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): February 18, 2025

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.)**

One World Trade Center, 22nd 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 2.02 Results of Operations and Financial Condition.

On February 18, 2025, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2024 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 8.01 Other Events.

On February 18, 2025, the Company updated its corporate presentation and posted such corporate presentation to the Company's website. The updated corporate presentation is filed as Exhibit 99.2 hereto and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 18, 2025.
99.2	Corporate Presentation.
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.

Date: February 18, 2025

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

Exhibit 99.1

Axsome Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

Total 4Q and full year 2024 net product revenue of $118.8 million and $385.7 million, respectively, representing 66% and 88% year-over-year growth

Auvelity® 4Q and full year 2024 net product sales of $92.6 million and $291.4 million, respectively, representing 89% and 124% year-over-year growth

Sunosi® 4Q and full year 2024 net product revenue of $26.2 million and $94.3 million, respectively, representing 16% and 26% year-over-year growth

Symbravo® approved in the U.S. for the acute treatment of migraine with or without aura in adults

Successful completion of Phase 3 clinical program of AXS-05 in Alzheimer's disease agitation announced; NDA submission anticipated in 2H 2025

Positive topline results of ENCORE Phase 3 trial of AXS-12 in narcolepsy announced; NDA submission anticipated in 2H 2025

Topline results of EMERGE Phase 3 trial of Symbravo in migraine in patients with prior inadequate response to oral CGRP inhibitors on track for 1Q 2025

Topline results of FOCUS and PARADIGM Phase 3 trials of solriamfetol in ADHD and MDD, respectively, on track for 1Q 2025

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

NEW YORK, February 18, 2025 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) disorders, today announced financial results for the fourth quarter and full year of 2024 and provided a general business update.

"2024 was another defining year for Axsome, driven by strong commercial growth and a rapidly advancing late-stage pipeline, which culminated in the successful completion of our Phase 3 clinical program for AXS-05 in Alzheimer's disease agitation, and most recently, the U.S. approval of Symbravo last month for the acute treatment of migraine with or without aura in adults," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "With potentially five marketed products across six CNS indications of great unmet need over the next 12-18 months, we are well positioned to continue delivering innovative new medicines to patients, and significant near- and long-term value to shareholders."

Fourth Quarter and Full Year 2024 Financial Highlights

- Total net product revenues were $118.8 million and $385.7 million for the fourth quarter and full year of 2024, representing 66% and 88% year-over-year growth, respectively. Total net product revenues for the comparable periods in 2023 were $71.5 million and $204.9 million, respectively.
- Auvelity net product sales were $92.6 million and $291.4 million for the fourth quarter and full year of 2024, representing 89% and 124% year-over-year growth, respectively. Auvelity net product sales for the comparable periods in 2023 were $49.0 million and $130.1 million, respectively.

- Sunosi net product revenues were $26.2 million and $94.3 million for the fourth quarter and full year of 2024, representing 16% and 26% year-over-year growth, respectively, which consisted of $24.7 million and $90.3 million in net products sales and $1.4 million and $4.0 million in royalty and milestone revenue associated with Sunosi sales in out-licensed territories, respectively. Sunosi net product revenues for the comparable periods in 2023 were $22.5 million and $74.8 million, which consisted of $21.7 million and $72.4 million in net product sales, respectively.

- Total costs of revenue were $10.5 million and $33.3 million for the fourth quarter and full year of 2024, respectively. Total cost of revenue for the fourth quarter of 2024 included a one-time $2.5 million sales-based milestone expense related to world-wide Sunosi sales. Total costs of revenue for the comparable periods in 2023 were $7.4 million and $26.1 million, respectively.

- Research and development (R&D) expenses were $55.0 million and $187.1 million for the fourth quarter and full year of 2024, respectively, compared to $30.8 million and $97.9 million for the comparable periods in 2023. The increase in R&D expenses for the year was primarily related to the Company's ongoing Phase 3 trials of solriamfetol in ADHD, MDD, BED, and SWD, the advancement of Phase 3 trials of AXS-05 and AXS-12, manufacturing costs for AXS-07 and AXS-14, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Selling, general, and administrative (SG&A) expenses were $113.3 million and $411.4 million for the fourth quarter and full year of 2024, respectively, compared to $86.8 million and $323.1 million for the comparable periods in 2023. The increase in SG&A expenses for the year was primarily related to commercialization activities for Auvelity and Sunosi, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Net loss for the fourth quarter of 2024 was $74.9 million, or $(1.54) per share, compared to a net loss of $98.7 million, or $(2.08) per share for the comparable period in 2023. The net loss in the fourth quarter of 2024 includes $35.9 million in non-cash charges, primarily consisting of $22.0 million in stock-based compensation expense, $11.0 million in acquisition-related contingent consideration expense, and $1.6 million in intangible asset amortization. Net loss for the full year of 2024 was $287.2 million, or $(5.99) per share, compared to a net loss of $239.2 million, or $(5.27) per share for the full year of 2023. The net loss for the full year of 2024 includes $124.9 million in non-cash charges, including $85.2 million in stock-based compensation expense, $28.1 million in acquisition-related contingent consideration expense, and $6.4 million in intangible amortization, compared to $62.6 million, $48.9 million, and $6.4 million for the full year of 2023, respectively.

- Cash and cash equivalents totaled $315.4 million at December 31, 2024, compared to $386.2 million at December 31, 2023.

- Shares of common stock outstanding were 48,667,587 at December 31, 2024.

Financial Guidance

- Axsome believes that its current cash is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan.

Commercial Highlights

Auvelity

- Approximately 158,000 prescriptions were written for Auvelity in the fourth quarter of 2024, representing an increase of 87% compared to the same period in 2023, and an increase of 10% compared to the third quarter of 2024.

- Payer coverage for Auvelity across all channels is at approximately 78% of all covered lives. The proportion of lives covered for Auvelity in the commercial and government (Medicare and Medicaid) channels are approximately 63% and 100%, respectively.

- The previously announced expansion of the Auvelity psychiatry sales force from 260 to 300 sales representatives is now complete. The sales force expansion is expected to support continued growth within the primary care market and further improvements in payer coverage.

Sunosi

- Approximately 49,000 prescriptions were written for Sunosi in the U.S. in the fourth quarter of 2024, representing an increase of 16% compared to the same period in 2023, and an increase of 4% compared to the third quarter of 2024.
- Payer coverage for Sunosi across all channels is at approximately 83% of all covered lives. The proportion of lives covered for Sunosi in the commercial and government channels are approximately 95% and 60%, respectively.

Symbravo

- On January 30, 2025, the U.S. Food and Drug Administration (FDA) approved Symbravo for the acute treatment of migraine with or without aura in adults. Symbravo represents a novel, multi-mechanistic approach to treating migraine that targets multiple pathways underlying a migraine attack, and is engineered with Axsome's patented MoSEIC™ (Molecular Solubility Enhanced Inclusion Complex) rapid absorption technology. Pre-launch activities, including sales force hiring and payer discussions, are underway. The Company anticipates Symbravo to be commercially available in the U.S. in approximately four months.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of multiple, innovative, late-stage, patent-protected product candidates addressing a broad range of serious psychiatric and neurological conditions. Recent and anticipated progress for key pipeline programs is summarized below.

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome's novel, oral, investigational N-methyl-D-aspartate (NMDA) receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for the treatment of Alzheimer's disease (AD) agitation and smoking cessation. AXS-05 has been granted FDA Breakthrough Therapy designation for AD agitation.

- **Alzheimer's Disease Agitation:** Axsome has completed the Phase 3 clinical program of AXS-05 in Alzheimer's disease agitation consisting of four controlled Phase 3 efficacy trials and a long-term safety trial. AXS-05 demonstrated statistically significant improvements in Alzheimer's disease agitation compared to placebo in three efficacy trials (ADVANCE-1, ACCORD-1, and ACCORD-2), with supportive efficacy and controlled safety results in a fourth trial (ADVANCE-2). Based on the results from these studies, Axsome plans to submit a New Drug Application (NDA) for AXS-05 for the treatment of Alzheimer's disease agitation to the FDA in the second half of 2025.
- **Smoking Cessation:** Axsome plans to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in 2025.

Solriamfetol

Solriamfetol is Axsome's dopamine and norepinephrine reuptake inhibitor (DNRI), TAAR1 agonist, and 5-HT_{1A} agonist being developed for the treatment of attention deficit hyperactivity disorder (ADHD), major depressive disorder (MDD), binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome is conducting the FOCUS study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in ADHD in adults. The Company is on track to report topline results from the FOCUS Phase 3 trial in the first quarter of 2025.
- **Major Depressive Disorder:** Axsome is conducting the PARADIGM study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in MDD. The study will examine the effect of solriamfetol in MDD patients with and without excessive daytime sleepiness (EDS). The Company is on track to report topline results from the PARADIGM Phase 3 trial in the first quarter of 2025.
- **Binge Eating Disorder:** Axsome is conducting the ENGAGE study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in BED. Based on current enrollment trends, the Company now anticipates topline results from the ENGAGE Phase 3 trial in 2026.
- **Shift Work Disorder:** Axsome is conducting the SUSTAIN study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in SWD in adults. The Company anticipates topline results from the SUSTAIN Phase 3 trial in 2026.

