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): June 29, 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, NY 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 8.01 Other Events.

On June 29, 2020, Intra-Cellular Therapies, Inc. (the "Company") announced topline results from Study ITI-214-104, a Phase I/II translational study of single ascending doses of ITI-214, a novel, selective phosphodiesterase-1 (PDE1) inhibitor, in patients with chronic systolic heart failure with reduced ejection fraction (HFrEF).

The Company's press release announcing topline results from Study ITCI-214-104 is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated June 29, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: June 29, 2020

Exhibit 99.1

Intra-Cellular Therapies Announces Positive Top-line Results from ITI-214 Phase I/II Study in Patients with Heart Failure

- *Study demonstrated inhibiting phosphodiesterase-1 with ITI-214 in patients with heart failure improved cardiac function by enhancing cardiac contractility and dilating systemic arteries without inducing abnormal heart rhythms.*

NEW YORK, June 29, 2020 (GLOBE NEWSWIRE) — Intra-Cellular Therapies, Inc. (Nasdaq:ITCI) today announced topline results from Study ITI-214-104, a Phase I/II translational study of single ascending doses of ITI-214, a novel, selective phosphodiesterase-1 (PDE1) inhibitor, in patients with chronic systolic heart failure with reduced ejection fraction (HFrEF). ITI-214 is the first PDE1 inhibitor to be tested in patients with HFrEF.

In this study, ITI-214 improved cardiac output by increasing heart contractility and decreasing vascular resistance. Agents that both increase heart contractility (inotropism) and decrease vascular resistance (vasodilation) are called inodilators. Inodilators in current clinical use are associated with the development of arrhythmias, which are abnormal heart rhythms that when serious can impair heart function and lead to mortality. ITI-214, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well tolerated in all patients.

The results of Study ITI-214-104 are consistent with our prior findings in preclinical models of heart failure and indicate that single-dose administration of ITI-214 can improve heart function in patients with HFrEF. These findings warrant further investigation of acute and chronic PDE-1 inhibition with ITI-214 in this patient population.

“ITI-214 improved the strength of heart contraction on top of lowering blood pressure stress on the heart. This occurred without impacting arrhythmia in patients with heart failure. These exciting results support a novel mechanism of action, and suggest that inhibition of the PDE-1 enzyme concurrent with standard-of-care may benefit heart

failure patients without incurring the risks associated with inodilators in current clinical use," said David Kass, M.D., the Abraham and Virginia Weiss Professor of Cardiology at Johns Hopkins University School of Medicine, who was involved in the study.

"Based on these findings, ITI-214 has the potential to be a safe, once-a-day oral inodilator with a novel mechanism of action that could have utility in clinical situations where there is great unmet medical need, ranging from the treatment of acute heart failure to the maintenance of patients with stable chronic HFrEF," said Sharon Mates, Ph.D., Chairman and CEO of Intra-Cellular Therapies, Inc.

The initiation of Study ITI-214-104 followed findings in preclinical models that ITI-214 had improved cardiac output through a mechanism of action different from those of available heart failure therapies. These findings in preclinical models of heart failure were published by researchers at Johns Hopkins University and Intra-Cellular Therapies scientists in the journal *Circulation*[1]. Currently available heart failure drugs that strengthen heart contractions, such as PDE3 inhibitors (amrinone and milrinone) and ß-adrenergic agonists (dobutamine), are associated with potentially dangerous complications, such as arrhythmias. ITI-214 does not interact with the ß-adrenergic signaling pathway and does not stimulate abnormal rhythms in an animal model of heart failure. These experimental results demonstrated that ITI-214 may exert its effects via distinct pathways, one of which involves adenosine A_{2B} receptor signaling, and suggest that ITI-214 may represent a mechanistically novel and potentially safe approach for the treatment of human heart failure.

About Study ITI-214-104

Study ITI-214-104 was a randomized, double-blind, placebo-controlled study of escalating single oral doses of ITI-214 (10, 30, and 90 mg) in patients with HFrEF NYHA class II-III. The primary objective of the study was to determine the effects of ITI-214 on cardiac function, using echocardiography with Doppler imaging, in patients with reduced ejection fraction (£35%) who were already maintained on standard-of-care treatment. Safety was evaluated by monitoring for hemodynamic effects and changes in cardiac rhythm.

