team, peer to peer medical education, journal advertising, virtual conferences & product theatre presentations and digital marketing efforts.
- CAPLYTA has now achieved formulary coverage for greater than 95% of covered lives in both Medicare Part D and State Medicaid, our two largest channels. We continue to see coverage determination improvements in the commercial payer channel with final coverage expected to be established by the end of this year.

- We are launching our new consumer campaign called “Real Progress”. The purpose of the campaign is to educate patients and caregivers about CAPLYTA and to open the dialogue about optimizing care and treatment options. “Real Progress” includes a national direct-to-consumer (or DTC) television advertising campaign and accompanying social media campaign, as well as a partnership with a leading telepsychiatry platform.
- Our LYTAlink™ patient access and affordability program is fully operational and performing as planned. The program offerings consist of coverage and reimbursement services, out-of-pocket copay support for commercially insured patients, medication compliance communications, and patient assistance relief specifically for eligible patients without insurance.

CLINICAL HIGHLIGHTS

- Lumateperone in Bipolar Depression: Study 402, our Phase 3 study evaluating lumateperone as adjunctive therapy in bipolar depression, has completed clinical conduct and we anticipate reporting topline results from this study by mid-September 2020. This global study enrolled patients with major depressive episodes associated with either Bipolar I or Bipolar II disorder, who were randomized (1:1:1) to receive lumateperone 42 mg, 28 mg or placebo once daily for six weeks, while being maintained on lithium or valproate as mood stabilizers. The primary endpoint is change from baseline on the Montgomery–Åsberg Depression Rating Scale (MADRS) total score at week 6.

  Study 403, a Phase 3 global study evaluating lumateperone 42 mg as monotherapy in the treatment of depression in patients with Bipolar I or Bipolar II disorder, is ongoing. We anticipate reporting top-line results from this study in the second half of 2021.

- ITI-214 in Heart Failure: We reported positive results from our Phase 1/2 clinical trial of ITI-214, our phosphodiesterase 1 (PDE1) inhibitor, in patients with chronic systolic heart failure. This study evaluated the hemodynamic profile and safety of single ascending doses of ITI-214. In the study, ITI-214 improved cardiac output both by increasing heart contractility and by decreasing vascular resistance, that is, ITI-214 functions as an inodilator. The improvement in cardiac output was not associated with the development of arrhythmias in patients. Details of these results will be presented at upcoming medical conferences.
- Other Clinical Programs: We plan to initiate our lumateperone clinical program in major depressive disorder later this year. In addition, we expect to initiate human testing of our lumateperone long-acting injectable program later this year. We also expect to initiate early stage clinical studies for ITI-333, our novel, oral modulator of mu opioid and serotonin receptors for the treatment of opioid and other substance use disorders, pain, and mood disorders.

Selected Second Quarter 2020 Financial Results

The Company recorded net product sales of CAPLYTA for the second quarter of 2020 of approximately $1.9 million. No net product sales were reported for the comparable period of 2019.

The Company reported a net loss of $63.7 million, or $0.96 per share (basic and diluted), for the second quarter of 2020 compared to a net loss of $37.4 million, or $0.68 per share (basic and diluted), for the second quarter of 2019.

Research and development (R&D) expenses for the second quarter of 2020 were $25.2 million, compared to $23.7 million for the second quarter of 2019. The $1.5 million increase is primarily due to an increase of approximately $9.2 million of lumateperone clinical costs and an increase of approximately $0.6 million in stock compensation expense and overhead expenses and is offset by a decrease of approximately $5.3 million of manufacturing costs, and a decrease of approximately $3.0 million for non-clinical related efforts.

Selling, general and administrative (SG&A) expenses were $41.4 million for the second quarter of 2020, compared to $15.4 million for the same period in 2019. The increase of $26.0 million is due to an increase of $20.6 million for selling related costs and an increase of $5.4 million for general and administrative costs. The increase in selling related costs is due primarily to hiring a sales force, resulting in an increase in labor expenses of $15.0 million and commercialization and marketing costs of $5.0 million. The increase in general and administrative costs is due primarily to an increase in labor related expenses of $2.3 million, information technology expenses of $1.5 million, and professional fees of $1.0 million.

Cash, cash equivalents, restricted cash and investment securities totaled $409.2 million at June 30, 2020, compared to $224.0 million at December 31, 2019. In January 2020, the Company completed a $295.0 million public offering resulting in net proceeds to the Company of approximately $277.0 million from the sale of 10 million shares of its common stock, after deducting underwriting discounts and commissions and offering expenses paid by the Company.

Conference Call and Webcast Details

The Company will host a live conference call and webcast today at 8:30 AM Eastern Time to discuss the Company’s financial results and provide a corporate update. 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 1574586. Please dial in approximately 10 minutes prior to the call.

CAPLYTA™ (lumateperone) is indicated for the treatment of schizophrenia in adults. CAPLYTA is available in 42 mg capsules.

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. Reactions have included pruritus, rash (e.g. allergic dermatitis, papular rash, and generalized rash), and urticaria.

