

**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): February 07, 2022

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)

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, Par Value \$0.0001 Per Share	AXSM	NASDAQ Global 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.

Axsome Therapeutics, Inc. (“Axsome” or “the Company”) is providing the following updates regarding the Company’s AXS-07 drug product candidate program:

NDA Facility Inspection

Axsome previously disclosed that the U.S. Food and Drug Administration (the “FDA”) had notified the Company that, due to COVID-19 pandemic-related travel restrictions, they may be unable to complete a required contract manufacturing facility inspection for the Company’s New Drug Application (“NDA”) for AXS-07 prior to the AXS-07 Prescription Drug User Fee Action (“PDUFA”) date of April 30, 2022. Axsome has now been informed by the FDA that the FDA does not anticipate any issues with completing this facility inspection prior to the AXS-07 PDUFA date.

Baudax Litigation

On February 1, 2022, Axsome and Baudax Bio, Inc. (“Baudax”) entered into a Litigation Discontinuance Agreement pursuant to which Baudax was to voluntarily dismiss, with prejudice, its lawsuit against the Company in the United States District Court for the District of Delaware (the “Baudax Action”). The Baudax Action, which was never served on Axsome, alleged that the Company’s AXS-07 drug product candidate infringes on U.S. Patents 8,512,727 and 10,471,067, both owned by assignment by Baudax. A notice of dismissal with prejudice was filed by Baudax in the Baudax action on February 7, 2022.

As part of the resolution of the Baudax Action, Baudax executed a covenant not to sue pursuant to which Baudax will refrain from commencing any future litigation relating to AXS-07. Also in connection with the resolution, the Company made a one-time payment of \$312,500 to Baudax, and the Company has not incurred any obligation to pay any royalty or other contingent consideration nor has it agreed to any other restriction on its manufacture or distribution of AXS-07.

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 thereunto duly authorized.

Axsome Therapeutics, Inc.

Date: February 7, 2022

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