



## Intra-Cellular Therapies Reports Fourth Quarter and Full-Year 2020 Financial Results And Provides Corporate Update

February 25, 2021

*Successfully launched CAPLYTA® (lumateperone) in late March 2020 and demonstrated strong commercial execution in the midst of COVID-19.*

*CAPLYTA achieved net product revenues of \$12.4 million and \$22.5 million for fourth quarter and full year 2020, respectively.*

*Fourth quarter CAPLYTA total prescriptions (TRx) increased 77% versus the previous quarter.*

*Pursuing CAPLYTA label expansion including bipolar depression and major depressive disorder:*

*Submitted CAPLYTA supplemental new drug applications (sNDAs) to the FDA for the treatment of bipolar depression in adults as both monotherapy and adjunctive treatment with lithium or valproate.*

*Initiated late-stage programs in adjunctive major depressive disorder (MDD) and in patients with bipolar depression and MDD exhibiting mixed features, and advanced the lumateperone long-acting injectable (LLAI) formulation into clinical testing.*

*ITI-1284, a new molecular entity:*

*Continued pipeline expansion with the introduction of ITI-1284, a deuterated form of lumateperone delivered sublingually as an orally disintegrating tablet.*

*ITI-1284 has completed Phase I studies and is being developed for behavioral disturbances in dementia, dementia-related psychosis, and certain depressive disorders in the elderly.*

NEW YORK, Feb. 25, 2021 (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 ended December 31, 2020, and provided a corporate update.

"2020 was a transformational year for our company with the launch of our first product, CAPLYTA. I am proud of the important progress that our organization has achieved. We navigated unprecedented and challenging COVID-19 circumstances and still accomplished key commercial and clinical development milestones," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We look forward to continuing our progress as we seek to expand our CAPLYTA label to include patients with bipolar depression. We are excited about our late-stage lumateperone programs in depressive disorders and the advancement of a long-acting injectable formulation into clinical trials as well as further expanding our pipeline with ITI-1284."

### **YE 2020 Financial Highlights:**

- Total revenues were \$22.8 million for the full year 2020. Net product revenues of CAPLYTA were \$22.5 million for the full year 2020. No net product revenues were reported for the comparable periods of 2019.
- Net loss for the year ended December 31, 2020 was \$227.0 million or \$3.23 per share (basic and diluted) compared to a net loss of \$147.7 million or \$2.68 per share (basic and diluted) for the year ended December 31, 2019.
- Cost of product sales was approximately \$1.9 million for the year ended December 31, 2020. Cost of product sales consisted primarily of product royalty fees, overhead and minimal direct costs.
- Research and development (R&D) expenses for the year ended December 31, 2020 were \$65.8 million, compared to \$89.1 million for the year ended December 31, 2019, representing a decrease of approximately \$23.3 million, or 26%.
- Selling, general and administrative (SG&A) expenses were \$186.4 million for the year ended December 31, 2020, compared to \$64.9 million for the year ended December 31, 2019.
  - Selling costs were \$132.5 million for the year ended December 31, 2020 as compared to pre-commercialization costs of \$32.5 million in the same period in 2019. General and administrative expenses for the year ended December 31, 2020 were \$53.9 million, compared to \$32.4 million for the same period in 2019.
- Cash, cash equivalents, restricted cash and investment securities totaled \$658.8 million at December 31, 2020, compared

to \$224.0 million at December 31, 2019.

#### Fourth Quarter Financial Highlights:

- Net product revenues of CAPLYTA were \$12.4 million for the fourth quarter of 2020, compared to \$7.4 million in net product revenues in the third quarter of 2020.
- Net loss for the quarter ended December 31, 2020 was \$60.7 million compared to a net loss of \$40.6 million for the quarter ended December 31, 2019.
- Research and development (R&D) expenses for the fourth quarter of 2020 were \$14.3 million, compared to \$19.1 million for the fourth quarter of 2019. This decrease is due primarily to a decrease in manufacturing expense, and a decrease of lumateperone clinical and non-clinical expenses.
- Selling, general and administrative (SG&A) expenses were \$58.3 million for the fourth quarter of 2020, compared to \$22.8 million for the same period in 2019. This increase is primarily due to an increase in sales related labor costs and commercialization costs.