Symbravo

Symbravo (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, selective COX-2 inhibitor and 5-$HT_{1B/1D}$ agonist indicated for the acute treatment of migraine with or without aura in adults.

Migraine: Axsome is conducting the EMERGE study, a Phase 3, single-group, multicenter trial evaluating the efficacy and safety of Symbravo for the acute treatment of migraine in adults with a prior inadequate response to an oral CGRP inhibitor. The Company anticipates topline results from the EMERGE Phase 3 trial in the first quarter of 2025.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, investigational, highly selective and potent norepinephrine reuptake inhibitor and cortical dopamine modulator being developed for the treatment of narcolepsy. AXS-12 has been granted FDA Orphan Drug designation for narcolepsy.

- **Narcolepsy:** Axsome has completed three controlled Phase 2 and Phase 3 efficacy trials and a long-term safety trial of AXS-12 in patients with narcolepsy with cataplexy. AXS-12 demonstrated statistically significant efficacy compared to placebo in all three efficacy trials (CONCERT, SYMPHONY, and ENCORE). Based on the results from these studies, Axsome plans to submit an NDA for AXS-12 for the treatment of cataplexy in patients with narcolepsy to the FDA in the second half of 2025.

AXS-14

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

- **Fibromyalgia:** Axsome plans to submit an NDA to the FDA for AXS-14 for the management of fibromyalgia in the first quarter of 2025.

Corporate Update

- In February 2025, Axsome announced that it has entered into a settlement agreement resolving all outstanding patent litigation related to Auvelity (dextromethorphan HBr – bupropion HCl). The litigation resulted from submission by Teva of an ANDA to the FDA seeking approval to market a generic version of Auvelity in the United States prior to the expiration of applicable Axsome patents. Under the terms of the settlement agreement, Axsome will grant Teva a license to sell its generic version of Auvelity beginning on or after March 31, 2039, if pediatric exclusivity is granted, or on or after September 30, 2038, if no pediatric exclusivity is granted, subject to FDA approval and conditions and exceptions customary for agreements of this type.

Anticipated Milestones

- **Regulatory and Commercial:**
    - AXS-14 for fibromyalgia, NDA submission (1Q 2025)
    - AXS-05 for Alzheimer's disease agitation, NDA submission (2H 2025)
    - AXS-12 for narcolepsy, NDA submission (2H 2025)
- **Clinical Trial Topline Results:**
    - Phase 3 EMERGE trial of AXS-07 in migraine in patients with inadequate response to oral CGRP inhibitors (1Q 2025)
    - Phase 3 FOCUS trial of solriamfetol in ADHD in adults (1Q 2025)
    - Phase 3 PARADIGM trial of solriamfetol in major depressive disorder (1Q 2025)
    - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (2026)
    - Phase 3 SUSTAIN trial of solriamfetol in shift work disorder (2026)
- **Clinical Trial Initiations and Progress:**
    - Pivotal Phase 2/3 trial of AXS-05 in smoking cessation, initiation (2025)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its fourth quarter and full year 2024 financial results and provide a business update. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic) or +1 (201) 389-0851 (international). A live webcast of the conference call can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com. A replay of the conference call will be available for approximately 30 days following the live event.

About Axsome Therapeutics

Axsome Therapeutics is a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) conditions. We deliver scientific breakthroughs by identifying critical gaps in care and develop differentiated products with a focus on novel mechanisms of action that enable meaningful advancements in patient outcomes. Our industry-leading neuroscience portfolio includes FDA-approved treatments for major depressive disorder and excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea and multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that impact over 150 million people in the United States. Together, we are on a mission to solve some of the brain's biggest problems so patients and their loved ones can flourish.

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 commercial success of the Company's Sunosi®, Auvelity®, and Symbravo® products and the success of the Company's efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the Company's ability to maintain and expand payer coverage; the success, timing and cost of the Company's ongoing clinical trials and anticipated clinical trials for the Company's current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company's ability to fully fund the Company's disclosed clinical trials, which assumes no material changes to the Company's currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company's ongoing clinical trials, and/or data readouts, 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 the Company's current product candidates; the Company's ability to fund additional clinical trials to continue the advancement of the Company's product candidates; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, the Company's product candidates, including statements regarding the timing of any NDA submission; 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 products and product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the commercialization of Sunosi, Auvelity, and Symbravo and for the Company's commercial launch of its other product candidates, if approved, and the potential impact on the Company's anticipated cash runway; the Company's ability to convert sales to recognized revenue and maintain a favorable gross to net sales; unforeseen circumstances or other disruptions to normal business operations arising from or related to domestic political climate, geo-political conflicts or a global pandemic 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

Axsome Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 315,353	$ 386,193
Accounts receivable, net	142,001	94,820
Inventories, net	15,732	15,135
Prepaid and other current assets	11,978	8,115
Total current assets	485,064	504,263
Equipment, net	584	846
Right-of-use asset - operating lease	5,383	6,772
Goodwill	12,042	12,042
Intangible asset, net	46,894	53,286
Non-current inventory and other assets	18,531	11,027
Total assets	$ 568,498	$ 588,236
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 71,997	$ 40,679
Accrued expenses and other current liabilities	147,987	90,501
Operating lease liability, current portion	1,835	1,267
Contingent consideration, current	8,285	6,407
Total current liabilities	230,104	138,854
Contingent consideration, non-current	91,680	73,300
Loan payable, long-term	180,710	178,070
Operating lease liability, long-term	6,046	7,035
Finance lease liability, long-term	2,943	—
Total liabilities	511,483	397,259
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 48,667,587 and 47,351,363 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively)	5	5
Additional paid-in capital	1,179,797	1,026,543
Accumulated deficit	(1,122,787)	(835,571)
Total stockholders' equity	57,015	190,977
Total liabilities and stockholders' equity	$ 568,498	$ 588,236

Axsome Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 117,325	$ 70,747	$ 381,677	$ 202,460
License revenue	—	—	—	65,735
Royalty and milestone revenue	1,441	784	4,016	2,405
Total revenues	118,766	71,531	385,693	270,600
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	10,514	7,377	33,303	26,065
Research and development	55,006	30,803	187,077	97,944
Selling, general and administrative	113,271	86,810	411,359	323,123
Loss in fair value of contingent consideration	10,985	43,207	28,124	48,918
Intangible asset amortization	1,607	1,607	6,392	6,375
Total operating expenses	191,383	169,804	666,255	502,425
Loss from operations	(72,617)	(98,273)	(280,562)	(231,825)
Interest expense, net	(2,210)	(703)	(6,569)	(6,453)
Loss before income taxes	(74,827)	(98,976)	(287,131)	(238,278)
Income tax benefit (expense)	(85)	325	(85)	(960)
Net loss	$ (74,912)	$ (98,651)	$ (287,216)	$ (239,238)
Net loss per common share, basic and diluted	$ (1.54)	$ (2.08)	$ (5.99)	$ (5.27)
Weighted average common shares outstanding, basic and diluted	48,541,905	47,329,782	47,914,253	45,425,212

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4Q and Full Year 2024

Corporate Presentation

February 18, 2025

Forward Looking Statements & Safe Harbor

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 commercial success of the Company’s Sunosi®, Auvelity®, and Symbravo® products and the success of the Company’s efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the Company’s ability to maintain and expand payer coverage; the success, timing and cost of the Company’s ongoing clinical trials and anticipated clinical trials for the Company’s current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company’s ability to fully fund the Company’s disclosed clinical trials, which assumes no material changes to the Company’s currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company’s ongoing clinical trials, and/or data readouts, 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 the Company’s current product candidates; the Company’s ability to fund additional clinical trials to continue the advancement of the Company’s product candidates; the timing of and the Company’s ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, the Company’s product candidates, including statements regarding the timing of any NDA submission; 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 products and product candidates, if approved; the Company’s anticipated capital requirements, including the amount of capital required for the commercialization of Sunosi, Auvelity, and Symbravo and for the Company’s commercial launch of its other product candidates, if approved, and the potential impact on the Company’s anticipated cash runway; the Company’s ability to convert sales to recognized revenue and maintain a favorable gross to net sales; unforeseen circumstances or other disruptions to normal business operations arising from or related to domestic political climate, geo-political conflicts or a global pandemic 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.

This presentation contains statements regarding the Company’s observations based upon the reported clinical data. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about the Company's 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.

Axsome, Auvelity, Sunosi, Symbravo, and MoSEIC, are trademarks or registered trademarks of Axsome Therapeutics, Inc. or its affiliates. Except as with respect to Auvelity and Sunosi for their approved indications, the development products referenced herein have not been approved by the FDA.

© Axsome Therapeutics, Inc.

