
**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**

August 20, 2019
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.)

200 Broadway, 3rd Floor
New York, New York
(Address of principal executive offices)

10038
(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:

| <u>Title of each class:</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered:</u> |
|--|--------------------------|---|
| 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.

On August 20, 2019, Axsome Therapeutics, Inc. (the “Company”) issued a press release announcing that David Marek has been appointed as the Company’s Chief Commercial Officer, effective August 31, 2019. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release dated August 20, 2019. |

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: August 20, 2019

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



Axsome Therapeutics Appoints David Marek as Chief Commercial Officer

NEW YORK, August 20, 2019 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced the appointment of David Marek as Chief Commercial Officer, effective August 31, 2019. Mr. Marek joins Axsome from Amgen, where he was Vice President, and General Manager of Amgen’s Neuroscience business unit, and previously held executive positions at WebMD and at Saatchi & Saatchi Healthcare Advertising.

“As our innovative CNS pipeline rapidly matures towards four pivotal clinical trial readouts, and two potential NDA filings and product launches, we are pleased to welcome Dave to the Axsome team as Chief Commercial Officer,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “Dave’s expertise in both digital and traditional media, creative commercialization strategies, value and access, and new product launches, is an important addition to Axsome as we create and execute our commercial plans and continue our growth into a leading CNS biopharmaceutical company.”

At Amgen, Mr. Marek led the U.S. commercialization strategy and launch of Aimovig™ for migraine prevention, achieving industry-record launch performance for a biologic. Prior to heading the Neuroscience business unit, he was Vice President of Marketing of Amgen’s U.S. Inflammation and Nephrology business leading it to attain over \$9 billion in annual revenue. Before Amgen, Mr. Marek served as Executive Vice President, Consumer Services, and Commercial Strategy Officer of WebMD, one of the largest providers of healthcare digital content, and the top healthcare website by unique visitors. Prior to WebMD, Mr. Marek was the Managing Director of Saatchi & Saatchi Healthcare Advertising where he developed and implemented creative strategies to grow many of the most successful pharmaceutical brands. Mr. Marek began his career at Eli Lilly and Company, followed by AstraZeneca, where he served in a variety of marketing and sales roles of increasing responsibility. He earned his Bachelor of Arts degree in Business Administration from Washington State University.

“Axsome’s growing pipeline of clinically and mechanistically differentiated, late-stage product candidates for CNS conditions with high medical need exemplify its patient-centric approach to innovation,” said Mr. Marek. “I am excited to join Axsome at such a significant time as we approach multiple clinical trial readouts later this year, and I look forward to working with the rest of the team to bring our novel investigational medicines to patients as expediently and as efficiently as possible.”

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. Axsome’s core CNS product candidate portfolio includes four clinical-stage candidates, AXS-05, AXS-07, AXS-09, and AXS-12. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), a Phase 3 trial in major depressive disorder (MDD), and a Phase 2/3 trial in agitation associated with Alzheimer’s disease (AD). AXS-05 is also being developed for smoking cessation treatment. AXS-07 is currently in a Phase 3 trial for the acute treatment of migraine. AXS-12 is currently in a Phase 2 trial in narcolepsy. The Axsome Pain and Primary Care business unit (Axsome PPC) houses Axsome’s pain and primary care assets, including AXS-02 and AXS-06, and intellectual property which covers these and related product candidates and molecules being developed by Axsome and others. AXS-02 is being developed for osteoporosis, the pain of knee osteoarthritis, and chronic low back pain. AXS-06 is being developed for osteoarthritis and rheumatoid arthritis. AXS-02, AXS-05, AXS-06, AXS-07, AXS-09, and AXS-12 are investigational drug products not approved by the FDA. For more information, please visit the Company’s website at axsome.com. The Company may occasionally disseminate material, nonpublic information on the company website.

Forward Looking Statements

Certain matters discussed in this press release are “forward-looking statements”. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company’s statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, and the number or type of studies or nature of results necessary to support the filing of a new drug application (“NDA”) for any of our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates (including, but not limited to, FDA’s agreement with the Company’s plan to discontinue the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee’s recommendations); the potential for the ASCEND clinical trial to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; the Company’s ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company’s research and development programs and collaborations; the success of the Company’s license agreements; the acceptance by the market of the Company’s product candidates, if approved; the Company’s anticipated capital requirements, including the Company’s anticipated cash runway and the Company’s current expectations regarding its plans for future equity financings prior to the readout from its Phase 3 trials; and other factors, including general economic conditions and regulatory developments, not within the Company’s control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

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