#### COMMERCIAL HIGHLIGHTS

- CAPLYTA was launched in late March 2020. Our commercial organization has successfully adapted to the COVID-19 market environment and continues to effectively engage with our prescribing audience through a hybrid model of virtual engagements and in-person interactions, enhanced by an expanded digital marketing initiative.
- Fourth quarter CAPLYTA results reflect strong commercial execution delivering continued robust prescription growth, increasing total prescriptions 77% versus the third quarter.
- Established strong CAPLYTA market access coverage with greater than 95% of covered lives in both Medicare Part D and State Medicaid, the major payer channels in schizophrenia. Our LytaLink program continues to be highly competitive and effective in supporting prescribing physicians and eligible patients' access to CAPLYTA.

#### 2020/2021 CLINICAL HIGHLIGHTS

##### Lumateperone - Bipolar Depression Program:

- We submitted our sNDAs to the FDA for lumateperone as monotherapy and as adjunctive treatment with lithium or valproate for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults. We anticipate an FDA target action date in the second half of 2021.
- We reported positive topline results from Study '402, a global Phase 3 clinical trial evaluating lumateperone as adjunctive therapy to lithium or valproate in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. Lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score. Lumateperone was generally well-tolerated in the trial.

##### Other Lumateperone Programs

- Mixed Features program: Study '403 is a large global clinical trial evaluating lumateperone 42 mg in two patient populations: patients with MDD and patients with bipolar depression who exhibit mixed features. The primary endpoint is change from baseline on the MADRS total score at week 6 versus placebo. Results from this study are anticipated in the second half of 2022.
- Adjunctive MDD program: Commenced a Phase 3 clinical program evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Clinical conduct in two studies, Studies '501 and '502, is anticipated to begin in 2021.
- Lumateperone Long Acting Injectable (LLAI) formulation: Commenced Study ITI-007-025, a Phase 1 single ascending dose study of LLAJ, a formulation designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month. Initial results from this study are anticipated in the second half of 2021.

##### CAPLYTA- Schizophrenia

- Recently 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*.

##### Other Programs

- ITI-1284 program: We recently announced our pipeline expansion with ITI-1284 ODT-SL. ITI-1284 is a deuterated form of lumateperone, a new molecular entity formulated as an orally disintegrating tablet for sublingual administration that has recently completed Phase 1 studies. In these studies, ITI-1284 was generally safe and well-tolerated. We plan to initiate studies evaluating ITI-1284 for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and the treatment of certain depressive disorders in the elderly.
- Phosphodiesterase type I inhibitor (PDE1) program: Our PDE1 inhibitor program is focused on diseases in which the PDE1 enzyme is over-expressed and/or abnormal immune cell function contributes to disease pathology providing opportunities to pursue innovative treatments for multiple diseases including Parkinson's, heart failure and other diseases. We have previously reported positive results from Phase 1/2a studies evaluating lenrispodun (ITI-214), our lead molecule, in patients with Parkinson's disease and in patients with chronic systolic heart failure. We plan to advance lenrispodun into a Phase 2 clinical study in Parkinson's disease in 2021.
- ITI-333 program in opioid use disorder: Commenced Study ITI-333-001, a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. Results from this study are anticipated in the second half of 2021.

#### 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 8499868. Please dial in approximately 10 minutes prior to the call.

CAPLYTA® (lumateperone) is indicated for the treatment of schizophrenia in adults. 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.**

**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.
- **Sleepiness and Trouble Concentrating**. 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, moderate or strong CYP3A4 inhibitors and UGT 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 (24% vs. 10%) and dry mouth (6% vs. 2%).

[Please click here to see full Prescribing Information including Boxed Warning.](#)

#### **About CAPLYTA (lumateperone)**

CAPLYTA 42mg/day is an oral, once daily atypical antipsychotic approved for the treatment of schizophrenia of adults. While the mechanism of action of CAPLYTA in the treatment of schizophrenia 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.