Our Mission

Develop and deliver
transformative medicines
for the hundreds of millions of
people impacted by central
nervous system conditions



axsome

We focus on therapeutic areas with critical gaps in care and a significant unmet need for new treatment options…

Psychiatry

Major Depressive Disorder

21M+	People in the U.S. live with MDD
	of patients fail to achieve remission from initial therapy

Alzheimer's Disease Agitation

4M+	people with Alzheimer's disease experience agitation
1	FDA-approved product

Smoking Cessation

34M+	adults in the U.S. currently smoke cigarettes
~70%	of smokers say they want to quit

ADHD

22M+	adults and children in the U.S. live with ADHD
	of adult ADHD patients do not receive any type of treatment

Binge Eating Disorder

7M+	people in the U.S. experience BED in their lifetime
2-3x	more likely to have psychiatric and medical comorbidities

Neurology

Obstructive Sleep Apnea

22M+	U.S. adults are affected by OSA
~80%	of patients remain undiagnosed

Migraine

39M+	adults in the U.S. suffer from migraine
>70%	of migraine sufferers are not fully satisfied with their current treatment

Narcolepsy

185K	people in the U.S. are affected by narcolepsy
~70%	of patients suffer from cataplexy

Fibromyalgia

17M+	people in the U.S. have fibromyalgia
>15	years since the last FDA-approved therapeutic

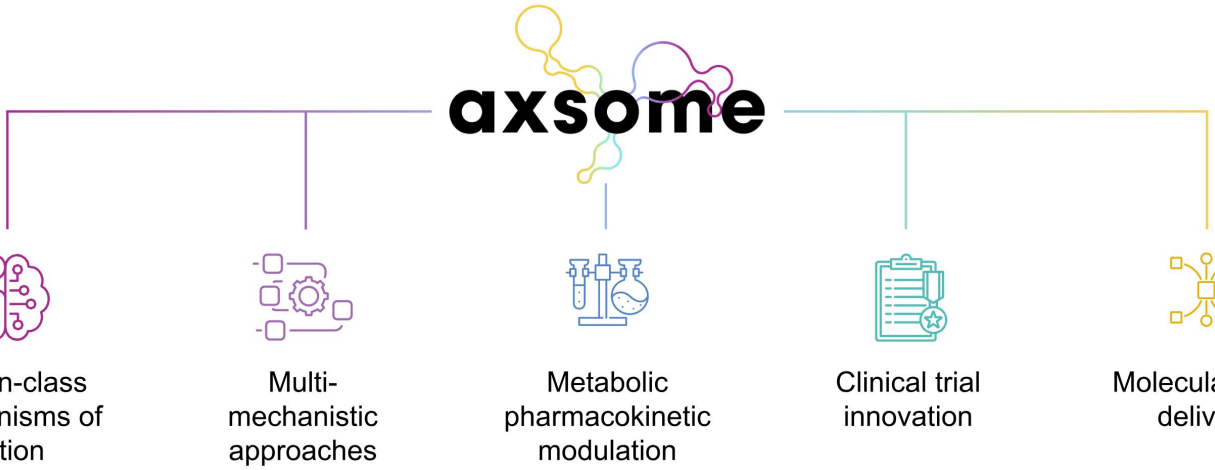
Shift Work Disorder

15M+	working Americans suffer from shift work disorder
0	new medications approved in nearly two decades

Potential to reach **>150M** people in the U.S. across 10 serious CNS conditions

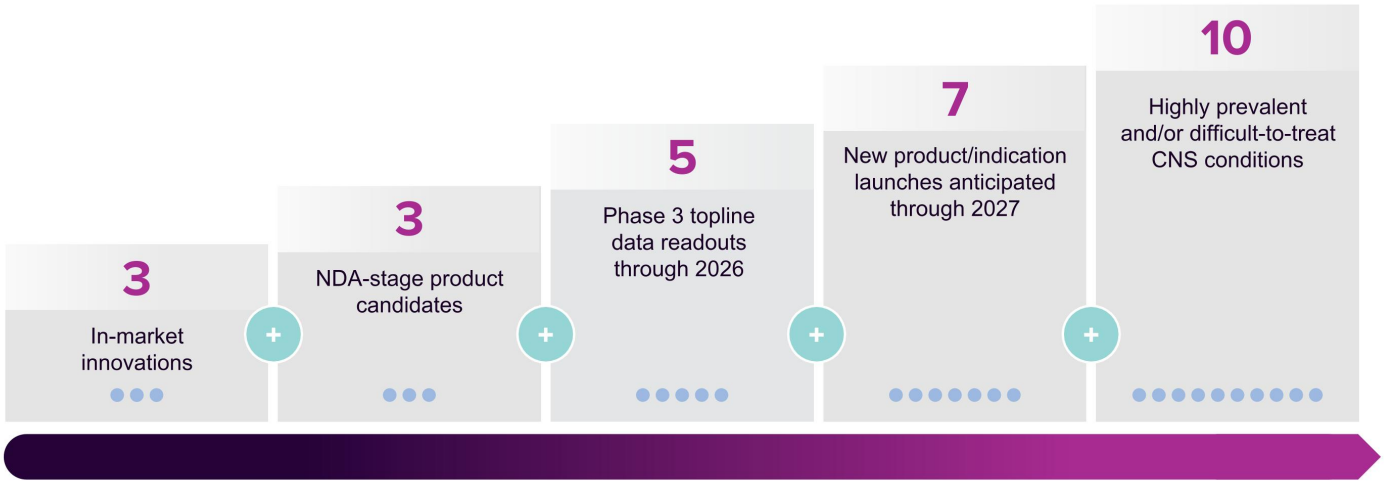
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…And lead in innovation to expand the therapeutic possibilities for CNS conditions



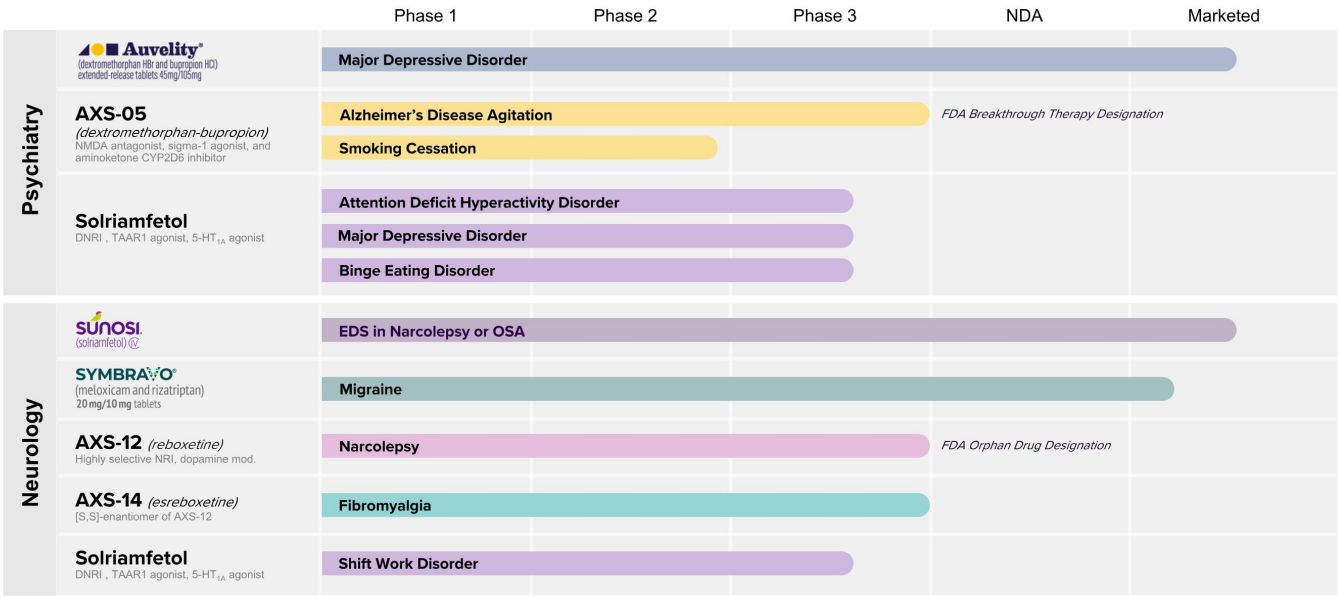
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Well-positioned to deliver significant near- and long-term value to patients and shareholders through 2040s and beyond



