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): November 12, 2024

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	**10007**
(Address of Principal Executive Offices)	**(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 November 12, 2024, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 30, 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 November 12, 2024, 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 November 12, 2024.
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: November 12, 2024

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

Exhibit 99.1

Axsome Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

Total 3Q 2024 net product revenue of $104.8 million, representing 81% year-over-year growth

Auvelity® 3Q 2024 net product sales of $80.4 million, representing 113% year-over-year growth

Sunosi® 3Q 2024 net product revenue of $24.4 million representing 21% year-over-year growth

Second expansion of Auvelity psychiatry sales force planned for 1Q 2025

NDA resubmission for AXS-07 for the treatment of migraine accepted by the FDA with PDUFA goal date of January 31, 2025

Topline results of ADVANCE-2 and ACCORD-2 Phase 3 trials of AXS-05 in Alzheimer's disease agitation on track for 4Q 2024

Topline results of ENCORE Phase 3 trial of AXS-12 in narcolepsy on track for 4Q 2024

Topline results of FOCUS Phase 3 trial of solriamfetol in ADHD anticipated 1Q 2025

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

NDA submission for AXS-14 for the management of fibromyalgia anticipated November 2024

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

NEW YORK, November 12, 2024 (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 third quarter of 2024 and provided a general business update.

"In the third quarter, we continued our strong commercial performance and advanced our innovative, industry-leading, late-stage development pipeline towards important near-term milestones," said Herriot Tabuteau, MD, Chief Executive Officer. "In response to continued strong demand growth, a second expansion of the Auvelity sales force is planned for the first quarter of 2025. In addition, with the January 31, 2025, PDUFA date for our AXS-07 product candidate for migraine fast approaching, commercial preparations are underway for a timely and successful launch, if approved."

"We expect a busy end to the year with several clinical catalysts anticipated, including a planned simultaneous release of topline results from the ongoing Phase 3 ADVANCE-2 and ACCORD-2 trials of AXS-05 in Alzheimer's disease agitation in the fourth quarter," Dr. Tabuteau added. "Our growth as an organization positions us well to potentially deliver multiple innovative new medicines to the millions of individuals living with central nervous system disorders in the U.S. Importantly, we have the resources in hand to execute our operating plans and create substantial value for shareholders."

Third Quarter 2024 Financial Highlights

- Total net product revenue for the third quarter of 2024 was $104.8 million, representing 81% year-over-year growth. Total net product revenue for the comparable period in 2023 was $57.8 million.
- Auvelity net product sales were $80.4 million for the third quarter of 2024, representing 113% year-over-year growth. Auvelity net product sales for the comparable period in 2023 were $37.7 million.

- Sunosi net product revenue was $24.4 million for the third quarter of 2024, representing 21% year-over-year growth, which consisted of $23.4 million in net product sales and $1.0 million in royalty revenue associated with sales in out-licensed territories. Sunosi net product revenue for the comparable period in 2023 was $20.1 million, consisting of $19.4 million in net product sales and $0.7 million in royalty revenue.
- Total cost of revenue was $8.4 million for the third quarter of 2024. Total cost of revenue for the comparable period in 2023 was $6.5 million.
- Research and development (R&D) expenses were $45.4 million for the third quarter of 2024, compared to $28.8 million for the comparable period in 2023. The increase was primarily related to the Company's ongoing Phase 3 trials of solriamfetol in four new indications and of AXS-05 in Alzheimer's disease agitation, chemistry, manufacturing, and controls costs associated with pipeline products, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.
- Selling, general, and administrative (SG&A) expenses were $95.6 million for the third quarter of 2024, compared to $83.2 million for the comparable period in 2023. The increase was primarily related to commercialization expenses for Auvelity and Sunosi and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.
- Net loss for the third quarter of 2024 was $64.6 million or $(1.34) per share, compared to a net loss of $62.2 million or $(1.32) per share for the comparable period in 2023. The net loss in the third quarter of 2024 reflects $40.9 million in non-cash charges, including a fair market value adjustment for contingent consideration of $16.4 million.
- Cash and cash equivalents totaled $327.3 million at September 30, 2024, compared to $386.2 million at December 31, 2023.
- Shares of common stock outstanding were 48,436,108 at September 30, 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 144,000 prescriptions were written for Auvelity in the third quarter of 2024, representing an increase of 108% compared to the same period in 2023, and an increase of 17% compared to the second 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.
- In response to demand growth and in anticipation of continued expansion and evolution of covered lives, Axsome is planning a second expansion of its Auvelity psychiatry sales force to approximately 300 sales representatives. The expansion is expected to complete in the first quarter of 2025.

