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 9, 2021

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 9, 2021, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2021, 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 "Second Quarter Financial Highlights," 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 9, 2021, the Company also provided a corporate update. The information set forth under the headings "Commercial Highlights," "Clinical Highlights" 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 9, 2021.
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 9, 2021

Exhibit 99.1

INTRA-CELLULAR THERAPIES REPORTS SECOND QUARTER 2021 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

CAPLYTA supplemental new drug applications (sNDAs) for the treatment of bipolar depression are under review by the FDA, with a PDUFA target action date of December 17, 2021.

Second quarter CAPLYTA total prescriptions (TRx) increased 22% versus the previous quarter.

Total revenues for the second quarter were $20.0 million. CAPLYTA achieved net product revenues of $19.0 million for the second quarter.

Patient enrollment in Study '501, a Phase 3 clinical trial evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD), has commenced.

NEW YORK, August 9, 2021 /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, 2021 and provided a corporate update.

"We are pleased with our strong results in the second quarter. Our sNDAs for bipolar depression are under review by the FDA and our CAPLYTA strategy continues to make substantial progress with our commercialization in schizophrenia, along with our preparations for a potential label expansion into bipolar depression. We have initiated patient enrollment in our Phase 3 program in MDD and continue our programs studying other depressive disorders," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

Second Quarter Financial Highlights

- Total revenues were $20.0 million for the second quarter of 2021, compared to $1.9 million of total revenues for the second quarter of 2020. Net product revenues of CAPLYTA were $19.0 million for the second quarter of 2021, compared to $1.9 million in net product revenues of CAPLYTA for the same period in 2020. Net product revenues of CAPLYTA increased 22% from $15.6 million in the prior quarter.

- Cost of product sales were $2.0 million in the second quarter of 2021 compared to $0.1 million for the second quarter of 2020.
- Research and development (R&D) expenses for the second quarter of 2021 were $17.3 million, compared to $25.2 million for the second quarter of 2020. This decrease is due primarily to a decrease in lumateperone clinical trial costs.
- Selling, general and administrative (SG&A) expenses were $69.9 million for the second quarter of 2021, compared to $41.4 million for the same period in 2020. This increase is primarily due to an increase in commercialization and marketing costs.
- Net loss for the second quarter of 2021 was $68.7 million compared to a net loss of $63.7 million for the second quarter of 2020.
- Cash, cash equivalents, restricted cash and investment securities totaled $556.2 million at June 30, 2021, compared to $658.8 million at December 31, 2020.

COMMERCIAL HIGHLIGHTS

- Our hybrid commercialization model and our digital marketing initiatives continued to deliver consistent revenue and prescription growth despite COVID-19 disruptions.
- Second quarter CAPLYTA results reflect continued prescription growth, increasing total prescriptions by 22% versus the first quarter of 2021.
- CAPLYTA market access coverage is strong with greater than 95% of covered lives in both Medicare Part D and State Medicaid, the major payer channels in schizophrenia. Our LytaLink program continues to be highly competitive and effective in supporting prescribing physicians and eligible patients' access to CAPLYTA.
- Our bipolar depression launch preparations are on track.

CLINICAL HIGHLIGHTS

Lumateperone:

- Bipolar Depression Program: The lumateperone sNDAs for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate are under review by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) target action date is December 17, 2021 for these applications.

- Adjunctive MDD program: Patient enrollment has commenced for Study ‘501, our Phase 3 clinical trial evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Patient enrollment in a second Phase 3 trial, Study ‘502, is anticipated to begin shortly.
- Mixed Features program: Clinical conduct continues in Study ‘403 evaluating lumateperone 42 mg in patients with MDD and in patients with bipolar depression who exhibit mixed features.
- Lumateperone Long Acting Injectable (LLAI) formulation: Study ITI-007-025, a Phase 1 single ascending dose study of LLAI, a formulation designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month, is ongoing. Initial results from this study are anticipated in the second half of 2021.
- Presentations: In the second quarter of 2021, presented at the American Psychiatric Association (APA) Meeting, the International Conference for Bipolar Disorders (ISBD) Annual Meeting, and the American Society of Clinical Psychopharmacology. The presentations included results from Study ‘402, a Phase 3 clinical trial evaluating lumateperone as adjunctive therapy in bipolar depression, analyses from Study ‘404 describing the efficacy results of patients with bipolar depression who exhibit mixed features, and the overall safety and tolerability profile of the bipolar depression monotherapy program. We also presented analyses from Study ‘303, our long-term safety schizophrenia study, evaluating the antidepressant effects of CAPLYTA in patients with schizophrenia with co-morbid depression.

