Intra-Cellular Therapies Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 4, 2023

Q1 2023 total revenues of $95.3 million, compared to $35.0 million in the same period in 2022

CAPLYTA Q1 2023 net product sales were $94.7 million, compared to $34.8 million for the same period in 2022, representing a 173% increase

Q1 2023 CAPLYTA total prescriptions increased 159%, versus the same period in 2022 and 16% sequentially versus Q4 2022

Reiterating CAPLYTA 2023 net product sales guidance of $430 to $455 million

Announced robust positive results from Study 403 in patients with mixed features in major depressive disorder (MDD) and mixed features in bipolar depression

NEW YORK, May 04, 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 first quarter ended March 31, 2023 and provided a corporate update.

“We are pleased with the progress we have made in the first quarter and we are confident in the continued growth of CAPLYTA,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “We are excited about our recent positive results in our clinical study in patients with mixed features in MDD and mixed features in bipolar depression. We are also encouraged by the progress we have made with our pipeline programs.”

First Quarter Financial Highlights:

- Total revenues were $95.3 million for the first quarter of 2023, compared to $35.0 million for the same period in 2022. Net product sales of CAPLYTA were $94.7 million for the first quarter of 2023, compared to $34.8 million for the same period in 2022, representing a year-over-year increase of 173% and an 8% increase over the fourth quarter of 2022. First quarter CAPLYTA total prescriptions increased sequentially by 16% versus the fourth quarter of 2022.
- Net loss for the first quarter of 2023 was $44.1 million compared to a net loss of $72.1 million for the same period in 2022.
- Cost of product sales was $6.8 million in the first quarter of 2023 compared to $3.2 million for the same period in 2022.
- Selling, general and administrative (SG&A) expenses were $98.9 million for the first quarter of 2023, compared to $75.5 million for the same period in 2022. This increase is primarily due to an increase in marketing and advertising costs.
- Research and development (R&D) expenses were $38.0 million for the first quarter of 2023, compared to $29.0 million for the same period in 2022. This increase is primarily due to higher lumateperone project costs and non-lumateperone project costs.
- Cash, cash equivalents, restricted cash and investment securities totaled $540.5 million at March 31, 2023, compared to $593.7 million at December 31, 2022.

Reiterating Fiscal 2023 Financial Outlook:

- Reiterating our financial guidance for FY 2023 including CAPLYTA net product sales of $430 to $455 million.

COMMERCIAL HIGHLIGHTS

- CAPLYTA’s strong uptake continued in the first quarter of 2023 with total prescriptions increasing by 159% compared to the first quarter of 2022. First quarter CAPLYTA total prescriptions increased sequentially by 16% versus the fourth quarter of 2022.
- CAPLYTA maintained broad coverage in the Medicare Part D and Medicaid channels, with greater than 98% of lives covered and increased Commercial coverage to approximately 90% of lives covered by the end of the first quarter of 2023.
- Our LytaLink patient and prescriber support program continues to be very effective in supporting patient access to CAPLYTA.

CLINICAL HIGHLIGHTS

Lumateperone:

- Mixed Features program: Announced robust positive results from Study 403 evaluating lumateperone 42mg as monotherapy in the treatment of major depressive episodes in patients with MDD with mixed features and in patients with bipolar depression with mixed features.

  In this study, lumateperone 42mg met the primary endpoint by demonstrating a statistically significant reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score compared to placebo at Week 6 in the combined patient population of MDD with mixed features and bipolar depression with mixed features (5.7 point reduction v. placebo; $p<0.0001$; Cohen's d effect size (ES) of 0.64). Robust results were also seen in the individual patient population of MDD with mixed features (5.9 point reduction v. placebo*;* $p<0.0001$; ES= 0.67), and in the individual patient population of bipolar depression with mixed features (5.7 point reduction v. placebo; $p<0.0001$; ES= 0.64).

  Lumateperone 42mg also met the key secondary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the clinician's assessment of improvement in the overall severity on the Global Impression of Severity Scale (CGI-S) score compared to placebo at Week 6 in the combined patient population of MDD with mixed features and bipolar depression with mixed features ($p<0.0001$; ES= 0.59) and in the individual patient population of MDD with mixed features ($p=0.0003$; ES= 0.57), as well as the individual patient population of bipolar depression with mixed features $p<0.0001$; ES=0.61). Lumateperone was generally safe and well tolerated, with a side effect profile consistent with prior lumateperone trials.

- Adjunctive MDD program: Lumateperone is in Phase 3 clinical development as a novel treatment for MDD. Patient enrollment in Study 501 and Study 502, global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD, is ongoing. In addition, we recently initiated a third global Phase 3 trial, Study 505, also evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Subject to the results of Studies 501 and 502, we expect to file a supplemental New Drug Application with the FDA in 2024 for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD.

