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 8, 2025

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.)**

135 Route 202/206, Suite 6
Bedminster, NJ 07921
(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 January 8, 2025, Intra-Cellular Therapies, Inc. (the "Company") entered into an agreement with Sandoz Inc. ("Sandoz") resolving patent litigation related to the Company's product CAPLYTA® (lumateperone), which is approved by the U.S. Food and Drug Administration (the "FDA") for the adult treatment of schizophrenia and for the adult treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. The pending patent litigation was filed by the Company in the U.S. District Court for the District of New Jersey in response to Sandoz notifying the Company that it had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to market generic versions of CAPLYTA prior to expiration of the Company's Orange Book listed patents. As a result of this settlement agreement, the Company has granted Sandoz the right to sell generic versions of CAPLYTA in the United States beginning July 1, 2040, or earlier under certain circumstances. As required by law, the Company will submit the agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice. Similar patent litigation brought by the Company against other parties remains pending in the U.S. District Court for the District of New Jersey.

The Company's press release announcing the settlement agreement with Sandoz 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 January 10, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The press release may contain hypertext links to information on the Company's website. The information on the Company's 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/ Sanjeev Narula
Sanjeev Narula
Executive Vice President, Chief Financial Officer and Treasurer

Date: January 10, 2025

Exhibit 99.1

Intra-Cellular Therapies Settles CAPLYTA® (lumateperone) Patent Litigation with Sandoz

BEDMINSTER, N.J., Jan. 10, 2025 (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 entered into a settlement agreement with Sandoz Inc. (Sandoz) resolving patent litigation related to Intra-Cellular Therapies' product CAPLYTA® (lumateperone). The litigation, which is pending in the U.S. District Court for the District of New Jersey, resulted from submission by Sandoz of an Abbreviated New Drug Application to the U.S. Food and Drug Administration seeking approval to market a generic equivalent of CAPLYTA in the United States. The settlement agreement permits Sandoz to begin selling generic versions of CAPLYTA on July 1, 2040, or earlier under certain circumstances. As required by law, Intra-Cellular Therapies will submit the agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice. Similar patent litigation brought by Intra-Cellular Therapies against other parties remains pending in the U.S. District Court for the District of New Jersey.

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.

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