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): February 27, 2019

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))

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 February 27, 2019, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the fourth quarter and year ended December 31, 2018, 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 in the first four paragraphs under the heading "Selected Fourth Quarter and Year End 2018 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 February 27, 2019, the Company also provided a corporate update. The information set forth in the last paragraph under the heading "Selected Fourth Quarter and Year End 2018 Financial Results" and 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 February 27, 2019.

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
Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary

Date: February 27, 2019

INTRA-CELLULAR THERAPIES REPORTS FOURTH QUARTER AND FULL-YEAR 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

NEW YORK, February 27, 2019 /GLOBE NEWSWIRE/ — Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today announced its financial results for the fourth quarter and year ended December 31, 2018, and provided a corporate update.

“2018 was an important year for ITCI,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “The FDA accepted for review our NDA for lumateperone for the treatment of schizophrenia. We also made significant progress in building our commercial infrastructure in preparation for potential launch, including the hiring of our commercial senior leadership team. In addition, we continued to advance our clinical and preclinical development programs including lumateperone for bipolar depression, ITI-214 and ITI-333 and look forward to providing additional updates on these programs in the year ahead.”

Corporate Update

Lumateperone Programs

Schizophrenia

- Our new drug application (NDA) for lumateperone, an investigational agent for the treatment of schizophrenia, is under review by the U.S. Food and Drug Administration (FDA). The PDUFA target action date is September 27, 2019.
- We continue to expand our infrastructure to support the commercialization of lumateperone, pending FDA approval. In the fourth quarter of 2018, we appointed Mark Neumann as Executive Vice President, Chief Commercial Officer. Mark has extensive marketing and sales experience in various therapeutic areas, including neuroscience and cardiology. In addition, we have continued to expand our commercial leadership team and have now hired senior leaders across all the key commercial functions.
- As our clinical programs have advanced, we have supplemented our clinical development expertise with additional senior team members. Last year, we appointed Dr. Suresh

Durgam as Senior Vice President, Late Stage Clinical Development and Medical Affairs, and Dr. Michael Olchaskey as Senior Vice President, Head of Regulatory Affairs. Both have extensive experience in bringing neuropsychiatric products through late stage clinical development and regulatory approval. They join Dr. Andrew Satlin, our Chief Medical Officer, and Dr. Kimberly Vanover, our Senior Vice President of Early Stage Clinical Development and Translational Medicine, to lead our clinical team.

- Favorable safety data from our lumateperone open-label safety switching study (Study 303) in patients with stable symptoms of schizophrenia were replicated and extended from short-term to long-term exposure. This second part of the study enrolled 603 patients for up to one year of treatment with lumateperone after a switch from standard-of-care (SOC) antipsychotic therapy. We analyzed data from over 300 patients who completed at least six months of treatment and over 100 patients who completed one year of treatment, meeting ICH criteria for long-term safety evaluation. The results demonstrated that lumateperone was generally well tolerated and exhibited statistically significant improvements from baseline on key safety measures of body weight and cardiometabolic and endocrine parameters, without motor side effects often associated with other antipsychotic medications. In contrast to many other antipsychotics that cause weight gain, mean body weight significantly decreased at six months (-1.82 kg at Day 175, $p < 0.001$) and one year (-3.16 kg at Day 350, $p < 0.001$) of treatment with lumateperone after switch from SOC antipsychotic treatment. Of the 603 patients in the study, 24% experienced a decrease of $\geq$ 7% from their SOC baseline body weight over the course of the study, whereas only 8% experienced a body weight increase of $\geq$7%. The favorable cardiometabolic and endocrine safety profile seen in short-term studies of lumateperone persisted over a one-year duration of treatment, with statistically significant ($p < 0.001$) reductions from SOC baseline in total cholesterol, LDL cholesterol and prolactin and stable blood levels of glucose, insulin, and HDL cholesterol. There were no signs of treatment-emergent extrapyramidal side effects, akathisia, or dyskinesia. We plan to present further analyses from this study at medical meetings later this year.

Bipolar Depression

- We continue to advance our lumateperone bipolar depression Phase 3 clinical program. This program consists of two monotherapy studies and one adjunctive study. We have completed patient enrollment in both monotherapy studies: Study 401 conducted in the U.S. and Study 404 conducted globally. We anticipate reporting topline results from Study 401 and Study 404 simultaneously in the second quarter of 2019. Subject to the outcome of these trials, we expect to submit for FDA regulatory approval of lumateperone for bipolar depression in the second half of 2019.

Major Depressive Disorder

- We believe lumateperone has the potential to exhibit potent and rapid antidepressant effects and have commenced a program in major depressive disorder (MDD), beginning

with a dose-finding trial. 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. Pharmacokinetic studies evaluating these formulations of lumateperone are currently ongoing.

