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 3, 2023

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 2.02 Results of Operations and Financial Condition.

On August 3, 2023, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2023, 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 3, 2023, the Company also provided a corporate update. The information set forth under the headings "Clinical Highlights," "About CAPLYTA (lumateperone)" 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 3, 2023
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 3, 2023

INTRA-CELLULAR THERAPIES REPORTS SECOND QUARTER 2023 FINANCIAL RESULTS AND RAISES 2023 CAPLYTA SALES GUIDANCE

Q2 2023 total revenues increased to $110.8 million, compared to $55.6 million in the same period in 2022

CAPLYTA Q2 2023 net product sales were $110.1 million, compared to $55.1 million for the same period in 2022, representing a 100% increase

CAPLYTA's strong prescription uptake continues: Q2 2023 CAPLYTA total prescriptions increased 96%, versus the same period in 2022 and 13% sequentially versus Q1 2023

2023 CAPLYTA net product sales guidance raised to $445 - $465 million

NEW YORK, August 3, 2023 /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, 2023 and provided a corporate update.

"Our continued commercial execution resulted in another quarter of solid growth for CAPLYTA. Due to CAPLYTA's strong performance to date and our confidence in continued growth, we are raising our 2023 full year net product sales guidance," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We have also continued to progress our pipeline including our clinical and preclinical development programs."

Second Quarter Financial Highlights:

Total revenues were $110.8 million for the second quarter of 2023, compared to $55.6 million for the same period in 2022. Net product sales of CAPLYTA were $110.1 million for the second quarter of 2023, compared to $55.1 million for the same period in 2022, representing a year-over-year increase of 100% and a 16% sequential increase over the first quarter of 2023.

- Net loss for the second quarter of 2023 was $42.8 million compared to a net loss of $86.6 million for the same period in 2022.
- Cost of product sales was $7.2 million in the second quarter of 2023 compared to $4.7 million for the same period in 2022.

- Selling, general and administrative (SG&A) expenses were $101.0 million for the second quarter of 2023, compared to $100.3 million for the same period in 2022.
- Research and development (R&D) expenses were $49.8 million for the second quarter of 2023, compared to $38.5 million for the same period in 2022. This increase is primarily due to higher lumateperone project costs.
- Cash, cash equivalents, restricted cash and investment securities totaled $514.6 million at June 30, 2023.

Fiscal 2023 Financial Outlook:

- Full year 2023 CAPLYTA net product sales guidance increased to $445 to $465 million from the previous range of $430 to $455 million.
- Full year 2023 SG&A expense guidance of $420 to $450 million and R&D expense guidance of $195 to $220 million reiterated.

CLINICAL HIGHLIGHTS

Lumateperone:

- Adjunctive Major Depressive Disorder (MDD) program: Patient enrollment is ongoing in Studies 501, 502 and 505, our global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD.
- Mixed Features program: Last quarter, we announced robust positive results from Study 403 evaluating lumateperone 42mg as monotherapy in the treatment of major depressive episodes in patients with MDD with mixed features and in patients with bipolar depression with mixed features. These strong results reaffirm lumateperone's efficacy and safety profile and highlight its potential across mood disorders. We plan to present data from Study 403 at upcoming major psychiatry meetings in the second half of 2023.

  We also conducted an important post-hoc analysis of a pre-specified patient population in Study 403 evaluating the antidepressant effects of lumateperone in patients with mixed features exhibiting anxious distress, commonly known as anxious depression. In patients meeting the DSM-5 criteria for anxious distress at study entry, lumateperone significantly improved on the Montgomery Asberg Depression Rating Scale (MADRS) total score compared with placebo in the combined MDD and bipolar depression mixed features population with anxious distress. The MADRS mean difference vs. placebo was -6.1 points, with a robust effect size of -0.67 with a p value of less than <0.0001. Robust results were also seen in each individual patient population of patients with MDD and patients with bipolar depression. The strong results seen in this analysis further strengthen our confidence in CAPLYTA's potential as a treatment for MDD.

