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): August 2, 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 August 2, 2018, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 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 "Second Quarter 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 August 2, 2018, the Company also provided a corporate update. The information set forth in the last paragraph under the heading "Second Quarter 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 August 2, 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: August 2, 2018

Exhibit 99.1

Intra-Cellular Therapies Provides Corporate Update and Reports Second Quarter 2018 Financial Results

NEW YORK, August 2, 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 provided a corporate update and announced its financial results for the second quarter ended June 30, 2018.

"In the first half of 2018, we made great progress advancing our development programs and as we continue to build our team, we are pleased with the progress we have made in our activities to prepare for the commercialization of lumateperone," said Dr. Sharon Mates, Chairman and CEO of ITCI. "We are excited about our prospects for the remainder of the year as we expect to complete our New Drug Application (NDA) submission shortly for lumateperone for the treatment of schizophrenia, announce top-line results from our first Phase 3 study in bipolar depression, conduct an interim analysis on our Phase 3 study in agitation in patients with dementia, including Alzheimer's disease, and present results from our ITI-214 study in patients with Parkinson's disease (PD)."

Corporate Update

Lumateperone Programs

- In the second quarter of 2018, we announced the initiation of a rolling submission of our NDA with the U.S. Food and Drug Administration (FDA) for lumateperone for the treatment of schizophrenia. We expect to complete this NDA submission mid-2018, in the third quarter.
- We presented data on lumateperone and other development programs at several scientific and medical conferences, including the American Psychiatric Association (APA), the Society of Biological Psychiatry (SOBP), the American Society of Clinical Psychopharmacology (ASCP), and the International College of Neuropsychopharmacology (CINP).
- At ASCP, we presented data highlighting symptom improvement by lumateperone on negative symptoms, depression, and social function in patients with schizophrenia. One of our presentations at ASCP focused on the effect of lumateperone on a specific domain of negative symptoms of schizophrenia known to correlate with social function. The other presentation addressed the potential of lumateperone to improve symptoms of depression in patients with schizophrenia. These presentations build on prior data and continue to support our belief that the unique pharmacology of lumateperone can translate into an advancement in the treatment of schizophrenia.

- Later this year, we will be presenting results from the second part of our lumateperone open-label safety switching study. To assess long-term safety and to observe the impact of switching from standard-of-care antipsychotic medications, we are conducting an open-label safety switching study in stable patients with schizophrenia switched to lumateperone (ITI-007 60 mg) from standard-of-care antipsychotic therapy. This study has two parts. Positive results from the first part were reported last year for patients who were switched to a 6-week treatment duration with lumateperone followed by a 2-week period in which they were switched back to standard-of-care. The second part of the study, our long-term safety study in schizophrenia, follows patients for up to 1-year of treatment with lumateperone following switch from standard-of-care.
- We continue to advance our lumateperone bipolar depression Phase 3 clinical program. This program consists of two monotherapy studies and one adjunctive study. We anticipate top-line results from the first monotherapy study (Study 401) 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 submit an NDA for bipolar depression in 2H 2019. Our adjunctive study (Study 402), which is being conducted globally, is ongoing.
- Our lumateperone program in patients with 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.
- We plan to initiate our clinical program of lumateperone in depressive disorders in 2H 2018.

ITI-214 (PDE1 inhibitor) Programs

Parkinson's Disease (PD)

- We continue to advance our Phase 1/2 randomized, double-blind, placebo-controlled, multiple ascending dose clinical trial to evaluate ITI-214, our PDE1 inhibitor, in patients with PD. The primary objective is to evaluate the safety and tolerability of ITI-214 in patients with mild to moderate PD. 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 explored. Clinical conduct has been completed for the first four cohorts (1, 3, 10 and 30 mg). At these doses, ITI-214 demonstrated a favorable safety profile and was generally well tolerated. Based on this favorable safety and tolerability profile, the study has been expanded to include a higher dose cohort (90 mg) and clinical conduct is ongoing. We plan to present results from this trial later this year.

Heart Failure

- The journal *Circulation* recently published online a paper entitled "Acute Enhancement of Cardiac Function by Phosphodiesterase Type 1 Inhibition: A Translational Study in the Dog and Rabbit" highlighting ITI-214's novel mechanism of action in heart failure and demonstrating positive results in animal models of heart failure. The data published in *Circulation* indicates 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 offers a potential new treatment for heart failure with a novel mechanism of action that may provide an effective and safer alternative to existing therapies.

- We have initiated our ITI-214 program for the treatment of heart failure. Clinical conduct is ongoing in 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.

ITI-333 Program

- ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opiate receptors continues to advance in preclinical development. We plan to develop ITI-333 for the treatment of opioid and other substance use disorders, pain, and mood disorders. We expect to initiate clinical trials in 2019.