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

Other pipeline programs:

- ITI-1284-ODT-SL program: ITI-1284 is a deuterated form of lumateperone, a new chemical entity formulated as an oral disintegrating tablet for sublingual administration. We plan to initiate Phase 2 programs in agitation in patients with Alzheimer's disease (AD), in psychosis in patients with AD and in generalized anxiety disorder in 2023.
- Phosphodiesterase type I inhibitor (PDE1) program: Our portfolio of PDE1 inhibitors is being developed to treat diseases in which PDE1 activity is over active.
- Lenrispodun (ITI-214) is our lead PDE1 inhibitor compound. Patient enrollment in a Phase 2 clinical trial in Parkinson's disease (PD) commenced in the first quarter of 2023. The objective of this proof-of-concept study is to evaluate improvements in motor symptoms in patients with PD. Changes in cognition and inflammatory biomarkers will also be assessed.
- ITI-1020 is our second drug candidate in our PDE1 inhibitor program. We have an active Investigational New Drug application to evaluate ITI-1020 as a novel cancer immunotherapy. We have commenced a Phase 1 program in healthy volunteers.
- 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, pain and mood disorders. We have two ongoing studies: a multiple ascending dose study in healthy volunteers evaluating pharmacokinetics, safety and tolerability and a neuroimaging study.

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. 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.

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

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

About CAPLYTA (lumateperone)

CAPLYTA 42 mg is an oral, once daily atypical antipsychotic approved in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. While the mechanism of action of CAPLYTA is unknown, the efficacy of CAPLYTA could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Lumateperone is being studied for the treatment of major depressive disorder, and other neuropsychiatric and neurological disorders. Lumateperone is not FDA-approved for these disorders.

About Intra-Cellular Therapies

Intra-Cellular Therapies is a biopharmaceutical company founded on Nobel prize-winning research that allows us to understand how therapies affect the inner-workings of cells in the body. The company leverages this intracellular approach to develop innovative treatments for people living with complex psychiatric and neurologic diseases. For more information, please visit www.intracellulartherapies.com.

Forward-Looking Statements

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, our financial and operating performance, including our future revenues and expenses, our expectations regarding the commercialization of CAPLYTA; our plans to conduct clinical or non-clinical trials and the timing of those trials, including enrollment, initiation or completion of clinical conduct, or the availability of results; plans to make regulatory submissions to the FDA and the timing of such submissions; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; insurance coverage for CAPLYTA; the goals of our development programs; our beliefs about the potential utility of our product candidates; and development efforts and plans under the caption “About Intra-Cellular Therapies.” All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, the following: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; 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.

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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 March 31,	
	2023	2022
Revenues		
Product sales, net	**$ 94,731**	$ 34,755
Grant revenue	**575**	241
Total revenues	**95,306**	34,996
Operating expenses:		
Cost of product sales	**6,751**	3,155
Selling, general and administrative	**98,923**	75,460
Research and development	**38,024**	29,043
Total operating expenses	**143,698**	107,658

Loss from operations		**(48,392)**		(72,662)
Interest income		**4,349**		548
Loss before provision for income taxes		**(44,043)**		(72,114)
Income tax expense		**(10)**		(5)
Net loss	**$**	**(44,053)**	$	(72,119)
Net loss per common share:				
Basic & Diluted	**$**	**(0.46)**	$	(0.78)
Weighted average number of common shares:				
Basic & Diluted		**95,134,694**		92,604,290

The condensed consolidated statements of operations for the quarters ended March 31, 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)

		March 31, 2023		December 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	**$**	**75,727**	$	148,615
Investment securities, available-for-sale		**462,981**		443,290
Restricted cash		**1,750**		1,750
Accounts receivable, net		**81,545**		75,189
Inventory		**28,341**		23,920
Prepaid expenses and other current assets		**55,750**		45,193
Total current assets		**706,094**		737,957
Property and equipment, net		**1,779**		1,913
Right of use assets, net		**14,199**		14,824
Other assets		**86**		86
Total assets	**$**	**722,158**	$	754,780
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	**$**	**8,441**	$	10,395
Accrued and other current liabilities		**21,067**		19,657
Accrued customer programs		**29,892**		25,621
Accrued employee benefits		**16,656**		22,996
Operating lease liabilities		**3,531**		4,567
Total current liabilities		**79,587**		83,236
Operating lease liabilities, non-current		**14,961**		15,474
Total liabilities		**94,548**		98,710
Stockholders' equity:				
Common stock, $0.0001 par value: 175,000,000 shares authorized at March 31, 2023 and December 31, 2022; 95,680,029 and 94,829,794 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively		**10**		9
Additional paid-in capital		**2,151,837**		2,137,737
Accumulated deficit		**(1,521,539)**		(1,477,486)
Accumulated comprehensive loss		**(2,698)**		(4,190)
Total stockholders' equity		**627,610**		656,070
Total liabilities and stockholders' equity	**$**	**722,158**	$	754,780

The condensed consolidated balance sheets at March 31, 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.