



## **Intra-Cellular Therapies Reports Third Quarter 2023 Financial Results and Raises 2023 CAPLYTA Sales Guidance**

November 2, 2023

*Q3 2023 total revenues increased to \$126.2 million, compared to \$71.9 million in the same period in 2022*

*CAPLYTA Q3 2023 net product sales were \$125.8 million, compared to \$71.9 million for the same period in 2022, representing a 75% increase*

*CAPLYTA's strong prescription uptake continues: Q3 2023 CAPLYTA total prescriptions increased 71%, versus the same period in 2022*

*2023 CAPLYTA net product sales guidance raised to \$460 - \$470 million*

NEW YORK, Nov. 02, 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 third quarter ended September 30, 2023 and provided a corporate update.

"Our third quarter results represent another period of significant CAPLYTA growth, and we are again increasing our revenue guidance for the full year 2023," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We continue to solidify CAPLYTA's position as an important option in the treatment of bipolar depression and schizophrenia and we remain focused on advancing our pipeline, including additional lumateperone development programs."

### **Third Quarter Financial Highlights:**

Total revenues were \$126.2 million for the third quarter of 2023, compared to \$71.9 million for the same period in 2022. Net product sales of CAPLYTA were \$125.8 million for the third quarter of 2023, compared to \$71.9 million for the same period in 2022, representing a year-over-year increase of 75% and a 14% sequential increase over the second quarter of 2023.

- Net loss for the third quarter of 2023 was \$24.3 million compared to a net loss of \$53.5 million for the same period in 2022.
- Cost of product sales was \$9.1 million in the third quarter of 2023 compared to \$5.9 million for the same period in 2022.
- Selling, general and administrative (SG&A) expenses were \$105.2 million for the third quarter of 2023, compared to \$88.4 million for the same period in 2022.
- Research and development (R&D) expenses were \$41.6 million for the third quarter of 2023, compared to \$33.3 million for the same period in 2022.
- Cash, cash equivalents, restricted cash and investment securities totaled \$494.8 million at September 30, 2023.

### **Fiscal 2023 Financial Outlook:**

- Full year 2023 CAPLYTA net product sales guidance increased to \$460 to \$470 million from the previous range of \$445 to \$465 million.
- Full year 2023 SG&A expense guidance lowered to \$405 to \$420 million and R&D expense guidance lowered to \$185 to \$200 million.

### **CLINICAL HIGHLIGHTS**

Lumateperone:

- Adjunctive Major Depressive Disorder (MDD) program: 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 are ongoing. We expect to report topline results from Study 501 and from Study 502 in the first and second quarters of 2024, respectively. Subject to the results of these studies, we anticipate filing a supplemental NDA in the second half of 2024.

- Mixed Features program: We presented results from Study 403 at the 2023 Psych Congress and at the European College of Neuropsychopharmacology Congress.

In this study, lumateperone 42mg was statistically significant on the primary endpoint of symptom reduction on the Montgomery Asberg Depression Rating Scale (MADRS) for the combined mixed features patient population of MDD and bipolar depression and the individual patient populations of MDD with mixed features and bipolar depression with mixed features. The robust effect sizes ranged from 0.64 to 0.67. Lumateperone was generally safe and well tolerated, with a side effect profile consistent with prior trials. There were no notable changes in weight, body mass index or waist circumference and no clinically relevant changes in metabolic parameters.

We plan to continue presenting analyses from Study 403 at upcoming medical conferences including a post-hoc analysis evaluating the antidepressant effects of lumateperone in a pre-specified patient population with mixed features exhibiting anxious distress, commonly known as anxious depression.

- Lumateperone Long Acting Injectable (LAI) formulation: We have completed the pre-clinical development of an LAI formulation, and we have conducted a Phase 1 single ascending dose study with this formulation. We expect to initiate a Phase 1 single ascending dose study with four additional formulations in the first half of 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.

