Intra-Cellular Therapies Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 9, 2020

Positive topline results reported from Study '402, a Phase 3 Study evaluating lumateperone as an adjunctive treatment to lithium or valproate in patients with bipolar depression.

Company is preparing sNDA for the treatment of bipolar depression for submission to the FDA. Study '402 , in conjunction with our previously reported positive Phase 3 monotherapy study, Study 404, forms the basis for our sNDA.

Strong CAPLYTA commercial performance with week-over-week and quarter-over-quarter prescription growth despite COVID-19 disruptions.

Expanding lumateperone development in Major Depressive Disorder (MDD) and other depressive disorders and advancing a Long-Acting Injectable (LAI) formulation:

A post-hoc analysis of Study '404 , our global Phase 3 study in bipolar depression, demonstrated that lumateperone was effective in the subset of patients presenting with mixed features in bipolar depression (p=0.003).

Study '403 has been amended to evaluate lumateperone in patients with Bipolar depression and MDD with mixed features.

Commencing two Phase 3 clinical studies evaluating lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD.

Following discussions with the FDA, initiating clinical studies of our lumateperone LAI subcutaneous formulation.

NEW YORK, Nov. 09, 2020 (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 third quarter ended September 30, 2020, and provided a corporate update.

"Our Company is in a strong position. CAPLYTA is approved for the treatment of schizophrenia in adults and I am pleased with the prescription growth of CAPLYTA as we continue to provide this important medicine to patients. In addition, we have a broad development plan for lumateperone in other major neuropsychiatric conditions. We are soon submitting an sNDA for lumateperone for a second major indication, bipolar depression and initiating late stage studies in adjunctive MDD and in major depressive episodes with mixed features in patients with either bipolar disorder or MDD," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "Our robust pipeline including our LAI formulation of lumateperone, ITI-214 and ITI-333 continue to advance and we are well capitalized to fund our commercial activities and development programs."

CORPORATE UPDATE

COMMERCIAL HIGHLIGHTS

- Third quarter CAPLYTA results reflect strong commercial execution delivering continued robust week-over-week and quarter-over-quarter prescription growth; third quarter total prescriptions increased by approximately 280% versus the previous quarter. Our commercial organization continues to adapt to the dynamic COVID-19 environment and effectively engage with our prescribing audience through a mix of personal and non-personal activities. Importantly, healthcare practitioners' feedback on patient experience with CAPLYTA continues to be very positive.
- CAPLYTA's market access continues to be strong 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 support eligible patients' access pathway for CAPLYTA.

CLINICAL HIGHLIGHTS

Lumateperone - Bipolar Depression Program:

- In September 2020, we reported positive topline results from Study 402, a 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 MADRS total score (p=0.0206). Lumateperone 42 mg also met the key secondary endpoint, the CGI-BP-S Depression Score (p=0.0082). Lumateperone demonstrated a favorable safety profile and was generally well-tolerated in the trial. Rates of akathisia, restlessness, extrapyramidal symptoms, and changes in weight were similar to placebo, consistent with the safety profile demonstrated in our prior studies in schizophrenia and bipolar depression.

- Study 402, in conjunction with our previously reported positive Phase 3 monotherapy study, Study 404, forms the basis for our supplemental new drug application (sNDA) for the treatment of bipolar depression in patients with Bipolar I or II disorder as monotherapy and adjunctive therapy. Our sNDA preparations remain on track and we expect to submit our application to the U.S. Food and Drug Administration (FDA) early in the first quarter of 2021 and anticipate an FDA target action date for the application in the second half of 2021. There are over 11 million adult Americans living with Bipolar disorder. Lumateperone has the potential to be the only approved treatment for bipolar depression in patients with either Bipolar I or Bipolar II disorder as an adjunctive treatment to mood stabilizers or as monotherapy.

Lumateperone - Development in Major Depressive Disorder (MDD) and other depressive disorders and advancing a Long-Acting Injectable (LAI) formulation

- We have amended our ongoing monotherapy bipolar depression study, Study 403, to focus on studying lumateperone in two patient populations: patients with MDD as well as patients with bipolar depression who present clinically with mixed features. This global study evaluates lumateperone 42 mg. The primary endpoint is change from baseline on the Montgomery–Åsberg Depression Rating Scale (MADRS) total score at week 6 versus placebo.

  In a post-hoc analysis of Study 404, in a subgroup of patients with bipolar depression with mixed features, lumateperone 42 mg had a statistically significant improvement from baseline on the MADRS total score versus placebo (p=0.003). These findings will be presented at future medical meetings.

  Approximately one third of patients with either MDD or bipolar depression can exhibit manic symptoms that are below the clinical threshold for mania or hypomania. These patients respond poorly to antidepressants, have greater symptom severity, have a higher risk of suicide attempts, and experience severe illness with more co-morbidities. The fifth edition of the Diagnostic and Statistical Manual of Mental Disorders or DSM-5 incorporates a mixed features specifier as a way to better characterize these patients.

- We have commenced our Phase 3 clinical program evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. Clinical conduct in two Phase 3 trials is anticipated to begin in 2021.

Lumateperone Long Acting Injectable (LAI) formulation:

- We recently completed a successful Type C meeting with the FDA. We plan to initiate clinical testing of our lumateperone long-acting injectable program later this year. An ascending single dose safety and pharmacokinetic (PK) study will be conducted followed by a multiple ascending dose safety and PK study administered subcutaneously.

