UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 2, 2020

Intra-Cellular Therapies, Inc.
(Exact name of registrant as specified in its charter)

Commission File Number: 001-36274

Delaware	**36-4742850**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

430 East 29th Street
New York, New York 10016
(Address of principal executive offices, including zip code)

(646) 440-9333
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**ITCI**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 2.02 Results of Operations and Financial Condition.

On March 2, 2020, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the fourth quarter and year ended December 31, 2019, and provided a corporate update.

A copy of the Company's press release containing such announcements is attached hereto as Exhibit 99.1. The information in the press release set forth under the heading "Selected Fourth Quarter and Year End 2019 Financial Results," together with the condensed consolidated financial information included in the press release, are incorporated by reference into this Item 2.02 of this Current Report on Form 8-K.

ITEM 8.01 Other Events.

In the press release dated March 2, 2020, the Company also provided a corporate update. The information set forth under the headings "Corporate Update" and "About Intra-Cellular Therapies," together with the forward-looking statement disclaimer at the end of the press release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated March 2, 2020.
104	Cover Page Interactive Data file (embedded within the Inline XBRL document).

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTRA-CELLULAR THERAPIES, INC.

By: /s/ Lawrence J. Hineline
Lawrence J. Hineline
Senior Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary

Date: March 2, 2020

INTRA-CELLULAR THERAPIES REPORTS FOURTH QUARTER AND FULL-YEAR 2019 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

NEW YORK, March 2, 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 fourth quarter and year ending December 31, 2019, and provided a corporate update.

“We are very excited about the recent FDA approval of CAPLYTA™ (lumateperone) for the treatment of schizophrenia and we are fully prepared for our planned commercial launch later this month,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “We have also continued to advance our pipeline programs in 2019 and anticipate a number of meaningful developments in 2020, including reporting topline data from our lumateperone Phase 3 trial in bipolar depression and topline data from our ITI-214 Phase 1/2 trial in heart failure.”

CORPORATE UPDATE

CAPLYTA™

Schizophrenia

- In December 2019, we announced that the U.S. Food and Drug Administration (FDA) had approved CAPLYTA for the treatment of schizophrenia in adults. Our preparations for the commercial launch of CAPLYTA later this month are fully on track.
- In support of our commercialization efforts, we expect to deploy a national sales force consisting of approximately 240 sales representatives. Our sales leadership team and the substantial majority of our sales representatives are on board and training activities are ongoing. Our market access team is actively engaged in product discussions with payors. Manufacturing and supply chain related activities are in place to support commercial supply. At the time of launch CAPLYTA will be priced in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia.
- The efficacy of CAPLYTA 42 mg was demonstrated in two placebo-controlled trials, showing a statistically significant benefit over placebo on the primary endpoint, the Positive and Negative Syndrome Scale (PANSS) total score. The most common adverse reactions (³5% and twice the rate of placebo) for the recommended dose of CAPLYTA vs. placebo were somnolence/sedation (24% vs.10%) and dry mouth (6% vs. 2%).

In pooled data from short term studies, mean changes from baseline in weight gain, fasting glucose, triglycerides and total cholesterol were similar between CAPLYTA and placebo. The incidence of extrapyramidal symptoms was 6.7% for CAPLYTA and 6.3% for placebo.

- At the 2019 American College of Neuropsychopharmacology (ACNP) annual meeting, we made presentations highlighting results from CAPLYTA short-term placebo controlled studies and the long-term safety study. We recently announced the publication of results from the CAPLYTA clinical trial (ITI-007-301) in adult patients with schizophrenia. The article, “Efficacy and Safety of Lumateperone for Treatment of Schizophrenia: A Randomized Clinical Trial” (Correll et al. 2020), is available online in JAMA Psychiatry.

Lumateperone Programs

Bipolar Depression

- In July 2019, we announced positive topline results from Study 404, a Phase 3 trial of lumateperone in patients with a major depressive episode associated with either Bipolar I or Bipolar II disorder. Lumateperone met its primary endpoint of superior improvement from baseline at Week 6 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo ($p<0.0001$; effect size = 0.56). These benefits were statistically significant in both Bipolar I and Bipolar II patients. In a second Phase 3 trial, Study 401, lumateperone did not separate from placebo; the placebo response was high in this trial. The results from Study 404 were presented at ACNP in December 2019.
- Our global adjunctive bipolar depression Phase 3 trial, Study 402, is ongoing. We anticipate reporting topline results from this trial in mid-2020. We have commenced an additional Phase 3 study, Study 403, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. Subject to the results of Study 402 and our interactions with the FDA regarding our bipolar depression program, in late 2020 we expect to submit a supplemental new drug application (sNDA) to the FDA for regulatory approval for lumateperone for the treatment of bipolar depression.

