

**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): March 25, 2022

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 1.01 Entry into a Material Definitive Agreement.

Acquisition of Assets of Jazz Pharmaceuticals

On March 25, 2022, the Company entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Jazz Pharmaceuticals plc, a public limited liability corporation organized under the laws of Ireland (“Jazz Pharmaceuticals”), pursuant to which the Company will acquire Sunosi® (the “Product”) from Jazz Pharmaceuticals (the “Acquisition”), a dual-acting dopamine and norepinephrine reuptake inhibitor indicated to improve wakefulness in adult patients living with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea, which was approved by the U.S. Food and Drug Administration (“FDA”) in 2019 and by the European Medicines Agency (the “EMA”) in 2020.

Pursuant to the Purchase Agreement, the Company agreed to (i) purchase the Product in consideration for an aggregate initial purchase price of \$50,000,000 plus \$3,000,000 as payment for the certain specified inventory to be transferred to the Company; (ii) assume certain liabilities in connection with the Acquisition; and (iii) make non-refundable, non-creditable royalty payments to Jazz Pharmaceuticals equal to a (A) high-single digit royalty for any Current Indication (as defined the Purchase Agreement), or (B) mid-single digit royalty for any Future Indication (as defined in the Purchase Agreement), of Net Sales (as defined in the Purchase Agreement) in the U.S. Territory (as defined in the Purchase Agreement) made during the applicable Royalty Term (as defined in the Purchase Agreement). There are no royalty payments due for Net Sales outside of the U.S. Territory.

The Company will also assume the commitments of Jazz Pharmaceuticals to SK Biopharmaceuticals (“SK”) and Aerial Biopharma (“Aerial”). SK is the originator of the Product and retains rights in twelve Asian markets, including China, Korea, and Japan. In 2014, Jazz Pharmaceuticals acquired from Aerial worldwide rights to the Product excluding those Asian markets. The assumed commitments to SK and Aerial include single-digit tiered royalties based on the Company’s sales of the Product, and up to \$165 million in revenue milestones and \$1 million in development milestones.

In connection with the Acquisition and on the terms and conditions set forth in the Purchase Agreement, Jazz Pharmaceuticals will sell, convey, transfer, assign and deliver to the Company, at an initial closing, all right, title and interest of Jazz Pharmaceuticals and its affiliates to the following assets related exclusively to the Product, including certain: (i) specified U.S. intellectual property rights, including certain patent rights, trademark rights, domain names and the associated goodwill; (ii) specified contracts, including any purchase orders issued thereunder; (iii) patent files; (iv) packaging materials, finished product inventories and product samples, work-in-process inventories, active pharmaceutical ingredients and other raw materials; (v) clinical and pre-clinical data; (vi) claims of Jazz Pharmaceuticals against third parties; (vii) labeling, informational letters, sales training materials, trade show materials, advertising, marketing, sales, artwork and promotional materials; and (viii) medical affairs collateral that is reasonably available to and in the physical possession of or under the control of Jazz Pharmaceuticals. The Company will also receive the right, title and interest to the FDA Product approval. At a second closing, the Company will acquire ex-U.S. Sunosi assets, including the marketing authorization from the EMA and United Kingdom’s Medicines and Healthcare Products Regulatory Agency.

The Purchase Agreement contains customary representations and warranties of a transaction of this type that the parties made to, and are solely for the benefit of, each other. Investors and security holders should not rely on the representations and warranties as characterizations of the actual facts because they were made only as of the date of the Purchase Agreement. Moreover, information concerning the subject matter of such representations and warranties may change after the date of the Purchase Agreement, which subsequent information may or may not be fully reflected in public disclosures.

The Purchase Agreement provides for an initial closing of the assets in the U.S. Territory within three business days after satisfaction of closing conditions, with Purchaser having the right to not close sooner than forty (40) days of signing the Purchase Agreement (with a right to extend by an additional five days), and a sequential closing of the assets in the ex-U.S. Territory within sixty (60) days of the U.S. closing. The Purchase Agreement also provides for customary conditions to closing, including the receipt of antitrust approval from the Federal Trade Commission pursuant to the Hart-Scott-Rodino Act, and the receipt of certain required financial statements from Jazz Pharmaceuticals required by Regulation S-X of the Securities Exchange Act of 1934, as amended. Axsome has also agreed to extend employment offers to certain U.S. employees of the Sunosi business prior to the initial closing. The Purchase Agreement also provides for customary termination provisions.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the complete terms and conditions of the Purchase Agreement to be filed as an exhibit to an amendment to this Current Report on Form 8-K to be filed with the SEC.

