Intra-Cellular Therapies Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 10, 2022

First quarter 2022 results reflect strong CAPLYTA® (lumateperone) launch in bipolar depression

First quarter 2022 CAPLYTA new and total prescriptions increased 63% and 45%, respectively, versus the fourth quarter 2021

First quarter 2022 CAPLYTA new and total prescriptions increased 154% and 134%, respectively, versus the same period in 2021

New-to-brand CAPLYTA prescriptions, representing new patient starts, have increased approximately 300% following bipolar depression approval

Total revenues for the first quarter 2022 were $35 million, compared to $15.9 million for the same period in 2021, representing a 120% increase

CAPLYTA net product revenues of $34.8 million for the first quarter 2022, representing a 36% increase over the fourth quarter 2021 and a 123% increase over the same period in 2021

NEW YORK, May 10, 2022 (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, 2022 and provided a corporate update.

"We are encouraged by the robust uptake of CAPLYTA in the first full quarter following our late December 2021 launch in bipolar depression and are confident in our ability to deliver continued strong growth and to improve the lives of patients. We continue to advance our pipeline, including our lumateperone programs in major depressive disorder (MDD) and mixed features," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

First Quarter Financial Highlights:

- Total revenues were $35.0 million for the first quarter of 2022, compared to $15.9 million of total revenues for the first quarter of 2021. Net product revenues of CAPLYTA were $34.8 million for the first quarter of 2022, compared to $15.6 million in net product revenues of CAPLYTA for the same period in 2021, representing a year-over-year increase of 123% and a 36% increase over the fourth quarter of 2021.
- Cost of product sales were $3.2 million in the first quarter of 2022, compared to $1.5 million for the first quarter of 2021.
- Research and development (R&D) expenses for the first quarter of 2022 were $29.0 million, compared to $15.1 million for the first quarter of 2021. This increase is due to higher lumateperone clinical trial and non-clinical related costs and an increase in non-lumateperone project costs.
- Selling, general and administrative (SG&A) expenses were $75.5 million for the first quarter of 2022, compared to $52.6 million for the first quarter of 2021. This increase is primarily due to an increase in commercialization, marketing and labor related costs.
- Net loss for the quarter ended March 31, 2022 was $72.1 million, compared to a net loss of $52.7 million for the quarter ended March 31, 2021.
- Cash, cash equivalents, restricted cash and investment securities totaled $773.2 million at March 31, 2022, compared to $413.7 million at December 31, 2021. On January 7, 2022, we completed a public offering of our common stock in which we sold approximately 10.95 million shares of common stock for aggregate gross proceeds of $460.0 million and net proceeds, after deducting underwriting discounts and commissions and offering expenses, of approximately $433.7 million.

COMMERCIAL HIGHLIGHTS

- CAPLYTA launched in bipolar depression immediately following its U.S. Food and Drug Administration (FDA) approval in late December 2021. CAPLYTA is the first and only 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.
- Significant inflection in both new and total prescriptions reflecting robust growth following approval in bipolar depression.

First quarter CAPLYTA new and total prescriptions increased by 63% and 45%, respectively, versus the fourth quarter of 2021. First quarter CAPLYTA new and total prescriptions increased by 154% and 134%, respectively, versus the first quarter of 2021.

- New-to-brand prescriptions, representing new CAPLYTA patient starts, have increased by approximately 300% following bipolar depression approval. New-to-brand prescriptions are considered a key leading indicator of growth during the launch phase, reflecting early adoption by prescribers. These encouraging uptake trends have been accompanied by positive physician receptivity to CAPLYTA.
- CAPLYTA maintained broad coverage in the Medicare Part D and Medicaid channels, with greater than 98% of lives covered and expanded coverage in the commercial channel to over 80% of lives covered. Our LytaLink patient support program continues to be very effective in supporting patient access.

CLINICAL HIGHLIGHTS

Lumateperone:

- Received approval by the FDA for two new dosage strengths of CAPLYTA, 10.5 mg and 21 mg capsules, to provide dosage recommendations for patients concomitantly taking strong or moderate CYP3A4 inhibitors, and 21 mg for patients with moderate or severe hepatic impairment (Child-Pugh class B or C). This strengthens CAPLYTA's overall profile even further by expanding the appropriate patient base within the highly prevalent conditions of bipolar disorder and schizophrenia.
- Adjunctive MDD program: Patient enrollment in pivotal studies 501 and 502 is ongoing. These are Phase 3 double blind, placebo-controlled, 6-week global studies evaluating lumateperone 42 mg as adjunctive treatment to anti-depressants. The primary endpoint is change from baseline versus placebo on the MADRS total score at week 6, and the CGI-S scale is the key secondary endpoint. We expect to file a supplemental New Drug Application (sNDA) with the FDA for lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in 2024.
- Mixed Features program: Clinical conduct is ongoing in Study 403, a global clinical trial evaluating lumateperone 42 mg in patients with MDD and in patients with bipolar depression who exhibit mixed features. We expect to complete clinical conduct in this Study in the second half of 2022.
- Lumateperone Long Acting Injectable (LLAI) formulation: Initial clinical conduct in our Phase 1 single ascending study has been completed, and we are encouraged by the safety and tolerability results we have seen to date. We are exploring alternate sites of injection with the current formulation as well as progressing the development of other formulations. The goal of our program is to develop LLAI formulations that are effective, safe and well-tolerated with treatment durations of one month and longer. Together, these Phase 1 studies will assist us in designing formulation and dosing strategies for our efficacy studies.