Sunosi

- Approximately 47,000 prescriptions were written for Sunosi in the U.S. in the third quarter of 2024, representing an increase of 15% compared to the same period in 2023, and an increase of 5% compared to the second 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.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline encompassing five innovative, late-stage, patent-protected product candidates for nine 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 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:** The comprehensive development program of AXS-05 in AD agitation consists of four pivotal, Phase 3, placebo-controlled efficacy trials, including the completed, positive ADVANCE-1 and ACCORD-1 trials, and the ongoing ADVANCE-2 and ACCORD-2 trials.

  ADVANCE-2 is a randomized, double-blind, placebo-controlled, parallel group trial. ACCORD-2 is a double-blind, placebo-controlled, randomized withdrawal trial. Target enrollment in both trials has been reached. The Company remains on track to report topline results from the ADVANCE-2 and ACCORD-2 trials in the fourth quarter and anticipates doing so simultaneously.

  Smoking Cessation: Axsome plans to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in 2025.

AXS-07

AXS-07 (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational selective COX-2 inhibitor and 5-$HT_{1B/1D}$ agonist being developed for the acute treatment of migraine.

- **Migraine:** Axsome's New Drug Application (NDA) for AXS-07 for the acute treatment of migraine is currently under review by the FDA with a PDUFA goal date of January 31, 2025.

  Axsome is conducting the EMERGE study, a Phase 3, single-group, multicenter trial evaluating the efficacy and safety of AXS-07 for the acute treatment of migraine headache in adults with a prior inadequate response to an oral CGRP inhibitor. The Company remains on track to announce topline results from the EMERGE trial in the fourth quarter of 2024.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent, highly selective investigational 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 is conducting the ENCORE study, a two-period Phase 3 trial evaluating the long-term efficacy and safety of AXS-12 in narcolepsy, consisting of a 24-week open-label period followed by a 3-week, double-blind, placebo-controlled, randomized withdrawal period. Enrollment in the ENCORE trial is complete, and the Company remains on track to report topline results from the trial in the fourth quarter of 2024.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, potent, highly selective investigational 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 is completing preparations for the submission of the NDA for AXS-14 for the management of fibromyalgia and expects to submit the NDA to the FDA in November 2024.

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 anticipates completion of enrollment in the FOCUS trial in December 2024 and topline results 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 anticipates completion of enrollment in the PARADIGM trial in the fourth quarter of 2024 and topline results 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. The Company anticipates topline results from the trial in 2025.
- **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 trial in 2026.

Scientific Presentations

- In September 2024, the Company presented multiple data analyses at Sleep Europe 2024, including results from the SYMPHONY Phase 3 trial of AXS-12 in narcolepsy and findings from the CRESCENDO patient survey underscoring the unmet needs of patients with type 1 narcolepsy.
- In October and November 2024, the Company presented multiple data analyses at Psych Congress 2024 and NEI Congress 2024, respectively, including new findings from a pooled analysis of the GEMINI and ASCEND clinical trials of Auvelity supporting its differentiated safety and tolerability profile.

Corporate Update

- In August 2024, Axsome announced that the patent litigation with Sandoz Inc. (Sandoz) related to Sunosi (solriamfetol) was dismissed following Sandoz's withdrawal of its ANDA for a generic equivalent of Sunosi. As a result, the litigation with Sandoz has been dismissed without prejudice.

