# 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): November 10, 2021**

# Axsome Therapeutics, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-37635** | **45-4241907** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **22 Cortlandt Street, 16th Floor** | |
| **New York, New York** | **10007** |
| **(Address of Principal Executive Offices)** | **(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 7.01 Regulation FD Disclosure.**

Axsome Therapeutics, Inc. (“Axsome” or “the Company”) is aware of a complaint for patent infringement filed in the U.S. District Court for the District of Delaware by Baudax Bio, Inc. (“Baudax”) against the Company with respect to Axsome’s AXS-07 drug product candidate. Axsome has not been served with the complaint, which alleges that AXS-07 infringes U.S. Patents 8,512,727 and 10,471,067, both owned by assignment by Baudax.

U.S. Patent 8,512,727 contains the following independent claims:

> 1. An intravenous injection pharmaceutical dosage form comprising: (a) a liquid dispersion medium selected from the group consisting of water, an aqueous salt solution, safflower oil, ethanol, t-butanol, hexane and glycol; (b) particles of meloxicam or a salt thereof having an effective average particle size of less than 200 nm; and (c) polyvinylpyrrolidone and sodium deoxycholate as surface stabilizers adsorbed on the surface of the meloxicam particles, wherein: (i) the surface stabilizer are essentially free of intermolecular cross-linkages; (ii) meloxicam is present in an amount of from about 99.5% to about 0.001%, by weight, based on the total combined weight of the meloxicam and the surface stabilizers; and (iii) the surface stabilizers are present in an amount of from about 0.01% to about 99.5%, by weight, based on the total combined weight of the meloxicam and the surface stabilizers.
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> 5. A method of making an intravenous injection pharmaceutical dosage form comprising contacting meloxicam particles with polyvinylpyrrolidone and sodium deoxycholate as surface stabilizers in the presence of a liquid dispersion medium selected from the group consisting of water, an aqueous salt solution, safflower oil, ethanol, t-butanol, hexane and glycol for a time and under conditions sufficient to provide the intravenous injection pharmaceutical dosage form comprising meloxicam particles having an effective average particle size of less than 200 nm, wherein: (i) the surface stabilizers are essentially free of intermolecular cross-linkages; (ii) meloxicam is present in an amount of from about 99.5% to about 0.001%, by weight, based on the total combined weight of the meloxicam and the surface stabilizers; and (iii) the surface stabilizers are present in an amount of from about 0.01% to about 99.5%, by weight, based on the total combined weight of the meloxicam and the surface stabilizers.
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> 13. A method of treating a subject in need thereof comprising intravenously injecting to the subject an effective amount of a pharmaceutical dosage form comprising: (a) a liquid dispersion medium selected from the group consisting of water, an aqueous salt solution, safflower oil, ethanol, t-butanol, hexane and glycol; (b) particles of meloxicam or a salt thereof; and (c) polyvinylpyrrolidone and sodium deoxycholate as surface stabilizers, wherein: (i) the surface stabilizers are essentially free of intermolecular cross-linkages; (ii) the meloxicam particles have an effective average particle size of less than 200 nm; (iii) meloxicam is present in an amount of from about 99.5% to about 0.001, by weight, based on the total combined weight of the meloxicam and the surface stabilizers; and (iv) the surface stabilizer is present in an amount of from about 0.01% to about 99.5%, by weight, based on the total combined dry weight of meloxicam and the surface stabilizers.

U.S. Patent 10,471,067 contains the following independent claims:

> 1. An injectable pharmaceutical dosage form comprising: 30 mg of meloxicam, or a salt thereof, wherein the meloxicam is in the form of particles having an effective average particle size of less than or about 2000 nm; polyvinylpyrrolidone; sodium deoxycholate; sucrose; and water; wherein the dosage form does not comprise a combination of meloxicam and a vasomodulator.
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> 6. An injectable pharmaceutical dosage form consisting essentially of: 30 mg of meloxicam, or a salt thereof, wherein the meloxicam is in the form of particles having an effective average particle size of less than about 400 nm; polyvinylpyrrolidone; sodium deoxycholate; sucrose; and water.

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Axsome's AXS-07 drug product candidate (20 mg MoSEIC™ meloxicam/10 mg rizatriptan) is formulated into tablets for oral delivery. Axsome's New Drug Application for AXS-07 for the acute treatment of migraine is currently under review by the U.S. Food and Drug Administration.

The information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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: November 10, 2021

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