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): November 3, 2022

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 November 3, 2022, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the third quarter ended September 30, 2022, 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 "Third 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 November 3, 2022, the Company also provided a corporate update. The information set forth under the headings "Commercial Highlights," "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 November 3, 2022.
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: November 3, 2022

Exhibit 99.1

INTRA-CELLULAR THERAPIES REPORTS THIRD QUARTER 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

CAPLYTA net product revenues for the third quarter 2022 were $71.9 million, compared to $21.6 million for the same period in 2021, representing a 233% increase over the same period in 2021 and a 30% increase over the second quarter 2022

Third quarter 2022 CAPLYTA total prescriptions increased 220%, versus the same period in 2021 and 26% sequentially versus the second quarter 2022

NEW YORK, November 3, 2022 /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 third quarter ended September 30, 2022 and provided a corporate update.

“The successful launch of CAPLYTA continues with another quarter of strong revenue growth. In addition to our efforts to fuel continued commercial success, we are making investments to broaden CAPLYTA’s indications and advance our pipeline,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

THIRD QUARTER FINANCIAL HIGHLIGHTS

- Total revenues were $71.9 million for the third quarter of 2022, compared to $22.2 million for the third quarter of 2021. Net product revenues of CAPLYTA were $71.9 million for the third quarter of 2022, compared to $21.6 million for the same period in 2021, representing a year-over-year increase of 233% and a 30% increase over the second quarter of 2022.
- Cost of product sales were $5.9 million in the third quarter of 2022, compared to $2.0 million for the third quarter of 2021.

- Selling, general and administrative (SG&A) expenses were $88.4 million for the third quarter of 2022, compared to $70.5 million for the third quarter of 2021. This increase is primarily due to an increase in marketing and advertising expenses and labor related costs.
- Research and development (R&D) expenses for the third quarter of 2022 were $33.3 million, compared to $27.0 million for the third quarter of 2021. This increase is due to higher lumateperone clinical trial and non-clinical related costs and an increase in non-lumateperone program costs.
- Net loss for the quarter ended September 30, 2022 was $53.5 million, compared to a net loss of $76.9 million for the quarter ended September 30, 2021.
- Cash, cash equivalents, restricted cash and investment securities totaled $630.5 million at September 30, 2022, compared to $413.7 million at December 31, 2021. In January 2022, the Company completed a $460.0 million public offering resulting in net proceeds to the Company of approximately $433.7 million.

COMMERCIAL HIGHLIGHTS

- Following its initial approval in schizophrenia in 2019, CAPLYTA received U.S. Food and Drug Administration (FDA) approval for bipolar depression in December 2021, becoming the first medicine approved in the U.S. for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate.
- CAPLYTA's successful launch in bipolar depression continues. Third quarter CAPLYTA total prescriptions increased by 220% versus the third quarter of 2021. Third quarter CAPLYTA total prescriptions increased by 26% versus the second quarter of 2022.
- In the third quarter we launched two new dosage strengths of CAPLYTA, 10.5 mg and 21 mg. These dosage strengths expand the patient population for CAPLYTA by providing dosage recommendations for patients taking strong or moderate CYP3A4 inhibitors and patients with moderate or severe hepatic impairment.
- CAPLYTA maintained broad coverage in the Medicare Part D and Medicaid channels, with greater than 98% of lives covered and approximately 85% of lives covered in the commercial channel. Our LytaLink patient and prescriber support programs are highly effective at addressing coverage and reimbursement processes and overall patient affordability where appropriate.

CLINICAL HIGHLIGHTS

Clinical Programs:

- Adjunctive MDD program: Studies 501 and 502 are global, double-blind placebo-controlled studies evaluating lumateperone 42 mg as adjunctive treatment to antidepressants. The primary endpoint is change from baseline on the Montgomery-Asberg Depression Rating scale (MADRS) total score at week 6. Additionally, Study 503 is an open label roll-over study to assess long-term safety in this patient population. Patient enrollment in these studies is ongoing and we expect to file a supplemental New Drug Application (sNDA) with the FDA for lumateperone as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in 2024.
- Mixed Features program: We have completed patient enrollment in Study 403 and expect to report topline results in the first quarter of 2023. Study 403 is a global clinical trial evaluating lumateperone 42 mg in patients with MDD and in patients with bipolar depression who exhibit mixed features. Efficacy is assessed at week 6 and there is a follow-up safety visit two weeks after the last medication dose. The primary endpoint is change from baseline versus placebo on the MADRS total score at week 6, and the key secondary endpoint is the Clinical Global Impression (CGI-S) scale.
- Lumateperone Long Acting Injectable (LAI) formulation: We have completed a Phase 1 single ascending dose study with our initial formulation. This study evaluated the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We have also explored alternate sites of injection with this formulation and have been progressing other formulations. We are completing our analyses of these studies which will enable us to define the next steps in this program. The goal of our program is to develop LAI formulations that are effective, safe and well-tolerated with treatment durations of one month and longer.
- 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 have completed a food intake study showing food had no significant impact on the pharmacokinetic (PK) profile. We have also completed Phase 1 safety studies demonstrating ITI-1284 is safe and generally well tolerated in normal healthy volunteers and normal healthy elderly volunteers. Other Phase 1 studies are ongoing or planned and include drug-drug interaction studies and mass balance studies. We also continue to progress our toxicology program for ITI-1284.
- Phosphodiesterase type I inhibitor (PDE1) program: In our PDE 1 inhibitor program, for lenrispodun, we have recently completed or have ongoing Phase 1 trials including drug-drug interaction, bioavailability from scale up batches and food effect studies.
- ITI-333 program: ITI-333 neuroimaging studies are ongoing. These studies are investigating brain occupancy for receptors related to substance use disorder and pain. Following these studies, we plan to initiate a multiple ascending dose study.