Other Programs:

- ITI-1284-ODT-SL program: ITI-1284 ODT-SL Phase 1 studies are either ongoing or planned, including food effect and brain-imaging studies. We expect to commence clinical conduct in our agitation in patients with probable Alzheimer's disease program in 2022, followed by additional studies in dementia-related psychosis and certain depressive disorders in the elderly. We have previously completed single and multiple ascending dose studies in healthy young and elderly subjects, demonstrating rapid absorption and excellent drug exposure, allowing doses to be selected for our next studies.
- Phosphodiesterase type I inhibitor (PDE1) program: Lenrispodun (ITI-214) is our lead compound in this program. We expect to initiate patient enrollment/clinical conduct in our lenrispodun Phase 2 clinical trial for the treatment of Parkinson's disease in the first half of 2022.

  In preclinical studies, we have shown that PDE1 inhibitors can inhibit the recruitment of immune cells such as microglia and macrophages into tumors, thereby altering the tumor microenvironment. We have shown that lenrispodun can potentiate the action of PD-1 inhibitors in various models of colorectal, kidney, breast and glioblastoma cancers. Recently, at the American Association for Cancer Research (AACR) Annual Meeting, we presented preclinical data describing the antitumor effects of PDE1 inhibitors when administered in conjunction with checkpoint inhibitor immunotherapy in an animal model of breast cancer. Additional data from this program will be presented at upcoming conferences this year.

- ITI-333 program in Opioid Use Disorder: Following the positive results from our Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers, our plan is to advance the development of ITI-333 with neuroimaging studies, followed by a multiple ascending dose 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. The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellulartherapies.com. Please connect to the Company's website at least 5-10 minutes prior to the live webcast to ensure adequate time for any necessary software download. Alternatively, please call 1-(844) 835-6563 (U.S.) or 1-(970) 315-3916 (international) to listen to the live conference call. The conference ID number for the live call is 9526447. Please dial in approximately 10 minutes prior to the call.

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. CAPLYTA is available in 42 mg capsules.

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 anti-depressant-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 (10.5 mg) or moderate CYP3A4 inhibitors (21 mg).

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 (21 mg).

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation, dizziness, nausea, and dry mouth.

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 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; 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,	
	2022	2021
Revenues		
Product sales, net	**$ 34,755**	$ 15,579
Grant revenue	**241**	299
Total revenues	**34,996**	15,878
Operating expenses:		
Cost of product sales	**3,155**	1,455
Research and development	**29,043**	15,058
Selling, general and administrative	**75,460**	52,584

Total operating expenses		**107,658**		69,097
Loss from operations		**(72,662)**		(53,219)
Interest income		**548**		484
Loss before provision for income taxes		**(72,114)**		(52,735)
Income tax expense		**5**		5
Net loss	**$**	**(72,119)**	$	(52,740)
Net loss per common share:				
Basic & Diluted	**$**	**(0.78)**	$	(0.65)
Weighted average number of common shares:				
Basic & Diluted		**92,604,290**		80,946,450

The condensed consolidated statements of operations for the quarters ended March 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 except share and per share amounts)

		March 31, 2022		December 31, 2021
		(Unaudited)		
Assets				
Current assets:				
Cash and cash equivalents	**$**	**129,295**	$	92,365
Investment securities, available-for-sale		**642,553**		319,969
Restricted cash		**1,400**		1,400
Accounts receivable, net		**32,832**		20,156
Inventory		**7,893**		7,948
Prepaid expenses and other current assets		**34,369**		25,443
Total current assets		**848,342**		467,281
Property and equipment, net		**2,185**		1,791
Right of use assets, net		**17,967**		20,764
Other assets		**86**		86
Total assets	**$**	**868,580**	$	489,922
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	**$**	**11,649**	$	8,691
Accrued and other current liabilities		**12,258**		11,073
Accrued customer programs		**10,888**		5,964
Lease liabilities, short-term		**7,636**		6,732
Accrued employee benefits		**16,643**		20,897
Total current liabilities		**59,074**		53,357
Lease liabilities		**16,756**		18,675
Total liabilities		**75,830**		72,032
Stockholders' equity:				
Common stock, $0.0001 par value: 175,000,000 shares authorized at March 31, 2022 and December 31, 2021; 94,020,425 and 81,896,965 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively		**9**		8
Additional paid-in capital		**2,089,418**		1,639,476
Accumulated deficit		**(1,293,349)**		(1,221,230)
Accumulated comprehensive loss		**(3,328)**		(364)
Total stockholders' equity		**792,750**		417,890
Total liabilities and stockholders' equity	**$**	**868,580**	$	489,922

The condensed consolidated balance sheets at March 31, 2022 and December 31, 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.