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): March 27, 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.

As previously disclosed, in February 2024, Intra-Cellular Therapies, Inc. (the "Company") received notices from Alkem Laboratories Ltd., Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd., Dr. Reddy's Laboratories Inc. (on behalf of Dr. Reddy's Laboratories Ltd.), MSN Laboratories Private Ltd., Sandoz Inc., Hetero USA, Inc. (the U.S. Regulatory Agent for Hetero Labs Limited Unit - V, a division of Hetero Labs Limited) and Zydus Pharmaceuticals (USA), Inc. (each an "ANDA Filer"), that each company had filed an abbreviated new drug application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval of generic version of the Company's product, CAPLYTA. The ANDAs each contained Paragraph IV Patent Certifications alleging that certain of the Company's patents covering CAPLYTA are invalid and/or will not be infringed by each ANDA Filer's manufacture, use or sale of the medicine for which the ANDA was submitted.

Under the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Act"), the Company had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court to trigger a stay precluding the FDA's approval of any ANDA from being effective any earlier than 7.5 years from the date of approval of the CAPLYTA new drug application or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. After conducting the necessary due diligence, and within the 45 day period required under the Act, the Company filed lawsuits on March 27, 2024 and March 28, 2024 in the U.S. Federal District Court for the District of New Jersey against each of the seven generic drug manufacturers who notified the Company of their ANDA filings.

While the Company intends to vigorously defend and enforce its intellectual property rights protecting CAPLYTA, the Company can offer no assurance as to when the lawsuits will be decided, whether the lawsuits will be successful, or that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of the Company's patents.

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: April 1, 2024