# 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**

**March 1, 2021**
Date of report (Date of earliest event reported)

# 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**<br>**New York, New York**<br>(Address of principal executive offices) | **10007**<br>(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:**

| **Title of each class:** | **Trading Symbol(s)** | **Name of each exchange on which registered:** |
|---|---|---|
| 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 2.02 Results of Operations and Financial Condition.**

On March 1, 2021, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2020 and provided an update on the Company's operations. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated March 1, 2021. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**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: March 1, 2021

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

AXSOME THERAPEUTICS

**Axsome Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update**

*Company to host conference call today at 8:00 AM Eastern*

NEW YORK, March 1, 2021 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today reported financial results for the fourth quarter and year ended December 31, 2020.

“The focused execution of the Axsome team made 2020 a year of significant accomplishments. We had successful pre-NDA meetings with the FDA for AXS-05 in major depressive disorder and for AXS-07 in migraine, reported positive results from the pivotal ADVANCE-1 trial of AXS-05 in Alzheimer’s disease agitation, initiated the second pivotal trial of AXS-05 in this indication, received two new FDA Breakthrough Therapy designations, and built out our commercialization infrastructure,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “So far this year, we have submitted to the FDA the NDA for AXS-05 in major depressive disorder, and are nearing submission of the NDA for AXS-07 in the acute treatment of migraine, which is expected early in the second quarter. Our focus for the remainder of the year will be on the regulatory activities surrounding these NDAs, launch readiness to ensure a successful transition to commercialization, assuming product approvals, and continued advancement of the rest of our differentiated late-stage CNS pipeline.”

**Business Update**

For the many people living with serious CNS disorders, Axsome accelerates the invention and development of life-changing medicines. The Company is developing a portfolio of differentiated, patent-protected, CNS product candidates with four in active clinical development.

***CNS Pipeline***

- **AXS-05:** AXS-05 (dextromethorphan-bupropion) is Axsome’s novel, oral, investigational NMDA receptor antagonist with multimodal activity being developed for the following indications: major depressive disorder (MDD), Alzheimer’s disease (AD) agitation, and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designations for MDD, and for AD agitation.

  **Depression:** Axsome has submitted a New Drug Application (NDA) to the FDA for AXS-05 for the treatment of MDD. The Company intends to issue a press release following the FDA's decision on the filing of the application.

  In December 2020, Axsome announced positive results from the COMET Phase 3 long-term trial in patients with MDD and the three Phase 2 open-label MDD efficacy trials in patients who had failed one prior antidepressant (COMET-AU), patients who had failed two prior antidepressants (COMET-TRD), and patients with suicidal ideation. Patients treated with AXS-05 in these trials experienced rapid, substantial, and durable improvement in depressive symptoms and functional impairment that was sustained over the 12-month treatment period. AXS-05 was well tolerated over the long-term treatment period with a safety profile consistent with that observed in the previously reported controlled trials.

  **AD Agitation:** In December 2020, Axsome initiated the ACCORD study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter, randomized withdrawal trial to evaluate the efficacy and safety of AXS-05 in the treatment of Alzheimer’s disease (AD) agitation.

  **Smoking Cessation:** Axsome is scheduled to meet with the FDA in the third quarter of 2021 to discuss the continued clinical development of AXS-05 as an aid to smoking cessation treatment. Axsome previously announced positive results from a Phase 2 trial of AXS-05 for smoking cessation treatment conducted under a research collaboration between Axsome and Duke University.

- **AXS-07:** AXS-07 (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for the acute treatment of migraine.

  **Migraine:** Axsome is compiling the NDA for AXS-07 for the acute treatment of migraine. Submission of this NDA is expected in early second quarter.

  In December 2020, Axsome announced positive results from the MOVEMENT Phase 3 long-term trial of AXS 07 in the acute treatment of migraine. In this trial, treatment with AXS-07 resulted in rapid, substantial, and durable relief of migraine pain and associated symptoms. AXS-07 was well tolerated over the 12-month treatment period with a safety profile consistent with that observed in the previously reported controlled trials.