Second Amendment to the Loan and Security Agreement

On March 27, 2022, in connection with the Acquisition (as described below), Axsome Therapeutics Inc., a Delaware corporation (the “Company”), entered into a Second Amendment to Loan and Security Agreement (the “Second Amendment”) with Hercules Capital, Inc., a Maryland corporation (“Hercules”), in its capacity as administrative agent and collateral agent, and the other financial institutions or entities party thereto as lenders (the “Lenders”). The Second Amendment amended the terms of that certain Loan and Security Agreement, dated as of September 25, 2020, by and among the Company, Hercules and the Lenders (as amended by that certain First Amendment to Loan and Security Agreement, dated as of October 14, 2021, and as further amended by the Second Amendment, the “Loan Agreement”) to, among other things, (i) reflect the terms of the Acquisition (as defined below); (ii) subject to the terms and conditions in the Loan Agreement, change the Term Loan Advance (as defined in the Loan Agreement) amounts and dates available under Tranche 1 through Tranche 5, including increasing the Tranche 1 Advance (as defined in the Loan Agreement) from \$60,000,000 to \$95,000,000, changing the Tranche 2 Advances (as defined in the Loan Agreement) from two sub-tranches of \$50,000,000 each to three sub-tranches of \$35,000,000, \$35,000,000 and \$30,000,000, respectively, changing the Tranche 3 Advance (as defined in the Loan Agreement) from one tranche of \$20,000,000 to two sub-tranches of \$15,000,000 and \$5,000,000, respectively, decreasing the Tranche 4 Advance (as defined in the Loan Agreement) from \$55,000,000 to \$50,000,000, and decreasing the Tranche 5 Advance (as defined in the Loan Agreement) from \$75,000,000 to \$35,000,000; (iii) modify the interest rate (a floating rate based on the greater of (a) 8.95% or (b) US WSJ Prime + 5.70%) to not exceed 10.70%; and (iv) change the minimum cash requirement of the Company from \$15,000,000 (plus certain accounts payable amounts) to \$40,000,000 (plus certain accounts payable amounts), provided that upon U.S. Food and Drug Administration (the “FDA”) approval of the Company’s AXS-05 product candidate for the treatment of major depressive disorder, the minimum cash requirement shall be \$25,000,000 (plus certain accounts payable amounts). In connection with the Second Amendment, the parties also clarified certain terms of the Warrant Agreement previously issued to Hercules. The Second Amendment shall only be effective upon the closing of the Acquisition.

Conditioned upon the closing of the Second Amendment, Agent will also purchase between \$5,000,000 and \$8,000,000 of the Company’s unregistered common stock, at a share price equal to the lesser of (a) the three-day volume weighted average price as of the date of the Second Amendment, or (b) the three-day volume weighted average price as of the Second Amendment Effective Date, pursuant to a stock purchase agreement to be agreed upon by the parties; provided, that, in no case shall the share price be less than a 20% discount to the three-day volume weighted average price of the Company’s common stock at the time of the purchase.

The foregoing description of the Second Amendment does not purport to be complete and is qualified in its entirety by reference to the complete terms and conditions of the Second Amendment to be filed as an exhibit to the Company’s next Form 10-Q to be filed with the Securities and Exchange Commission (the “SEC”).

Item 8.01 Other Events.

On March 28, 2022, the Company issued a press release announcing the Acquisition, and the Company will post a copy of a presentation regarding the Acquisition on the Company’s website. A copy of the press release is attached hereto as Exhibit 99.1, and a copy of the presentation is attached hereto as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 28, 2022.
99.2	Acquisition Presentation dated March 28, 2022.
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 thereunto duly authorized.

Axsome Therapeutics, Inc.