- We have presented preclinical data demonstrating lumateperone's potential as an antidepressant and the molecular pharmacology consistent with a rapid acting profile. Lumateperone, as a standalone agent, indirectly enhances glutamatergic neurotransmission through both AMPA and NMDA channels in the prefrontal cortex. Additionally, we presented data demonstrating that lumateperone increases protein phosphorylation of key proteins in the mTOR pathway. These findings, in addition to the potent SERT activity previously described with lumateperone and the improvement in depressive symptoms found in patients with schizophrenia and co-morbid depression, suggest the potential for lumateperone to exhibit potent and rapid antidepressant effects.

ITI-214 (PDE1 inhibitor) Programs

Parkinson's Disease

- Last year, we presented top-line results from our Phase 1/2 randomized, double-blind, placebo-controlled, multiple ascending dose clinical trial to evaluate ITI-214 in patients with mild-to-moderate Parkinson's disease (PD). The primary objective was to evaluate safety and tolerability. Efficacy in improving motor and non-motor symptoms of PD was explored using multiple scales, providing input from both subjects and site raters. Topline results demonstrate ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. No serious adverse events were reported in the trial, and no clinically significant effects of ITI-214 compared to placebo were observed on vital signs, or cardiovascular or laboratory parameters.
- This year, we plan to advance our PD program with a Phase 2, proof-of-concept clinical trial of ITI-214, our phosphodiesterase 1 (PDE1) inhibitor, for the treatment of PD.

Heart Failure

- Data from preclinical models of heart failure, published last year in the journal *Circulation*, indicate ITI-214 acts by a novel mechanism of action via modulation of the adenosine A2B receptor signaling pathway and increases cardiac contractility without increasing intracellular calcium. The pharmacological profile of ITI-214 introduces a new mechanism of action for the treatment of heart failure that is different from ß-adrenergic agonism and PDE3 inhibition and that may provide an effective and safer alternative to existing therapies.

- We initiated our ITI-214 clinical program for the treatment of heart failure. A randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate hemodynamic effects and safety in patients with systolic heart failure is ongoing. Clinical conduct of the first dose cohort, which evaluated ITI-214 10 mg, is complete. ITI-214 was well tolerated and the safety profile supported advancement to the next cohort, which will evaluate 30 mg.

ITI-333 Program

- ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opioid receptors, continues to advance in preclinical development. In preclinical models of acute and inflammatory pain, ITI-333 exhibits potent analgesia but is not associated with dependence or abuse liability, effects commonly associated with opioid use. ITI-333 also dose-dependently reduces symptoms associated with naloxone-precipitated opioid withdrawal and suppresses cue-induced heroin reinstatement responding, models predictive of relapse behavior, at doses that do not decrease gastrointestinal motility or depress respiratory function. We plan to develop ITI-333 for the treatment of opioid and other substance use disorders, pain, and mood disorders. We expect to initiate our clinical program later this year.

Selected Fourth Quarter and Year End 2018 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $40.7 million, or $0.75 per share (basic and diluted), for the fourth quarter of 2018 compared to a net loss of $30.2 million, or $0.56 per share (basic and diluted), for the fourth quarter of 2017. The Company reported a net loss of $155.1 million, or $2.84 per share (basic and diluted), for the full year ended December 31, 2018 compared with a net loss of $97.8 million, or $2.12 per share (basic and diluted), for the full year ended December 31, 2017.

Research and development (R&D) expenses for the fourth quarter of 2018 were $33.6 million, compared to $26.9 million for the fourth quarter of 2017. The $6.7 million increase is primarily due to higher clinical and non-clinical related costs for lumateperone, manufacturing costs and labor costs in the fourth quarter of 2018. Research and development expenses for the year ended December 31, 2018 were $132.2 million, compared to $79.4 million for the year ended December 31, 2017. The $52.8 million increase is primarily due to higher clinical and non-clinical related costs for lumateperone, manufacturing costs and labor costs in addition to other non ITI-007 related projects.

General and administrative (G&A) expenses were $9.0 million for the fourth quarter of 2018, compared to $5.8 million for the same period in 2017. The increase of $3.2 million is due primarily to increases in precommercialization costs, labor costs and stock compensation expense. General and administrative expenses for the year ended December 31, 2018 were $30.1 million, compared to $23.7 million for the year ended December 31, 2017. The increase of $6.4 million is primarily due to increases in precommercialization costs, labor costs, and stock compensation expense.

Cash, cash equivalents and investment securities totaled $347.5 million at December 31, 2018, compared to $464.3 million at December 31, 2017.

We expect total spend for 2019 to range between $225 to $240 million. We expect these funds will be used primarily for pre-commercialization preparation, initial commercialization activities and related infrastructure expansion in connection with the commercialization of lumateperone, if approved, for the treatment of schizophrenia; the development of lumateperone in our late stage clinical programs; the development of our other product candidates, including ITI-214; the continuation of manufacturing activities in connection with the development of lumateperone; and general operations. We anticipate the $347.5 million of existing cash, cash equivalents and investment securities as of December 31, 2018 will fund our operations into the second half of 2020.

