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

October 30, 2024

CAPLYTA Q3 2024 net product sales were $175.2 million, compared to $125.8 million for the same period in 2023, representing a 39% increase

CAPLYTA's strong prescription uptake continues: Q3 2024 CAPLYTA total prescriptions increased 38%, versus the same period in 2023

CAPLYTA 2024 net product sales guidance range raised to $665 to $685 million

Following a successful pre-supplemental NDA (sNDA) meeting with the U.S. Food and Drug Administration (FDA), the lumateperone sNDA submission for adjunctive treatment of major depressive disorder (MDD) is anticipated in the fourth quarter of 2024

Patient enrollment ongoing in ITI-1284 Phase 2 studies in generalized anxiety disorder (GAD), psychosis associated with Alzheimer's disease and agitation associated with Alzheimer's disease

Pipeline advancing with ongoing programs in major neuropsychiatric disorders including lumateperone Phase 3 pediatric program and the lumateperone long-acting injectable (LAI) program

BEDMINSTER, N.J., Oct. 30, 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 third quarter ended September 30, 2024 and provided a corporate update.

"We are encouraged by CAPLYTA's strong growth trajectory in the third quarter and look forward to further growth in the remainder of 2024 and beyond. We are on track to submit our sNDA for the adjunctive treatment of MDD later this year and our commercial team is actively preparing for a potential launch in 2025," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

Third Quarter Financial Highlights

- Total revenues were $175.4 million for the third quarter of 2024, compared to $126.2 million for the same period in 2023. Net product sales of CAPLYTA were $175.2 million for the third quarter of 2024, compared to $125.8 million for the same period in 2023.
- Net loss for the third quarter of 2024 was $26.3 million compared to a net loss of $24.3 million for the same period in 2023.
- Cost of product sales was $15.3 million in the third quarter of 2024 compared to $9.1 million for the same period in 2023.
- Selling, general and administrative (SG&A) expenses were $132.1 million for the third quarter of 2024, compared to $105.2 million for the same period in 2023.
- Research and development (R&D) expenses were $66.8 million for the third quarter of 2024, compared to $41.6 million for the same period in 2023.
- Cash, cash equivalents, investment securities, and restricted cash totaled $1.0 billion at September 30, 2024.

Commercial Update

- CAPLYTA total prescriptions increased 38% in the third quarter of 2024, compared to the same period in 2023 and 9% in the third quarter of 2024, compared to the second quarter of 2024.
- In the third quarter of 2024, we completed an expansion of our sales force, adding approximately 150 sales representatives to leverage the growing opportunity with primary care physicians in CAPLYTA's current indications. A second primary care physician sales force expansion is planned for 2025 in connection with the potential approval of CAPLYTA for the adjunctive treatment of MDD.

Fiscal 2024 Financial Outlook

- Raised CAPLYTA full year 2024 net product sales guidance range to $665 to $685 million.
- Narrowed full year 2024 SG&A expense guidance range to $490 to $510 million and full year 2024 R&D expense guidance range to $220 to $230 million.

CLINICAL HIGHLIGHTS

Lumateperone:

- Adjunctive MDD program: In the third quarter of 2024, we had a successful pre-sNDA meeting with the FDA for lumateperone for the adjunctive treatment of MDD. The positive and robust results from Phase 3 Studies 501 and 502 form the basis of our sNDA, which we anticipate submitting to the FDA in the fourth quarter of 2024.

  Results from Study 501 were presented at the European College of Neuropsychopharmacology Congress in September. This week, we are presenting results from Studies 501 and 502 at the Psych Congress being held in Boston, MA. As previously disclosed, Studies 501 and 502 demonstrated robust efficacy of lumateperone added to an antidepressant for the treatment of MDD in the primary endpoint, the Montgomery Asberg Depression Rating Scale (MADRS) total score, with a large separation versus placebo of 4.9 points in Study 501 and 4.5 points in Study 502, and a robust effect size of 0.61 in Study 501 and 0.56 in Study 502. In both studies, symptom improvement occurred as early as one week. Both studies also met the key secondary endpoint (CGI-S) and showed statistically significant efficacy in the patient self-reported measure of symptom severity of depression as measured by the Quick Inventory of Depressive Symptomatology Self Report (QIDS). We will continue to share results from our Phase 3 MDD studies with the medical community at other upcoming conferences in 2024 and 2025.

