



Intra-Cellular Therapies Reports Fourth Quarter and Full-Year 2022 Financial Results and Provides Corporate Update

March 1, 2023

Full year 2022 total revenues of \$250.3 million, compared to \$83.8 million in 2021

CAPLYTA fourth quarter 2022 net product sales grew to \$87.4 million, a 243% increase over the same period in 2021 and a 22% sequential increase over the third quarter 2022

Full year 2022 CAPLYTA net product sales grew to \$249.1 million, a 205% increase over 2021

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

NEW YORK, March 01, 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 fourth quarter and year ended December 31, 2022 and provided a corporate update.

"The robust growth of CAPLYTA in 2022 marked an extraordinary year for our company. During the year we launched our new bipolar depression indication for CAPLYTA and made considerable progress in advancing our late and early-stage clinical programs," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "I am very proud of our accomplishments and the strong foundation we have built. We expect 2023 to be another year of significant growth for CAPLYTA and the company."

Fourth Quarter Financial Highlights:

- Net product sales of CAPLYTA were \$87.4 million for the fourth quarter of 2022, compared to \$25.5 million for the same period in 2021, representing a year-over-year increase of 243% and a 22% increase over the third quarter of 2022.
- Net loss for the fourth quarter of 2022 was \$44.0 million compared to a net loss of \$85.7 million for the same period in 2021.
- Cost of product sales were \$6.8 million in the fourth quarter of 2022 compared to \$2.5 million for the same period in 2021.
- Selling, general and administrative (SG&A) expenses were \$94.6 million for the fourth quarter of 2022, compared to \$79.7 million for the same period in 2021. This increase is primarily due to an increase in commercialization, marketing and advertising costs.
- Research and development (R&D) expenses for the fourth quarter of 2022 were \$33.9 million, compared to \$29.5 million for the fourth quarter of 2021. This increase is primarily due to higher lumateperone and non-lumateperone project costs, including the ITI-1284, ITI-214, and ITI-333 programs.

2022 Financial Highlights:

- Total revenues were \$250.3 million for the full year 2022, compared to \$83.8 million for the full year 2021, representing an increase of 199%. Net product sales of CAPLYTA were \$249.1 million for the full year 2022, compared to \$81.7 million for the full year 2021, representing an increase of 205%.
- Net loss for the year ended December 31, 2022 was \$256.3 million or \$2.72 per share (basic and diluted) compared to a net loss of \$284.1 million or \$3.50 per share (basic and diluted) for the year ended December 31, 2021.
- Cost of product sales was approximately \$20.4 million for the year ended December 31, 2022, compared to \$8.0 million for the year ended December 31, 2021.
- SG&A expenses were \$358.8 million for the year ended December 31, 2022, compared to \$272.6 million for the year ended December 31, 2021. This increase is primarily due to an increase in commercialization, marketing and advertising costs.
- R&D expenses were \$134.7 million for the year ended December 31, 2022, compared to \$88.8 million for the year ended December 31, 2021. This increase is primarily due to higher lumateperone clinical and non-clinical project costs, and

higher non-lumateperone project costs, including the ITI-1284, ITI-214, and ITI-333 programs.

- Cash, cash equivalents, restricted cash and investment securities totaled \$593.7 million at December 31, 2022, compared to \$413.7 million at December 31, 2021.

Fiscal 2023 Financial Outlook:

- CAPLYTA 2023 net product sales are expected to be \$430 to \$455 million.
- SG&A expenses for the full year 2023 are expected to be \$420 to \$450 million, including approximately \$29 million of non-cash, share-based compensation expense. SG&A guidance reflects our commitment to continue to support CAPLYTA commercialization through investments in our sales and marketing activities.
- R&D expenses for the full year 2023 are expected to be \$195 to \$220 million, including approximately \$17 million of non-cash, share-based compensation expense. R&D guidance reflects investments to support our robust pipeline including our lumateperone clinical programs in mood disorders, our long-acting injectable program, and our other platforms including our phosphodiesterase-1 inhibitors, ITI-1284 and ITI-333.

	Expectations (in \$ millions)	
	low	high
CAPLYTA Net Product Sales	\$ 430	\$ 455
SG&A expenses (GAAP)	\$ 420	\$ 450
R&D expenses (GAAP)	\$ 195	\$ 220

COMMERCIAL HIGHLIGHTS

- Successfully launched CAPLYTA for the treatment of bipolar depression in adults. CAPLYTA is the only U.S. Food and Drug Administration (FDA) approved treatment for depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate.
- CAPLYTA prescriptions tripled in 2022, following the launch in bipolar depression, representing 193% total prescription growth in 2022 over 2021. CAPLYTA's strong uptake continued in the fourth quarter with total prescriptions increasing by 225% compared to the fourth quarter of 2021. Fourth quarter CAPLYTA total prescriptions increased sequentially by 21% versus the third quarter of 2022 while total prescriptions in the overall oral antipsychotic market remained flat.
- In 2022 we received FDA approval and subsequently 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. CAPLYTA has broad Commercial coverage and we expect to expand this coverage to 90% of lives 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:

- Adjunctive MDD program: Patient enrollment is ongoing in Studies 501 and 502, our global Phase 3 major depressive disorder (MDD) studies evaluating lumateperone 42 mg for the adjunctive treatment of depression in patients who have partially responded to antidepressants. Subject to the results of Studies 501 and 502, we expect to file a supplemental New Drug Application with the FDA for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in 2024.
- Mixed Features program: We expect to report topline results from Study 403 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. The primary endpoint is change from baseline versus placebo on the Montgomery-Asberg Depression Rating scale (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: 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. In 2022 we completed a Phase 1 single ascending dose study with our initial formulation. We have progressed the preclinical development of other

formulations and anticipate initiating Phase 1 single ascending dose studies with several formulations in 2023.

