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 1, 2018

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 March 1, 2018, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the fourth quarter and year ended December 31, 2017, 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 2017 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 1, 2018, the Company also provided a corporate update. The information set forth in the last paragraph under the heading "Selected Fourth Quarter and Year End 2017 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 March 1, 2018.

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: March 1, 2018

INTRA-CELLULAR THERAPIES REPORTS FOURTH QUARTER AND FULL-YEAR 2017 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

NEW YORK, March 1, 2018 /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, 2017, and provided a corporate update.

Selected Fourth Quarter and Year End 2017 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $30.2 million, or $0.56 per share (basic and diluted), for the fourth quarter of 2017 compared to a net loss of $27.5 million, or $0.64 per share (basic and diluted), for the fourth quarter of 2016. The Company reported a net loss of $97.8 million, or $2.12 per share (basic and diluted), for the full year ended December 31, 2017 compared with a net loss of $116.4 million, or $2.69 per share (basic and diluted), for the full year ended December 31, 2016.

Research and development (R&D) expenses for the fourth quarter of 2017 were $26.9 million, compared to $21.2 million for the fourth quarter of 2016. The $5.7 million increase is primarily due to higher clinical trial related costs in the fourth quarter of 2017. Research and development expenses for the year ended December 31, 2017 were $79.4 million, compared to $93.8 million for the year ended December 31, 2016. The decrease of $14.4 million is primarily due to lower clinical trials related costs and, to a lesser degree, lower non-clinical and manufacturing costs, offset in part by an increase in labor related costs, in 2017.

General and administrative (G&A) expenses were $5.8 million for the fourth quarter of 2017, compared to $7.0 million for the same period in 2016. The decrease of $1.2 million is due primarily to lower marketing and consulting costs and lower stock compensation expense in the fourth quarter of 2017. General and administrative expenses for the year ended December 31, 2017 were $23.7 million, compared to $24.8 million for the year ended December 31, 2016. The decrease of $1.1 million is primarily due to lower marketing and consulting costs, offset in part by higher capital tax expense, in 2017.

Cash, cash equivalents and investment securities totaled $464.3 million at December 31, 2017, compared to $384.1 million at December 31, 2016. In October 2017, the Company raised gross proceeds of approximately $172 million, with net proceeds of $162 million, in a public offering of its common stock.

The Company expects that its cash, cash equivalents and investment securities of $464.3 million as of December 31, 2017 will be used primarily to advance the lumateperone development program, including to fund clinical trials of lumateperone in bipolar depression, behavioral disturbances in patients with dementia, depressive disorders and other lumateperone clinical trials and related clinical and non-clinical activities; to fund pre-commercial activities for lumateperone for the treatment of schizophrenia and bipolar disorder and, if lumateperone receives regulatory approval, initial commercialization efforts; to fund pre-commercial activities for lumateperone for the treatment of behavioral disturbances in patients with dementia, including Alzheimer's disease; to fund pre-clinical and clinical development of the Company's ITI-007 long-acting injectable program; and to fund non-clinical activities, including the continuation of manufacturing activities, in connection with the development of lumateperone. The Company expects funds will also be used for other clinical and pre-clinical programs, including the Company's phosphodiesterase (PDE) development activities.

Corporate Update

Lumateperone Programs

Schizophrenia

- Following guidance received from the U.S. Food and Drug Administration (FDA) in 2017, we intend to submit a new drug application (NDA) for lumateperone for the treatment of schizophrenia by mid-2018. A pre-NDA meeting with the FDA is scheduled to be held in late Q1 2018.
- In November 2017, we announced that the FDA has granted Fast Track designation for lumateperone for the treatment of schizophrenia. We requested Fast Track designation for lumateperone based on clinical evidence that lumateperone has the potential to address the unmet medical need for the treatment of schizophrenia with significant improvements on several clinically significant safety parameters, including metabolic, motor and cardiovascular issues associated with many currently available antipsychotic agents.
- In September 2017, we announced positive topline data from our 6-week open-label safety switching study with lumateperone in patients with schizophrenia. This trial evaluated stable patients with schizophrenia in an outpatient setting similar to common clinical practice and assessed both the impact of switching to lumateperone from standard-of-care antipsychotics (SOC) as well as the impact of switching back to SOC from lumateperone. In this trial, statistically significant improvements from SOC were observed in body weight, cardiometabolic and endocrine parameters in patients with stable symptoms of schizophrenia when switched to lumateperone and worsened again when switched back to SOC. These data are consistent with previous study results reflecting a safety profile similar to placebo in placebo-controlled trials with lumateperone in patients with acutely exacerbated schizophrenia and extend this favorable safety profile to this stable patient population. In this study, symptoms of

schizophrenia did not worsen upon switch to lumateperone from SOC. Rather, statistically significant improvement from baseline was observed in the Positive and Negative Syndrome Scale (PANSS) mean total score. Notably, greater improvements were observed in subgroups of patients with comorbid symptoms of depression and those with prominent negative symptoms.

Bipolar Depression

- Our lumateperone bipolar depression Phase 3 clinical program consists of two monotherapy studies and one adjunctive study. We anticipate top-line results from the first monotherapy study (Study 401, which is being conducted in the United States) will be available in 2H 2018 and the top-line results from our global monotherapy study (Study 404) will be available in 2019. Subject to the outcomes of these trials, we expect to file an NDA for bipolar depression in 2H 2019. In connection with the global strategy of this program, we are expanding our adjunctive study (Study 402) to clinical sites outside the United States and we expect to provide our anticipated timelines for this study after completing the expansion.

