



## Intra-Cellular Therapies Reports Fourth Quarter and Full-Year 2021 Financial Results and Provides Corporate Update

March 1, 2022

*Received FDA approval for CAPLYTA® (lumateperone) for the treatment of bipolar depression in adults.*

*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.*

*Total revenues for the fourth quarter were \$25.7 million, compared to \$12.5 million for the same period in 2020, representing a 106% increase. Total revenues for the year were \$83.8 million, compared to \$22.8 million in 2020, representing a 267% increase.*

*Achieved CAPLYTA net product revenues of \$25.5 million for the fourth quarter representing a 106% increase over the same period in 2020 and an 18% increase over the prior quarter. For the full year, CAPLYTA net revenues were \$81.7 million, compared to \$22.5 million in 2020, representing a 263% increase.*

*Fourth quarter CAPLYTA total prescriptions increased 15% versus the previous quarter and 98% versus the same period in 2020.*

*Advancing CAPLYTA development programs for the treatment of additional mood disorders:*

*Patient enrollment is ongoing in pivotal program evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD).*

*Clinical trial in patients with bipolar depression or MDD exhibiting mixed features is ongoing.*

NEW YORK, March 01, 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 fourth quarter and year ended December 31, 2021 and provided a corporate update.

"2021 was an extremely productive year for ITCI, culminating in the approval of CAPLYTA for the treatment of bipolar depression. This momentum has continued in 2022 with CAPLYTA's robust prescription growth and I am very proud of our team's efforts," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We remain focused on maximizing CAPLYTA's potential with continued progress in our late-stage programs in MDD and additional mood disorders to help more patients with major neuropsychiatric conditions. In addition, we continue to advance our other pipeline programs."

### **YE 2021 Financial Highlights:**

- Total revenues were \$83.8 million for the full year 2021, compared to \$22.8 million in total revenues for the full year 2020, representing an increase of 267%. Net product revenues of CAPLYTA were \$81.7 million for the full year 2021, compared to \$22.5 million in net product revenues of CAPLYTA for the full year 2020, representing an increase of 263%.
- Net loss for the year ended December 31, 2021 was \$284.1 million or \$3.50 per share (basic and diluted) compared to a net loss of \$227.0 million or \$3.23 per share (basic and diluted) for the year ended December 31, 2020.
- Cost of product sales was approximately \$8.0 million for the year ended December 31, 2021, compared to \$1.9 million for the year ended December 31, 2020.
- Research and development (R&D) expenses for the year ended December 31, 2021 were \$88.8 million, compared to \$65.8 million for the year ended December 31, 2020. This increase is due to higher lumateperone clinical and non-clinical trial costs and an increase in share based compensation costs.
- Selling, general and administrative (SG&A) expenses were \$272.6 million for the year ended December 31, 2020, compared to \$186.4 million for the year ended December 31, 2020. This increase is primarily due to an increase in marketing costs in addition to labor related and share-based compensation costs.
- Cash, cash equivalents and investment securities totaled \$412.3 million at December 31, 2021, compared to \$657.4 million at December 31, 2020. Additionally, on January 7, 2022, the Company completed a public offering of common stock in which the Company sold 10,952,381 shares of common stock at an offering price of \$42.00 per share for aggregate gross proceeds of \$460.0 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds

to the Company were approximately \$433.7 million.

#### Fourth Quarter Financial Highlights:

- Net product revenues of CAPLYTA were \$25.5 million for the fourth quarter of 2021, compared to \$12.4 million in net product revenues of CAPLYTA for the same period in 2020, representing a year-over-year increase of 106%. Net product revenues for the fourth quarter of 2021 increased \$3.9 million or 18% from the prior quarter.
- Net loss for the fourth quarter of 2021 was \$85.7 million compared to a net loss of \$60.7 million for the same period in 2020.
- Cost of product sales were \$2.5 million in the fourth quarter of 2021 compared to \$1.1 million for the same period in 2020.
- Research and development (R&D) expenses for the fourth quarter of 2021 were \$29.5 million, compared to \$14.3 million for the fourth quarter of 2020. This increase is due to higher lumateperone clinical and non-clinical trial costs and an increase in share-based compensation costs.
- Selling, general and administrative (SG&A) expenses were \$79.7 million for the fourth quarter of 2021, compared to \$58.3 million for the same period in 2020. This increase is primarily due to an increase in commercialization, marketing and labor related costs.