- Lumateperone Long Acting Injectable (LAI) formulation: We expect to initiate Phase 1 single ascending dose studies with several formulations of our LAI later in 2023, and expect these studies to continue through 2024. The goal of the program is to develop LAI formulations that are effective, safe, and well-tolerated with treatment durations of one month or longer.

- Presentations and Publications: In the second quarter of 2023, there were CAPLYTA presentations at several medical meetings including the American Psychiatric Association (APA), the International Society for Bipolar Disorders (ISBD), and the American Society of Clinical Psychopharmacology (ASCP). The presentations primarily highlighted important aspects of CAPLYTA's clinical profile in both the acute and the long-term treatment of a broad patient population with bipolar I and bipolar II disorder as monotherapy and as adjunctive therapy.

  The article, "The Efficacy of Lumateperone in Patients With Bipolar Depression With Mixed Features (McIntyre RS, et al 2023) was published in the Journal of Clinical Psychiatry. The authors of this post hoc analysis of Study 404 concluded that lumateperone 42mg significantly improved symptoms of depression and disease severity in patients with a major depressive episode associated with bipolar I or bipolar II disorder, with or without mixed features.

Other pipeline programs:

- ITI-1284-ODT-SL program: ITI-1284 is a deuterated form of lumateperone, a new chemical entity formulated as an oral disintegrating tablet for sublingual administration. We plan to initiate Phase 2 programs in generalized anxiety disorder, in psychosis in patients with Alzheimer's disease (AD), and in agitation in patients with AD in 2023.

- Phosphodiesterase type I inhibitor (PDE1) program: We continue to develop our portfolio of PDE1 inhibitors:

  Lenrispodun (ITI-214) Parkinson's disease (PD) program: Patient enrollment in our Phase 2 clinical trial is ongoing. The objective of this study is to evaluate improvements in motor symptoms in patients with PD. Changes in cognition and inflammatory biomarkers are also being assessed.

  ITI-1020 cancer immunotherapy program: Our Phase 1 single ascending dose study in healthy volunteers is ongoing. The objective of this study is to evaluate pharmacokinetics, safety, and tolerability of different doses of ITI-1020.

- ITI-333 program: ITI-333, a 5-HT2A receptor antagonist and μ-opioid receptor partial agonist, provides potential utility in the treatment of opioid use disorder and pain. We have completed the single ascending dose study and a multiple ascending dose study and a positron emission tomography (PET) study are ongoing.

- ITI-1500 Non-Hallucinogenic Psychedelic Program: This program is focused on the development of novel non-hallucinogenic psychedelics. Compounds in this series interact with serotonergic (5-HT2a) receptors in a unique way, potentially allowing the development of this new drug class in mood, anxiety and other neuropsychiatric disorders without the liabilities of known psychedelics including the hallucinogenic potential and risk for cardiac valvular pathologies. Our lead compound in this program, ITI-1549, is currently being evaluated in IND enabling studies.

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. To attend the live conference call by phone, please use this registration link (https://register.vevent.com/register/BI096f6f0766f746f592599ba0431eda8c). All participants must use the link to complete the online registration process in advance of the conference call.

The live and archived webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at www.intracellulartherapies.com. Please log in approximately 5-10 minutes prior to the event to register and to download and install any necessary software.

CAPLYTA® (lumateperone) is indicated in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

Important Safety Information

Boxed Warnings:

- **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.**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adults in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA have not been established in pediatric patients.**

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.
- **Potential for Cognitive and Motor Impairment**. 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. Dose reduction is recommended for concomitant use with strong CYP3A4 inhibitors or moderate CYP3A4 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. Dose reduction is recommended for patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation, dizziness, nausea, and dry mouth.

CAPLYTA is available in 10.5 mg, 21 mg, and 42 mg capsules.