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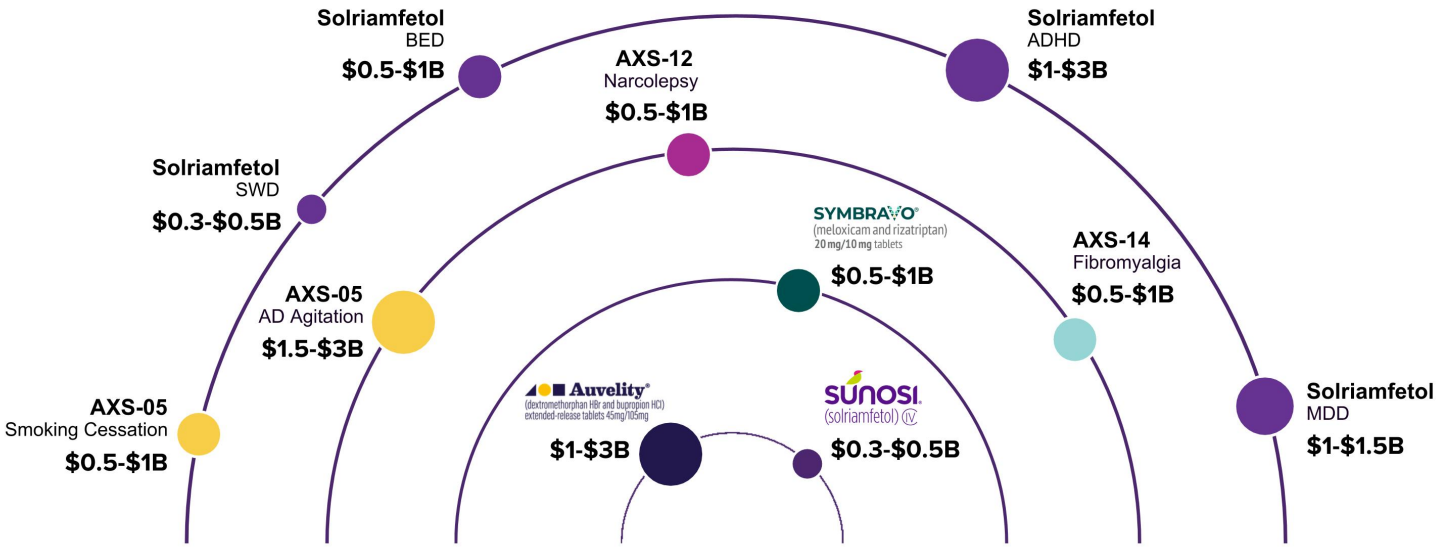
Advancing an industry-leading neuroscience pipeline



NMDA = N-methyl-D-aspartate; CYP2D6 = Cytochrome P450 Family 2 Subfamily D Member 6; DNRI = Dopamine-norepinephrine reuptake inhibitor; TAAR1 = Trace amine-associated receptor 1; 5-HT = 5-Hydroxytryptamine; NRI = Norepinephrine reuptake inhibitor;
Please see full Prescribing Information for Auvelity, Sunosi, and Symbravo at www.Auvelity.com, www.Sunosi.com, and www.Symbravo.com, respectively.

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$16.5B peak sales potential driven by current commercial and late-stage assets



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2024 – Year of strong execution and continued transformation

- Delivered **high double-digit revenue growth**
- Driving Auvelity growth toward **blockbuster potential with robust IP**
- Expanded commercial portfolio with **U.S. approval of Symbravo**, third in-market innovation in three years
- Achieved multiple clinical milestones including **five Phase 3 data readouts** and **three Phase 3 trial initiations**
- Majority of novel pipeline products now in regulatory or commercial stages



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4Q 2024 highlights

Expanding commercial success

- Symbravo approved in the U.S. for the acute treatment of migraine with or without aura in adults
- 4Q 2024 total net product revenue of $118.4M
  - Auvelity: $92.6M
  - Sunosi: $26.2M
- FY 2024 total net product revenue of $385.7M
  - Auvelity: $291.4M
  - Sunosi: $94.3M

Rapidly advancing late-stage pipeline

- Successful completion of Ph 3 clinical program of AXS-05 in AD agitation announced; NDA submission anticipated in 2H 2025
- Positive topline results of third Ph 3 trial of AXS-12 in narcolepsy announced; NDA submission anticipated in 2H 2025
- Topline results of FOCUS and PARADIGM Ph 3 trials of solriamfetol in ADHD and MDD, respectively, on track for 1Q 2025
- Topline results from EMERGE Ph 3 trial of Symbravo in migraine in patients with prior inadequate response to oral CGRP inhibitors on track for 1Q 2025

Financial strength and operational excellence

- 4Q and full year 2024 product revenue growth of **+66%** and **+88%**, respectively*
- $315.4M cash and cash equivalents as of December 31, 2024
- Current cash expected to fund operations into cash flow positivity

*Product revenue growth vs. comparable periods in 2023

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Key achievements in 2024 set the stage for multiple value-driving catalysts ahead

	2024	2025 & 2026
Regulatory	✓ Symbravo approved in the U.S. for the acute treatment of migraine with or without aura in adults (January 2025)	• NDA submission for AXS-14 in fibromyalgia (1Q 2025) • NDA submission for AXS-05 in Alzheimer's disease agitation (2H 2025) • NDA submission for AXS-12 in narcolepsy (2H 2025)
Clinical Trial Topline Results	✓ Positive topline results from SYMPHONY Ph 3 trial of AXS-12 in narcolepsy (1Q 2024) ✓ Positive topline results from ENCORE Ph 3 trial of AXS-12 in narcolepsy (4Q 2024) ✓ Successful completion and results of Ph 3 clinical program of AXS-05 in Alzheimer's disease agitation (4Q 2024)	• EMERGE Ph 3 trial of AXS-07 in CGRP non-responders (1Q 2025) • FOCUS Ph 3 trial of solriamfetol in ADHD (1Q 2025) • PARADIGM Ph 3 trial of solriamfetol in MDD (1Q 2025) • ENGAGE Ph 3 trial of solriamfetol in BED (2026) • SUSTAIN Ph 3 trial of solriamfetol in SWD (2026)
Clinical Trial Initiations & Progress Updates	✓ Initiated PARADIGM Ph 3 trial of solriamfetol in MDD (1Q 2024) ✓ Initiated ENGAGE Ph 3 trial of solriamfetol in BED (2Q 2024) ✓ Initiated SUSTAIN Ph 3 trial of solriamfetol in SWD (2Q 2024)	• Initiate Phase 2/3 trial of AXS-05 in smoking cessation (2025)

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4Q and full year 2024 financial highlights

$ millions	4Q 2024	4Q 2023	% change	FY 2024	FY 2023	% change
Net product revenue	$118.8	$71.5	66%	$385.7	$204.9	88%
Auvelity net product sales	$92.6	$49.0	89%	$291.4	$130.1	124%
Sunosi net product revenue*	$26.2	$22.5	16%	$94.3	$74.8	26%
R&D expense	$55.0	$30.8	79%	$187.1	$97.9	91%
SG&A expense	$113.3	$86.8	31%	$411.4	$323.1	27%

4Q = Three months ended December 31; FY = Year ended December 31 ; *Includes royalty revenue associated with sales in out-licensed territories and excludes a one-time upfront license payment received from Pharmanovia in 1Q 2023

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Financial snapshot

Runway to reach ***cash flow positivity***, based on the current operating plan

Cash Balance: (as of December 31, 2024)	$315.4 M
Debt (Face Value): (as of December 31, 2024)	$180 M
Market Cap: (as of February 14, 2025)	$6.4 B
Shares Outstanding: (as of December 31, 2024)	48.7 M
Options, RSUs, and Warrants Outstanding*:	9.5 M

*Consists of 8.4 M options, 0.9 M RSUs, 0.08 M warrants, and 0.06 M ESPP as of December 31, 2024

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Commercial Highlights



axsome®

Building a leading commercial portfolio in CNS

Auvelity®
(dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg

MAJOR DEPRESSIVE DISORDER

+87% Rx growth in 4Q

+89% sales growth in 4Q

+124% sales growth in 2024

SUNOSI®
(solriamfetol) (IV)

EDS IN NARCOLEPSY OR OSA

+16% Rx growth in 4Q

+16% revenue growth in 4Q

+26% revenue growth in 2024

SYMBRAVO®
(meloxicam and rizatriptan)
20 mg/10 mg tablets

MIGRAINE WITH OR WITHOUT AURA

Approved in the U.S. on January 30, 2025

Commercial launch anticipated in ~4 months

axsome

EDS = Excessive daytime sleepiness; OSA = Obstructive sleep apnea
Rx, sales, and revenue growth vs. comparable periods in 2023

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Auvelity®
(dextromethorphan HBr and bupropion HCl)
extended-release tablets 45mg/105mg

Novel and differentiated oral treatment for major depressive disorder in adults[1,2]

- Rapid acting NMDA receptor antagonist and sigma-1 receptor agonist for MDD[1]
- Rapid symptom improvement starting at week 1, sustained at week 6 vs. placebo[1]
- Rapid remission as early as week 2, sustained and increased vs. control through week 6[3]



NMDA = N-methyl-D-aspartate; MDD = Major depressive disorder

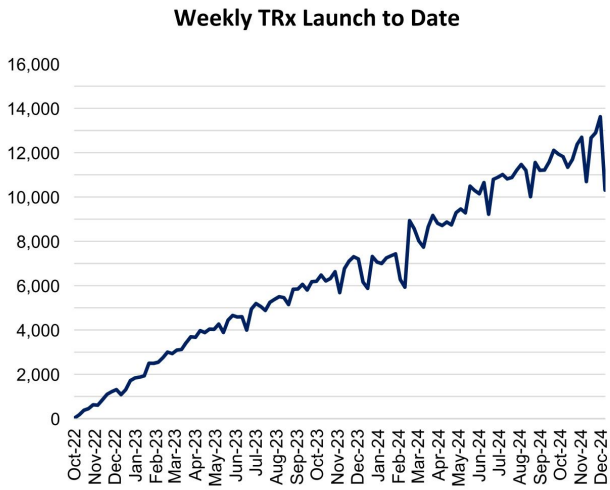
1. Auvelity [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY; 2. Thomas, D. & Wessel, C. BIO (2017); 3. Iosifescu, D.V. et al. *J Clin Psychiatry* (2022)

