

**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): May 10, 2021

Intra-Cellular Therapies, Inc.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-36274

Delaware
(State or other jurisdiction
of incorporation)

36-4742850
(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 May 10, 2021, Intra-Cellular Therapies, Inc. (the “Company”) announced its financial results for the first quarter ended March 31, 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 “First 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 May 10, 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 May 10, 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. Hinline

Lawrence J. Hinline

Senior Vice President of Finance, Chief Financial Officer, Treasurer
and Assistant Secretary

Date: May 10, 2021

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

CAPLYTA supplemental new drug applications (sNDAs) for the treatment of bipolar depression in adults as both monotherapy and adjunctive treatment with lithium or valproate have been accepted for review by the FDA, with a PDUFA target action date of December 17, 2021.

First quarter CAPLYTA total prescriptions (TRx) increased 23% versus the previous quarter.

Total revenues for the first quarter were \$15.9 million. CAPLYTA achieved net product revenues of \$15.6 million for the first quarter.

Introduced ITI-1284 ODT-SL, a deuterated form of lumateperone delivered sublingually as an orally disintegrating tablet.

NEW YORK, May 10, 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 first quarter ended March 31, 2021 and provided a corporate update.

“The acceptance of our sNDAs by the FDA is an important step towards a potential new treatment option for patients living with bipolar depression, a condition with a limited number of approved treatments. While preparing for this significant opportunity, our team will continue to execute on our commercial objectives for CAPLYTA and advance our robust pipeline,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

First Quarter Financial Highlights:

- Total revenues were \$15.9 million for the first quarter of 2021, compared to \$1.1 million of total revenues for the first quarter of 2020. Net product revenues of CAPLYTA were \$15.6 million for the first quarter of 2021, compared to \$0.9 million in net product revenues of CAPLYTA for the same period in 2020.
- Cost of product sales were \$1.5 million in the first quarter of 2021 compared to \$0.1 million for the first quarter of 2020.
- Research and development (R&D) expenses for the first quarter of 2021 were \$15.1 million, compared to \$16.0 million for the first quarter of 2020. This decrease is due primarily to a decrease in manufacturing expense and is partially offset by an increase of lumateperone clinical and non-clinical expenses.
- Selling, general and administrative (SG&A) expenses were \$52.6 million for the first quarter of 2021, compared to \$34.1 million for the same period in 2020. This increase is primarily due to an increase in sales related labor costs and commercialization costs.
- Net loss for the quarter ended March 31, 2021 was \$52.7 million compared to a net loss of \$47.4 million for the quarter ended March 31, 2020.
- Cash, cash equivalents, restricted cash and investment securities totaled \$613.4 million at March 31, 2021, compared to \$658.8 million at December 31, 2020.

COMMERCIAL HIGHLIGHTS

- Despite the continued impact of COVID-19 on the healthcare system during the first quarter, our commercial organization continued to effectively engage with our prescribing audience through a hybrid model of in-person and virtual interactions, enhanced by digital marketing initiatives.
- First quarter CAPLYTA results reflect strong commercial execution delivering continued prescription growth, increasing total prescriptions 23% versus the fourth quarter.
- 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.

CLINICAL HIGHLIGHTS

Lumateperone—Bipolar Depression Program:

- The U.S. Food and Drug Administration (FDA) has accepted for review the sNDAs for lumateperone 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. The FDA has assigned a PDUFA target action date of December 17, 2021 for these applications.
- At the American Psychiatric Association (APA) Annual Meeting held from May 1-3, 2021, we had several presentations describing lumateperone study results. These included results from Study '402, a global Phase 3 clinical trial evaluating lumateperone as adjunctive therapy to lithium or valproate in the treatment of major depressive episodes associated with bipolar I or bipolar II disorder and analyses from Study '404 highlighting the efficacy results of patients with bipolar depression who exhibit mixed features. Another presentation summarized the overall safety and tolerability profile of the bipolar depression monotherapy program.

Other Lumateperone Programs

- Mixed Features program: Study '403 evaluating lumateperone 42 mg in patients with major depressive disorder (MDD) and in patients with bipolar depression who exhibit mixed features is ongoing.
- Adjunctive MDD program: Clinical conduct in two studies, Studies '501 and '502, our Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD is anticipated to begin later this year.
- 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.