Date: March 28, 2022

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



Axsome Therapeutics to Acquire Sunosi® from Jazz Pharmaceuticals, Expanding Axsome's Leadership in Neuroscience

Sunosi is the first and only dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) approved by the FDA to improve wakefulness in adults living with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea

Acquisition accelerates Axsome's transformation into a global commercial entity ahead of potential near-term launches of AXS-05 in major depressive disorder (MDD) and AXS-07 in migraine

Highly synergistic with Axsome's existing neuroscience portfolio and Digital Centric Commercialization™ (DCC) platform

Anticipated long-lived exclusivity for Sunosi with potential for significant additional indications

Immediately revenue generating, and expected to be breakeven to operating plan in 2023, and substantially accretive thereafter

Company to host conference call today at 8:00 AM ET

NEW YORK, March 28, 2022 (GLOBE NEWSWIRE) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced that the Company has entered into a definitive agreement to acquire Sunosi® (solriamfetol) from Jazz Pharmaceuticals (NASDAQ: JAZZ). Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA).

Upon closing, the transaction will accelerate Axsome's transition to a global commercial entity, leverage Axsome's first-in-class Digital Centric Commercialization™ platform ahead of potential near-term launches of AXS-05 in depression and AXS-07 in migraine, and strengthen Axsome's industry-leading neuroscience portfolio.

Sunosi was approved by the U.S. Food and Drug Administration (FDA) in 2019 and by the European Medicines Agency (EMA) in 2020. Sunosi is the first and only DNRI approved to treat EDS in adults living with narcolepsy or OSA. Sunosi net sales were \$57.9 million in 2021, representing year-over-year growth of 104%. In addition to further growth potential in the current indication for Sunosi, there are opportunities to pursue new high-value indications in psychiatry and neurology.

"This acquisition immediately transforms Axsome into a global commercial entity, upon closing, and accelerates our growth as a premier biopharmaceutical company focused on delivering potentially life-changing medicines to people living with serious CNS conditions," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Sunosi has demonstrated clinically meaningful efficacy, possesses a unique mechanism of action, and has generated positive patient and physician feedback. We are excited by its significant growth potential and excellent strategic fit with the Axsome portfolio. Furthermore, the addition of Sunosi augments and accelerates our commercial preparedness ahead of the potential near-term launches of our two existing lead assets, AXS-05 and AXS-07, and allows us to fully leverage our first-in-class Digital Centric Commercialization™ platform with three complementary assets. We are committed to ensuring uninterrupted patient access to Sunosi during the transition period and look forward to building on the strong foundation for Sunosi laid by Jazz."

"In assessing the overall treatment landscape, we determined Axsome would be well positioned to maximize the value of Sunosi, both to patients and to Jazz. Axsome is well placed to leverage its complementary commercial business to ensure Sunosi can effectively reach those who can benefit from this important medicine," said Bruce Cozadd, Chief Executive Officer of Jazz. "Further, we believe Axsome's track record of clinical development provides a promising foundation for the exploration of Sunosi in additional indications."

Sunosi Transaction Rationale

- **Adds a High-potential Commercial Asset to Axsome's Industry-leading, Late-stage Neuroscience Portfolio:** The acquisition of Sunosi immediately transforms Axsome into a global commercial entity upon closing. Sunosi complements Axsome's existing neuroscience portfolio led by AXS-05 for major depressive disorder (MDD) and AXS-07 for migraine, both of which are undergoing NDA reviews with anticipated FDA actions this year. The transaction positions Axsome to potentially make three important new medicines available in 2022 to patients living with CNS disorders.

Sunosi has high clinical and commercial potential based on 1) its well-established and clinically meaningful efficacy in EDS associated with narcolepsy and OSA, 2) consistent positive feedback from patients, health care professionals, and providers, 3) potential for rapid development in new indications, and 4) patent expiries out to 2040 before potential extensions. Based on further growth potential in the current indication, and potential new indications, the Company estimates peak revenue potential of greater than \$1 billion for Sunosi.