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 8789239. Please dial in approximately 10 minutes prior to the call.

About Intra-Cellular Therapies

Intra-Cellular Therapies is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative diseases and diseases of the elderly, including Parkinson's and Alzheimer's disease. The Company is developing its lead drug candidate, lumateperone (also known as ITI-007), for the treatment of schizophrenia, bipolar disorder, behavioral disturbances in patients with dementia, including Alzheimer's disease, depression and other neuropsychiatric and neurological disorders. Lumateperone is under review by the FDA for the treatment of schizophrenia and is in Phase 3 clinical development for the treatment of bipolar depression. The Company is also utilizing its phosphodiesterase (PDE) platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS and other disorders. The lead molecule in the Company's PDE1 portfolio, ITI-214, is in development for the treatment of symptoms associated with Parkinson's disease and for the treatment of heart failure.

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 expected use of our cash, cash equivalents and investment securities; our beliefs about the extent to which the results of our clinical trials to date support our NDA submission for lumateperone for the treatment of schizophrenia; 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 NDA submission for bipolar depression; our expectations about presenting data at upcoming scientific and medical conferences; our development plans for our PDE program, including ITI-214 and our expected timing of the initiation of additional clinical trials for ITI-214; the potential for ITI-214 to provide an effective and safer alternative to existing therapies; our development plans for our ITI-333 program and our expected timing of the initiation of clinical trials for ITI-333 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 NDA for lumateperone for the treatment of schizophrenia will be approved by the FDA; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with lumateperone 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; fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process; 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.

Contact:

Intra-Cellular Therapies, Inc.
Juan Sanchez, M.D.
Vice President, Corporate Communications and Investor Relations
646-440-9333

Burns McClellan, Inc.
Lisa Burns
agray@burnsmc.com
212-213-0006

MEDIA INQUIRIES:

Patrick Ryan, Esq.
Corporate Media Relations, W2Owcg
pryan@wcgworld.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	**2018(1)**	2017(1)
	(Unaudited)	(Unaudited)	**(Unaudited)**	(Audited)
Revenues	**$ —**	$ 5,055	**$ —**	$ 245,837
Costs and expenses:				
Research and development	**33,605,629**	26,929,041	**132,166,913**	79,419,009
General and administrative	**9,017,311**	5,784,278	**30,099,855**	23,666,957
Total costs and expenses	**42,622,940**	32,713,319	**162,266,768**	103,085,966
Loss from operations	**(42,622,940)**	(32,708,264)	**(162,266,768)**	(102,840,129)
Interest income	**(1,874,904)**	(1,441,117)	**(7,140,957)**	(4,005,864)
Income tax (benefit) expense	**—**	(1,058,435)	**1,600**	(1,060,851)
Net loss	**$ (40,748,036)**	$ (30,208,712)	**$ (155,127,411)**	$ (97,773,414)
Net loss per common share:				
Basic & Diluted	**$ (0.75)**	$ (0.56)	**$ (2.84)**	$ (2.12)
Weighted average number of common shares:				
Basic & Diluted	**54,750,566**	54,407,104	**54,707,865**	46,181,926

(1) The condensed consolidated statements of operations for the years ended December 31, 2018 and 2017 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, 2018 (1) (Unaudited)	December 31, 2017 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 54,947,502**	$ 37,790,114
Investment securities, available-for-sale	**292,583,046**	426,540,921
Prepaid expenses and other current assets	**7,908,133**	4,884,293
Total current assets	**355,438,681**	469,215,328
Property and equipment, net	**1,159,766**	1,137,171
Long term deferred tax asset, net	**529,218**	1,058,435
Other assets	**78,833**	75,765
Total assets	**$ 357,206,498**	$ 471,486,699
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**13,961,060**	6,173,539
Accrued and other current liabilities	**20,044,866**	6,424,221
Accrued employee benefits	**2,293,259**	1,611,846
Total current liabilities	**36,299,185**	14,209,606
Long-term deferred rent	**3,192,432**	2,840,132
Total liabilities	**39,491,617**	17,049,738
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 54,895,295 and 54,597,679 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	**5,490**	5,460
Additional paid-in capital	**880,753,339**	862,479,505
Accumulated deficit	**(562,376,191)**	(407,248,780)
Accumulated comprehensive loss	**(667,757)**	(799,224)
Total stockholders' equity	**317,714,881**	454,436,961
Total liabilities and stockholders' equity	**$ 357,206,498**	$ 471,486,699

(1) The condensed consolidated balance sheets at December 31, 2018 and 2017 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.