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Growth driven by robust, growing underlying demand

Auvelity

- ***~165,000*** new patients and ***>32,000*** unique writers since launch
- ~78% of all covered lives between commercial and government (Medicare and Medicaid) channels
- ***Key drivers of prescribing Auvelity*** – fast acting, lack of weight gain or sexual dysfunction, improved daily functioning and quality of life
- ~50% of prescriptions from 1st or 2nd line usage
- ~50% of patients start on Auvelity as a monotherapy (i.e., new patient or switch)

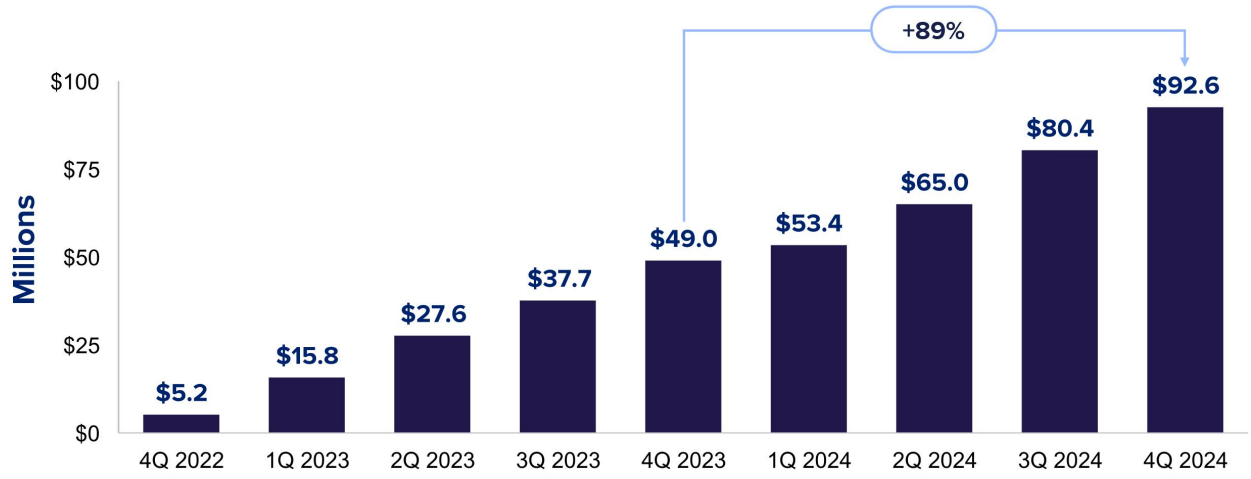


Source: Symphony METYS.

TRx = Total prescriptions

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Auvelity quarterly net sales performance



FY 2024 net product sales of $291.4M represents ***124%*** year-over-year growth

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First and only DNRI approved for EDS associated with narcolepsy or OSA[1]

- First and only wakefulness promoting agent proven to improve wakefulness through 9 hours[1]
- 90% of patients reported feeling better with Sunosi 150 mg[2]
- Improvements in cognitive functioning vs. placebo demonstrated in clinical trials



EDS = Excessive daytime sleepiness; OSA = Obstructive sleep apnea; DNRI = Dopamine-norepinephrine reuptake inhibitor

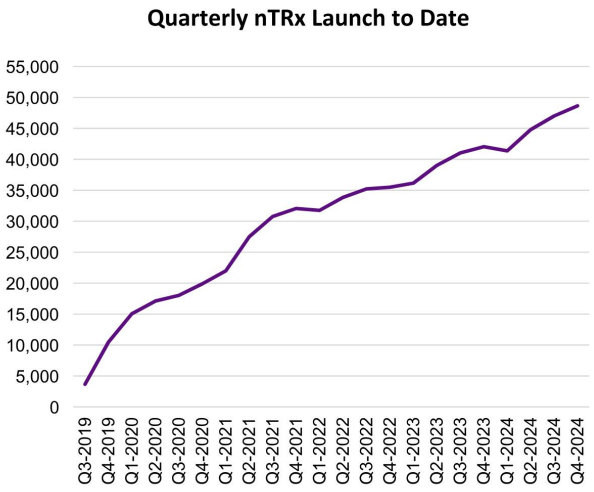
1. SUNOSI [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY; 2. Schweitzer, P.K. et al. *Am J Resp Crit Care Med.* (2019)

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Continued success supported by strong fundamentals

Sunosi

- ***~81,000*** new patients and ***>13,500*** unique writers since initial launch
- ~83% of all covered lives between commercial and government channels
- ***High patient satisfaction for Sunosi*** – drivers include minimal or no side effects, low abuse potential, does not interfere with nighttime sleep, and durable reduction in daytime sleepiness
- >50% of patients who switch or add on to current treatment with Sunosi come from other WPA agents

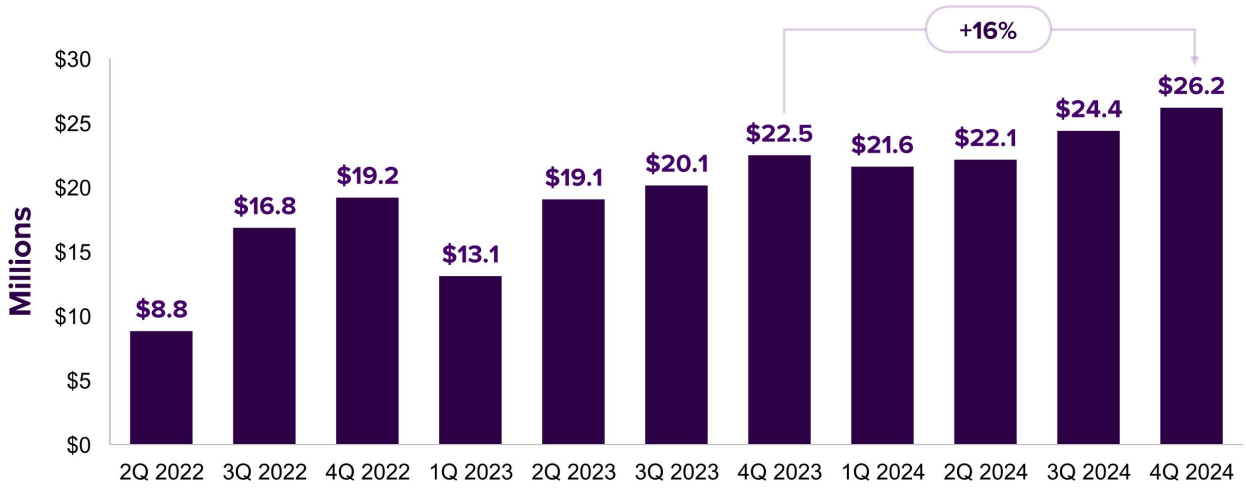


Source: Symphony METYS. nTRx normalizes number of pills in each Trx for 30-day period.

nTRx = Normalized total prescriptions

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Sunosi quarterly net revenue performance



FY 2024 net product revenue of $94.3M represents ***26%*** year-over-year growth

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SYMBRAVO®
(meloxicam and rizatriptan)
20 mg/10 mg tablets

Novel, multi-mechanistic approach for the acute treatment of migraine[1]

- Single, oral dose provided rapid migraine pain freedom and return to normal functioning within 2 hours[1]
- Superior efficacy demonstrated across a broad range of migraine severity (mild, moderate, severe)[1]
- Harnesses Axsome's rapid absorption technology to target multiple pathways underlying a migraine attack



1. SYMBRAVO [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY

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Positioning Symbravo for immediate impact and long-term growth

Launch readiness

- Sales force hiring underway
- Initial launch strategy prioritizing headache centers and headache specialists
- Actively engaged with payers across channels to ensure patient access
- Commercial availability anticipated in approximately 4 months

Unmet needs in migraine

- High patient dissatisfaction due to limited efficacy and/or burdensome side effects
- >80% of patients discontinue their acute migraine treatment in the first 12 months[1]
- Inadequate acute treatment is associated with increased risk of progression to chronic migraine[2]
- Positive feedback from headache specialists highlight potential utility of Symbravo in different patient settings

1. Symphony Health Claims, New to Brand Patients (2022-2023); 2. Lipton et al. *Neurology* (2015)

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Development Pipeline



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AXS-05 (dextromethorphan-bupropion)

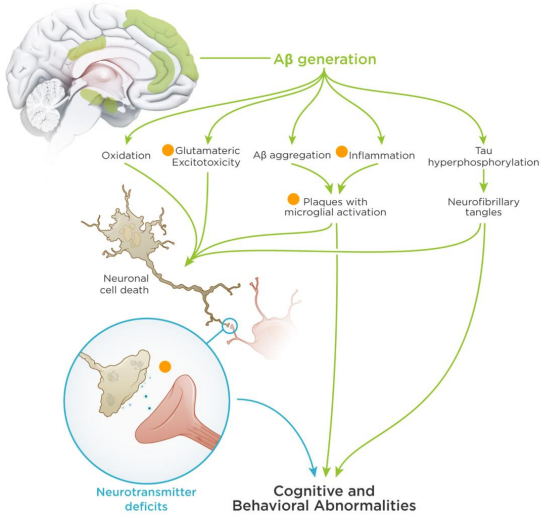
Potentially first-in-class, best-in-class treatment for Alzheimer's disease agitation