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.
 - In 2022, we completed a food intake study and a water intake study. In these studies, ITI-1284 was generally safe and well-tolerated. Previously, we completed Phase 1 safety studies in which ITI-1284 was generally safe and well tolerated in normal healthy volunteers and normal healthy elderly volunteers. Other Phase 1 studies are ongoing or planned and our toxicology program for ITI-1284 continues to progress.
 - In 2023, we plan to begin Phase 2 programs in agitation in patients with Alzheimer's disease (AD), generalized anxiety disorder, and psychosis in patients with AD.
- Phosphodiesterase type I inhibitor (PDE1) program: Our portfolio of PDE1 inhibitors is being developed to treat diseases in which PDE1 activity is highly active.
 - Lenrispodun (ITI-214) is our lead PDE1 inhibitor compound. We completed Phase 1 trials including drug-drug interaction, bioavailability from scale up batches and food effect studies. We also conducted a Phase 1/2 trial in patients with Parkinson's disease to evaluate safety and tolerability in this patient population. We expect to commence clinical conduct in a Phase 2 trial in Parkinson's disease later this month.
 - We have an active Investigational New Drug application to evaluate our newest candidate within the PDE1 inhibitor program, ITI-1020, as a novel cancer immunotherapy. A Phase 1 program in healthy volunteers is anticipated to commence in the first half of 2023.
- ITI-333 program: ITI-333, a 5-HT_{2A} receptor antagonist and μ -opioid receptor partial agonist, provides potential utility in the treatment of opioid use disorder, pain and mood disorders. A multiple ascending dose study in healthy volunteers evaluating pharmacokinetics (PK), safety and tolerability commenced clinical conduct in the first quarter of 2023. Our neuroimaging study is ongoing.

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-HT_{2A} 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 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; 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 December 31,		Twelve Months Ended December 31,	
	2022(1)	2021(1)	2022 (1)	2021 (1)
Revenues				
Product sales, net	\$ 87,433	\$ 25,516	\$ 249,132	\$ 81,708
Grant revenue	436	155	1,182	2,095
Total revenues, net	<u>87,869</u>	<u>25,671</u>	<u>250,314</u>	<u>83,803</u>
Operating expenses:				
Cost of product sales	6,788	2,539	20,443	8,035
Selling, general and administrative	94,631	79,678	358,782	272,611
Research and development	33,862	29,458	134,715	88,845
Total operating expenses	<u>135,281</u>	<u>111,675</u>	<u>513,940</u>	<u>369,491</u>
Loss from operations	<u>(47,412)</u>	<u>(86,004)</u>	<u>(263,626)</u>	<u>(285,688)</u>
Interest income	3,386	270	7,376	1,568
Loss before provision for income taxes	<u>(44,026)</u>	<u>(85,734)</u>	<u>(256,250)</u>	<u>(284,120)</u>
Income tax expense	—	—	(6)	(6)
Net loss	<u>\$ (44,026)</u>	<u>\$ (85,734)</u>	<u>\$ (256,256)</u>	<u>\$ (284,126)</u>
Net loss per common share:				
Basic & Diluted	\$ (0.45)	\$ (1.05)	\$ (2.72)	\$ (3.50)
Weighted average number of common shares:				
Basic & Diluted	<u>94,751,563</u>	<u>81,475,688</u>	<u>94,046,670</u>	<u>81,253,394</u>

(1) The condensed consolidated statements of operations for the years ended December 31, 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)(Unaudited)

December 31,
2022 (1)

December 31,
2021 (1)

Assets

Current assets:

Cash and cash equivalents	\$ 148,615	\$ 92,365
Investment securities, available-for-sale	443,290	319,968
Restricted cash	1,750	1,400
Accounts receivable, net	75,189	20,156
Inventory	23,920	7,948
Prepaid expenses and other current assets	45,193	25,444
Total current assets	<u>737,957</u>	467,281
Property and equipment, net	1,913	1,791
Right of use assets, net	14,824	20,764
Other assets	86	86
Total assets	<u>\$ 754,780</u>	<u>\$ 489,922</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 10,395	\$ 8,691
Accrued and other current liabilities	19,657	11,073
Accrued customer programs	25,621	5,964
Accrued employee benefits	22,996	20,897
Operating lease liabilities	4,567	6,732
Total current liabilities	<u>83,236</u>	53,357
Operating lease liabilities, non-current	15,474	18,675
Total liabilities	<u>98,710</u>	72,032

Stockholders' equity:

Common stock, \$0.0001 par value: 175,000,000 shares authorized at December 31, 2022 and December 31, 2021, 94,829,794 and 81,886,965 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	9	8
Additional paid-in capital	2,137,737	1,639,476
Accumulated deficit	(1,477,486)	(1,221,230)
Accumulated comprehensive loss	(4,190)	(364)
Total stockholders' equity	<u>656,070</u>	417,890
Total liabilities and stockholders' equity	<u>\$ 754,780</u>	<u>\$ 489,922</u>

- (1) The condensed consolidated balance sheets at December 31, 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.



Source: Intra-Cellular Therapies Inc.