#### COMMERCIAL HIGHLIGHTS

- CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults in late December 2021. CAPLYTA is the 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. We launched CAPLYTA in bipolar depression immediately following approval.
- Robust initial prescription growth following CAPLYTA launch in bipolar depression. Comparing the first seven weeks of 2022 following the launch to the same period in the prior quarter, new prescriptions of CAPLYTA have grown by 48% and total prescriptions by 35%. These encouraging trends have been accompanied by positive physician receptivity to CAPLYTA's bipolar approval in a broad patient population.
- During 2021, our commercial organization delivered consistent quarter over quarter prescription growth with strong execution in a market environment impacted by the ongoing pandemic. Fourth quarter CAPLYTA total prescriptions increased by 15% versus the third quarter of 2021 and increased by 98% versus the same period in 2020.
- 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

##### CAPLYTA 2021 Journal Publications:

- Announced the online publication of "Safety and tolerability of lumateperone 42 mg: An open-label antipsychotic switch study in outpatients with stable schizophrenia" (Correll et al., 2021) in the journal, *Schizophrenia Research*.
- Announced the publication of Study 404, a Phase 3 clinical study evaluating lumateperone as monotherapy in patients with bipolar depression. The article titled "Efficacy and Safety of Lumateperone for Major Depressive Episodes Associated with Bipolar I or Bipolar II Disorder: A Phase 3 Randomized Placebo-Controlled Trial," was published in *The American Journal of Psychiatry*.

##### Lumateperone:

- Adjunctive MDD program: In 2021, we initiated patient enrollment in pivotal studies 501 and 502. 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.
- Mixed Features program: 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. Clinical conduct is ongoing.
- Lumateperone Long Acting Injectable (LLAI) formulation: In 2021, we initiated Study ITI-007-025, a Phase 1 single ascending dose study of LLAIs to evaluate the pharmacokinetics, safety and tolerability of our initial formulation of LLAIs in patients with stable symptoms of schizophrenia. We have completed initial clinical conduct in this study and are

encouraged by the safety and tolerability results we have seen to date. We are now 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 LLAI formulations that are effective, safe and well-tolerated with treatment durations of one month and longer.

#### Other Programs:

- ITI-1284-ODT-SL program: Our ITI-1284-ODT-SL program focused on the treatment of agitation in patients with probable Alzheimer's disease (AD), dementia-related psychosis and certain depressive disorders in the elderly. We expect to commence clinical conduct in our AD agitation program in 2022. Additional studies in dementia-related psychosis, and certain depressive disorders in the elderly, are also planned for 2022.
- Phosphodiesterase type I inhibitor (PDE1) program: Our PDE1 inhibitor program is focused on diseases in which the PDE1 enzyme activity is increased and/or deleterious immune cell changes lead to poor outcomes, including certain cancers. Lenrispodun (ITI-214) is our lead compound in this program.
  - Initiated our Phase 2 clinical program with lenrispodun for Parkinson's disease and expect to commence patient enrollment in the first half of 2022.
  - Presented preclinical data describing the antitumor effects of PDE1 inhibitors when administered in conjunction with checkpoint inhibitor immunotherapy at the American Association for Cancer Research (AACR) Annual Meeting. Additional data from this program will be presented at upcoming conferences this year.
- ITI-333 program in opioid use disorder: Study ITI-333-001, a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers has been completed. In this study, ITI-333 was generally safe and well-tolerated and achieved plasma exposures at or above those required for efficacy.

