Intra-Cellular Therapies Reports Second Quarter 2024 Financial Results, Provides Corporate Update and Raises 2024 CAPLYTA Sales Guidance

August 7, 2024

CAPLYTA Q2 2024 net product sales were $161.3 million, compared to $110.1 million for the same period in 2023, representing a 46% increase

CAPLYTA's strong prescription uptake continues: Q2 2024 CAPLYTA total prescriptions increased 36%, versus the same period in 2023

CAPLYTA 2024 net product sales guidance raised to $650 to $680 million

Announced positive Phase 3 results from Study 501 and Study 502 evaluating lumateperone as an adjunctive therapy to antidepressants in patients with major depressive disorder (MDD)

Supplemental NDA (sNDA) submission for lumateperone as an adjunctive therapy to antidepressants in patients with MDD anticipated in the second half of 2024

Commenced patient enrollment in ITI-1284 Phase 2 Studies in Generalized Anxiety Disorder and Psychosis associated with Alzheimer's disease

NEW YORK, Aug. 07, 2024 (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, 2024 and provided a corporate update.

"We are very pleased with the strong performance of CAPLYTA during the second quarter and look forward to continued growth for the remainder of 2024," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "Our team is also focused on preparing our sNDA for MDD for submission later this year and continues to advance our robust pipeline."

Second Quarter Financial Highlights:

- Total revenues were $161.4 million for the second quarter of 2024, compared to $110.8 million for the same period in 2023. Net product sales of CAPLYTA were $161.3 million for the second quarter of 2024, compared to $110.1 million for the same period in 2023.
- Net loss for the second quarter of 2024 was $16.2 million compared to a net loss of $42.8 million for the same period in 2023.
- Cost of product sales was $11.4 million in the second quarter of 2024 compared to $7.2 million for the same period in 2023.
- Selling, general and administrative (SG&A) expenses were $121.6 million for the second quarter of 2024, compared to $101.0 million for the same period in 2023.
- Research and development (R&D) expenses were $56.2 million for the second quarter of 2024, compared to $49.8 million for the same period in 2023.
- Cash, cash equivalents, investment securities, and restricted cash totaled $1.025 billion at June 30, 2024.

Commercial Update

- CAPLYTA total prescriptions increased 36% in the second quarter of 2024, compared to the same period in 2023 and 10% in the second quarter of 2024, compared to the first quarter of 2024.
- To fully leverage the growing opportunity with primary care physicians in our current CAPLYTA indications, we plan to increase the size of our sales force during the third quarter of this year to expand our reach and frequency in primary care offices. In connection with this expansion, we are adding approximately 150 sales representatives. We expect to complete a second sales force expansion in 2025 in connection with the potential approval of CAPLYTA for the adjunctive treatment of MDD.
- Received notification from the Centers for Medicare and Medicaid Services that CAPLYTA qualified for the Specified Small Manufacturer Exception pertaining to the Part D redesign of the Inflation Reduction Act.

Fiscal 2024 Financial Outlook:

- CAPLYTA full year 2024 net product sales guidance range raised to $650 to $680 million.
- Full year 2024 SG&A expense guidance range increased to $480 to $510 million. This increase is primarily the result of sales, marketing and other expenses associated with the sales force expansion in the primary care segment in the second half of 2024.
- Full year 2024 R&D expense guidance range lowered to $210 to $230 million.

CLINICAL HIGHLIGHTS

Lumateperone:

- Adjunctive MDD program: Studies 501 and 502 are our global Phase 3 pivotal clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Following the positive and robust results in Study 501 in April 2024 and in Study 502 in June 2024, we anticipate submitting an sNDA with the U.S. Food and Drug Administration (FDA) in the second half of 2024.

  In these studies, lumateperone robustly met the primary endpoint by demonstrating reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score compared to placebo plus antidepressants at Week 6. Results for the primary endpoint are summarized as follows:

Primary Endpoint: Change from baseline vs. placebo on the MADRS Total Score at Week 6 (modified intent-to-treat study population)

		Least Squares (LS) Mean Reduction vs. Baseline[1]	LS mean difference[1]	p value	Cohen's d effect size
STUDY 501	Lumateperone 42 mg +ADT	14.7	-4.9	<0.0001	0.61
	placebo +ADT	9.8			
STUDY 502	Lumateperone 42 mg+ADT	14.7	-4.5	<0.0001	0.56
	placebo +ADT	10.2			

[1] rounded to nearest tenth; ADT: Antidepressant therapy

Similarly, in both pivotal studies, lumateperone met the key secondary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the Clinical Global Impression Scale for Severity of Illness (CGI-S). Statistically significant efficacy was also seen in both studies in the patient reported Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR) scale, a self-reported measure of symptom severity of depression.

Lumateperone was generally safe and well-tolerated in these studies and adverse events were similar to those seen in prior studies of lumateperone in bipolar depression, MDD with mixed features, and schizophrenia. In Study 501 and Study 502, mean changes in key metabolic parameters, including glucose, insulin, triglycerides, and total, LDL and HDL cholesterol, were similar between lumateperone and placebo. Importantly, mean changes in weight were also similar to placebo.

