

**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 10, 2023**

**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.**

On February 10, 2023, Axsome Therapeutics, Inc. (the “Company”) received a Paragraph IV Certification Notice Letter (the “Notice Letter”) from Teva Pharmaceuticals, Inc. (“Teva”), providing notification to the Company that Teva has submitted an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture, use, or sell a generic version of Auvelity® (dextromethorphan HBr-bupropion HCl).

In the Notice Letter, Teva alleges that four of the patents listed in the FDA Orange Book for Auvelity, U.S. Patent Numbers 10,780,064; 10,925,842; 10,940,124; and 10,966,942, each of which expires in 2040, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission.

The Paragraph IV Certification does not challenge any of the remaining Orange Book listed patents for Auvelity which have expirations out to 2034.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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 13, 2023

By: /s/ Herriot Tabuteau, M.D.

Name: Herriot Tabuteau, M.D.

Title: President and Chief Executive Officer

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