# 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 18, 2024**

# 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 18, 2024, Intra-Cellular Therapies, Inc. (the "Company") announced positive topline results from Study 502 evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of major depressive disorder.

The Company's press release announcing the results 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 18, 2024 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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.

**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 18, 2024

**Exhibit 99.1**

**Intra-Cellular Therapies Announces Positive Topline Results in Second Phase 3 Trial Evaluating Lumateperone as Adjunctive Therapy in Patients with Major Depressive Disorder**

*In Study 502, lumateperone 42 mg achieved statistically significant and clinically meaningful results in both the primary and the key secondary endpoints*

*Lumateperone 42 mg met the primary endpoint of change from baseline at Week 6 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo (4.5 point reduction v. placebo; p<0.0001; Cohen's d effect size (ES)=0.56)*

*Lumateperone 42 mg also met the key secondary endpoint of change from baseline at Week 6 on the Clinical Global Impression Scale for Severity of Illness (CGI-S) (p<0.0001; ES=0.51)*

*Statistically significant efficacy was also seen in the Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR) scale, a patient self-reported measure of symptom severity of depression (p<0.0001)*

*Favorable safety and tolerability profile generally consistent with prior lumateperone trials*

*Supplemental NDA (sNDA) submission for the adjunctive treatment of major depressive disorder (MDD) anticipated in the second half of 2024*

**Conference call scheduled today at 8:30 a.m. ET**

NEW YORK, June 18, 2024 (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 positive topline results from Study 502 evaluating lumateperone 42 mg as an adjunctive therapy to antidepressants for the treatment of MDD. This trial, in conjunction with our previously

reported positive Phase 3 study, Study 501, forms the basis for our lumateperone sNDA for the adjunctive treatment of MDD. We expect to submit this sNDA to the U.S. Food and Drug Administration (FDA) in the second half of 2024.

“We are confident that the efficacy results from Studies 501 and 502, along with the favorable safety and tolerability profiles from these studies, will make lumateperone a drug of choice for patients suffering with MDD who are having an inadequate response to antidepressant therapy,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. “We are very pleased with the robust efficacy results from Study 502 which are consistent with the compelling results from Study 501. These results, further support our vision for CAPLYTA to become a leading option for patients and providers across mood disorders.”

Lumateperone 42 mg given once daily as adjunctive therapy to antidepressants met the primary endpoint in Study 502 by demonstrating a statistically significant and clinically meaningful reduction in the MADRS total score compared to placebo at Week 6. In the modified intent-to-treat (mITT) study population, the least squares (LS) mean reduction from baseline for lumateperone 42 mg was 14.7 points, versus 10.2 points for placebo (LS mean difference = -4.5 points; $p<0.0001$; ES= 0.56). Numerical improvement versus placebo on the MADRS total score was seen as early as Week 1 ($p=0.0504$) and statistically significant separation starting at Week 2 and maintained throughout the study.

Lumateperone 42 mg also met the key secondary endpoint in the study by demonstrating a statistically significant and clinically meaningful reduction in the CGI-S score compared to placebo at Week 6 ($p<0.0001$; ES= 0.51). Statistically significant separation on the CGI-S versus placebo was observed starting at Week 3 and maintained throughout the study.

In this study, lumateperone 42 mg robustly improved depressive symptoms as reported by patients as measured by the Quick Inventory of Depressive Symptomatology Self Report (QIDS-SR-16) ($p<0.0001$). The QIDS-SR-16 is a 16-item patient-rated scale of symptom severity in depression. It assesses nine key symptoms of depression: insomnia/hypersomnia, low mood, appetite/weight changes, impaired self-perception, concentration difficulties, loss of interest/pleasure, suicidal ideation, psychomotor agitation and fatigue.

Lumateperone was generally safe and well-tolerated in this study. The most common adverse events (≥5% and greater than twice placebo) were dizziness, somnolence, dry mouth, nausea, diarrhea and fatigue. Adverse events were mostly mild to moderate and resolved within the course of the study. These adverse events were generally similar to those seen in prior studies of lumateperone as a treatment for MDD, bipolar depression and schizophrenia.

In this study, 480 patients were randomized (1:1) to lumateperone 42 mg plus antidepressant or placebo plus antidepressant to evaluate the efficacy and safety of lumateperone as an adjunctive treatment to antidepressants in patients with MDD. The baseline MADRS total score was 30.8 for lumateperone 42 mg and 31.5 for placebo.

“MDD is the leading cause of disability in the world, where about two-thirds of patients fail to achieve remission with first-line treatment,” said Dr. Suresh Durgam, Executive Vice President, Chief Medical Officer of Intra-Cellular Therapies. “In both pivotal registrational studies, Study 501 and Study 502, lumateperone demonstrated a robust effect as an adjunctive treatment to antidepressants in patients with MDD who had inadequate response to antidepressant therapy. The consistent efficacy, safety and tolerability profile of lumateperone has the potential to be a compelling treatment option for MDD.”

**About the Lumateperone Adjunctive MDD Program**

Studies 501 and 502 evaluated lumateperone 42 mg as an adjunctive treatment to antidepressants in patients with MDD who had inadequate response to antidepressant therapy.

These are both multicenter, randomized, double-blind, placebo-controlled, parallel-group, fixed-dose studies conducted globally in patients with a primary diagnosis of MDD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria who have had an inadequate response to ongoing anti-depressant therapy.

Eligible patients had a minimum MADRS total score of 24, a minimum CGI-S score of 4 and an inadequate response to one or two SSRI/SNRIs (less than 50% improvement) following monotherapy treatment for at least 6 weeks duration.