CAPLYTA- Schizophrenia

- Announced the publication of “Safety and tolerability of lumateperone 42 mg: An open-label antipsychotic switch study in outpatients with stable schizophrenia” (Correll et al. 2021) in the journal, *Schizophrenia Research*.
- At APA we 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, with and without concomitant antidepressant treatments.

Other Programs

- ITI-1284 program: We introduced ITI-1284 ODT-SL, a deuterated form of lumateperone, a new molecular entity formulated as an orally disintegrating tablet for sublingual administration. We plan to initiate studies evaluating ITI-1284 ODT-SL for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and the treatment of certain depressive disorders in the elderly.
- Phosphodiesterase type I inhibitor (PDE1) program: Our PDE1 inhibitor program is focused on diseases in which the PDE1 enzyme is over-expressed and/or abnormal immune cell function contributes to disease pathology. This suggests therapeutic potential across a variety of diseases, including neurological and cardiovascular diseases, as well as cancer.
 - We plan to advance our lead molecule, lenrispodun (ITI-214), into a Phase 2 clinical study in Parkinson's disease in the second half of 2021.
 - At the American Association for Cancer Research (AACR) Virtual Annual Meeting, we presented preclinical data supporting the potential of PDE1 inhibition to enhance the anti-tumor effects of immunotherapies by altering the tumor micro-environment. Our prior studies elucidating the neuroprotective and anti-inflammatory effects of PDE1 inhibitors in the brain by regulating microglia function (brain resident macrophage-like cells) led to our exploration of similar effects outside the brain. Therefore, we hypothesized PDE1 inhibition could result in antitumor effects by controlling similar functions of macrophages in the tumor micro-environment. Our experiments indicate PDE1 inhibition prevents the migration and accumulation of monocytes and macrophages in the tumor micro-environment and could represent a novel and broadly applicable approach to the treatment of immune responsive 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.

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 3244409. 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-HT_{2A} 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 our lumateperone clinical studies 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 development plans for our ITI-1284 program; 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.

Contact:

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INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Revenues		
Product sales, net	\$ 15,578,905	\$ 882,516
Grant revenue	299,424	200,963
Total revenues	15,878,329	1,083,479
Operating expenses:		
Cost of product sales	1,455,215	69,311
Research and development	15,058,168	16,003,326
Selling, general and administrative	52,583,639	34,096,366
Total operating expenses	69,097,022	50,169,003
Loss from operations	(53,218,693)	(49,085,524)
Interest income	483,750	1,678,203
Loss before provision for income taxes	(52,734,943)	(47,407,321)
Income tax expense	5,000	3,281
Net loss	\$(52,739,943)	\$(47,410,602)
Net loss per common share:		
Basic & Diluted	\$ (0.65)	\$ (0.73)
Weighted average number of common shares:		
Basic & Diluted	80,946,450	65,106,103

- (1) The condensed consolidated statements of operations for the quarters ended March 31, 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

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 129,979,888	\$ 60,045,933
Investment securities, available-for-sale	481,984,786	597,402,126
Restricted cash	1,400,000	1,400,000
Accounts receivable, net less allowance of \$120,000 at March 31, 2021 and December 31, 2020	13,661,992	10,764,583
Inventory	7,579,393	7,056,385
Prepaid expenses and other current assets	14,494,384	14,235,455
Total current assets	649,100,443	690,904,482
Property and equipment, net	1,871,338	1,998,346
Right of use assets, net	23,430,703	24,324,762
Other assets	86,084	86,084
Total assets	\$ 674,488,568	\$ 717,313,674
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 8,720,957	\$ 5,501,825
Accrued and other current liabilities	13,491,620	10,902,117
Lease liabilities, short-term	5,573,240	5,541,802
Accrued employee benefits	11,915,893	14,907,479
Total current liabilities	39,701,710	36,853,223
Lease liabilities	22,637,100	23,600,347
Total liabilities	62,338,810	60,453,570
Stockholders' equity:		
Common stock, \$0.0001 par value: 100,000,000 shares authorized; 81,133,849 and 80,142,797 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	8,113	8,046
Additional paid-in capital	1,601,739,075	1,593,475,506
Accumulated deficit	(989,843,975)	(937,104,032)
Accumulated comprehensive income	246,545	480,584
Total stockholders' equity	612,149,758	656,860,104
Total liabilities and stockholders' equity	\$ 674,488,568	\$ 717,313,674

- (1) The condensed consolidated balance sheets at March 31, 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.