In Alzheimer's disease, insoluble Aβ production and accumulation ***triggers secondary steps*** leading to synaptic loss and neuronal cell death[1,2]

Reductions in certain ***neurotransmitters*** are thought to contribute to cognitive and behavioral symptoms including agitation and aggression[1-4]

AXS-05 ***modulates the function*** of neurotransmitters implicated in Alzheimer's disease (glutamate, sigma-1, norepinephrine, and dopamine)[1-4]

Brain regions implicated in AD agitation[4]



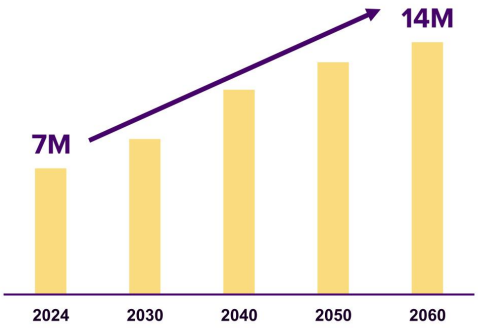
AXS-05 pharmacological actions[5,6]

1. Cummings, J.L. *N Engl J Med.* (2004); 2. Querfurth, H.W. & LaFerla, F.M. *N Engl J Med.* (2010); 3. Porsteinsson, A.P. & Antonsdottir, I.M. *Expert Opin Pharmacother.* (2017); 4. Rosenberg, P.B., Nowrangi, M.A., & Lyketsos, C.G. *Mol Aspects Med.* (2015); 5. Stahl, S.M. *CNS Spectr.* (2019); 6. Cheng, W. et al. *Mol Med Rep.* (2015)

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Alzheimer’s disease (AD) agitation

Number of U.S. adults aged 65+ with Alzheimer’s dementia expected to double by 2060[1]



Alzheimer’s disease (AD) is the most common form of dementia, affecting approximately ***7M*** people in the U.S.[1]

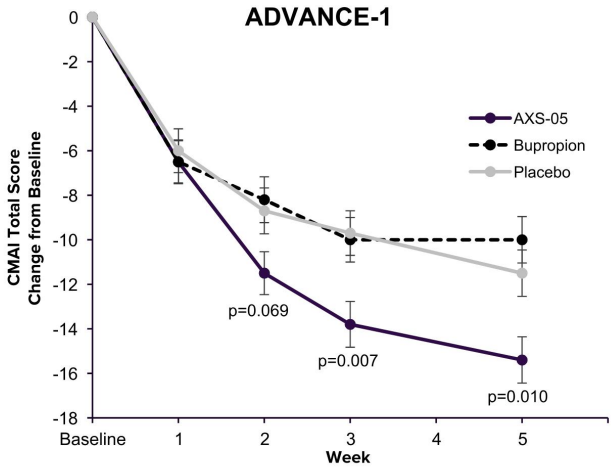
Agitation is reported in ***~70%*** of people with AD and is characterized by emotional distress, verbal and physical aggressiveness, disruptive irritability, and disinhibition[1,2]

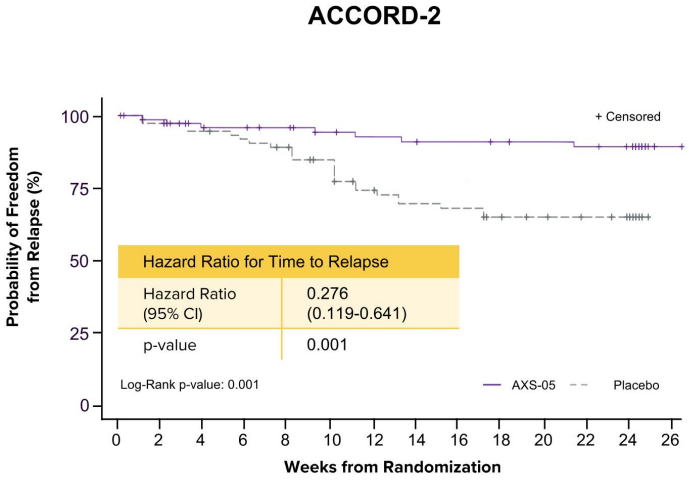
AD agitation is associated with accelerated cognitive decline, increased caregiver burden, and increased mortality[3]

1. Alzheimer’s Association (2024); 2. Tractenberg, R.E. et al. *J Neuropsychiatry Clin Neurosci.* (2002); 3. Porsteinsson, A.P. & Antonsdottir, I.M. *Expert Opin Pharmacother.* (2017)

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Statistically significant and clinically meaningful improvements in Alzheimer's disease agitation





New Drug Application (NDA) submission anticipated 2H 2025

CMAI = Cohen-Mansfield Agitation Inventory

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Smoking cessation

70% of smokers want to quit[2]



Only ***3-5%*** who attempt to quit without assistance are successful for 6-12 months[2]



~34M adults in the U.S. smoke cigarettes, ~50% of whom live with a smoking-related disease[1]



Single ***largest cause*** of ***preventable disease*** and death in the U.S., accounting for nearly 1 in 5 deaths[1]



Associated with over ***$300 billion*** in annual costs in the U.S.[1]

1. U.S. Department of Health and Human Services (2020); 2. Hughes J.R. et al. *Addiction* (2004)

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Solriamfetol Phase 3 development programs

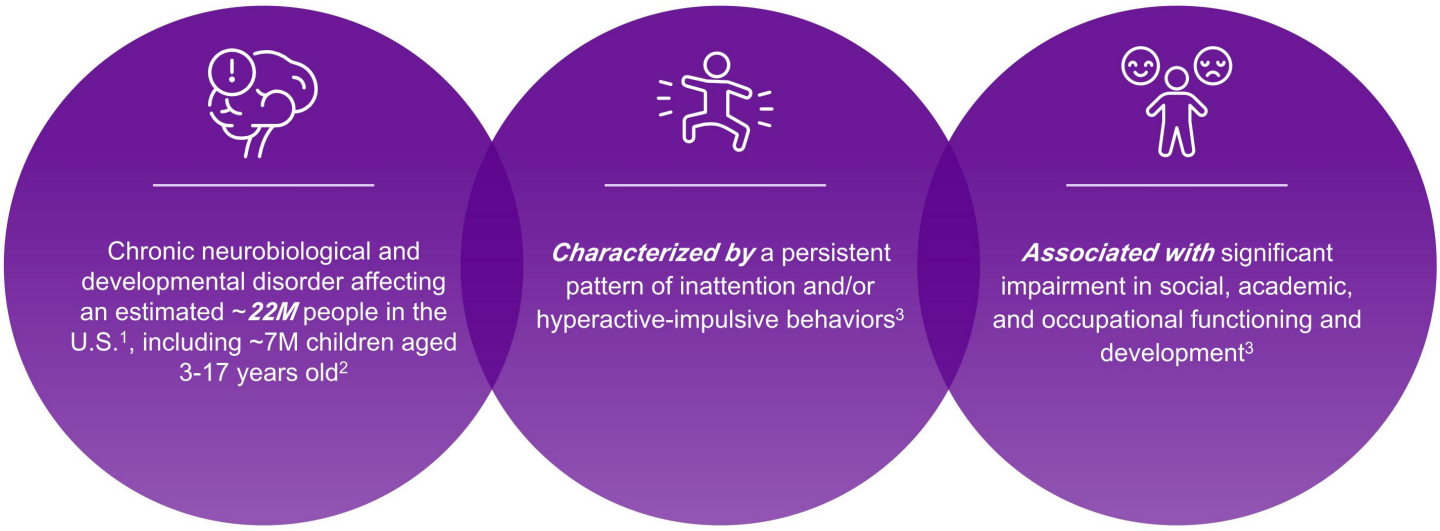
Solriamfetol

ADHD	MDD	BED	SWD
FOCUS *Phase 3 (N=450)*	**PARADIGM** *Phase 3 (N=300)*	**ENGAGE** *Phase 3 (N=450)*	**SUSTAIN** *Phase 3 (N=450)*
• Efficacy and safety of solriamfetol vs. placebo in adults with attention deficit hyperactivity disorder • 6-week, double-blind, randomized, placebo-controlled, parallel group trial • Trial in pediatric patients planned	• Efficacy and safety of solriamfetol vs. placebo in adults with major depressive disorder • 6-week, double-blind, randomized, placebo-controlled, parallel group trial	• Efficacy and safety of solriamfetol vs. placebo in adults with binge eating disorder • 12-week, double-blind, randomized, placebo-controlled, parallel group trial	• Efficacy and safety of solriamfetol vs. placebo in adults with shift work disorder • 12-week, double-blind, randomized, placebo-controlled, parallel group trial
Topline data 1Q 2025	***Topline data 1Q 2025***	***Topline data 2026***	***Topline data 2026***