- Lumateperone bipolar mania program: In the second quarter of 2024, we initiated two multicenter, randomized, double-blind, placebo-controlled, Phase 3 studies evaluating lumateperone in the acute treatment of manic or mixed episodes associated with bipolar I disorder (bipolar mania).
- Lumateperone pediatric program: We expect to begin patient enrollment in two studies in pediatric patients for the treatment of irritability associated with autism spectrum disorder in the second half of 2024. In addition, patient enrollment is ongoing in our double-blind, placebo-controlled study in bipolar depression and in our open-label safety study in schizophrenia and bipolar disorder in pediatric patients.
- Lumateperone Long Acting Injectable (LAI) program: We expect to commence clinical conduct in a Phase 1 single ascending dose study with several formulations shortly. 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: We have initiated patient enrollment in our Phase 2 clinical study evaluating ITI-1284 as adjunctive therapy to anti-anxiety medications in patients with generalized anxiety disorder (GAD). We expect to initiate a second Phase 2 GAD study, evaluating ITI-1284 as monotherapy, later this year. We have also initiated patient enrollment in a Phase 2 clinical study evaluating ITI-1284 as monotherapy in patients with psychosis associated with Alzheimer’s disease. We anticipate commencing patient enrollment in our Phase 2 program in agitation associated with Alzheimer’s disease shortly.

- Phosphodiesterase type I inhibitor (PDE1) program: Our portfolio of PDE1 inhibitors continues to advance in clinical development.

  Lenrispodun (ITI-214) Parkinson's disease (PD) program: Our Phase 2 clinical trial is ongoing with topline results anticipated in 2025. 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. A multiple ascending dose study and a positron emission tomography (PET) study are both ongoing.

- ITI-1500 Non-Hallucinogenic Neuroplastogen Program: This program, previously referred to as our non-hallucinogenic psychedelic program, is focused on the development of novel neuroplastogens for the treatment of mood, anxiety, and other neuropsychiatric disorders without the hallucinogenic and cardiovascular effects of psychedelics. Our lead product candidate in this program, ITI-1549, continues to advance through IND enabling studies and is expected to enter human testing in 2025.

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/BIa69e7f7949b74f8d9bc7846c268b0ecd). 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 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.

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 the treatment of 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 psychiatric 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 expand our sales force; our plans to conduct clinical or non-clinical trials and the timing of developments with respect to those trials, including enrollment, initiation or completion of clinical conduct, or the availability or reporting 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; there is no guarantee that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of our patents; 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, Russia 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 June 30,		Six Months Ended June 30,	
	2024	2023	**2024**	2023
Revenues				
Product sales, net	**$ 161,276**	$ 110,128	**$ 306,119**	$ 204,859
Grant revenue	**112**	664	**135**	1,239
Total revenues, net	**161,388**	110,792	**306,254**	206,098
Operating expenses:				
Cost of product sales	**11,354**	7,163	**21,254**	13,914
Selling, general and administrative	**121,574**	101,014	**234,659**	199,937
Research and development	**56,183**	49,794	**99,016**	87,818
Total operating expenses	**189,111**	157,971	**354,929**	301,669
Loss from operations	**(27,723)**	(47,179)	**(48,675)**	(95,571)
Interest income	**11,560**	4,530	**17,624**	8,879
Loss before provision for income taxes	**(16,163)**	(42,649)	**(31,051)**	(86,692)
Income tax expense	**(57)**	(135)	**(416)**	(145)
Net loss	**$ (16,220)**	$ (42,784)	**$ (31,467)**	$ (86,837)
Net loss per common share:				
Basic & Diluted	**$ (0.16)**	$ (0.45)	**$ (0.31)**	$ (0.91)
Weighted average number of common shares:				
Basic & Diluted	**103,723,007**	95,948,063	**100,299,141**	95,543,626

(1) The condensed consolidated statements of operations for the three and six months ended June 30, 2024 and 2023 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)(1)

	June 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	**$ 693,306**	$ 147,767
Investment securities, available-for-sale	**329,601**	350,174
Restricted cash	**1,750**	1,750
Accounts receivable, net	**145,714**	114,018
Inventory	**20,082**	11,647
Prepaid expenses and other current assets	**73,798**	42,443
Total current assets	**1,264,251**	667,799
Property and equipment, net	**1,445**	1,654
Right of use assets, net	**14,507**	12,928
Inventory, non-current	**32,562**	38,621
Other assets	**7,739**	7,293
Total assets	**$ 1,320,504**	$ 728,295
Liabilities and stockholders' equity		

Current liabilities:				
Accounts payable	**$**	**17,548**	$	11,452
Accrued and other current liabilities		**39,713**		27,944
Accrued customer programs		**77,971**		53,173
Accrued employee benefits		**22,372**		27,364
Operating lease liabilities		**4,171**		3,612
Total current liabilities		**161,775**		123,545
Operating lease liabilities, non-current		**14,117**		13,326
Total liabilities		**175,892**		136,871
Stockholders' equity:				
Common stock		**11**		10
Additional paid-in capital		**2,793,896**		2,208,470
Accumulated deficit		**(1,648,627)**		(1,617,160)
Accumulated comprehensive (loss) income		**(668)**		104
Total stockholders' equity		**1,144,612**		591,424
Total liabilities and stockholders' equity	**$**	**1,320,504**	$	728,295

(1) The condensed consolidated balance sheets at June 30, 2024 and December 31, 2023 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.