Presentations:

- We presented at several medical conferences featuring CAPLYTA including the US Psych Congress and the European College of Neuropsychopharmacology (ECNP) Congress. In these conferences, we presented important data substantiating the favorable long-term safety profile of lumateperone in patients with bipolar depression, consistent with the long-term safety profile seen in our studies of lumateperone in patients with schizophrenia. We also presented analyses from our bipolar program including findings consistent with broad antidepressant effects, marked improvements in patients' daily functioning, and further evidence of a favorable metabolic profile.

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/BIc63e50ba892948f5932b126e73007d48). 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. Breastfeeding is not recommended. 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.

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 expectations regarding the commercialization of CAPLYTA; our plans to conduct clinical or nonclinical 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; the goals of our development programs; our beliefs about the potential utility of our product candidates; future financial results; 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 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; any other impacts on our business as a result of or related to the COVID-19 pandemic; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the conflict in Ukraine; 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; 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
(in thousands except share and per share amounts) (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	**2022**	2021
Revenues				
Product sales, net	**$ 71,870**	$ 21,606	**$ 161,699**	$ 56,192
Grant revenue	**—**	601	**746**	1,940
Total revenues	**71,870**	22,207	**162,445**	58,132
Operating expenses:				
Cost of product sales	**5,850**	2,001	**13,655**	5,496
Selling, general and administrative	**88,375**	70,498	**264,151**	192,933
Research and development	**33,274**	27,032	**100,853**	59,387
Total operating expenses	**127,499**	99,531	**378,659**	257,816
Loss from operations	**(55,629)**	(77,324)	**(216,214)**	(199,684)
Interest income	**2,122**	393	**3,990**	1,298
Loss before provision for income taxes	**(53,507)**	(76,931)	**(212,224)**	(198,386)
Income tax (expense) benefit	**(1)**	23	**(6)**	(6)
Net loss	**$ (53,508)**	$ (76,908)	**$ (212,230)**	$ (198,392)
Net loss per common share:				
Basic & Diluted	**$ (0.57)**	$ (0.95)	**$ (2.26)**	$ (2.44)
Weighted average number of common shares:				
Basic & Diluted	**94,516,794**	81,354,724	**93,809,124**	81,178,482

The condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021 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)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 135,358**	$ 92,365
Investment securities, available-for-sale	**493,383**	319,968
Restricted cash	**1,750**	1,400
Accounts receivable, net	**61,538**	20,156
Inventory	**23,597**	7,948
Prepaid expenses and other current assets	**44,130**	25,444
Total current assets	**759,756**	467,281
Property and equipment, net	**2,084**	1,791
Right of use assets, net	**20,073**	20,764
Other assets	**86**	86
Total assets	**$ 781,999**	$ 489,922
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 14,219**	$ 8,691
Accrued and other current liabilities	**14,850**	11,073
Accrued customer programs	**19,946**	5,964
Accrued employee benefits	**21,150**	20,897
Lease liabilities, short-term	**7,245**	6,732
Total current liabilities	**77,410**	53,357
Lease liabilities	**19,167**	18,675
Total liabilities	**96,577**	72,032
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 shares authorized at September 30, 2022 and December 31, 2021, 94,701,662 and 81,886,965 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	**9**	8
Additional paid-in capital	**2,124,369**	1,639,476
Accumulated deficit	**(1,433,460)**	(1,221,230)
Accumulated comprehensive loss	**(5,496)**	(364)
Total stockholders' equity	**685,422**	417,890
Total liabilities and stockholders' equity	**$ 781,999**	$ 489,922

The condensed consolidated balance sheets at September 30, 2022 and December 31, 2021 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.