- **Highly Synergistic with Axsome's Therapeutic Focus and First-in-class Digital Centric Commercialization™ (DCC) Platform:** Sunosi is highly synergistic with Axsome's anticipated commercialization of AXS-05 for depression and AXS-07 for migraine based on the overlap of these conditions with EDS, and complementary prescriber call points. Depression and migraine patients have among the highest prevalence of clinically significant EDS (37%-50%)^{1,2}, and neurologists and psychiatrists are among the key prescribers for wake-promoting agents (40% of prescriptions)³.

Axsome's first-in-class DCC platform has been designed to optimize physician targeting and engagement, and promotional spend. The DCC platform and Axsome's therapeutic focus will allow for increased reach to key Sunosi prescriber groups.

- **Anticipated to Deliver Substantial Shareholder Value:** Sunosi will be immediately revenue generating upon closing, and is expected to be breakeven to Axsome's operating plan in 2023 and substantially accretive thereafter.

Transaction Details

Under the terms of the agreement, Axsome will receive from Jazz worldwide commercial, development, manufacturing, and intellectual property rights to Sunosi, except for certain Asian markets. Jazz will receive from Axsome a total upfront payment of \$53 million, a high single-digit royalty on Axsome's U.S. net sales of Sunosi in the current indication and a mid-single-digit royalty on Axsome's U.S. net sales of Sunosi in future indications.

Axsome will also assume the commitments of Jazz to SK Biopharmaceuticals (SK) and Aerial Biopharma (Aerial). SK is the originator of Sunosi and retains rights in 12 Asian markets, including China, Korea, and Japan. In 2014, Jazz acquired from Aerial worldwide rights to Sunosi excluding those Asian markets. The assumed commitments to SK and Aerial include single-digit tiered royalties based on Axsome sales of Sunosi, and up to \$165 million in revenue milestones and \$1 million in development milestones.

Financing

Axsome expects to finance the transaction via its existing \$300 million term loan facility with Hercules Capital, Inc.

Closing Conditions

The transaction has been unanimously approved by Axsome's Board of Directors, and is subject to customary closing conditions, including the expiration or termination of the waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976. The transaction is structured to be completed in sequential closings for the U.S. and ex-U.S. territories. Subject to the satisfaction or waiver of the closing conditions, the companies expect the U.S. transaction to close in the second quarter of 2022, and the ex-U.S. transaction to close within 60 days following the U.S. transaction close.

Additional Information

Axsome intends to file a Form 8-K with the SEC on the same day as this press release. The disclosure in this press release is subject to any additional details contained in such Form 8-K. Investors and stockholders are encouraged to read the Form 8-K.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss the acquisition of Sunosi. To participate in the live conference call, please dial (844) 200-6205 (toll-free domestic) or (929) 526-1599 (international) and use the conference ID 015166. 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.

Advisors

DLA Piper LLP acted as legal counsel to Axsome.

About Sunosi® (solriamfetol)

Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor shown to improve wakefulness in adults living with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA). Sunosi received U.S. Food and Drug Administration approval on March 20, 2019 to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA and was designated a Schedule IV medicine by the U.S. Drug Enforcement Agency on June 17, 2019. SK Biopharmaceuticals Co., Ltd., the discoverer of the compound, maintains rights in 12 Asian markets, including Korea, China and Japan. Sunosi has orphan drug designation for narcolepsy in the United States.

Important Safety Information

SUNOSI (solriamfetol) is available in 75 mg and 150 mg tablets and is a federally controlled substance (C-IV) because it contains solriamfetol that can be a target for people who abuse prescription medicines or street drugs. Keep SUNOSI in a safe place to protect it from theft. Never give or sell your SUNOSI to anyone else, because it may cause death or harm them and it is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Before taking SUNOSI, tell your doctor about all of your medical conditions, including if you:

- have heart problems, high blood pressure, kidney problems, diabetes, or high cholesterol
- have had a heart attack or a stroke
- have a history of mental health problems (including psychosis and bipolar disorders), or of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant. It is not known if SUNOSI will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if SUNOSI passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SUNOSI.

What are the possible side effects of SUNOSI?

