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 7, 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))

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 August 7, 2019, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 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 in the first four paragraphs under the heading "Selected Second Quarter 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 August 7, 2019, the Company also provided a corporate update. The information set forth in the last paragraph under the heading "Selected Second Quarter 2019 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 7, 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
Senior Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary

Date: August 7, 2019

Intra-Cellular Therapies Provides Corporate Update and Reports Second Quarter 2019 Financial Results

NEW YORK, August 7, 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 provided a corporate update and announced its financial results for the second quarter ended June 30, 2019.

“We continue to advance our lumateperone schizophrenia program and prepare for commercial launch pending FDA approval,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “In addition, we are pleased with the progress we have made in our other development programs, in particular our recent positive results with lumateperone for the treatment of bipolar depression.”

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). We recently met with the FDA and reached agreement to submit additional non-clinical information in connection with the FDA’s ongoing review of our NDA for lumateperone for the treatment of schizophrenia. The FDA has informed us that the planned submission of this additional information constitutes a major amendment to the NDA, resulting in a three-month extension of the Prescription Drug User Fee Act (PDUFA) goal date to December 27, 2019 in order to provide time for a full review of the submission. We intend to provide the FDA with the requested information in the coming weeks and we believe this information will be sufficient to address the FDA’s requests.
- We continue to make substantial progress in establishing our commercial capabilities and infrastructure to support the potential launch of lumateperone in the first quarter of 2020, pending timely FDA approval of the NDA. All manufacturing and supply chain related activities remain on track to support commercial supply. Our build-out of sales, marketing and managed care functions to support commercial operations and launch are also on track.
- At the 2019 American Psychiatric Association (APA) annual meeting, we presented posters highlighting lumateperone’s favorable safety and tolerability profile in schizophrenia clinical studies. In addition, we successfully launched our disease awareness campaign to highlight the significant unmet medical needs that remain in the treatment of schizophrenia.

Bipolar Depression

- We presented positive topline results in our bipolar depression program from Study ‘404, a Phase 3 trial of lumateperone in patients with bipolar depression. Study 404 met its primary endpoint of change from baseline at Week 6 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo ($p<0.001$; effect size = 0.56). These benefits were statistically significant in both Bipolar I and Bipolar II patients. The study also met its key secondary objective on the Clinical Global Impression Scale for Bipolar for Severity of Illness (CGI-BP-S) Total Score ($p<0.001$; effect size = 0.46); lumateperone was also positive on the CGI component that specifically assesses depression (CGI-BP-S Depression Score; $p<0.001$; effect size = 0.50). In a second Phase 3 trial, Study ‘401, lumateperone did not separate from placebo. A high placebo response was observed in the trial. In both trials, lumateperone demonstrated a favorable safety profile and was generally well-tolerated. Importantly, the rates of akathisia, restlessness and extrapyramidal symptoms combined were less than 1% and similar to placebo in both studies. This safety profile is consistent with previous studies in patients with schizophrenia and provides further evidence supporting lumateperone’s favorable safety and tolerability profile across different patient populations. We plan to present additional details at upcoming medical conferences later this year. Our global adjunctive bipolar depression study, Study ‘402, is ongoing.

Major Depressive Disorder

- We believe lumateperone has the potential to exhibit potent and rapid antidepressant effects and have an ongoing program in major depressive disorder. 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. We are continuing to explore the pharmacokinetics of these formulations.

Other Programs

ITI-214 Program

- Our randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214, our phosphodiesterase 1 (PDE1) inhibitor, to evaluate hemodynamic effects and safety in patients with systolic heart failure is ongoing. Clinical conduct for the second cohort, 30 mg, is ongoing following completion of the 10 mg dose cohort where no safety concerns were identified. In addition, we are evaluating a Phase 2, proof-of-concept clinical trial of ITI-214 for the treatment of Parkinson’s disease. We are also exploring ITI-214 and other PDE1 inhibitors in other CNS and non-CNS indication.

ITI-333 Program

- We plan to develop ITI-333, our novel, oral modulator of serotonin, dopamine, and mu opioid receptors, for the treatment of opioid and other substance use disorders, pain, and mood disorders. We expect to initiate our clinical program in late 2019 or early 2020.