#### 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](http://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 5899935. 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 Warning:

- **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 and moderate or strong 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. Use of CAPLYTA should be avoided in patients with moderate or severe liver problems.

**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-HT<sub>2A</sub> receptors and postsynaptic antagonist activity at central dopamine D<sub>2</sub> 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](http://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 trials and the timing of those trials; 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; 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**

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021(1)	2020(1)
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues				
Product sales, net	\$ 25,516,026	\$ 12,403,754	\$ 81,707,874	\$ 22,530,753
Grant revenue	154,900	50,516	2,095,143	282,226
Total revenues, net	<b>25,670,926</b>	12,454,270	<b>83,803,017</b>	22,812,979
Costs and expenses:				
Cost of product sales	2,538,028	1,141,072	8,034,589	1,895,029
Research and development	29,459,100	14,298,586	88,845,513	65,782,137
Selling, general and administrative	79,678,352	58,347,948	272,611,040	186,363,444
Total operating expenses	<b>111,675,480</b>	73,787,606	<b>369,491,142</b>	254,040,610
Loss from operations	<b>(86,004,554)</b>	(61,333,336)	<b>(285,688,125)</b>	(231,227,631)
Interest income	270,617	644,390	1,568,090	4,235,481
Income tax expense	-	(10,232)	(5,631)	(13,513)
Net loss	<b>\$ (85,733,937)</b>	<b>\$ (60,699,178)</b>	<b>\$ (284,125,666)</b>	<b>\$ (227,005,663)</b>
Net loss per common share:				
Basic & Diluted	<b>\$ (1.05)</b>	<b>\$ (0.76)</b>	<b>\$ (3.50)</b>	<b>\$ (3.23)</b>
Weighted average number of common shares:				
Basic & Diluted	<b>81,475,688</b>	80,293,750	<b>81,253,394</b>	70,364,800

(1) The condensed consolidated statements of operations for the years ended December 31, 2021 and 2020 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**

	December 31, 2021 (1)	December 31, 2020 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 92,364,990	\$ 60,045,933
Investment securities, available-for-sale	319,968,348	597,402,126
Restricted cash	1,400,000	1,400,000
Accounts receivable, net	20,155,994	10,764,583
Inventory	7,948,126	7,056,385
Prepaid expenses and other current assets	25,443,372	14,235,455
Total current assets	<b>467,280,830</b>	690,904,482
Property and equipment, net	<b>1,790,724</b>	1,998,346

Right of use assets, net	<b>20,764,458</b>	24,324,762
Other assets	<b>86,084</b>	86,084
Total assets	<b>\$ 489,922,096</b>	\$ 717,313,674
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	<b>\$ 8,691,220</b>	\$ 5,501,825
Accrued and other current liabilities	<b>11,072,996</b>	7,896,942
Accrued customer programs	<b>5,963,610</b>	3,005,175
Lease liabilities, short-term	<b>6,731,792</b>	5,541,802
Accrued employee benefits	<b>20,896,860</b>	14,907,479
Total current liabilities	<b>53,356,478</b>	36,853,223
Lease liabilities	<b>18,674,943</b>	23,600,347
Total liabilities	<b>72,031,421</b>	60,453,570
Stockholders' equity:		
Common stock, \$0.0001 par value: 175,000,000 and 100,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 81,886,965 and 80,463,089 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	<b>8,189</b>	8,046
Additional paid-in capital	<b>1,639,475,837</b>	1,593,475,506
Accumulated deficit	<b>(1,221,229,698)</b>	(937,104,032)
Accumulated comprehensive (loss) income	<b>(363,653)</b>	480,584
Total stockholders' equity	<b>417,890,675</b>	656,860,104
Total liabilities and stockholders' equity	<b>\$ 489,922,096</b>	\$ 717,313,674

(1) The condensed consolidated balance sheets at December 31, 2021 and 2020 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.