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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**March 5, 2019**

Date of report (Date of earliest event reported)

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**Axsome Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37635**  
(Commission  
File Number)

**45-4241907**  
(IRS Employer  
Identification No.)

**25 Broadway, 9th Floor**  
**New York, New York**  
(Address of principal executive offices)

**10004**  
(Zip Code)

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

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

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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  x

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.  x

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## Item 1.01. Entry Into a Material Definitive Agreement.

On March 5, 2019, (the “Effective Date”), Axsome Therapeutics, Inc., a Delaware corporation (the “Company”), entered into a Loan and Security Agreement (the “Loan Agreement”) with (a) Silicon Valley Bank, a California corporation (“SVB”), in its capacity as administrative agent and collateral agent (“Agent”), (b) Silicon Valley Bank, a California corporation, as a lender, and (c) Westriver Innovation Lending Fund VIII, L.P., a Delaware limited partnership (“WestRiver”), as a lender. SVB and WestRiver are referred to herein collectively as the “Lenders.”

The Loan Agreement established a term loan facility in the aggregate principal amount of up to \$24,000,000 (the “Term Loan”). An initial \$20,000,000 (the “Term A Loan Advance”) was funded to the Company on the Effective Date. Availability of \$4,000,000 under the second term loan advance (the “Term B Loan Advance,” and together with the Term A Loan Advance, the “Loan Advances”) is conditioned upon the Company’s achievement of positive data, on or prior to August 15, 2019, with respect to the Company’s Phase 2 clinical trial for AXS-12, sufficient to submit a Phase 3 protocol to the U.S. Food and Drug Administration (“FDA”), provided that the Company has not received any objections from the FDA within thirty days after submission of such Phase 3 protocol (the “Milestone Event”). The Company may only request the Term B Loan Advance during the period commencing upon achievement of the Milestone Event and continuing through August 15, 2019. A portion of the Term A Loan Advance was used to satisfy the Company’s existing obligations under its previously disclosed term loan facility with SVB, and such obligations are considered fully repaid and extinguished.

The Loan Advances mature on February 1, 2023 and have an interest-only monthly payment period of 12 months after the Effective Date, which may be extended to 18 months upon receipt by the Company of the Term B Loan Advance. Following the interest-only payment period, the Company will begin making monthly payments of principal and interest until the maturity date. Interest will accrue on the unpaid principal balance of the outstanding Loan Advances at a floating per annum rate equal to the greater of (i) seven and one-half of one percent (7.50%) and (ii) two percent (2.0%) above the prime rate.

Subject to certain exceptions, the Loan Agreement contains covenants prohibiting the Company from, among other things: (a) conveying, selling, leasing, transferring or otherwise disposing of its properties or assets; (b) liquidating or dissolving; (c) engaging in any business other than the business currently engaged in or reasonably related thereto by it or any of its subsidiaries; (d) engaging in business combinations or acquisitions; (e) incurrence of additional indebtedness; (f) allowing any lien or encumbrance on any of its property; (g) paying any dividends; and (h) making payment on subordinated debt.

The Term Loan is secured by a first priority perfected security interest in substantially all of the assets of the Company, excluding (i) the intellectual property of the Company, (ii) any rights held under a license that are not assignable by their terms without the consent of the licensor thereof, and (iii) any interest greater than 65% of the issued and outstanding shares of capital stock owned by the Company of its Australian and Irish subsidiaries, whether currently owned or hereafter acquired. Under the Loan Agreement, the Company and its subsidiaries may not grant a security interest in their intellectual property to any party.

In connection with the Loan Agreement, the Company issued to each of SVB and WestRiver (each, a “Holder”) a warrant, dated March 5, 2019 (individually a “Warrant”, and collectively, the “Warrants”) to purchase shares of the Company’s common stock, \$0.0001 par value per share (the “Common Stock”) at a price per share equal to \$8.10. Each of the Warrants is exercisable for such number of shares of Common Stock as shall equal (i) 35,000, multiplied by (ii) a fraction, the numerator of which shall equal the aggregate amount of the Loan Advances then-tendered to the Company and the denominator of which shall equal \$24,000,000. The Warrants are exercisable until March 5, 2026 and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of Common Stock is greater than the exercise price then in effect.

The Company expects to file the form of Warrant and the Loan Agreement as exhibits to the Company’s next periodic filing. The foregoing descriptions of the Warrants and the Loan Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the form of Warrant and the Loan Agreement, when filed.

The full text of the press release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of the Registrant.**

The information set forth in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 2.03.

**Item 3.02. Unregistered Sales of Equity Securities.**

To the extent required by Item 3.02 of Form 8-K, the information regarding the Warrants set forth under Item 1.01 of this Form 8-K is incorporated by reference in this Item 3.02. The Company issued to each Holder a Warrant in reliance on the exemption from registration provided for under Section 4(a) (2) of the Securities Act of 1933, as amended (the "Securities Act"). The Company relied on this exemption from registration based in part on the representations made by each Holder, including the representations with respect to each Holder's status as an accredited investor, as such term is defined in Rule 501(a) of the Securities Act, and each Holder's investment intent.

