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

August 9, 2022

Total revenues for the second quarter 2022 were $55.6 million, compared to $20.0 million for the same period in 2021, representing a 178% increase

CAPLYTA net product revenues for the second quarter 2022 were $55.1 million, representing a 190% increase over the same period in 2021 and a 58% increase over the first quarter 2022

Second quarter 2022 CAPLYTA new and total prescriptions increased 225% and 191%, respectively, versus the same period in 2021

Second quarter 2022 CAPLYTA new and total prescriptions increased 55% and 51%, respectively, versus the first quarter 2022

NEW YORK, Aug. 09, 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 second quarter ended June 30, 2022 and provided a corporate update.

“In this quarter, CAPLYTA experienced significant revenue growth, increasing nearly 60% over the first quarter of 2022, driven by strong uptake in bipolar depression. We expect to continue to deliver strong revenue growth throughout 2022 and also look forward to advancing our development programs,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

SECOND QUARTER FINANCIAL HIGHLIGHTS

- Total revenues were $55.6 million for the second quarter of 2022, compared to $20.0 million for the second quarter of 2021. Net product revenues of CAPLYTA were $55.1 million for the second quarter of 2022, compared to $19.0 million for the same period in 2021, representing a year-over-year increase of 190% and a 58% increase over the first quarter of 2022.
- Cost of product sales were $4.7 million in the second quarter of 2022, compared to $2.0 million for the second quarter of 2021.
- Selling, general and administrative (SG&A) expenses were $100.3 million for the second quarter of 2022, compared to $69.9 million for the second quarter of 2021. This increase is primarily due to an increase in marketing and advertising expenses and labor related costs.
- Research and development (R&D) expenses for the second quarter of 2022 were $38.5 million, compared to $17.3 million for the second 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.
- Net loss for the quarter ended June 30, 2022 was $86.6 million, compared to a net loss of $68.7 million for the quarter ended June 30, 2021.
- Cash, cash equivalents, restricted cash and investment securities totaled $679.2 million at June 30, 2022, compared to $413.7 million at December 31, 2021. In January 2022, the Company completed a $460.0 million public offering resulting in net proceeds to the Company of approximately $433.7 million from the sale of 10,952,381 shares of its common stock, after deducting underwriting discounts and commissions and offering expenses.

COMMERCIAL HIGHLIGHTS

- Q2 2022 marks the second full quarter of the launch of the CAPLYTA's bipolar depression indication following 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.
- The significant launch inflection continued in both new and total prescriptions, reflecting sustained robust growth following approval in bipolar depression. Second quarter CAPLYTA new and total prescriptions increased by 55% and 51%, respectively, versus the first quarter of 2022. Second quarter CAPLYTA new and total prescriptions increased by 225% and 191%, respectively, versus the second quarter of 2021.

- Following FDA approval during the second quarter of 2022, two new dosage strengths of CAPLYTA, 10.5 mg and 21 mg, are expected to be available in pharmacies this month. This will expand the patient population who has access to CAPLYTA, specifically 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 and, during the quarter, we further expanded coverage in the Commercial channel to approximately 85% of lives covered. Our LytaLink patient support program continues to be highly effective in supporting patient access.

CLINICAL HIGHLIGHTS

Lumateperone:

- Mixed Features program: Patient enrollment is progressing well in Study 403, a global clinical trial evaluating lumateperone 42 mg in patients with major depressive disorder (MDD) and in patients with bipolar depression who exhibit mixed features. 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 complete clinical conduct in this study in late 2022.
- Adjunctive MDD program: Patient enrollment in pivotal global studies 501 and 502 evaluating lumateperone 42 mg as adjunctive treatment to anti-depressants is ongoing. 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.
- Presentations: In the second quarter of 2022, there were lumateperone research presentations at the American Psychiatric Association (APA) Meeting, the International Conference for Bipolar Disorders (ISBD) Annual Meeting, the American Society of Clinical Psychopharmacology (ASCP), and the Schizophrenia International Research Society (SIRS). The presentations included additional analyses from our lumateperone bipolar depression program including findings consistent with broad antidepressant effects, marked improvements in patients' daily functioning, and further evidence of a favorable metabolic profile.