Other Programs

- ITI-333: Based on a pre-IND meeting held with the FDA, we expect to initiate a single ascending dose safety and tolerability study evaluating ITI-333, our novel compound for the treatment of substance use disorders, in late 2020 or early 2021. We have received a grant from the National Institute on Drug Abuse as part of the NIH HEAL (Helping to End Addiction Long-term) initiative to support the early clinical development of ITI-333 for the treatment of opioid use disorder.

Selected Third Quarter 2020 Financial Results

The Company recorded net product sales of CAPLYTA for the third quarter of 2020 of approximately $7.4 million. No net product sales were reported for the comparable period of 2019.

The Company reported a net loss of $55.2 million, or $0.79 per share (basic and diluted), for the third quarter of 2020 compared to a net loss of $34.9 million, or $0.63 per share (basic and diluted), for the third quarter of 2019.

Research and development (R&D) expenses for the third quarter of 2020 were $10.3 million, compared to $21.3 million for the third quarter of 2019. The $11.0 million decrease is due primarily to a decrease of approximately $6.2 million of lumateperone clinical and non-clinical costs, a decrease of approximately $2.9 million in research manufacturing costs and overhead, a decrease of $2.7 million for other projects, and is offset by an increase of $0.7 million for stock based compensation.

Selling, general and administrative (SG&A) expenses were $52.5 million for the third quarter of 2020, compared to $15.0 million for the same period in 2019. Selling expenses were $38.3 million for the quarter ended September 30, 2020 as compared to pre-commercialization expenses of $6.4 million in the same period in 2019. This selling expense increase is primarily due to increases in sales related labor expenses of $15.4 million and commercialization and marketing expenses of $15.2 million. General and administrative expenses were $14.2 million in the quarter ended September 30, 2020 as compared to $8.6 million for the same period in 2019. This increase is due to increases in information technology expenses of $2.4 million, professional fees of $1.4 million, stock compensation expense of $1.4 million, labor and related expense of $0.4 million, and the remainder in other administrative expenses.

Cash, cash equivalents, restricted cash and investment securities totaled $723.3 million at September 30, 2020, compared to $224.0 million at December 31, 2019. In September 2020, the Company completed a public offering resulting in net proceeds to the Company of approximately $358 million, after deducting underwriting discounts and commissions and offering expenses, from the sale of 12.7 million shares of its common stock.

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 1859956. 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-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 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.

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 and expected timing to submit an sNDA to the FDA for lumateperone for the treatment of bipolar depression and the anticipated timing of the FDA target action date for this sNDA, if accepted by the FDA; our plans and expected timing to initiate our lumateperone clinical studies in major depressive disorder; our plans and expected timing to initiate human testing of our lumateperone long-acting injectable program; our plans and expected timing to initiate early stage clinical studies for ITI-333; our development plans for our PDE program, including ITI-214; 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 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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INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	**2020**	2019
Revenues				
Product sales, net	**$ 7,368,594**	$ —	**$ 10,126,999**	$ —
Grant revenue	**—**	—	**231,710**	—
Total revenues, net	**7,368,594**	—	**10,358,709**	—
Operating expenses:				
Cost of product sales	**556,107**	—	**753,957**	—
Research and development	**10,275,368**	21,339,792	**51,483,551**	70,059,113
Selling, general and administrative	**52,473,573**	15,036,444	**128,015,496**	42,184,078

Total operating expenses	**63,305,048**	36,376,236	**180,253,004**	112,243,191
Loss from operations	**(55,936,454)**	(36,376,236)	**(169,894,295)**	(112,243,191)
Interest income	**752,829**	1,513,837	**3,591,091**	5,105,464
Loss before provision for income taxes	**(55,183,625)**	(34,862,399)	**(166,303,204)**	(107,137,727)
Income tax expense	**—**	—	**3,281**	1,600
Net loss	**$ (55,183,625)**	$ (34,862,399)	**$ (166,306,485)**	$ (107,139,327)
Net loss per common share:				
Basic & Diluted	**$ (0.79)**	$ (0.63)	**$ (2.48)**	$ (1.94)
Weighted average number of common shares:				
Basic & Diluted	**69,530,039**	55,207,400	**67,030,991**	55,155,854

(1) The condensed consolidated statements of operations for the three and nine months ended September 30, 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

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	**$ 300,988,981**	$ 107,636,849
Investment securities, available-for-sale	**420,958,509**	116,373,335
Restricted cash	**1,400,000**	—
Accounts receivable, net	**7,480,604**	—
Inventory	**2,947,138**	—
Prepaid expenses and other current assets	**11,090,774**	6,313,785
Total current assets	**744,866,006**	230,323,969
Property and equipment, net	**2,049,552**	2,259,740
Right of use assets, net	**24,292,167**	18,252,074
Deferred tax asset, net	**—**	264,609
Other assets	**86,084**	86,084
Total assets	**$ 771,293,809**	$ 251,186,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 8,569,148**	$ 7,425,024
Accrued and other current liabilities	**12,186,380**	16,138,909
Lease liabilities, short-term	**5,267,258**	3,187,435
Accrued employee benefits	**12,005,931**	9,472,651
Total current liabilities	**38,028,717**	36,224,019
Lease liabilities	**23,869,557**	19,955,186
Total liabilities	**61,898,274**	56,179,205
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 80,142,797 and 55,507,497 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	**8,014**	5,551
Additional paid-in capital	**1,585,023,637**	904,971,772
Accumulated deficit	**(876,404,854)**	(710,098,369)
Accumulated comprehensive income	**768,738**	128,317
Total stockholders' equity	**709,395,535**	195,007,271
Total liabilities and stockholders' equity	**$ 771,293,809**	$ 251,186,476

(1) The condensed consolidated balance sheets at September 30, 2020 and December 31, 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.