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): January 3, 2022

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 January 3, 2022, Intra-Cellular Therapies, Inc. (the "Company") filed with the Securities and Exchange Commission a preliminary prospectus supplement to its effective shelf registration statement on Form S-3 (File No. 333-235817) (the "Preliminary Prospectus Supplement") pursuant to Rule 424(b)(5) under the Securities Act of 1933, as amended (the "Securities Act"), relating to a proposed public offering of shares of the Company's common stock. The Company included the following disclosure in the Preliminary Prospectus Supplement:

"While we have not finalized our financial results for the three months or the year ended December 31, 2021, we expect to report that, for the three months ended December 31, 2021, we had total revenues between approximately $22 million and $28 million, and as of December 31, 2021, we had cash, cash equivalents, investment securities and restricted cash of approximately $413 million. These amounts are preliminary, unaudited and may change, were prepared by management and are based on the most current information available to management, and are subject to completion by management of the financial statements as of and for the three months and the year ended December 31, 2021, or the 2021 financial statements, including completion of the review procedures, final adjustments and other developments that may arise between now and the time the financial results for this period are finalized, and completion of the audit of the 2021 financial statements. As a result, there can be no assurance that our total revenues for the three months ended December 31, 2021 or our cash, cash equivalents, investment securities and restricted cash as of December 31, 2021 will not differ from these estimates and any such change could be material. Additional information and disclosures are required for a more complete understanding of our financial position and results of operations as of and for the three months and the year ended December 31, 2021."

ITEM 8.01 Other Events.

On January 3, 2022, the Company issued a press release announcing it has commenced an underwritten public offering of $400 million of shares of its common stock, and its intention to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of common stock offered in the public offering. All of the shares in the offering will be sold by the Company. A copy of the press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

J.P. Morgan Securities LLC, SVB Leerink LLC, BofA Securities, Inc., Evercore Group L.L.C. and RBC Capital Markets, LLC are acting as joint book-running managers for the offering. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

In addition, the Preliminary Prospectus Supplement contains an updated summary description of the Company's business in the section entitled "Prospectus Supplement Summary," which is attached hereto as Exhibit 99.2 and incorporated herein by reference.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy the securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any offer, solicitation, or sale of the securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Intra-Cellular Therapies, Inc., dated January 3, 2022.
99.2	Prospectus Supplement Summary included in Intra-Cellular Therapies, Inc.'s Preliminary Prospectus Supplement dated January 3, 2022 to the Registration Statement on Form S-3 (File No. 333-235817).
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: January 3, 2022

Exhibit 99.1

Intra-Cellular Therapies Announces Proposed Public Offering of Common Stock

NEW YORK, January 3, 2022 (GLOBE NEWSWIRE) — Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, today announced that it has commenced an underwritten public offering of $400 million of shares of its common stock. In connection with the offering, Intra-Cellular Therapies intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of common stock offered in the public offering. All of the shares in the offering will be sold by Intra-Cellular Therapies.

J.P. Morgan, SVB Leerink, BofA Securities, Evercore ISI and RBC Capital Markets are acting as joint book-running managers for the offering. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

The public offering will be made pursuant to a shelf registration statement on Form S-3 that was previously filed with the Securities and Exchange Commission (the "SEC") and became effective upon filing. A preliminary prospectus supplement and accompanying base prospectus relating to and describing the terms of the offering will be filed with the SEC and will be available on the SEC's website located at http://www.sec.gov. The offering is being made only by means of a prospectus and related prospectus supplement, copies of which may be obtained from J.P. Morgan Securities LLC, Attention: Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, by telephone at 1-866-803-9204, or by email at prospectus-eq_fi@jpmchase.com, SVB Leerink LLC, Attention: Syndicate Department, 53 State Street, 40th Floor, Boston, MA 02109, by telephone at 1-800-808-7525, ext. 6105, or by email at syndicate@svbleerink.com, BofA Securities, Attention: Prospectus Department, NC1-004-03-43, 200 North College Street, 3rd floor, Charlotte, NC 28255-0001 or by e-mail at dg.prospectus_requests@bofa.com, Evercore Group L.L.C., Attention: Equity Capital Markets, 55 East 52nd Street, 35th Floor, New York, NY 10055, by telephone at (888) 474-0200 or by email at ecm.prospectus@evercore.com, or RBC Capital Markets, LLC, Attention: Equity Capital Markets, 200 Vesey Street, 8th Floor, New York, NY 10281, by telephone at (877) 822-4089 or by email at equityprospectus@rbccm.com. The final terms of the offering will be disclosed in a final prospectus supplement to be filed with the SEC.

This press release shall not constitute an offer to sell, or a solicitation of an offer to buy, nor will there be any sale of these securities in any state or other jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

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.

Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements, other than statements of historical fact, regarding, among other things, the proposed public offering of common stock. Intra-Cellular Therapies often uses words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “planned,” “continue,” “guidance,” and similar expressions to identify forward-looking statements. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to: uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, and other risks and uncertainties that are described under the heading “Risk Factors” in Intra-Cellular Therapies’ preliminary prospectus supplement to be filed with the SEC, Intra-Cellular Therapies’ most recent Annual Report on Form 10-K or in subsequent filings that it makes with the Securities and Exchange Commission. As a result of risks and uncertainties that Intra-Cellular Therapies faces, the results or events indicated by any forward-looking statement may not occur. Intra-Cellular Therapies cautions you not to place undue reliance on any forward-looking statement. In addition, any forward-looking statement in this press release represents Intra-Cellular Therapies’ views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Intra-Cellular Therapies disclaims any obligation to update any forward-looking statement, except as required by applicable law.

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Prospectus supplement summary

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the "Risk factors" section contained in this prospectus supplement, our consolidated financial statements and the related notes thereto and the other documents and information incorporated by reference in this prospectus supplement and the accompanying prospectus.

Overview

We are a biopharmaceutical company focused on the discovery, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. In December 2019, CAPLYTA (lumateperone) was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of schizophrenia in adults (42mg/day) and we initiated the commercial launch of CAPLYTA in late March 2020. In support of our commercialization efforts, we employ a national salesforce. In December 2021, CAPLYTA was approved by the FDA for the treatment of bipolar depression in adults (42mg/day). According to the National Institute of Mental Health, an estimated 4.4% of U.S. adults (approximately 11 million U.S. adults) experience bipolar disorder at some time in their lives. CAPLYTA is the only FDA-approved treatment for depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate. We initiated the commercial launch of CAPLYTA for the treatment of bipolar depression in December 2021. In support of the commercial launch of lumateperone for the treatment of bipolar depression, we have expanded our sales force from approximately 240 sales representatives to approximately 320 sales representatives. As used in this prospectus supplement, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults and for the treatment of bipolar depression in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia and bipolar depression.

Lumateperone is in Phase 3 clinical development as a novel treatment for major depressive disorder, or MDD. In the first quarter of 2020, as part of our lumateperone bipolar depression clinical program, we initiated our third monotherapy Phase 3 study, Study 403, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. Following the positive results in our adjunctive study that was part of our bipolar depression clinical program, Study 402, we amended Study 403 to evaluate major depressive episodes with mixed features in bipolar disorder in patients with Bipolar I or Bipolar II disorder and mixed features in patients with MDD. We expect to complete Study 403 in the second half of 2022 and following completion we intend to discuss the results with the FDA to determine whether Study 403, as amended, will provide supportive data for a potential future regulatory filing for this indication.

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At a dose of 42 mg, lumateperone has been shown effective in treating the symptoms associated with schizophrenia and bipolar depression, and we believe lumateperone may represent a potential treatment for mood disorders including MDD, post-traumatic stress disorder and intermittent explosive disorder. Patient enrollment in Study 501 and Study 502, our global Phase 3 clinical trials evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD has commenced. We expect to file an sNDA with the FDA for approval of lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in 2024. We have also initiated a Phase 3 study evaluating lumateperone for the prevention of relapse in patients with schizophrenia. The study is being conducted in five phases consisting of a screening phase, a 6-week, open-label run-in phase during which all patients will receive 42 mg of lumateperone per day, a 12-week, open-label stabilization phase during which all patients will receive 42 mg of lumateperone per day; a double-blind treatment phase 26 weeks in duration during which patients receive either 42 mg of lumateperone per day or placebo (1:1 ratio) and a 2-week safety follow-up phase. This study is being conducted in accordance with our post approval marketing commitment to the FDA in connection with the approval of CAPLYTA for the treatment of schizophrenia as is typical for antipsychotics.

Within the lumateperone portfolio, we are also developing a long-acting injectable, or LAI, formulation to provide more treatment options to patients suffering from mental illness. We have completed the preclinical development of an LAI formulation and in December 2020 we initiated a Phase 1 single ascending dose study of lumateperone LAI, a formulation of lumateperone designed to be administered subcutaneously and to maintain therapeutic levels of lumateperone for at least one month. This study will evaluate the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We recently completed initial clinical conduct in this study and the results will inform the dosing strategy for a multiple ascending dose study and an efficacy study. We are evaluating several additional formulations of the lumateperone LAI with treatment durations of one month and longer. Given the encouraging tolerability data to date with oral lumateperone, we believe that an LAI option, in particular, may lend itself to being an important formulation choice for certain patients.

