
**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 9, 2016

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.)

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)

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)).
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Item 2.02. Results of Operations and Financial Condition

On August 9, 2016, Axsome Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended June 30, 2016 and 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 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 Number | Description |
|---------------------------|-------------------------------------|
| 99.1 | Press release dated August 9, 2016. |

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 9, 2016

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

Name: Herriot Tabuteau, M.D.

Title: Chief Executive Officer



Axsome Therapeutics Reports Second Quarter 2016 Financial Results

NEW YORK, August 9, 2016 (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 reported financial results for the second quarter ended June 30, 2016.

“In the second quarter we continued to advance our three ongoing Phase 3 trials, and we expanded our late-stage pipeline with the receipt of positive FDA guidance on our development plans for AXS-05 in Alzheimer’s agitation,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome Therapeutics. “Based on this guidance, we look forward to filing an IND for a Phase 2/3 trial in this indication by year end.”

Second Quarter Highlights

- Received Pre-Investigational New Drug Application (Pre-IND) written guidance from the U.S. Food and Drug Administration (FDA) on AXS-05 for agitation in patients with Alzheimer’s disease.
- Received Fast Track designation from the FDA for AXS-02 for the pain of knee osteoarthritis (OA) associated with bone marrow lesions (BMLs).
- Added to the broad-market Russell 3000® and small-cap Russell 2000® Indexes, as part of the Russell U.S. Indexes annual reconstitution.

Second Quarter 2016 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were \$5.3 million for the quarter ended June 30, 2016 compared to \$1.6 million for the comparable period in 2015. The increase in R&D expenses was primarily due to the conduct of our Phase 3 clinical trials in complex regional pain syndrome (the CREATE-1 Study), treatment resistant depression (the STRIDE-1 Study), and knee OA associated with BMLs (the COAST-1 Study).
- **General and administrative (G&A) expenses:** G&A expenses were \$1.5 million for the quarter ended June 30, 2016 compared to \$0.5 million for the comparable period in 2015. The increase in G&A expenses was primarily due to external fees associated with operating as a public company, as well as an increase in personnel costs and stock compensation expense.
- **Net loss:** Net loss was \$6.8 million, or \$(0.36) per share for the quarter ended June 30, 2016, compared to a net loss of \$2.1 million, or \$(0.19) per share for the quarter ended June 30, 2015.
- **Cash:** As of June 30, 2016, Axsome had \$38.8 million of cash compared to \$48.0 million of cash as of December 31, 2015. Axsome currently anticipates that its cash will be sufficient to fund its anticipated operations into the third quarter of 2017.
- **Shares outstanding:** At June 30, 2016, Axsome had 19,149,417 shares of common stock outstanding.

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, including pain, for which there are limited existing treatment options. Axsome’s product candidate portfolio includes two late-stage candidates, AXS-02 and AXS-05. AXS-02 is currently in Phase 3 trials in complex regional pain syndrome (CRPS) and knee osteoarthritis (OA) associated with bone marrow lesions (BMLs) with an additional Phase 3 trial planned in chronic low back pain (CLBP) associated with Modic changes (MCs). AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), and a Phase 2/3 trial in agitation in patients with Alzheimer’s disease (AD) is planned. AXS-02 and AXS-05 are investigational product candidates not approved by the FDA. For more information, please visit the company website at www.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 and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; 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 Therapeutics, Inc. Selected Consolidated Financial Data

Statements of Operations Information (unaudited):

| | <u>Three Months Ended June 30,</u> | | <u>Six Months Ended June 30,</u> | |
|--|------------------------------------|-----------------------|----------------------------------|-----------------------|
| | <u>2016</u> | <u>2015</u> | <u>2016</u> | <u>2015</u> |
| Operating expenses: | | | | |
| Research and development | \$ 5,298,060 | \$ 1,628,394 | \$ 9,824,312 | \$ 3,044,677 |
| General and administrative | 1,529,220 | 456,410 | 2,885,833 | 973,250 |
| Total operating expenses | <u>6,827,280</u> | <u>2,084,804</u> | <u>12,710,145</u> | <u>4,017,927</u> |
| Loss from operations | (6,827,280) | (2,084,804) | (12,710,145) | (4,017,927) |
| Interest and other income (expense) | 15,090 | (211,062) | 32,014 | (339,843) |
| Change in fair value of warrant liability | — | 16,572 | — | 17,442 |
| Change in fair value of embedded derivative liabilities | — | 149,900 | — | 70,800 |
| Net loss | <u>\$ (6,812,190)</u> | <u>\$ (2,129,394)</u> | <u>\$ (12,678,131)</u> | <u>\$ (4,269,528)</u> |
| Net loss per common share — basic and diluted | <u>\$ (0.36)</u> | <u>\$ (0.19)</u> | <u>\$ (0.66)</u> | <u>\$ (0.38)</u> |
| Weighted average common shares outstanding — basic and diluted | <u>19,149,417</u> | <u>11,108,144</u> | <u>19,149,417</u> | <u>11,108,144</u> |

Balance Sheet Information:

| | <u>June 30, 2016</u> | <u>December 31, 2015*</u> |
|----------------------|----------------------|---------------------------|
| | (unaudited) | |
| Cash | \$ 38,751,750 | \$ 48,036,260 |
| Total assets | 40,007,913 | 49,076,156 |
| Accumulated deficit | (33,117,929) | (20,439,798) |
| Stockholders' equity | \$ 34,904,355 | \$ 46,444,261 |

*Condensed from audited financial statements.

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