ADHD = Attention deficit hyperactivity disorder; MDD = Major depressive disorder; BED = Binge eating disorder; SWD = Shift work disorder

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Attention deficit hyperactivity disorder (ADHD)



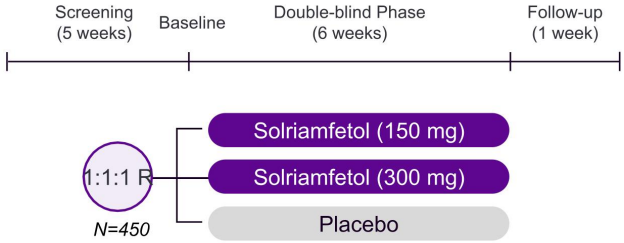
1. “Facts About ADHD in Adults.” CDC (2024); 2. “Data and Statistics on ADHD.” CDC (2024); 3. “Attention-Deficit/Hyperactivity Disorder.” NIMH (2024)

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Evaluating solriamfetol as a potential treatment for ADHD

- Preliminary clinical evidence in adult ADHD patients
- Solriamfetol targets neurotransmitter pathways in the brain implicated in ADHD
- Topline results from the FOCUS Phase 3 trial of solriamfetol in ADHD anticipated in 1Q 2025

FOCUS Phase 3 Trial



Key eligibility criteria

- 18-55 years of age with primary diagnosis of ADHD (DSM-5)

Primary endpoint

- Change from baseline in AISRS score

AISRS = Adult ADHD Investigator Symptom Report Scale

1. Surman, C.B.H. et al. *J Clin Psychiatry* (2023)

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Major depressive disorder (MDD)



>70% of patients experience only a partial improvement in symptoms with first-line standard of care



One of the most common mental disorders in the U.S., impacting ***~21M*** adults each year[1,2]



Serious and ***chronic mental health*** condition causing persistently low or depressed mood and a loss of interest or pleasure in daily activities, and may impair one's sleep, appetite, ability to concentrate, and/or self-worth[1]

1. "Major Depression." NIMH (2023); 2. Hasin, D.S. et al. *JAMA Psychiatry* (2018)

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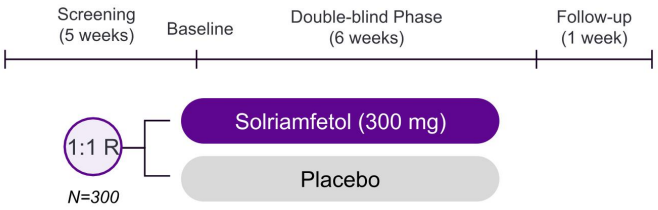
Evaluating solriamfetol as a potential treatment for MDD

Phase 3 trial evaluating the effect of solriamfetol in MDD patients with and without EDS

The combination of monoamine reuptake inhibition and TAAR1/5-HT_{1A} agonism showed synergistic results in two mouse models of depression[1]

Topline results from the PARADIGM Phase 3 trial of solriamfetol in MDD anticipated in 1Q 2025

PARADIGM Phase 3 Trial



Key eligibility criteria

- 18-65 years of age with confirmed diagnosis of moderate to severe MDD

Primary endpoint

- Change from baseline in MADRS score

EDS = Excessive daytime sleepiness; MADRS = Montgomery-Åsberg Depression Rating Scale; TAAR1 = Trace amine-associated receptor 1

1. Ren, X. et al. *Molecules* (2022)

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Binge eating disorder (BED)

~7 million people in the U.S. have BED[2]



BED is ***1.75x more common*** in women than in men[2]

Binge eating disorder (BED) is the most common eating disorder and is thought to involve issues with food reward processing, impulse control, and appetite regulation[1,2]

Unmet medical need associated with a 2- to 3-fold increased risk of psychiatric and medical comorbidities[3]

Solriamfetol's dopamine, norepinephrine, and TAAR1 mechanisms appear relevant to the pathophysiology of BED[4-6]

1. Kessler, R.M. et al. *Neurosci Biobehav Rev*. (2016); 2. Hudson, J.I. et al. *Biol Psychiatry* (2007); 3. McElroy, S.L. et al. *J Clin Psychiatry* (2020); 4. Giel, KL. et al. *Nat Rev Dis Primer* (2022); 5. Bello, N.T. & Hajnal, A. *Pharmacol Biochem Behav*. (2010); 6. Pruccoli et al. *Int J Mol Sci*. (2021)

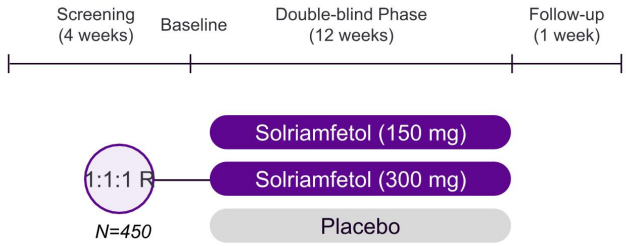
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Evaluating solriamfetol as a potential treatment for BED

Solriafemtol's dopamine, norepinephrine, and TAAR1 mechanisms appear relevant to the pathophysiology of BED[1-3]

Topline results from the ENGAGE Phase 3 trial of solriamfetol in binge eating disorder anticipated in 2026

ENGAGE Phase 3 Trial



Key eligibility criteria

- 18-55 years of age with diagnosis of BED (DSM-5)

Primary endpoint

- Change from baseline in days with binge eating episodes

TAAR1 = Trace amine-associated receptor 1

1. Giel, K.E. et al. *Nat Rev Dis Primers* (2022); 2. Bello, N.T. & Hajnal, A. *Pharmacol Biochem Behav.* (2010); 3. Pruccoli et al. *Int J Mol Sci.* (2021)

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Shift work disorder (SWD)

~15 million U.S. workers may suffer from SWD

10-43% have SWD[1,3]

Approximately ***1 in 3 people*** working in the U.S. work an alternate shift[2]



Shift work disorder (SWD) is a combination of excessive sleepiness during wakefulness and persistent insomnia during daytime sleep when working outside a 7 a.m. to 6 p.m. workday[1]



Shift work has long been associated with multiple serious health complaints and a 23% greater risk of sustaining a work-related injury[4-5]



No new medications approved since 2007 and considerable residual sleepiness reported when medication is used[6]

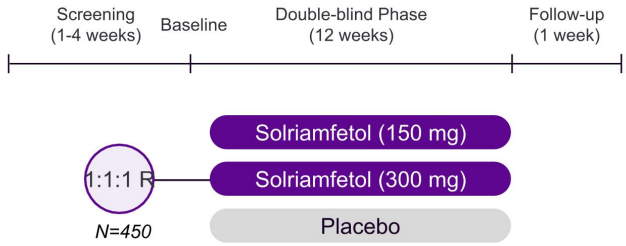
1. Sateia, M.J. *Chest* (2014); 2. Alterman, T. et al. *Am J Ind Med.* (2013); 3. Wickwire, E.M. *Chest* (2017); 4. Smith, L. et al. *Lancet* (1994); 5. Akerstedt, T. & Wright, KP. *Sleep Med Clin.* (2009); 6. Czeisler, C.A. et al. *N Engl J Med.* (2005)

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Evaluating solriamfetol as a potential treatment for SWD

Topline results from the SUSTAIN Phase 3 trial of solriamfetol in shift work disorder anticipated in 2026

SUSTAIN Phase 3 Trial



Key eligibility criteria

- 18-65 years of age with diagnosis of SWD (ICSD-2 or ICSD-3)

Primary endpoint

- Change from baseline in CGI-C score

CGI-C = Clinical Global Impression - Change

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AXS-12 (reboxetine)

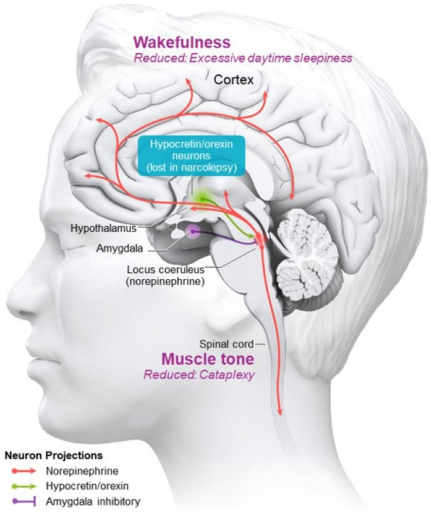
Novel pharmacological approach for the treatment of narcolepsy

Norepinephrine and dopamine play ***important roles*** in sleep-wake regulation (both) and in maintaining muscle tone during wakefulness (norepinephrine)[1-3]

The loss of orexin input ***inhibits the production*** of these neurotransmitters[1,2]

- Decreased norepinephrine signaling is thought to contribute to cataplexy, EDS, and cognitive impairment[1,4-7]
- Decreased dopamine signaling is thought to contribute to EDS and cognitive impairment[1,4]

AXS-12 ***inhibits the reuptake*** of both neurotransmitters, improving both norepinephrine and cortical dopamine signaling in the brain