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

About CAPLYTA (lumateperone)

CAPLYTA 42 mg is an oral, once daily atypical antipsychotic approved in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. While the mechanism of action of CAPLYTA 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 studied for the treatment of major depressive disorder, and other neuropsychiatric and neurological disorders. Lumateperone 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 financial and operating performance, including our future revenues and expenses, our expectations regarding the commercialization of CAPLYTA; our plans to conduct clinical or non-clinical trials and the timing of those trials, including enrollment, initiation or completion of clinical conduct, or the availability of results; plans to make regulatory submissions to the FDA and the timing of such submissions; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; insurance coverage for CAPLYTA; the goals of our development 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: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indications; 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 and bipolar depression following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product;; 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 bipolar depression 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; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the COVID-19 pandemic, the conflict in Ukraine, global economic uncertainty, inflation, higher interest rates or market disruptions; 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:

Intra-Cellular Therapies, Inc.
Juan Sanchez, M.D.
Vice President, Corporate Communications and Investor Relations
646-440-9333

Burns McClellan, Inc.
Cameron Radinovic
cradinovic@burnsmc.com
212-213-0006

INTRA-CELLULAR THERAPIES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except share and per share amounts) (Unaudited) (1)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	**2023**	2022
Revenues				
Product sales, net	**$ 110,128**	$ 55,074	**$ 204,859**	$ 89,829
Grant revenue	**664**	505	**1,239**	746
Total revenues, net	**110,792**	55,579	**206,098**	90,575
Operating expenses:				
Cost of product sales	**7,163**	4,650	**13,914**	7,805
Selling, general and administrative	**101,014**	100,316	**199,937**	175,776
Research and development	**49,794**	38,536	**87,818**	67,579
Total operating expenses	**157,971**	143,502	**301,669**	251,160
Loss from operations	**(47,179)**	(87,923)	**(95,571)**	(160,585)
Interest income	**4,530**	1,320	**8,879**	1,868
Loss before provision for income taxes	**(42,649)**	(86,603)	**(86,692)**	(158,717)
Income tax expense	**(135)**	—	**(145)**	(5)
Net loss	**$ (42,784)**	$ (86,603)	**$ (86,837)**	$ (158,722)
Net loss per common share:				
Basic & Diluted	**$ (0.45)**	$ (0.92)	**$ (0.91)**	$ (1.70)
Weighted average number of common shares:				
Basic & Diluted	**95,948,063**	94,285,117	**95,543,626**	93,449,424

(1) The condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022 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
(in thousands except share and per share amounts) (Unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	**$ 142,258**	$ 148,615
Investment securities, available-for-sale	**370,596**	443,290
Restricted cash	**1,750**	1,750
Accounts receivable, net	**95,964**	75,189
Inventory	**41,895**	23,920
Prepaid expenses and other current assets	**45,610**	45,193
Total current assets	**698,073**	737,957
Property and equipment, net	**1,656**	1,913
Right of use assets, net	**13,787**	14,824
Other assets	**86**	86
Total assets	**$ 713,602**	$ 754,780
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 7,733**	$ 10,395
Accrued and other current liabilities	**27,456**	19,657
Accrued customer programs	**31,710**	25,621
Accrued employee benefits	**21,623**	22,996
Operating lease liabilities	**3,558**	4,567
Total current liabilities	**92,080**	83,236
Operating lease liabilities, non-current	**14,432**	15,474
Total liabilities	**106,512**	98,710
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 shares authorized at June 30, 2023 and December 31, 2022; 96,083,387 and 94,829,794 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	**10**	9
Additional paid-in capital	**2,173,671**	2,137,737
Accumulated deficit	**(1,564,323)**	(1,477,486)
Accumulated comprehensive loss	**(2,268)**	(4,190)
Total stockholders' equity	**607,090**	656,070
Total liabilities and stockholders' equity	**$ 713,602**	$ 754,780

The condensed consolidated balance sheets at June 30, 2023 and December 31, 2022 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.