Long-Acting Injectable (LAI) Formulation

- Within the lumateperone portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from schizophrenia. We have completed the preclinical development of an LAI formulation and plan to initiate a Phase 1 clinical trial in 2020.

Major Depressive Disorder (MDD)

- We have commenced our program of lumateperone in MDD. In order to explore the effect of different modes of drug administration and the potential for rapid-onset antidepressant activity, our program includes the assessment of novel formulations of lumateperone and other novel compounds. Pharmacokinetic studies evaluating these novel formulations are currently ongoing. We anticipate initiating a Phase 2 clinical trial in major depressive disorder in 2020.

Other Programs

ITI-214 Program

- We intend to pursue the development of our phosphodiesterase program for the treatment of several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and/or increased inflammation is an important contributor to disease pathogenesis.
- Our Phase 1/2 clinical trial of escalating single doses of ITI-214, our phosphodiesterase 1 (PDE1) inhibitor, evaluating hemodynamic effects and safety in patients with systolic heart failure, is nearing completion. Assessment of vital signs, left ventricular contractility and power using echocardiography (ECG), and ectopic arrythmias using continuous ECG monitoring are being made following the administration of ITI-214. The trial evaluates three dose cohorts 10 mg, 30 mg and 90 mg and no safety concerns have been identified to date. We anticipate reporting topline results from this trial in the first half of 2020.

ITI-333 Program

- We plan to develop ITI-333, our novel, oral modulator of mu opioid and serotonin receptors, for the treatment of opioid and other substance use disorders, pain, and mood disorders. The pharmacological profile has the potential to translate into clinical utility as a therapeutic to ease opioid withdrawal symptoms and drug craving associated with opioid use disorder as well for analgesia with minimal addictive potential. This pharmacological profile was presented at ACNP in December 2019. We expect to initiate our clinical program in 2020.

Selected Fourth Quarter and Year End 2019 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $40.6 million, or $0.74 per share (basic and diluted), for the fourth quarter of 2019 compared to a net loss of $40.7 million, or $0.75 per share (basic and diluted), for the fourth quarter of 2018. The Company reported a net loss of $147.7 million, or $2.68 per share (basic and diluted), for the full year ended December 31, 2019 compared with a net loss of $155.1 million, or $2.84 per share (basic and diluted), for the full year ended December 31, 2018.

Research and development (R&D) expenses for the fourth quarter of 2019 were $19.1 million, compared to $33.6 million for the fourth quarter of 2018. The $14.5 million decrease is primarily due to lower clinical and non-clinical related costs for lumateperone, and is partially offset by higher manufacturing costs, non ITI-007 related projects and labor costs in the fourth

quarter of 2019. Research and development expenses for the year ended December 31, 2019 were $89.1 million, compared to $132.2 million for the year ended December 31, 2018. The $43.1 million decrease is due primarily to lower clinical trial costs and to a lesser extent manufacturing costs for lumateperone, and is partially offset by higher non ITI-007 related projects and labor costs.

General and administrative (G&A) expenses were $22.8 million for the fourth quarter of 2019, compared to $9.0 million for the same period in 2018. The increase of $13.8 million is due primarily to an increase in precommercialization costs, and to a lesser extent labor costs and stock compensation expense. General and administrative expenses for the year ended December 31, 2019 were $64.9 million, compared to $30.1 million for the year ended December 31, 2018. The increase of $34.8 million is primarily due to increases in precommercialization costs, labor costs, stock compensation expense and facilities related costs.

Cash, cash equivalents and investment securities totaled $224.0 million at December 31, 2019, compared to $347.5 million at December 31, 2018. In January 2020, the Company completed a $295.0 million follow on public offering resulting in net proceeds to the Company of approximately $276.9 million from the sale of 10 million shares of its common stock, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

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 4676624. Please dial in approximately 10 minutes prior to the call.

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.

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**, which is a potentially fatal reaction. Signs and symptoms include: hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and close monitoring.
- **Tardive Dyskinesia**, a syndrome of potentially irreversible, dyskinetic, and involuntary movements which may increase as the duration of treatment and total cumulative dose increases. Discontinue CAPLYTA if clinically appropriate.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. 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)**. Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Discontinue CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors.
- **Orthostatic Hypotension and Syncope**. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease.
- **Falls**. CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for risk when using CAPLYTA.
- **Seizures**. Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment**. Advise patients to use caution when operating machinery or motor vehicles until they are reasonably certain CAPLYTA therapy does not affect them adversely.