Thirty-five patients were enrolled in this study, 9 in each of three dose cohorts and 8 in the placebo arm. The mean age of the patients was 54; 57% were male, and 57% were black. The etiology of the heart failure was ischemic heart disease in 31% of the patients. The mean left ventricular ejection fraction at screening was 25%.

In this study, compared to placebo, single doses of ITI-214 increased mean left ventricular (LV) power index and cardiac output while systemic vascular resistance and mean arterial blood pressure decreased. Reported adverse events were all mild to moderate and consisted of three occurrences of orthostatic hypotension and three episodes of non-postural hypotension. Patients were monitored by continuous telemetry, and no changes in heart rhythms were noted. No serious adverse events were reported. Further details of these results will be presented at upcoming medical conferences.

About Heart Failure

According to the U.S. Centers for Disease Control and Prevention, heart failure affects about 6.5 million adults in the United States and contributes to an estimated one in eight deaths. Heart failure is a chronic condition marked by weakening of the heart muscle that leads to shortness of breath and general body weakness that worsens with physical exertion. There is no cure for heart failure, and there is significant unmet need, particularly for safe agents that can both increase the strength of the heart as well as reduce vascular afterload.

Currently available heart failure drugs that can improve the contractile strength of the heart muscle, such as the PDE3 inhibitors amrinone and milrinone, and the ß-adrenergic agonist dobutamine, increase cyclic AMP and thereby increase intracellular calcium in cardiac muscle cells. Both approaches are associated with safety risks, most notably arrhythmia.

PDE1 inhibition also modifies cyclic AMP, but it does so in a different manner linked with a novel intracellular pathway that involves adenosine A_{2B} receptor signaling but not ß-adrenergic signaling to stimulate heart contractility. ITI-214 did not cause calcium levels to rise in cardiomyocyte cells. In all of the studies to date, activation of the PDE1-regulated pathway has not triggered arrhythmia.

About ITI-214

ITI-214 is a potent and selective phosphodiesterase type 1 (PDE1) inhibitor. ITI-214 is the lead compound in the Company's PDE1 portfolio and is in development for the treatment of symptoms associated with Parkinson's disease and for the treatment of heart failure. ITI-214 has been generally well tolerated with a favorable safety profile in six Phase 1 clinical trials. ITI-214 works by slowing the breakdown of cyclic nucleotides (cAMP, cGMP), thus allowing these molecules to build up in the cells and to exert important functions. The PDE1 enzyme is highly active in pathological or disease states, and our PDE1 molecules are designed to reestablish normal function in these disease states through the inhibition of the PDE1 enzyme.

In heart disease, excessive PDE1 activity may limit the beneficial effects of cAMP or cGMP, so inhibitors like ITI-214 have the potential to act as a therapy. ITI-214 is an inodilator that can improve cardiac function by both increasing the force of heart contractions and reducing the resistance to pushing blood through the vascular system. Preclinical research has shown that ITI-214 increases cardiac contractility and decreases vascular resistance without increasing abnormal heart rhythms, and the clinical results announced herein indicate that similar, potentially therapeutic physiologic effects can be attained in heart failure patients. ITI-214 is being developed for the potential treatment of heart failure with reduced ejection fraction (HFrEF).

Previous studies have described the mechanism of action of ITI-214 in the brain. The mechanism of action of ITI-214 and our other PDE1 inhibitors suggests therapeutic potential across a variety of diseases including neurological and cardiovascular diseases.

1. Bui AL, et al. Nat Rev Cardiol. 2011;8: 30-41. 2. Hashimoto et al., Circulation 138:1974-1987 (2018)

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, the therapeutic value, clinical and non-clinical development plans and commercial potential of our drug product candidates; the progress, timing and results of our clinical trials and preclinical studies; our beliefs about the extent to which the results of our clinical trials and preclinical studies to date support new drug application filings for product candidates; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of our drug product candidates; the potential for ITI-214 to represent a novel approach for the treatment of human heart failure; that ITI-214 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 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 our 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; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; any other impacts on our business as a result of or related to the COVID-19 pandemic; 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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