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 (NMS)**, which is a potentially fatal reaction. Signs and symptoms include: high fever, stiff muscles, confusion, changes in breathing, heart rate, and blood pressure, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Patients who experience signs and symptoms of NMS should immediately contact their doctor or go to the emergency room.
- **Tardive Dyskinesia**, a syndrome of uncontrolled body movements in the face, tongue, or other body parts, which may increase with duration of treatment and total cumulative dose. TD may not go away, even if CAPLYTA is discontinued. It can also occur after CAPLYTA is discontinued.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. 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)**. Complete blood counts should be performed in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. CAPLYTA should be discontinued if clinically significant decline in WBC occurs in absence of other causative factors.
- **Decreased Blood Pressure & Dizziness**. Patients may feel lightheaded, dizzy or faint when they rise too quickly from a sitting or lying position (orthostatic hypotension). Heart rate and blood pressure should be monitored and patients should be warned with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- **Falls**. CAPLYTA may cause sleepiness or dizziness and can slow thinking and motor skills, which may lead to falls and, consequently, fractures and other injuries. Patients should be assessed for risk when using CAPLYTA.

- **Seizures**. CAPLYTA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Sleepiness and Trouble Concentrating**. Patients should use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- **Body Temperature Dysregulation**. CAPLYTA should be used 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**. CAPLYTA should be used with caution in patients at risk for aspiration.

Drug Interactions: CAPLYTA should not be used with CYP3A4 inducers, moderate or strong CYP3A4 inhibitors and UGT inhibitors.

Special Populations: Newborn infants 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. Use of CAPLYTA should be avoided in patients with moderate or severe liver problems.

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 42mg/day is an oral, once daily atypical antipsychotic approved for the treatment of schizophrenia of adults. While the mechanism of action of CAPLYTA in the treatment of schizophrenia is unknown, 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 (lumateperone) is being investigated for the treatment of bipolar depression, depression and other neuropsychiatric and neurological disorders. CAPLYTA is not FDA approved for these disorders.

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 the commercialization of CAPLYTA; our expectations about coverage of CAPLYTA by payors; our plans and the expected timing for the availability and reporting of data from our ongoing Phase 3 trials in bipolar depression; our plans and expected timing to initiate our lumateperone clinical program in major depressive disorder; our plans and expected timing to initiate human testing of our lumateperone long-acting injectable program; our plans and expected timing to initiate early stage clinical studies for ITI-333; our development plans for our PDE program, including ITI-214; 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 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 following commercial launch of 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 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 or in clinical trials for other indications; 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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INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	**2020**	2019
Revenues				
Product sales, net	**$ 1,875,889**	$ —	**$ 2,758,405**	$ —
Grant revenue	**30,747**	—	**231,710**	—
Total revenues	**1,906,636**	—	**2,990,115**	—
Operating expenses:				
Cost of product sales	**128,539**	—	**197,850**	—
Research and development	**25,204,857**	23,728,464	**41,208,183**	48,719,321
Selling, general and administrative	**41,445,557**	15,442,650	**75,541,923**	27,147,634
Total operating expenses	**66,778,953**	39,171,114	**116,947,956**	75,866,955
Loss from operations	**(64,872,317)**	(39,171,114)	**(113,957,841)**	(75,866,955)
Interest income	**1,160,059**	1,731,550	**2,838,262**	3,591,627
Loss before provision for income taxes	**(63,712,258)**	(37,439,564)	**(111,119,579)**	(72,275,328)
Income tax expense	**—**	1,600	**3,281**	1,600
Net loss	**$(63,712,258)**	$(37,441,164)	**$(111,122,860)**	$(72,276,928)
Net loss per common share:				
Basic & Diluted	**$ (0.96)**	$ (0.68)	**$ (1.69)**	$ (1.31)
Weighted average number of common shares:				
Basic & Diluted	**66,429,371**	55,145,901	**65,767,737**	55,129,654

(1) The condensed consolidated statements of operations for the quarters ended June 30, 2020 and 2019 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020 *(Unaudited)*	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	**$ 129,290,445**	$ 107,636,849
Investment securities, available-for-sale	**278,468,502**	116,373,335
Restricted cash	**1,400,000**	—
Accounts receivable, net	**2,353,255**	—
Inventory	**2,335,042**	—
Prepaid expenses and other current assets	**4,726,134**	6,313,785
Total current assets	**418,573,378**	230,323,969
Property and equipment, net	**2,000,687**	2,259,740
Right of use assets, net	**20,270,675**	18,252,074
Deferred tax asset, net	**—**	264,609
Other assets	**86,084**	86,084
Total assets	**$ 440,930,824**	$ 251,186,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 5,472,987**	$ 7,425,024
Accrued and other current liabilities	**19,383,111**	16,138,909
Lease liabilities, short-term	**3,973,920**	3,187,435
Accrued employee benefits	**11,412,697**	9,472,651
Total current liabilities	**40,242,715**	36,224,019
Lease liabilities	**21,158,241**	19,955,186
Total liabilities	**61,400,956**	56,179,205
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 66,777,737 and 55,507,497 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	**6,678**	5,551
Additional paid-in capital	**1,199,576,320**	904,971,772
Accumulated deficit	**(821,221,229)**	(710,098,369)
Accumulated comprehensive income	**1,168,099**	128,317
Total stockholders' equity	**379,529,868**	195,007,271
Total liabilities and stockholders' equity	**$ 440,930,824**	$ 251,186,476

(1) The condensed consolidated balance sheets at June 30, 2020 and December 31, 2019 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.