  At SIRS, we presented safety analyses from our open-label safety switching study evaluating lumateperone 42 mg in patients with stable schizophrenia. Overall, data from this post-hoc analysis further support the favorable safety and tolerability profile of lumateperone 42 mg in patients with schizophrenia who switched from another antipsychotic, irrespective of the previous antipsychotic. In addition, patients switching from risperidone/paliperidone or olanzapine to lumateperone had significant improvements in cardiometabolic parameters and prolactin concentrations.
- Lumateperone Long Acting Injectable (LAI) formulation: We have completed the preclinical development of an LAI formulation, and we have conducted a Phase 1 single ascending dose study with this formulation. This study evaluated the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We are exploring alternate sites of injection with this formulation as well as progressing other formulations. This will assist us in evaluating dosing strategies and formulation for our efficacy studies. 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.

Other 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 are presently evaluating ITI-1284-ODT-SL in Phase 1 studies including drug-drug interaction studies. We expect to commence clinical conduct in Phase 2 clinical trials in agitation in patients with probable Alzheimer's disease, in dementia-related psychosis and certain depressive disorders in the elderly in 2023.
- Phosphodiesterase type I inhibitor (PDE1) program: We have initiated our Phase 2 clinical program with lenrispodun for Parkinson's disease and expect to commence patient enrollment in the second half of 2022.

  We continue to investigate the anti-cancer effects of PDE1 inhibitors. In April of this year, we presented preclinical data at the AACR Annual meeting describing the antitumor effects of PDE1 inhibitors, when administered in conjunction with checkpoint inhibitor immunotherapy in an animal model of triple negative breast cancer. We have now shown that our PDE1 inhibitors can potentiate the action of checkpoint inhibitors in various models of colorectal, kidney, breast and glioblastoma cancers. We plan to present additional data from this program at future scientific meetings.
- ITI-333 program in Opioid Use Disorder: We continue to advance the development of ITI-333. Following the recent completion of our single ascending dose study, we have commenced a neuroimaging study to investigate brain occupancy for receptors that play a role in substance use disorder and also have applicability for pain. The results of this study will support the dose selection for future studies.

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-(877) 407-8291 (U.S.) or 1-(201) 689-8345 (international) to listen to the live conference call. 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.

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.

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, including the availability of two new dosage strengths 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; future financial results; 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 June 30,		Six Months Ended June 30,	
	2022	2021	**2022**	2021
Revenues				
Product sales, net	**$ 55,074**	$ 19,007	**$ 89,829**	$ 34,586
Grant revenue	**505**	1,040	**746**	1,339

Total revenues	**55,579**	20,047	**90,575**	35,925
Operating expenses:				
Cost of product sales	**4,650**	2,040	**7,805**	3,495
Selling, general and administrative	**100,316**	69,851	**175,776**	122,435
Research and development	**38,536**	17,297	**67,579**	32,355
Total operating expenses	**143,502**	89,188	**251,160**	158,285
Loss from operations	**(87,923)**	(69,141)	**(160,585)**	(122,360)
Interest income	**1,320**	421	**1,868**	905
Loss before provision for income taxes	**(86,603)**	(68,720)	**(158,717)**	(121,455)
Income tax expense	**—**	24	**5**	29
Net loss	**$ (86,603)**	$ (68,744)	**$ (158,722)**	$ (121,484)
Net loss per common share:				
Basic & Diluted	**$ (0.92)**	$ (0.85)	**$ (1.70)**	$ (1.50)
Weighted average number of common shares:				
Basic & Diluted	**94,285,117**	81,229,788	**93,449,424**	81,088,900

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

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 77,235**	$ 92,365
Investment securities, available-for-sale	**600,594**	319,968
Restricted cash	**1,400**	1,400
Accounts receivable, net	**46,976**	20,156
Inventory	**25,022**	7,948
Prepaid expenses and other current assets	**37,979**	25,444
Total current assets	**789,206**	467,281
Property and equipment, net	**2,137**	1,791
Right of use assets, net	**20,477**	20,764
Other assets	**86**	86
Total assets	**$ 811,906**	$ 489,922
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 10,749**	$ 8,691
Accrued and other current liabilities	**17,274**	11,073
Accrued customer programs	**16,483**	5,964
Accrued employee benefits	**18,385**	20,897
Lease liabilities, short-term	**7,743**	6,732
Total current liabilities	**70,634**	53,357
Lease liabilities	**19,075**	18,675
Total liabilities	**89,709**	72,032
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 shares authorized at June 30, 2022 and December 31, 2021, 94,367,233 and 81,886,965 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	**9**	8
Additional paid-in capital	**2,106,942**	1,639,476
Accumulated deficit	**(1,379,952)**	(1,221,230)
Accumulated comprehensive loss	**(4,802)**	(364)
Total stockholders' equity	**722,197**	417,890

Total liabilities and stockholders' equity	**$**	**811,906**	$	489,922

The condensed consolidated balance sheets at June 30, 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.