- **AXS-12:** AXS-12 (reboxetine) is Axsome's novel, oral, potent, and highly selective norepinephrine reuptake inhibitor for the treatment of narcolepsy. AXS-12 has been granted FDA Orphan Drug designation for the treatment of narcolepsy as well as Breakthrough Therapy designation for the treatment of cataplexy in patients with narcolepsy.

  **Narcolepsy:** Axsome is planning to initiate a Phase 3 trial of AXS-12 in the treatment of narcolepsy in the second quarter. The planned Phase 3 trial will be a randomized, double-blind, placebo-controlled, parallel-group study.

- **AXS-14:** AXS-14 (esreboxetine) is Axsome's novel, oral, potent, and highly selective norepinephrine reuptake inhibitor for the treatment of fibromyalgia. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine.

  **Fibromyalgia:** Axsome is scheduled to meet with the FDA in the second quarter, to discuss the further clinical development of AXS-14 for the treatment of fibromyalgia. AXS-14 has previously met the primary endpoints and demonstrated positive and statistically significant results in a Phase 3 and in a Phase 2 trial for the treatment of fibromyalgia.

***Commercial***

- Launch readiness activities continue to advance and all functional commercial leadership is in place. Sales force structure and design have been finalized and the hiring of sales managers and representatives is expected to commence in the coming months. The infrastructure for Axsome's proprietary DCC™, or digital centric commercialization, platform is in place, and payer engagement activities have started.

***Corporate***

- In January 2021, Axsome appointed Kevin Laliberte, PharmD, as Executive Vice President, Product Strategy. Prior to Axsome, Dr. Laliberte was Senior Vice President, Product Development at Dova Pharmaceuticals. Prior to Dova, he was Senior Vice President, Product Development and Clinical Operations at United Therapeutics, where he was responsible for all development activities for small molecules. Dr. Laliberte earned his Doctor of Pharmacy degree from the University of Michigan, Ann Arbor and completed his post doctorate fellowship at the University of North Carolina, Chapel Hill and GlaxoSmithKline.

**Anticipated Milestones**

- **NDA Submissions:**
  - AXS-07 for the acute treatment of migraine, submission (early 2Q 2021)
- **Clinical Trial Readouts:**
  - Phase 2 MERIT trial of AXS-05 in TRD, topline data (2H 2021)

- **Clinical Trial Initiations:**
    - Phase 3 trial of AXS-12 in the treatment of narcolepsy (2Q 2021)
- **FDA Meetings:**
    - AXS-14 for fibromyalgia (2Q 2021)
    - AXS-05 for smoking cessation (3Q 2021)

**Fourth Quarter 2020 Financial Results**

- **Research and development (R&D) expenses:** R&D expenses were $17.4 million for the quarter ended December 31, 2020 and $19.2 million for the comparable period in 2019. The decrease was due to the completion of our Phase 3 efficacy and safety trials for AXS-05 and AXS-07. R&D expenses for the year ended December 31, 2020 were $70.2 million, compared to $53.6 million for the comparable period in 2019. The increase was primarily due to a one-time upfront charge related to our licensing agreement with Pfizer along with costs associated with NDA preparations.
- **General and administrative (G&A) expenses:** G&A expenses were $10.4 million for the quarter ended December 31, 2020 and $5.2 million for the comparable period in 2019. The increase was primarily due to increased personnel costs, mainly associated with stock compensation expense, along with the build-out of the commercial function. G&A expenses for the year ended December 31, 2020 were $28.9 million, compared to $13.6 million for the comparable period in 2019. The increase was primarily due to an increase in stock compensation expense along with the build-out of the commercial function.
- **Net loss:** Net loss was $29.2 million, or $(0.78) per share for the quarter ended December 31, 2020 compared to a net loss of $24.8 million, or $(0.71) per share for the comparable period in 2019. Net loss for the year ended December 31, 2020 was $102.9 million, or $(2.77) per share, of which $22.3 million were non-cash charges including stock compensation expense. Net loss for the year ended December 31, 2019 was $68.3 million, or $(2.01) per share, of which $6.1 million were non-cash charges consisting of stock compensation expense.
- **Cash:** At December 31, 2020, Axsome had $183.9 million of cash compared to $220.0 million at December 31, 2019.
- **Shares outstanding:** At December 31, 2020, Axsome had 37,374,088 shares of common stock outstanding.