- Lumateperone bipolar mania program: Patient enrollment is ongoing in our two multicenter, randomized, double-blind, placebo-controlled, Phase 3 studies evaluating lumateperone in adults in the acute treatment of manic or mixed episodes associated with bipolar I disorder (bipolar mania).
- Lumateperone pediatric program: 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. Patient enrollment in two Phase 3 studies in pediatric patients for the treatment of irritability associated with autism spectrum disorder is anticipated to commence in the fourth quarter of 2024.
- Lumateperone long acting injectable (LAI) program: A Phase 1 single ascending dose study evaluating several formulations has commenced clinical conduct. 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: Patient enrollment is ongoing in our Phase 2 clinical study evaluating ITI-1284 as adjunctive therapy to approved anti-anxiety medications in patients with GAD. A second Phase 2 GAD study, evaluating ITI-1284 as monotherapy, is expected to commence later this year.

  In the third quarter of 2024, we commenced enrollment in a Phase 2 clinical study evaluating ITI-1284 in patients with psychosis associated with Alzheimer's disease. In addition, we recently commenced patient enrollment in our Phase 2 program in agitation associated with Alzheimer's disease.

- 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 lenrispodun Phase 2 clinical trial is evaluating improvements in motor symptoms, changes in cognition and inflammatory biomarkers in patients with PD. We anticipate completion of this study by the end of 2025.

  ITI-1020 oncology program: Clinical conduct continues in our Phase 1 single ascending dose study in healthy volunteers evaluating the 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 has been completed and a positron emission tomography (PET) study is ongoing.
- ITI-1500 non-hallucinogenic neuroplastogen program: This 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. ITI-1549 is undergoing 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/BI1898608c75d549d2a97e359f537afbaa). 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 and any product approvals; 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.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	**2024**	2023
Revenues				
Product sales, net	**$ 175,159**	$ 125,810	**$ 481,278**	$ 330,669
Grant revenue	**216**	363	**351**	1,602
Total revenues, net	**175,375**	126,173	**481,629**	332,271
Operating expenses:				
Cost of product sales	**15,304**	9,129	**36,558**	23,043

Selling, general and administrative	**132,101**	105,207	**366,760**	305,144
Research and development	**66,819**	41,550	**165,835**	129,368
Total operating expenses	**214,224**	155,886	**569,153**	457,555
Loss from operations	**(38,849)**	(29,713)	**(87,524)**	(125,284)
Interest income	**12,899**	5,498	**30,523**	14,377
Loss before provision for income taxes	**(25,950)**	(24,215)	**(57,001)**	(110,907)
Income tax expense	**(374)**	(43)	**(790)**	(188)
Net loss	**$ (26,324)**	$ (24,258)	**$ (57,791)**	$ (111,095)
Net loss per common share:				
Basic & Diluted	**$ (0.25)**	$ (0.25)	**$ (0.57)**	$ (1.16)
Weighted average number of common shares:				
Basic & Diluted	**105,768,386**	96,143,083	**102,135,530**	95,745,641

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

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	**$ 464,312**	$ 147,767
Investment securities, available-for-sale	**542,250**	350,174
Restricted cash	**1,750**	1,750
Accounts receivable, net	**145,608**	114,018
Inventory	**23,539**	11,647
Prepaid expenses and other current assets	**94,272**	42,443
Total current assets	**1,271,731**	667,799
Property and equipment, net	**2,005**	1,654
Right of use assets, net	**14,011**	12,928
Inventory, non-current	**30,479**	38,621
Other assets	**6,219**	7,293
Total assets	**$ 1,324,445**	$ 728,295
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 10,338**	$ 11,452
Accrued and other current liabilities	**51,540**	27,944
Accrued customer programs	**70,536**	53,173
Accrued employee benefits	**29,496**	27,364
Operating lease liabilities	**4,203**	3,612
Total current liabilities	**166,113**	123,545
Operating lease liabilities, non-current	**13,506**	13,326
Total liabilities	**179,619**	136,871
Stockholders' equity:		
Common stock	**11**	10
Additional paid-in capital	**2,818,137**	2,208,470
Accumulated deficit	**(1,674,951)**	(1,617,160)
Accumulated comprehensive income	**1,629**	104
Total stockholders' equity	**1,144,826**	591,424
Total liabilities and stockholders' equity	**$ 1,324,445**	$ 728,295

(1) The condensed consolidated balance sheets at September 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.