Agitation Associated with Dementia, Including Alzheimer's Disease

- Our lumateperone program in agitation associated with dementia, including Alzheimer's disease currently consists of one Phase 3 clinical trial and clinical conduct is ongoing. Subject to timely patient enrollment, we expect that the outcome of the interim analysis for this trial will be available in 2H 2018.

Depressive Disorders

- In 2017, we presented exciting discoveries demonstrating the molecular mechanism supporting lumateperone's potential as a rapid acting antidepressant.
- In previous studies, schizophrenia patients with co-morbid depression experienced robust improvements in depressive symptoms. We plan to initiate our late stage clinical program of lumateperone in depressive disorders in 2018.

ITI-214 (PDE1 inhibitor) Programs

Parkinson's Disease

- In 2017, we initiated a Phase 1/2 randomized, double-blind, placebo-controlled, multiple rising dose clinical trial to evaluate ITI-214, our PDE1 inhibitor, in patients with Parkinson's disease (PD). The primary objective is to evaluate the safety and tolerability of ITI-214 in patients with mild to moderate PD who are maintained on stable PD therapy. Secondary objectives are to evaluate the pharmacokinetic profile of ITI-214 and explore its potential utility to control motor fluctuations and to evaluate treatment of non-motor symptoms (daytime sleepiness, dysautonomia) associated with PD. Biomarkers of disease progression (inflammation) will be assessed. Clinical conduct for the third cohort is ongoing following completion of the first and second cohorts, with no safety concerns identified to date. We anticipate top-line results from this trial will be available in 2H 2018.

Heart Failure

- In late Q1 2018, we plan to initiate a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure.

ITI-333 Program

- ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opiate receptors continues to advance in pre-clinical development. We plan to develop ITI-333 for the treatment of opioid and other substance use disorders, pain, and mood disorders.

“We continue to make important progress toward our goal of bringing lumateperone to patients suffering from schizophrenia and other neuropsychiatric disorders. We are excited about our prospects for 2018 and beyond and look forward to providing an update on our programs in the year ahead,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

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 797178. 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, a first-in-class molecule, is in Phase 3 clinical development for the treatment of schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer’s disease. 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.

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 an NDA filing for lumateperone for the treatment of schizophrenia and our expectations about the timing of such NDA filing; our plans and the expected timing for the availability of data from our ongoing Phase 3 trials in bipolar depression and agitation associated with dementia, including Alzheimer’s disease, and our expectations about the timing of our NDA filing for bipolar depression; our plans and the expected timing to initiate a late stage program in depression; our development plans for our PDE program, including ITI-214, including the anticipated timing for the availability of data from our ongoing Phase 1/2 trial of ITI-214 and the expected timing of the initiation of a trial of ITI-214 in patients with systolic heart failure; our development plans for our ITI-333 program 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: our current and planned clinical trials, other studies for lumateperone, and 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,		Twelve Months Ended December 31,	
	2017	2016	**2017(1)**	2016(1)
	(Unaudited)	(Unaudited)	**(Unaudited)**	(Audited)
Revenues	**$ 5,055**	$ 97,895	**$ 245,837**	$ 330,702
Costs and expenses:				
Research and development	**26,929,041**	21,179,010	**79,419,009**	93,831,530
General and administrative	**5,784,278**	6,951,498	**23,666,957**	24,758,063
Total costs and expenses	**32,713,319**	28,130,508	**103,085,966**	118,589,593
Loss from operations	**(32,708,264)**	(28,032,613)	**(102,840,129)**	(118,258,891)
Interest income	**(1,441,117)**	(805,150)	**(4,005,864)**	(2,935,077)
Interest expense	**—**	24,521	**—**	36,781
Income tax (benefit) expense	**(1,058,435)**	233,055	**(1,060,851)**	1,065,673
Net loss	**$ (30,208,712)**	$ (27,485,039)	**$ (97,773,414)**	$(116,426,268)
Net loss per common share:				
Basic & Diluted	**$ (0.56)**	$ (0.64)	**$ (2.12)**	$ (2.69)
Weighted average number of common shares:				
Basic & Diluted	**54,407,104**	43,272,233	**46,181,926**	43,240,188

(1) The condensed consolidated statements of operations for the years ended December 31, 2017 and 2016 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, 2017 (1) **(Unaudited)**	December 31, 2016 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 37,790,114**	$ 48,642,225
Investment securities, available-for-sale	**426,540,921**	335,458,459
Accounts receivable	**—**	94,339
Prepaid expenses and other current assets	**4,884,293**	4,005,093
Total current assets	**469,215,328**	388,200,116
Property and equipment, net	**1,137,171**	627,614
Long term deferred tax asset, net	**1,058,435**	—
Other assets	**75,765**	75,765
Total assets	**$ 471,486,699**	$ 388,903,495
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**6,173,539**	3,754,647
Accrued and other current liabilities	**6,424,221**	5,329,293
Accrued employee benefits	**1,611,846**	1,448,394
Total current liabilities	**14,209,606**	10,532,334
Long-term deferred rent	**2,840,132**	2,868,622
Total liabilities	**17,049,738**	13,400,956
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 54,597,679 and 43,292,906 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	**5,460**	4,329
Additional paid-in capital	**862,479,505**	685,290,815
Accumulated deficit	**(407,248,780)**	(309,475,366)
Accumulated comprehensive loss	**(799,224)**	(317,239)
Total stockholders' equity	**454,436,961**	375,502,539
Total liabilities and stockholders' equity	**$ 471,486,699**	$ 388,903,495

(1) The condensed consolidated balance sheets at December 31, 2017 and 2016 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.