Other Programs:

- ITI-1284 program: We plan to initiate our program for the development of ITI-1284-ODT-SL for the treatment of behavioral disturbances in dementia in the second half of 2021, and plan additional studies in dementia-related psychosis and certain depressive disorders in the elderly in 2022.
- Phosphodiesterase type I inhibitor (PDE1) program: Our PDE1 inhibitor program is focused on investigating the therapeutic potential of this mechanism of action across a variety of diseases, including neurological and cardiovascular diseases, as well as cancer.
    - A Phase 2 study evaluating lenrispodun (ITI-214) in Parkinson’s disease is expected to commence in the second half of 2021.
    - Presented preclinical data describing the antitumor effects of PDE1 inhibitors when administered in conjunction with checkpoint inhibitor immunotherapy at the American Association for Cancer Research (AACR) Annual Meeting. We are currently evaluating our PDE1 inhibitors in other cancer models and developing potential biomarkers that may assist in the translation of these data to the treatment of human cancers.

- ITI-333 program in opioid use disorder: Study ITI-333-001, a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers, is ongoing. Results from this study are anticipated in the second half of 2021.
- R&D day: The Company plans to host a virtual research and development (R&D) day focusing on our key pipeline programs later this year.

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 8494665. 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.

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 regarding the sNDAs, including the adequacy of the data contained in the sNDAs to serve as the basis for approval of lumateperone for the treatment of depressive episodes associated with bipolar I or II disorder both as monotherapy and as adjunctive therapy in adults; the potential approval by the FDA of the sNDAs for lumateperone for the treatment of bipolar depression; the potential timing of review and action by the FDA with respect to the sNDAs; our plans and expected timing to initiate Study '502, our second lumateperone Phase 3 clinical study in major depressive disorder; our plans and expected timing for results from our lumateperone long-acting injectable clinical trial; our plans and expected timing for results from our ITI-333 clinical trial; our development plans for our PDE program, including ITI-214, and the potential benefits of PDE1 inhibition; our plans and expected timing for initiation of our ITI-1284 programs; 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: whether the preclinical and clinical results of the lumateperone studies will meet the regulatory requirements for approval by the FDA for the proposed indications; whether the sNDAs will be approved by the FDA and whether the FDA will complete its review within its target timelines, including its target action date; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; 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,	
	2021	2020	**2021**	2020
Revenues				
Product sales, net	**$ 19,006,780**	$ 1,875,889	**$ 34,585,685**	$ 2,758,405
Grant revenue	**1,039,781**	30,747	**1,339,205**	231,710
Total revenues	**20,046,561**	1,906,636	**35,924,890**	2,990,115
Operating expenses:				
Cost of product sales	**2,040,031**	128,539	**3,495,246**	197,850
Research and development	**17,296,420**	25,204,857	**32,354,588**	41,208,183
Selling, general and administrative	**69,851,164**	41,445,557	**122,434,803**	75,541,923
Total operating expenses	**89,187,615**	66,778,953	**158,284,637**	116,947,956
Loss from operations	**(69,141,054)**	(64,872,317)	**(122,359,747)**	(113,957,841)
Interest income	**421,028**	1,160,059	**904,778**	2,838,262
Loss before provision for income taxes	**(68,720,026)**	(63,712,258)	**(121,454,969)**	(111,119,579)
Income tax expense	**23,756**	—	**28,756**	3,281
Net loss	**$(68,743,782)**	$(63,712,258)	**$(121,483,725)**	$(111,122,860)
Net loss per common share:				
Basic & Diluted	**$ (0.85)**	$ (0.96)	**$ (1.50)**	$ (1.69)
Weighted average number of common shares:				
Basic & Diluted	**81,229,788**	66,429,371	**81,088,900**	65,767,737

The condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020 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, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	**$ 121,030,152**	$ 60,045,933
Investment securities, available-for-sale	**433,727,230**	597,402,126
Restricted cash	**1,400,000**	1,400,000
Accounts receivable, net of $120,000 allowance at June 30, 2021 and December 31, 2020	**15,187,814**	10,764,583
Inventory	**7,768,848**	7,056,385
Prepaid expenses and other current assets	**22,189,200**	14,235,455
Total current assets	**601,303,244**	690,904,482
Property and equipment, net	**1,761,001**	1,998,346
Right of use assets, net	**22,546,333**	24,324,762
Other assets	**86,084**	86,084
Total assets	**$ 625,696,662**	$ 717,313,674
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 15,940,756**	$ 5,501,825
Accrued and other current liabilities	**14,054,009**	10,902,117
Lease liabilities, short-term	**5,595,057**	5,541,802
Accrued employee benefits	**14,832,115**	14,907,479
Total current liabilities	**50,421,937**	36,853,223
Lease liabilities	**21,688,851**	23,600,347
Total liabilities	**72,110,788**	60,453,570
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 and 100,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 81,311,878 and 80,463,089 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	**8,132**	8,046
Additional paid-in capital	**1,611,989,381**	1,593,475,506
Accumulated deficit	**(1,058,587,757)**	(937,104,032)
Accumulated comprehensive income	**176,118**	480,584
Total stockholders' equity	**553,585,874**	656,860,104
Total liabilities and stockholders' equity	**$ 625,696,662**	$ 717,313,674

(1) The condensed consolidated balance sheets at June 30, 2021 and December 31, 2020 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.