SUNOSI may cause serious side effects, including:

- **Increased blood pressure and heart rate.** SUNOSI can cause blood pressure and heart rate increases that can increase the risk of heart attack, stroke, heart failure, and death. Your doctor should check your blood pressure before and during treatment with SUNOSI. Your doctor may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure that does not go away during treatment with SUNOSI.
- **Mental (psychiatric) symptoms including anxiety, problems sleeping (insomnia), irritability, and agitation.** Tell your doctor if you develop any of these symptoms. Your doctor may change your dose or tell you to stop taking SUNOSI if you develop side effects during treatment with SUNOSI.

The most common side effects of SUNOSI include:

- headache
- decreased appetite
- problems sleeping
- nausea
- anxiety

These are not all the possible side effects of SUNOSI. Call your doctor for advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please find full prescribing information here: <https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf>

About Obstructive Sleep Apnea and Excessive Daytime Sleepiness

Obstructive sleep apnea, commonly referred to as sleep apnea, is a highly prevalent disease (as high as 14% in men and 5% in women) in which excessive daytime sleepiness is a major presenting complaint in many cases. Positive Airway Pressure (PAP) therapy, with its most common form being Continuous Positive Airway Pressure (CPAP), has been shown to be an effective therapy for sleep apnea that frequently results in improvement in excessive daytime sleepiness in many patients; however, not all patients tolerate CPAP therapy and among those who tolerate CPAP, usage is highly variable. Excessive daytime sleepiness may persist in people with sleep apnea despite using CPAP.

About Narcolepsy

Narcolepsy is a serious and debilitating neurological condition that causes dysregulation of the sleep-wake cycle and is characterized clinically by excessive daytime sleepiness, cataplexy, hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep. Narcolepsy afflicts an estimated 185,000 individuals in the U.S. Narcolepsy interferes with cognitive, psychological, and social functioning, increases the risk of work- and driving-related accidents, and is associated with a 1.5-fold higher mortality rate.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for central nervous system (CNS) conditions that have limited treatment options. Through development of therapeutic options with novel mechanisms of action, we are transforming the approach to treating CNS conditions. At Axsome, we are committed to developing products that meaningfully improve the lives of patients and provide new therapeutic options for physicians. 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 expected closing of the transaction referenced in this press release, 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 potential filing issues or issues identified by FDA during the substantive review may impact the potential approvability of the Company’s NDA submission for AXS-05 in MDD or 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); whether issues identified by FDA during the substantive review may impact the potential approvability of the Company’s 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; 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 Contact:

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www.axsome.com

References

1. Stroe AF, et al. (2010) *Sleep Medicine* 11, 890–896
2. Hein M, et al. (2019) *J Affective Disorders* 243, 23–32
3. Symphony Health data, February 2022



Expanding Axsome's Leadership in Neuroscience
Axsome to Acquire Sunosi® (solriamfetol) from Jazz Pharmaceuticals

March 28, 2022

Forward Looking Statements & Safe Harbor



Certain information contained in this presentation may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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 expected closing of the transaction referenced in this presentation, 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 potential filing issues or issues identified by FDA during the substantive review may impact the potential approvability of the Company's NDA submission for AXS-05 in MDD or 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); whether issues identified by FDA during the substantive review may impact the potential approvability of the Company's 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; 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 presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, these projections, assumptions and estimates are necessarily subject to a high degree of uncertainty and risk.

Expanding Axsome's Leadership in Neuroscience



AXS-05

AXS-07



SUNOSI
(solriamfetol) (V)

Oral NMDA Receptor Antagonist with Multimodal Activity

MoSEIC™ COX-2 Pref. Inhibitor + 5-HT_{1B/1D} Agonist

DNRI
Dopamine
Norepinephrine
Reuptake
Inhibitor

Major Depressive Disorder

Migraine

EDS Associated with Narcolepsy or OSA

NDA under Review

NDA under Review

Approved

Potentially
Three
New, Marketed
Neuroscience
Products in
2022

Adds a Third High-potential Commercial-stage CNS Asset to Axsome Portfolio

- Transaction will immediately accelerate Axsome's transition to a global commercial entity ahead of potential near-term launches of AXS-05 in depression and AXS-07 in migraine in 2022
- Sunosi has high clinical and commercial potential based on strong efficacy, differentiated MOA, potential new indications, and long patent expiry