- **Body Temperature Dysregulation**. Use CAPLYTA 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**. Use CAPLYTA with caution in patients at risk for aspiration.

Drug Interactions: Avoid concomitant use with CYP3A4 inducers and moderate or strong CYP3A4 inhibitors.

Special Populations: Neonates 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. Avoid use in patients with moderate or severe hepatic impairment.

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 is an oral, once daily medicine approved for the treatment of schizophrenia of adults (42mg/day).

The mechanism of action of CAPLYTA in the treatment of schizophrenia is unknown. However, 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 is being developed for the treatment of bipolar depression, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. CAPLYTA has not been demonstrated to be safe and effective in these other areas.

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 timing of our commercial launch of CAPLYTA, the sales force that we expect to deploy in support of the product and the expected pricing of CAPLYTA; our plans and the expected timing for the availability and reporting of data from our ongoing Phase 3 trials in bipolar depression, and our expectations about the timing of our sNDA submission for bipolar depression; our expectations about the timing of the initiation of a clinical study in connection with our long acting injectable formulation of lumateperone; our expected timing of the initiation of a clinical trial of lumateperone in MDD; our development plans for our PDE program, including ITI-214 and our expected timing reporting topline results for our heart failure trial; our development plans for our ITI-333 program and our expected timing of the initiation of clinical trials for ITI-333; 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 launching or commercializing CAPLYTA; 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 once we have launched the product may be different than observed in clinical trials, and may vary among patients; 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; 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,	
	2019	2018	**2019(1)**	2018(1)
	(Unaudited)	(Unaudited)	**(Unaudited)**	(Audited)
Revenues	**$ 60,613**	$ —	**$ 60,613**	$ —
Costs and expenses:				
Research and development	**19,065,725**	33,605,629	**89,124,838**	132,166,913
General and administrative	**22,763,547**	9,017,311	**64,947,625**	30,099,855
Total costs and expenses	**41,829,272**	42,622,940	**154,072,463**	162,266,768
Loss from operations	**(41,768,659)**	(42,622,940)	**(154,011,850)**	(162,266,768)
Interest income	**(1,185,808)**	(1,874,904)	**(6,291,272)**	(7,140,957)
Income tax expense	**—**	—	**1,600**	1,600
Net loss	**$ (40,582,851)**	$ (40,748,036)	**$ (147,722,178)**	$ (155,127,411)
Net loss per common share:				
Basic & Diluted	**$ (0.74)**	$ (0.75)	**$ (2.68)**	$ (2.84)
Weighted average number of common shares:				
Basic & Diluted	**55,276,251**	54,750,566	**55,186,206**	54,707,865

(1) The condensed consolidated statements of operations for the years ended December 31, 2019 and 2018 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, 2019 (1) **(Unaudited)**	December 31, 2018 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 107,636,849**	$ 54,947,502
Investment securities, available-for-sale	**116,373,335**	292,583,046
Prepaid expenses and other current assets	**6,313,785**	7,908,133
Total current assets	**230,323,969**	355,438,681
Property and equipment, net	**2,259,740**	1,159,766
Right of use assets, net	**18,252,074**	—
Deferred tax asset, net	**264,609**	529,218
Other assets	**86,084**	78,833
Total assets	**$ 251,186,476**	$ 357,206,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**7,425,024**	13,961,060
Accrued and other current liabilities	**16,138,909**	20,044,866
Lease liabilities, short-term	**3,187,435**	—
Accrued employee benefits	**9,472,651**	2,293,259
Total current liabilities	**36,224,019**	36,299,185
Deferred rent	**—**	3,192,432
Lease liabilities	**19,955,186**	—
Total liabilities	**56,179,205**	39,491,617
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 55,507,497 and 54,895,295 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	**5,551**	5,490
Additional paid-in capital	**904,971,772**	880,753,339
Accumulated deficit	**(710,098,369)**	(562,376,191)
Accumulated comprehensive loss	**128,317**	(667,757)
Total stockholders' equity	**195,007,271**	317,714,881
Total liabilities and stockholders' equity	**$ 251,186,476**	$ 357,206,498

(1) The condensed consolidated balance sheets at December 31, 2019 and 2018 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.