**Item 8.01. Other Events.**

On March 6, 2019, the Company issued a press release announcing the signing of the Loan Agreement, and also provided a clinical trial update and a statement regarding its expected cash runway. 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	<a href="#">Press Release dated March 6, 2019</a>

**SIGNATURE**

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.**

Date: March 6, 2019

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



## Axsome Therapeutics Secures \$24 Million Growth Capital Loan Facility Led by Silicon Valley Bank

*\$46 million total raised in recent financings extends cash runway into at least 4Q 2021*

*Current financial position fully funds all five ongoing clinical trials*

NEW YORK, March 6, 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, has entered into a \$24 million growth capital term loan facility with Silicon Valley Bank (SVB) and WestRiver Innovation Lending Fund. Axsome received \$20 million at closing, and can draw the remaining \$4 million tranche, at its option, subject to the achievement of positive results from the Company's ongoing Phase 2 trial of AXS-12 in narcolepsy.

Axsome's recent financings total \$46 million, consisting of the initial \$20 million from the growth capital term loan, and \$26 million from the Company's at-the-market equity financings completed in January. Combined, these financings extend the Company's cash runway into at least the fourth quarter of 2021, based on current operating plans.

"This non-dilutive term loan complements our recently completed equity raises," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Together, these financings extend our cash runway well beyond the data readouts for our five ongoing clinical trials, in five different CNS indications, expected over the next several quarters. With our strengthened balance sheet, we are well positioned to continue advancing our portfolio of novel and differentiated investigational medicines, with the goal of providing effective new treatments that address the needs of patients living with serious CNS disorders."

The Company's resulting financial position fully funds all of its ongoing clinical trials beyond completion:

- **AXS-05**
  - **Treatment Resistant Depression:** The STRIDE-1 study is a Phase 3, multicenter, randomized, double-blind, controlled trial to assess the efficacy and safety of AXS-05 in patients with treatment resistant depression. To date, 95% of the target number of subjects have been randomized in this trial, and topline results are now anticipated in the second quarter of 2019.
  - **Alzheimer's Disease Agitation:** The ADVANCE-1 study is a Phase 2/3, multicenter, randomized, double-blind, controlled trial to evaluate the efficacy and safety of AXS-05 in patients with agitation associated with Alzheimer's disease. To date, just over 40% of the target number of subjects have been randomized in this trial, and full topline results are anticipated in the first half of 2020.
  - **Smoking Cessation:** AXS-05 is being evaluated in a Phase 2, randomized, double-blind, controlled trial for smoking cessation treatment, that is being conducted under a research collaboration between Duke University and Axsome. To date, 95% of the target number of subjects have been randomized in this trial, and topline results are now anticipated in the second quarter of 2019.
- **AXS-07**
  - **Migraine:** The MOMENTUM study is a Phase 3, randomized, double-blind, multicenter, controlled trial to assess the efficacy and safety of AXS-07 in the acute treatment of migraine. Enrollment in this trial has recently been initiated, and topline results are anticipated in the first quarter of 2020.
- **AXS-12**
  - **Narcolepsy:** The CONCERT study is a Phase 2, double-blind, randomized, placebo-controlled, crossover, multicenter trial of AXS-12 in patients with narcolepsy. Enrollment in this trial has recently been initiated, and topline results are anticipated in the second quarter of 2019.

Under terms of the new growth capital term loan agreement, a portion of the proceeds will be used to repay the Company's existing \$5.6 million principal loan balance with SVB and the associated \$0.85 million final payment. The new loan bears interest at an annual rate equal to the greater of (a) the prime rate plus 2.00% or (b) 7.50%. It matures in February 2023 and has an interest-only payment period of 12 months, which may be extended to 18

months upon the drawing of the second tranche. Axsome will issue warrants to purchase 70,000 shares of Axsome common stock, which will be earned based upon the usage of the facility. Additional details of the loan agreement, will be filed with the Securities and Exchange Commission on a Current Report on Form 8-K.

### **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 2/3 trial in agitation associated with Alzheimer's disease (AD), a Phase 2 trial in Major Depressive Disorder (MDD), and a Phase 2 trial in smoking cessation. AXS-07 is currently in a Phase 3 trial for the acute treatment of migraine. AXS-12 is being developed for the treatment of the symptoms of narcolepsy. The Axsome Pain and Primary Care business unit (Axsome PPC) houses Axsome's pain and primary care assets, including AXS-02 and AX-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](http://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". The Company 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 the Company's ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation, interim analyses and completion of the trials, futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company's ongoing clinical trials; the Company's ability to fund additional clinical trials to continue the advancement of its product candidates; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its product candidates; the Company's expected cash runway; 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; 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.

### **Axsome Contact:**

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