We are developing ITI-1284-ODT-SL for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and for the treatment of certain depressive disorders, in the elderly. ITI-1284-ODT-SL is a deuterated form of lumateperone, a new molecular entity formulated as an oral disintegrating tablet for sublingual administration. ITI-1284-ODT-SL is formulated as an oral solid dosage form that dissolves almost instantly when placed under the tongue, allowing for ease of use in the elderly and may be particularly beneficial for patients who have difficulty swallowing conventional tablets. Phase 1 single and multiple ascending dose studies in healthy volunteers and healthy elderly volunteers (> than 65 years of age) evaluated the safety, tolerability and pharmacokinetics of ITI-1284-ODT-SL. In these studies, there were no reported serious adverse events in either age group. In the elderly cohort, reported adverse events were infrequent with the most common adverse event being transient dry mouth (mild). Based on these results, we have initiated our program evaluating ITI-1284-ODT-SL for the treatment of agitation in patients with probable Alzheimer’s disease. We are in discussions with the FDA regarding the non-clinical toxicological profile of ITI-1284-ODT-SL. The FDA has informed us that they do not believe the deuterated and undeuterated forms of lumateperone are identical. As a result, the non-clinical data from lumateperone may not be broadly applied to ITI-1284-ODT-SL and we may be required to conduct additional toxicology studies in non-rodent species and this could delay the commencement of our clinical program. We expect to commence clinical conduct in this program in 2022. Additional studies in dementia-related psychosis, and certain depressive disorders in the elderly are also planned for 2022.

We have another major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibit the enzyme phosphodiesterase type 1, or PDE1. PDE1 enzymes are highly active in multiple disease states and our PDE1 inhibitors are designed to reestablish normal function in these disease states. Abnormal PDE1 activity is associated with cellular proliferation and activation of inflammatory cells. Our PDE1 inhibitors ameliorate both of these effects in animal models. We intend to pursue the development of our phosphodiesterase, or PDE, program, for the treatment of aberrant immune system activation in several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases, cancers and other non-CNS disorders. Lenrispodun (ITI-214) is our lead compound in this program. Following the favorable safety and tolerability results in our Phase 1 program, we initiated our development program for lenrispodun for Parkinson’s disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of lenrispodun in patients with Parkinson’s disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. In the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of lenrispodun has been completed and topline results demonstrated lenrispodun was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. We have initiated our Phase 2 clinical program with lenrispodun for Parkinson’s disease and expect to commence patient enrollment in the first half of 2022. In addition, in the second quarter of 2020, we announced topline results from Study ITI-214-104, a Phase 1/2 translational study of single ascending doses of lenrispodun in patients with chronic systolic heart failure with reduced ejection fraction. In this study, lenrispodun 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. Lenrispodun, which acts through a novel mechanism of action, was not associated with arrhythmias in this study and was generally well-tolerated in all patients.

We also have a development program with our ITI-333 compound as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. ITI-333 is a novel compound that uniquely combines activity as an antagonist at serotonin 5-HT2A receptors and a partial agonist at μ-opioid receptors. These combined actions support the potential utility of ITI-333 in the treatment of opioid use disorder and associated comorbidities (e.g., depression, anxiety, sleep disorders) without opioid-like safety and tolerability concerns. In December 2020, we initiated a Phase 1 single ascending dose study evaluating the safety, tolerability and pharmacokinetics of ITI-333 in healthy volunteers. This study was recently completed and ITI-333 achieved plasma exposures at or above those required for efficacy and was generally safe and well tolerated. We have received a grant from the National Institute on Drug Abuse under the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, that we expect will fund a significant portion of the early stage clinical development costs associated with this program.

We have assembled a management team with significant industry experience to lead the commercialization of our product and the discovery, development and potential commercialization of our product candidates. We complement our management team with a group of scientific and clinical advisors that includes recognized experts in the fields of schizophrenia and other CNS disorders.

Our therapeutic pipeline

Our strategy

Our goal is to discover, develop and commercialize novel small molecule therapeutics for the treatment of CNS diseases and other diseases in order to improve the lives of people suffering from such illnesses. Using our key understanding of intracellular signaling, we seek to accomplish our goal, using our in-house expert drug discovery and clinical development teams, in two ways:

- we seek to have the capability to develop first-in-class medications with novel mechanisms that have the potential to treat CNS diseases and other diseases for which there are no previously marketed drugs; and
- we seek to develop drugs that either can differentiate themselves in competitive markets by addressing aspects of CNS diseases and other diseases which are not adequately treated by currently marketed drugs or can be effective with fewer side effects.

The key elements of our strategy are to:

- continue to commercialize CAPLYTA, which has been approved by the FDA for the treatment of schizophrenia in adults, in the United States;
- commercialize CAPLYTA, which has been approved by the FDA for the treatment of bipolar depression in adults, in the United States;
- complete the development of lumateperone for additional neuropsychiatric indications, such as MDD;
- expand the commercial potential of lumateperone by investigating its usefulness in additional neurological areas, such as autism spectrum disorder, and in additional neuropsychiatric indications, such as sleep disorders associated with neuropsychiatric and neurological disorders;
- continue to advance our other product candidates in clinical development such as lenrispodun, for the treatment of CNS and other disorders; ITI-1284, for the treatment of neuropsychiatric disorders and behavioral disturbances in dementia; and ITI-333, for substance use disorders, pain and psychiatric comorbidities including depression and anxiety; and
- advance the earlier stage product candidates in our pipeline.