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

March 28, 2022

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.

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2. Hein M, et al. (2019) J Affective Disorders 243, 23–32
3. Symphony Health data, February 2022

Source: Axsome Therapeutics, Inc.