Highly Synergistic with Existing Axsome Portfolio and DCC™ Approach

- HCP targets for AXS-05 (psychiatry) and AXS-07 (neurology) have significant overlap with high potential Sunosi prescribers for current and potential future indications
- Axsome's Digital Centric Commercialization (DCC™) platform should optimize physician targeting and engagement, and promotional spend for Sunosi

Expected to Deliver Substantial Shareholder Value

- Accelerates sales trajectory, and potentially time to profitability
- Further expands development pipeline with potential new indications
- Sunosi will be immediately revenue generating upon closing; expected to be breakeven to Axsome's operating plan in 2023 and substantially accretive thereafter



Differentiated Profile

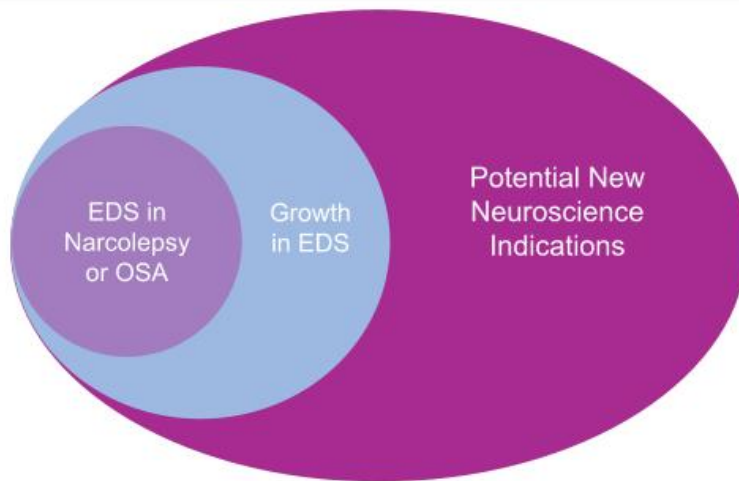
- First and only FDA-approved dual-acting DNRI to treat EDS in adults with narcolepsy or OSA
- Improves wakefulness and reduces EDS

Performance to Date

- Launched in 2019 in the U.S., and 2020 in the E.U.
- 2021 sales of \$57.9M, year-over-year growth of 104%
- 90% of commercial lives covered

Anticipated Long-Lived IP

- Patent expires out to 2040



>\$1 billion
peak potential with
current and potential
future indications

- Narcolepsy remains an unmet need, and OSA has an extremely low drug treatment rate (~6%)
- ~12 million diagnosed OSA patients in U.S.
- Potential new high-value indications in psychiatry and neurology to be explored

Target Sunosi Prescribers Overlap with Existing Axsome Portfolio



EDS in OSA and Narcolepsy Key Prescribers

Prescriber Overlap with Existing Axsome Portfolio



Psychiatrist

AXS-05

Major Depressive Disorder
NDA under Review



Neurologist

AXS-07

Migraine
NDA under Review



Sleep Specialist

AXS-12

Cataplexy in Narcolepsy
Phase 3 Ongoing

Depression and migraine patients have among the highest prevalence of clinically significant EDS (37%-50%)^{1,2}

1) A.F. Stroe et al. / Sleep Medicine 11 (2010) 890-896; 2) M. Hein et al. Journal of Affective Disorders 243 (2019) 23-32

Optimized engagements and HCP targeting via an integrated platform



Real-time Data

Insight-driven, quick analyses of real-time data from customer engagements



Seamless Integration

Fully integrated data, systems infrastructure, and Veeva partnership



Sophisticated Analytics

Analysis of customer engagements and behavior through AI modeling technology and expert data-science analysts



Targeted Deployment

Right customer, right channel, right message – Effective and efficient deployment of reps and content



Dedicated Digital Engagement team

Commitment to transforming the CNS treatment approach through innovation

DCC will further leverage Axsome's therapeutic focus to increase reach to key Sunosi prescriber groups