The primary endpoint results from Studies 501 and 502 are as follows:

**Primary Endpoint:** Change from baseline vs. placebo on the MADRS Total Score at Week 6 (mITT study population)

| | | Least Squares (LS) Mean Reduction vs. Baseline[1] | LS mean difference[1] | p value | Cohen's d effect size |
|---|---|---|---|---|---|
| **STUDY 501** | Lumateperone 42 mg +ADT | 14.7 | -4.9 | <0.0001 | 0.61 |
| | placebo +ADT | 9.8 | | | |
| **STUDY 502** | Lumateperone 42 mg+ADT | 14.7 | -4.5 | <0.0001 | 0.56 |
| | placebo +ADT | 10.2 | | | |

[1] rounded to nearest tenth; ADT: Antidepressant therapy

In the pooled safety data of Studies 501 and 502, the most common adverse events (≥5% and greater than twice placebo) with lumateperone versus placebo were: dizziness (16.6% v. 5.0%), dry mouth (12.6% v. 3.3%), somnolence (12.2% v. 2.3%), nausea (8.5% v. 4.0%) and fatigue (7.2% v. 1.2%).

**About Major Depressive Disorder**

Major Depressive Disorder (MDD) is a common mood disorder in the U.S. affecting an estimated 21 million adults each year. MDD represents the primary cause of disability in the world. Symptoms include sadness, hopelessness, helplessness, feelings of guilt, irritability, loss of interest in formerly pleasurable activities, cognitive impairment, disturbed sleep patterns, and suicide ideation or behavior. It can cause severe functional impairment, adversely affecting interpersonal relationships, and may impact quality of life. Approximately two-thirds of patients with depression fail to achieve remission with first-line treatment.

**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 results of Study 502. To attend the live conference call by phone please use this registration link

(https://register.vevent.com/register/BId2605f218b9c4962b3d61b1ec28c40cf). All participants must use the link to complete the online registration process in advance of the conference call.

The live and archived webcast can be accessed under “Events & Presentations” in the Investors section of the Company’s website at www.intracellulartherapies.com. Please log in approximately 5-10 minutes prior to the event to register and to download and install any necessary software.

CAPLYTA® (lumateperone) is indicated in adults for the treatment of schizophrenia and for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

**Important Safety Information**

**Boxed Warnings:**

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adults in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA have not been established in pediatric patients.**

**Contraindications:** CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA. Reactions have included pruritus, rash (e.g., allergic dermatitis, papular rash, and generalized rash), and urticaria.

**Warnings & Precautions:** Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis**, including stroke and transient ischemic attack. See Boxed Warning above.
- **Neuroleptic Malignant Syndrome (NMS)**, which is a potentially fatal reaction. Signs and symptoms include: high fever, stiff muscles, confusion, changes in breathing, heart rate, and blood pressure, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Patients who experience signs and symptoms of NMS should immediately contact their doctor or go to the emergency room.

- **Tardive Dyskinesia**, a syndrome of uncontrolled body movements in the face, tongue, or other body parts, which may increase with duration of treatment and total cumulative dose. TD may not go away, even if CAPLYTA is discontinued. It can also occur after CAPLYTA is discontinued.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases)**. Complete blood counts should be performed in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. CAPLYTA should be discontinued if clinically significant decline in WBC occurs in absence of other causative factors.
- **Decreased Blood Pressure & Dizziness**. Patients may feel lightheaded, dizzy or faint when they rise too quickly from a sitting or lying position (orthostatic hypotension). Heart rate and blood pressure should be monitored and patients should be warned with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- **Falls**. CAPLYTA may cause sleepiness or dizziness and can slow thinking and motor skills, which may lead to falls and, consequently, fractures and other injuries. Patients should be assessed for risk when using CAPLYTA.
- **Seizures**. CAPLYTA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment**. Patients should use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- **Body Temperature Dysregulation**. CAPLYTA should be used with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- **Dysphagia**. CAPLYTA should be used with caution in patients at risk for aspiration.

**Drug Interactions:** CAPLYTA should not be used with CYP3A4 inducers. Dose reduction is recommended for concomitant use with strong CYP3A4 inhibitors or moderate CYP3A4 inhibitors.

**Special Populations:** Newborn infants exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Dose reduction is recommended for patients with moderate or severe hepatic impairment.

**Adverse Reactions**: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation, dizziness, nausea, and dry mouth.

CAPLYTA is available in 10.5 mg, 21 mg, and 42 mg capsules.

Please click here to see full Prescribing Information including **Boxed Warning**.

**About CAPLYTA (lumateperone)**

CAPLYTA 42 mg is an oral, once daily atypical antipsychotic approved in adults for the treatment of schizophrenia and the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. While the mechanism of action of CAPLYTA is unknown, the efficacy of CAPLYTA could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Lumateperone is being studied for the treatment of major depressive disorder, and other psychiatric and neurological disorders. Lumateperone is not FDA-approved for these disorders.

**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, our expectations regarding the commercialization of CAPLYTA; our plans to conduct clinical or non-clinical trials and the timing of developments with respect to those trials, including enrollment, initiation or completion of clinical conduct, or the availability or reporting of results; plans to make regulatory submissions to the FDA and the timing of such submissions; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; the goals of our development programs; our beliefs about the potential utility of our product candidates; 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: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indications; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia and bipolar depression following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or bipolar depression or in ongoing or future trials and other development activities; there is no guarantee that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of our patents; there is no guarantee that our planned sNDA for the treatment of MDD will be submitted or approved, if at all, on the timeline that we expect; 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 or in clinical trials for other indications; 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; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the COVID-19 pandemic, the conflicts in Ukraine and the Middle East, global economic uncertainty, inflation, higher interest rates or market disruptions; 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.

**Contact:**

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