
**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**

July 13, 2021

Date of report (Date of earliest event reported)

Axsome Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-37635

(Commission
File Number)

45-4241907

(IRS Employer
Identification No.)

**22 Cortlandt Street, 16th Floor
New York, New York**

(Address of principal executive offices)

10007

(Zip Code)

Registrant's telephone number, including area code (212) 332-3241

(Former name or former address, if changed since last report)

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, Par Value \$0.0001 Per Share

AXSM

The Nasdaq Global Market

Check the appropriate box below if the Form 8-K 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)).

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.

Axsome Therapeutics, Inc. (the “Company”) today announced that it has been notified by the U.S. Food and Drug Administration (the “FDA”) that the FDA is rescinding the Company’s Breakthrough Therapy Designation for its AXS-12 product candidate for the treatment of cataplexy in narcolepsy, due to the FDA approving an additional drug product for the treatment of cataplexy in narcolepsy subsequent to granting AXS-12 Breakthrough Therapy Designation.

The Company does not currently anticipate any changes to the development plans or associated timelines for AXS-12 as a result of this change.

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.

Axsome Therapeutics, Inc.

Dated: July 13, 2021

By: /s/ Herriot Tabuteau, M.D.
Name: Herriot Tabuteau, M.D.
Title: President and Chief Executive Officer