Asset and Territory	<ul style="list-style-type: none">• Sunosi (solriamfetol)• Worldwide rights except for certain Asian markets including China, Korea, and Japan
Financial Terms	<ul style="list-style-type: none">• Jazz to receive from Axsome: \$53 million upfront; high single-digit royalty for the current indication and mid single-digit royalty for any future indication, of net sales in the U.S.• Axsome to assume the commitments of Jazz to SK Biopharma and Aerial Biopharma: single-digit tiered royalties on Axsome's sales of Sunosi, and up to \$165 million in revenue milestones and \$1 million in development milestones
Financing	<ul style="list-style-type: none">• Existing \$300 million term loan facility with Hercules Capital, Inc.
Financial Impact	<ul style="list-style-type: none">• Immediately revenue generating upon closing• Small loss in 2022, breakeven to Axsome's operating plan in 2023, significantly accretive thereafter
Approvals and Timing	<ul style="list-style-type: none">• The transaction has been unanimously approved by Axsome's Board of Directors• Anticipated closings in the second quarter of 2022 (separate closings for U.S. and Ex-U.S. territories)• Transaction subject to customary closing conditions, including the expiration or termination of the HSR waiting period

Transformational Acquisition to Deliver Significant Value



- ✓ **Anticipated to deliver substantial shareholder value.** Sunosi will be immediately revenue generating upon closing, and is expected to be breakeven to Axsome's operating plan in 2023 and substantially accretive thereafter
- ✓ **Potential for rapid development in new high-value indications** for Sunosi in both psychiatry and neurology. In addition, Axsome's DCC™ platform will increase reach to key Sunosi prescriber groups
- ✓ **Highly synergistic with Axsome's existing neuroscience portfolio** and commercialization plans for AXS-05 and AXS-07, both of which are undergoing NDA reviews with anticipated FDA actions this year

Acquisition immediately transforms Axsome into a global commercial entity upon closing, and accelerates our growth as a premier biopharmaceutical company focused on **delivering potentially life-changing medicines to people living with serious CNS conditions**

Robust, Late-Stage Neuroscience Pipeline

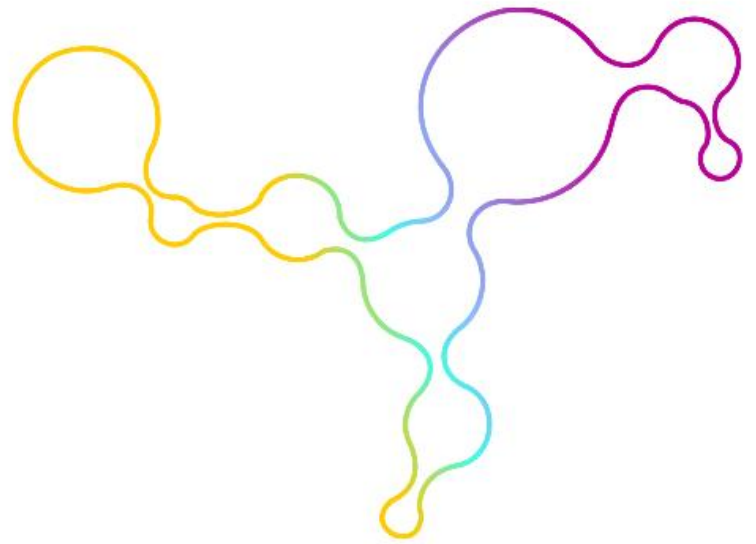


Product Candidate	MOA	Phase 1	Phase 2	Phase 3	NDA
AXS-05	NMDA receptor antagonist with multimodal activity	Major Depressive Disorder: Breakthrough Therapy Designation & Priority Review Alzheimer's Disease Agitation: Breakthrough Therapy Designation Smoking Cessation			
AXS-07	MoSEIC™ COX-2 pref. inhibitor + 5-HT _{1B/1D} agonist	Migraine			
AXS-12	Highly selective NE reuptake inhibitor	Cataplexy in Narcolepsy: Orphan Drug Designation			
AXS-14	Highly selective NE reuptake inhibitor	Fibromyalgia			



- EDS Associated with Narcolepsy or OSA
- Potential New Indications

The investigational candidates listed are not approved by the FDA and safety and effectiveness have not been established
 Abbreviations: MOA = Mechanism of Action; NE = Norepinephrine.



Q&A