Second Quarter 2018 Financial Results

The Company reported a net loss of $37.4 million, or $0.68 per share (basic and diluted), for the second quarter of 2018 compared to a net loss of $17.8 million, or $0.41 per share (basic and diluted), for the second quarter of 2017.

Research and development (R&D) expenses for the second quarter of 2018 were $32.4 million, compared to $12.5 million for the second quarter of 2017. The increase for the second quarter of 2018 is primarily due to an increase of approximately $18.7 million of external clinical and non-clinical costs. In the second quarter of 2018, external costs were incurred for the Phase 3 clinical trials of lumateperone in patients with bipolar depression and in patients with agitation associated with dementia, including Alzheimer's disease, and other lumateperone related trials and manufacturing, development and clinical costs for our phosphodiesterase (PDE) program. In the second quarter of 2017, external costs were incurred primarily for the Phase 3 clinical trials of lumateperone in patients with bipolar depression and in patients with agitation associated with dementia, including Alzheimer's disease, and other lumateperone related trials.

General and administrative (G&A) expenses were $6.7 million for the second quarter of 2018, compared to $6.3 million for the same period in 2017. The comparative increase is primarily due to labor and pre-commercialization costs, partially offset by lower stock compensation expense and professional fees.

Cash, cash equivalents, and investment securities totaled $403.8 million at June 30, 2018, compared to $464.3 million at December 31, 2017.

The Company expects that its cash, cash equivalents, and investment securities of $403.8 million as of June 30, 2018 will be used primarily to advance the lumateperone development program, including to fund clinical trials of lumateperone in patients with bipolar depression, in patients with agitation associated with dementia, including Alzheimer's disease, 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 agitation associated with dementia, including Alzheimer's disease; to fund preclinical and clinical development of the Company's ITI-007 long-acting injectable program; to fund non-clinical activities, including the continuation of manufacturing activities, in connection with the development of lumateperone; and to fund other clinical and preclinical programs, including the Company's PDE development activities including ITI-214, for the treatment of PD, heart failure and other disorders.

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 4697699. 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 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 an NDA submission for lumateperone for the treatment of schizophrenia and our expectations about the timing of completing such NDA submission; 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 submission for bipolar depression; the expected timing for conducting an interim analysis of the Phase 3 trial in agitation in patients with dementia, including Alzheimer's disease, and the expected timing for the availability of the outcome of this analysis; our plans and the expected timing to initiate a program in depression; the expected timing for the availability of data from the second part of our lumateperone open-label safety switching study; our expectations about presenting additional data at upcoming scientific and medical conferences; 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 in patients with PD; 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: 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
(Unaudited)

	Three Months Ended June 30,	
	2018 (1)	**2017** (1)
Revenues	**$ —**	$ 114,741
Costs and expenses:		
Research and development	**32,439,270**	12,478,638
General and administrative	**6,728,987**	6,254,616
Total costs and expenses	**39,168,257**	18,733,254
Loss from operations	**(39,168,257)**	(18,618,513)
Interest income	**1,793,474**	857,809
Loss before provision for income taxes	**(37,374,783)**	(17,760,704)
Income tax expense	**1,600**	—
Net loss	**$(37,376,383)**	$(17,760,704)
Net loss per common share:		
Basic & Diluted	**$ (0.68)**	$ (0.41)
Weighted average number of common shares:		
Basic & Diluted	**54,696,698**	43,419,798

(1) The condensed consolidated statements of operations for the quarters ended June 30, 2018 and 2017 have not been audited and 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

	June 30, 2018 (1) (Unaudited)	December 31, 2017 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 69,767,045**	$ 37,790,114
Investment securities, available-for-sale	**333,997,440**	426,540,921
Prepaid expenses and other current assets	**5,896,583**	4,884,293
Total current assets	**409,661,068**	469,215,328
Property and equipment, net	**1,275,387**	1,137,171
Long term deferred tax asset, net	**1,058,435**	1,058,435
Other assets	**78,833**	75,765
Total assets	**$ 412,073,723**	$ 471,486,699
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**5,378,870**	6,173,539
Accrued and other current liabilities	**10,462,217**	6,424,221
Accrued employee benefits	**3,094,280**	1,611,846
Total current liabilities	**18,935,367**	14,209,606
Long-term deferred rent	**2,750,914**	2,840,132
Total liabilities	**21,686,281**	17,049,738
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 54,700,580 and 54,597,679 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	**5,470**	5,460
Additional paid-in capital	**871,516,637**	862,479,505
Accumulated deficit	**(480,105,241)**	(407,248,780)
Accumulated comprehensive loss	**(1,029,424)**	(799,224)
Total stockholders' equity	**390,387,442**	454,436,961
Total liabilities and stockholders' equity	**$ 412,073,723**	$ 471,486,699

(1) The condensed consolidated balance sheets at June 30, 2018 and December 31, 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.