1. Szabo, S.T. et al. *Sleep Med Rev.* (2019); 2. Krahn, L.E., Zee, P.C., & Thorpy, M.J. *Adv Ther.* (2022); 3. Scammell, T.E. *N Engl J Med.* (2015); 4. Stahl, S.M & Grady, M.M. *J Clin Psychiatry* (2003); 5. Burgess, C.R. & Peever, J.H. *Curr Biol.* (2013); 6. Wu, M.F. et al. *Neuroscience* (1999); 7. Bruinstroop, E. et al. *J Comp Neurol.* (2012)

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Narcolepsy



Rare and debilitating neurological condition that affects approximately ***185,000*** people in the U.S.[1]



Characterized by cataplexy, excessive daytime sleepiness (EDS), hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep[2-4]



An estimated ***70%*** of patients suffer from cataplexy, or the sudden reduction or loss of muscle tone while awake[5]

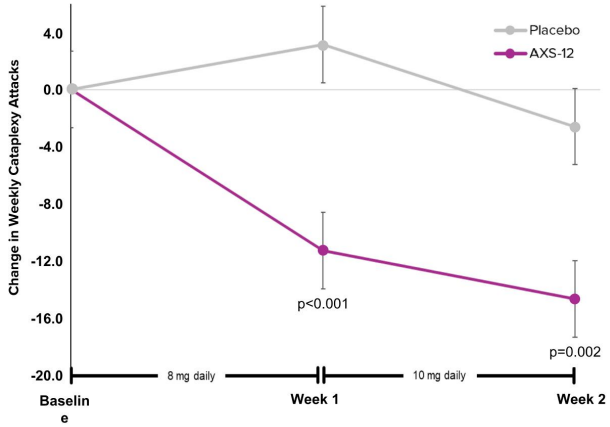
1. “About Narcolepsy.” Narcolepsy Network (2024); 2. Sateia, M.J. *Chest* (2014); 3. “Narcolepsy.” NINDS (2024); 4. España, R.A. & Scammell, T.E. *Sleep* (2011); 5. Swick, T.J. *Nat Sci Sleep* (2015)

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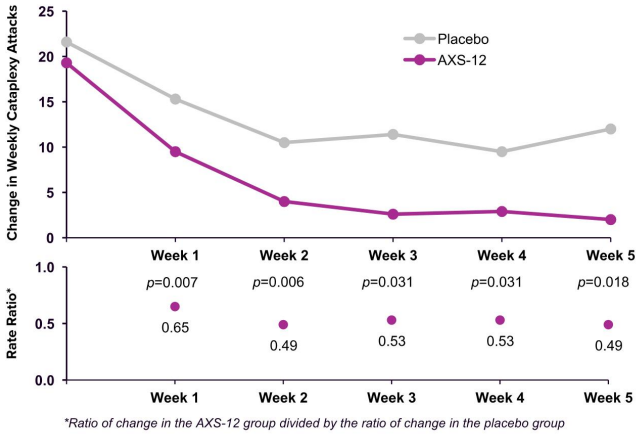
Statistically significant reductions in cataplexy frequency

Primary endpoint: Change from baseline in weekly cataplexy attacks

CONCERT



SYMPHONY



*Ratio of change in the AXS-12 group divided by the ratio of change in the placebo group

New Drug Application (NDA) submission anticipated 2H 2025

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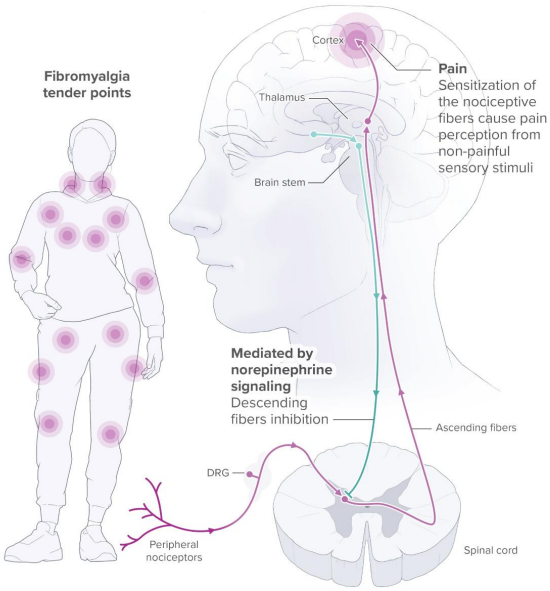
AXS-14 (esreboxetine)

Novel pharmacological approach for the management of fibromyalgia (FM)

Fibromyalgia pain is thought to be partially caused by ***dysregulated signaling*** in the descending analgesic system

Norepinephrine, one of the key neurotransmitters in this pathway, has predominantly ***pain-inhibitory effects***

AXS-14 is a ***more potent*** and ***selective*** enantiomer of racemic reboxetine that inhibits the reuptake of norepinephrine, resulting in increased norepinephrine activity and decreased pain signaling



Adapted from Siracusa, R. et al. *Int. J. Mol. Sci.* (2021)

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Fibromyalgia (FM)



Chronic and debilitating neurological syndrome impacting ***~17M*** people in the U.S.[1]



Characterized by widespread musculoskeletal pain, fatigue, disturbed sleep, depression, and cognitive impairment[2]



Limited treatment option with only 3 approved agents of variable and/or inadequate efficacy, with no novel therapeutics in ***over 15 years***

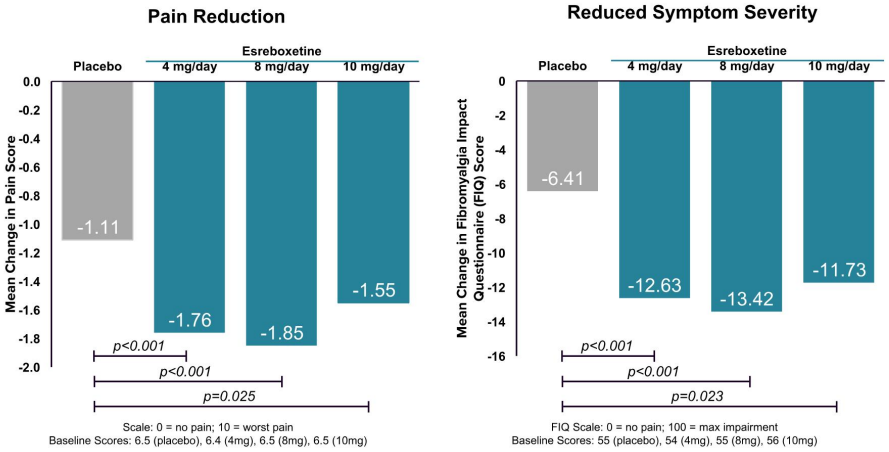
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Positive clinical data demonstrate statistically significant improvements in symptoms of fibromyalgia

- ~1,000 individuals with fibromyalgia dosed with esreboxetine across Phase 2 and Phase 3 clinical trials for up to 14 weeks
- Statistically significant and clinically meaningful reductions in pain scores, overall symptom severity, and improvements in patient-reported global functioning and fatigue

NDA submission anticipated 1Q 2025

Phase 3 Efficacy Results
(N=1,122)



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Strong intellectual property and barriers to entry

Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	• Entered into a settlement agreement resolving all outstanding patent litigation related to Auvelity • Settlement with only first filer for March 31, 2039 (with pediatric exclusivity) or September 30, 2038 (without pediatric exclusivity)
SYMBRAVO® (meloxicam and rizatriptan) 20 mg/10 mg tablets	• >99 issued U.S. patents and >131 issued O.U.S. patents • Claims extending to at least 2040; Multiple pending • Proprietary MoSEIC™ formulation and drug product formulation
SUNOSI® (solriamfetol) (IV) 75, 150 mg tablets	• Protected by a robust patent estate extending out to at least 2042 • >36 issued U.S. patents and >100 issued O.U.S. patents; Multiple pending • Proprietary drug substance and drug product formulation
AXS-12	• Orphan Drug Designation • 8 issued U.S. patents and >2 issued O.U.S. patents • Claims extending to at least 2039; Multiple pending • Proprietary drug substance and drug product formulation
AXS-05	• >140 issued U.S. patents and >93 issued O.U.S. patents • Claims extending to at least 2034-43; Multiple pending • Proprietary drug product formulation
AXS-14	• Multiple pending U.S. patents • Proprietary drug substance and drug product formulation

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Leadership team

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Founder & CEO
Goldman Sachs · BANK OF AMERICA

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Chief Financial Officer
Pierre Fabre · IMMUCOR · MERCK · Pfizer

Mark Jacobson, MA
Chief Operating Officer
Stemline

Hunter Murdock, JD
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AUROBINDO · SUN PHARMA · KIRKLAND & ELLIS LLP

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Former President, Co-CEO, Director United Therapeutics Corp.
Prior positions at Amgen and Burroughs Wellcome

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CEO, NuLids, LLC
Former COO of the Global Healthcare Group at UBS

Susan Mahony, PhD
Former SVP of Eli Lilly and President Lilly Oncology
Prior positions at BMS, Amgen and Schering-Plough

Mark Coleman, MD, Medical Director
Medical Director, National Spine and Pain Centers
Diplomat of the American Board of Anesthesiology

Herriot Tabuteau, MD
Chairman

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Thank you

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