**Financial Guidance**

- Axsome expects that its operating expenses will increase year over year in 2021 to support continued pipeline advancement and build-out of the commercial function.
- Axsome believes that its cash at December 31, 2020, along with the remaining committed capital from the $225 million term loan facility, is sufficient to fund anticipated operations, based on the current operating plan which includes costs for the commercial launch of AXS-05 in MDD and AXS-07 in migraine, into at least 2024.

**Conference Call Information**

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss fourth quarter and full year 2020 financial results as well as to provide a corporate update. To participate in the live conference call, please dial (866) 393-4306 (toll-free domestic) or (734) 385-2616 (international), and use the conference ID 3782547. The live webcast can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com. A replay of the webcast will be available for approximately 30 days following the live event.

**About Axsome Therapeutics, Inc.**

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. For the many people facing unsatisfactory treatments for CNS disorders, Axsome accelerates the invention and adoption of life-changing medicines. Axsome's core CNS product candidate portfolio includes five clinical-stage candidates, AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14. AXS-05 is being developed for major depressive disorder (MDD), Alzheimer's disease (AD) agitation, and as a treatment for smoking cessation. AXS-07 is being developed for the acute treatment of migraine. AXS-12 is being developed for the treatment of narcolepsy. AXS-14 is being developed for fibromyalgia. AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14 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, whether the FDA will accept and subsequently approve of the Company's NDA submission for AXS-05 in MDD and the timing of such approval, and whether the FDA will agree with the Company's discontinuation of the bupropion treatment arm of the ADVANCE study in accordance with the independent data monitoring committee's recommendations); the successful submission of and approval by the FDA of an NDA for AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment for the MOMENTUM clinical trial; the potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, 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 amount of capital required for the Company's commercial launch of its product candidates, and the potential impact on the Company's anticipated cash runway; as well as unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19; 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 Therapeutics, Inc.**
**Selected Consolidated Financial Data**

**Statements of Operations Information:**

| | Three months ended December 31, | | Twelve months ended December 31, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Operating expenses: | | | | |
| Research and development | $ 17,384,729 | $ 19,205,271 | $ 70,244,579 | $ 53,647,067 |
| General and administrative | 10,359,507 | 5,222,899 | 28,896,749 | 13,598,030 |
| Total operating expenses | 27,744,236 | 24,428,170 | 99,141,328 | 67,245,097 |
| Loss from operations | (27,744,236) | (24,428,170) | (99,141,328) | (67,245,097) |
| Interest and amortization of debt discount (expense) | (1,473,989) | (378,814) | (2,565,838) | (1,239,537) |
| Tax Credit | 53,578 | — | 53,578 | 139,448 |
| Loss on extinguishment of debt | — | — | (1,247,012) | — |
| Net loss | $ (29,164,647) | $ (24,806,984) | $ (102,900,600) | $ (68,345,186) |
| Net loss per common share, basic and diluted | $ (0.78) | $ (0.71) | $ (2.77) | $ (2.01) |
| Weighted average common shares outstanding, basic and diluted | 37,351,117 | 34,757,910 | 37,206,928 | 34,020,257 |

**Balance Sheet Information:**

| | **December 31, 2020** | **December 31, 2019** |
|---|---|---|
| Cash and cash equivalents | $ 183,876,453 | $ 219,966,167 |
| Total assets | 186,134,323 | 220,549,760 |
| Loan payable, current and long-term | 48,321,848 | 19,934,918 |
| Accumulated deficit | (278,796,093) | (175,895,493) |
| Stockholders' equity | $ 113,792,909 | $ 178,722,389 |

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