Selected Second Quarter 2019 Financial Results

Intra-Cellular Therapies (the Company or ITCI) reported a net loss of $37.4 million, or $0.68 per share (basic and diluted), for the second quarter of 2019 compared to a net loss of $37.4 million, or $0.68 per share (basic and diluted), for the second quarter of 2018.

Research and development (R&D) expenses for the second quarter of 2019 were $23.7 million, compared to $32.4 million for the second quarter of 2018. This decrease of $8.7 million is due primarily to a decrease of approximately $10.6 million associated with the lumateperone development programs and a decrease of approximately $3.6 million associated with non-lumateperone projects and overhead expenses, which is partially offset by $4.8 million for lumateperone non-clinical efforts and an increase in labor and stock compensation expense.

General and administrative (G&A) expenses were $15.4 million for the second quarter of 2019, compared to $6.7 million for the same period in 2018. The increase of $8.7 million is primarily the result of an increase in pre-commercialization costs of approximately $5.7 million, and to a lesser extent, labor, stock compensation and rent expense.

Cash, cash equivalents and investment securities totaled $285.3 million at June 30, 2019, compared to $347.5 million at December 31, 2018.

We expect these existing funds will be used primarily for pre-commercialization activities, 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.

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; the safety, tolerability and efficacy of our product candidates; our intent to provide the FDA with requested information in the coming weeks and our belief that this information will be sufficient to address the FDA’s requests; 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 for the commercial launch of lumateperone in the first quarter of 2020; 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; 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 and whether the FDA will complete its review within the target timelines, including the new PDUFA goal date; whether we will be able to provide in a timely manner the additional information that the FDA requests, whether such additional information will be satisfactory to the FDA, and whether the FDA will require further additional information; 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.

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

	Three Months Ended June 30, 2019 (1)	2018 (1)
Revenues	**$ —**	$ —
Costs and expenses:		
Research and development	**23,728,464**	32,439,270
General and administrative	**15,442,650**	6,728,987
Total costs and expenses	**39,171,114**	39,168,257
Loss from operations	**(39,171,114)**	(39,168,257)
Interest income	**1,731,550**	1,793,474
Loss before provision for income taxes	**(37,439,564)**	(37,374,783)
Income tax expense	**1,600**	1,600
Net loss	**$(37,441,164)**	$(37,376,383)
Net loss per common share:		
Basic & Diluted	**$ (0.68)**	$ (0.68)
Weighted average number of common shares:		
Basic & Diluted	**55,145,901**	54,696,698

(1) The condensed consolidated statements of operations for the quarters ended June 30, 2019 and 2018 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, 2019 (1) (Unaudited)	December 31, 2018 (1) (Audited)
Assets		
Current assets:		
Cash and cash equivalents	**$ 91,763,368**	$ 54,947,502
Investment securities, available-for-sale	**193,536,800**	292,583,046
Prepaid expenses and other current assets	**3,041,730**	7,908,133
Total current assets	**288,341,898**	355,438,681
Property and equipment, net	**2,082,933**	1,159,766
Right of use assets, net	**18,822,482**	—
Deferred tax asset, net	**529,218**	529,218
Other assets	**86,083**	78,833
Total assets	**$ 309,862,614**	$ 357,206,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**5,632,783**	13,961,060
Accrued and other current liabilities	**18,801,485**	20,044,866
Lease liabilities, short-term	**2,262,977**	—
Accrued employee benefits	**5,829,242**	2,293,259
Total current liabilities	**32,526,487**	36,299,185
Deferred rent	**—**	3,192,432
Lease liabilities	**20,567,765**	—
Total liabilities	**53,094,252**	39,491,617
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 55,186,745 and 54,895,295 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	**5,519**	5,490
Additional paid-in capital	**891,183,518**	880,753,339
Accumulated deficit	**(634,653,119)**	(562,376,191)
Accumulated comprehensive gain/(loss)	**232,444**	(667,757)
Total stockholders' equity	**256,768,362**	317,714,881
Total liabilities and stockholders' equity	**$ 309,862,614**	$ 357,206,498

(1) The condensed consolidated balance sheets at June 30, 2019 and December 31, 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.