#### 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 have initiated Phase 2 programs evaluating ITI-1284 in generalized anxiety disorder, psychosis in Alzheimer's disease, and agitation in Alzheimer's disease.

- 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-HT<sub>2A</sub> receptor antagonist and  $\mu$ -opioid receptor partial agonist, provides potential utility in the treatment of opioid use disorder and pain. A multiple ascending dose study and a positron emission tomography (PET) study are ongoing.
- ITI-1500 Non-Hallucinogenic Psychedelic Program: Our lead product candidate in this program, ITI-1549, continues to advance through IND enabling studies. This program is focused on the development of novel non-hallucinogenic psychedelics for the treatment of mood, anxiety and other neuropsychiatric disorders without the liabilities of known psychedelics, including the hallucinogenic potential and risk for cardiac valvular pathologies.

#### 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](#). 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](http://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<sup>®</sup> (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-HT<sub>2A</sub> receptors and postsynaptic antagonist activity at central dopamine D<sub>2</sub> 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](http://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; 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 conflicts in Ukraine and the Middle East, 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.

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### INTRA-CELLULAR THERAPIES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands except share and per share amounts) (Unaudited) (1)

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2023	2022	2023	2022
Revenues				
Product sales, net	\$ 125,810	\$ 71,870	\$ 330,669	\$ 161,699
Grant revenue	363	—	1,602	746
Total revenues, net	126,173	71,870	332,271	162,445
Operating expenses:				
Cost of product sales	9,129	5,850	23,043	13,655
Selling, general and administrative	105,207	88,375	305,144	264,151
Research and development	41,550	33,274	129,368	100,853
Total operating expenses	155,886	127,499	457,555	378,659
Loss from operations	(29,713)	(55,629)	(125,284)	(216,214)
Interest income	5,498	2,122	14,377	3,990
Loss before provision for income taxes	(24,215)	(53,507)	(110,907)	(212,224)
Income tax expense	(43)	(1)	(188)	(6)
Net loss	\$ (24,258)	\$ (53,508)	\$ (111,095)	\$ (212,230)
Net loss per common share:				
Basic & Diluted	\$ (0.25)	\$ (0.57)	\$ (1.16)	\$ (2.26)
Weighted average number of common shares:				

Basic &amp; Diluted

96,143,083

94,516,794

95,745,641

93,809,124

(1) The condensed consolidated statements of operations for the three and nine months ended September 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)

	<b>September 30, 2023</b>	December 31, 2022
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 99,402	\$ 148,615
Investment securities, available-for-sale	393,619	443,290
Restricted cash	1,750	1,750
Accounts receivable, net	102,670	75,189
Inventory	42,986	23,920
Prepaid expenses and other current assets	61,998	45,193
Total current assets	702,425	737,957
Property and equipment, net	1,789	1,913
Right of use assets, net	13,364	14,824
Other assets	86	86
Total assets	\$ 717,664	\$ 754,780
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 10,613	\$ 10,395
Accrued and other current liabilities	27,829	19,657
Accrued customer programs	35,618	25,621
Accrued employee benefits	25,448	22,996
Operating lease liabilities	3,584	4,567
Total current liabilities	103,092	83,236
Operating lease liabilities, non-current	13,891	15,474
Total liabilities	116,983	98,710
Stockholders' equity:		
Common stock, \$0.0001 par value: 175,000,000 shares authorized at September 30, 2023 and December 31, 2022; 96,225,617 and 94,829,794 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	10	9
Additional paid-in capital	2,190,587	2,137,737
Accumulated deficit	(1,588,581)	(1,477,486)
Accumulated comprehensive loss	(1,335)	(4,190)
Total stockholders' equity	600,681	656,070
Total liabilities and stockholders' equity	\$ 717,664	\$ 754,780

The condensed consolidated balance sheets at September 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.



Source: Intra-Cellular Therapies Inc.