CAPLYTA (lumateperone) is being investigated for the treatment of bipolar depression, depression and other neuropsychiatric and neurological disorders. CAPLYTA 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; the anticipated timing of the FDA target action date for our bipolar depression sNDAs, if accepted by the FDA, and the adequacy of the data contained in the sNDAs to serve as the basis for approval of lumateperone for the treatment of depressive episodes associated with bipolar I or II disorder both as monotherapy and as adjunctive therapy in adults; our plans and expected timing to initiate our lumateperone clinical studies in major depressive disorder; our plans and expected timing for results from our lumateperone long-acting injectable clinical trial; our plans and expected timing for results from our ITI-333 clinical trial; our development plans for our PDE program, including ITI-214; our development plans for our ITI-1284 program; 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: whether the sNDAs for lumateperone will be accepted for review by the FDA; if accepted, whether the preclinical and clinical results of the lumateperone studies will meet the regulatory requirements for approval by the FDA for the proposed indications; whether the sNDAs will be approved by the FDA and whether the FDA will complete its review within its target timelines, including its target action date once established; whether the FDA will require additional information, whether we will be able to provide in a timely manner any additional information that the FDA requests, and whether such additional information will be satisfactory to the FDA; 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 indication; 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 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; 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 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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**MEDIA INQUIRIES:**

**INTRA-CELLULAR THERAPIES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020(1)	2019(1)
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues				
Product sales, net	\$ 12,403,754	\$ —	\$ 22,530,753	\$ —
Grant revenue	50,516	60,613	282,226	60,613
Revenues, net	<b>12,454,270</b>	60,613	<b>22,812,979</b>	60,613
Costs and expenses:				
Cost of product sales	1,141,072	—	1,895,029	—
Research and development	14,298,586	19,065,725	65,782,137	89,124,838
Selling, general and administrative	58,347,948	22,763,547	186,363,444	64,947,625
Total costs and expenses	<b>73,787,606</b>	41,829,272	<b>254,040,610</b>	154,072,463
Loss from operations	<b>(61,333,336)</b>	(41,768,659)	<b>(231,227,631)</b>	(154,011,850)
Interest income	(644,390)	(1,185,808)	(4,235,481)	(6,291,272)
Income tax expense	10,232	—	13,513	1,600
Net loss	<b>\$ (60,699,178)</b>	\$ (40,582,851)	<b>\$ (227,005,663)</b>	\$ (147,722,178)
Net loss per common share:				
Basic & Diluted	\$ (0.76)	\$ (0.74)	\$ (3.23)	\$ (2.68)
Weighted average number of common shares:				
Basic & Diluted	<b>80,293,750</b>	55,276,251	<b>70,364,800</b>	55,186,206

(1) The condensed consolidated statements of operations for the years ended December 31, 2020 and 2019 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, 2020 (1)	December 31, 2019 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 60,045,933	\$ 107,636,849
Investment securities, available-for-sale	597,402,126	116,373,335
Restricted cash	1,400,000	—
Accounts receivable, less allowance of \$120,000 and \$0 at December 31, 2020 and 2019, respectively	10,764,583	—
Inventory	7,056,385	—
Prepaid expenses and other current assets	14,235,455	6,313,785
Total current assets	<b>690,904,482</b>	230,323,969
Property and equipment, net	1,998,346	2,259,740
Right of use assets, net	24,324,762	18,252,074
Deferred tax asset, net	—	264,609
Other assets	86,084	86,084
Total assets	<b>\$ 717,313,674</b>	\$ 251,186,476

**Liabilities and stockholders' equity**

## Current liabilities:

Accounts payable	\$ 5,501,825	\$ 7,425,024
Accrued and other current liabilities	10,902,117	16,138,909
Lease liabilities, short-term	5,541,802	3,187,435
Accrued employee benefits	14,907,479	9,472,651
Total current liabilities	36,853,223	36,224,019
Lease liabilities	23,600,347	19,955,186
Total liabilities	60,453,570	56,179,205

## Stockholders' equity:

Common stock, \$0.0001 par value: 100,000,000 shares authorized; 80,463,089 and 55,507,497 shares issued and outstanding at December 31, 2020 and 2019, respectively	8,046	5,551
Additional paid-in capital	1,593,475,506	904,971,772
Accumulated deficit	(937,104,032)	(710,098,369)
Accumulated comprehensive income	480,584	128,317
Total stockholders' equity	656,860,104	195,007,271
Total liabilities and stockholders' equity	\$ 717,313,674	\$ 251,186,476

(1) The condensed consolidated balance sheets at December 31, 2020 and 2019 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.