Anticipated Milestones

- **Regulatory:**
  - AXS-14 for fibromyalgia, NDA submission (November 2024)
  - AXS-07 for migraine, PDUFA goal date (January 31, 2025)
- **Clinical Trial Topline Results:**
  - Phase 3 ADVANCE-2 trial of AXS-05 in Alzheimer's disease agitation (4Q 2024)
  - Phase 3 ACCORD-2 trial of AXS-05 in Alzheimer's disease agitation (4Q 2024)
  - Phase 3 ENCORE trial of AXS-12 in narcolepsy (4Q 2024)
  - Phase 3 EMERGE trial of AXS-07 in patients with migraine with inadequate response to oral CGRP inhibitors (4Q 2024)
  - 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 (2025)
  - 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 third quarter 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 continued commercial success of the Company’s Sunosi® and Auvelity® 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; whether issues identified by FDA in the complete response letter 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 the Company’s special protocol assessment for the MOMENTUM clinical trial; 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 continued commercialization of Sunosi and Auvelity 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
(In thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 327,341	$ 386,193
Accounts receivables, net	124,096	94,820
Inventories, net	14,265	15,135
Prepaid and other current assets	13,411	8,115
Total current assets	479,113	504,263
Equipment, net	683	846
Right-of-use asset - operating lease	5,730	6,772
Goodwill	12,042	12,042
Intangible asset, net	48,501	53,286
Non-current inventory and other assets	15,389	11,027
Total assets	$ 561,458	$ 588,236
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 64,253	$ 40,679
Accrued expenses and other current liabilities	122,176	90,501
Operating lease liability, current portion	1,627	1,267
Contingent consideration, current	8,131	6,407
Total current liabilities	196,187	138,854
Contingent consideration, non-current	82,980	73,300
Loan payable, long-term	180,002	178,070
Operating lease liability, long-term	6,440	7,035
Finance lease liability, long-term	2,951	—
Total liabilities	468,560	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, 48,436,108 and 47,351,363 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively)	5	5
Additional paid-in capital	1,140,768	1,026,543
Accumulated deficit	(1,047,875)	(835,571)
Total stockholders' equity	92,898	190,977
Total liabilities and stockholders' equity	$ 561,458	$ 588,236

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 103,736	$ 57,127	$ 264,352	$ 131,713
License revenue	—	—	—	65,735
Royalty revenue	1,026	667	2,575	1,622
Total revenues	104,762	57,794	266,927	199,070
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	8,437	6,532	22,789	18,687
Research and development	45,388	28,767	132,071	67,141
Selling, general and administrative	95,564	83,188	298,088	236,314
Loss (Gain) in fair value of contingent consideration	16,391	(180)	17,139	5,711
Intangible asset amortization	1,606	1,607	4,785	4,768
Total operating expenses	167,386	119,914	474,872	332,621
Loss from operations	(62,624)	(62,120)	(207,945)	(133,551)
Interest expense, net	(1,978)	(757)	(4,359)	(5,751)
Loss before income taxes	(64,602)	(62,877)	(212,304)	(139,302)
Income tax benefit (expense)	—	678	—	(1,285)
Net loss	$ (64,602)	$ (62,199)	$ (212,304)	$ (140,587)
Net loss per common share, basic and diluted	$ (1.34)	$ (1.32)	$ (4.45)	$ (3.14)
Weighted average common shares outstanding, basic and diluted	48,140,519	47,117,196	47,703,508	44,783,380

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3Q 2024 Corporate Presentation
November 2024
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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 continued commercial success of the Company’s Sunosi® and Auvelity® 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; whether issues identified by FDA in the complete response letter 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 the Company’s special protocol assessment for the MOMENTUM clinical trial; 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 continued commercialization of Sunosi and Auvelity 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 presentation 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, 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

Our Mission

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

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

Psychiatry

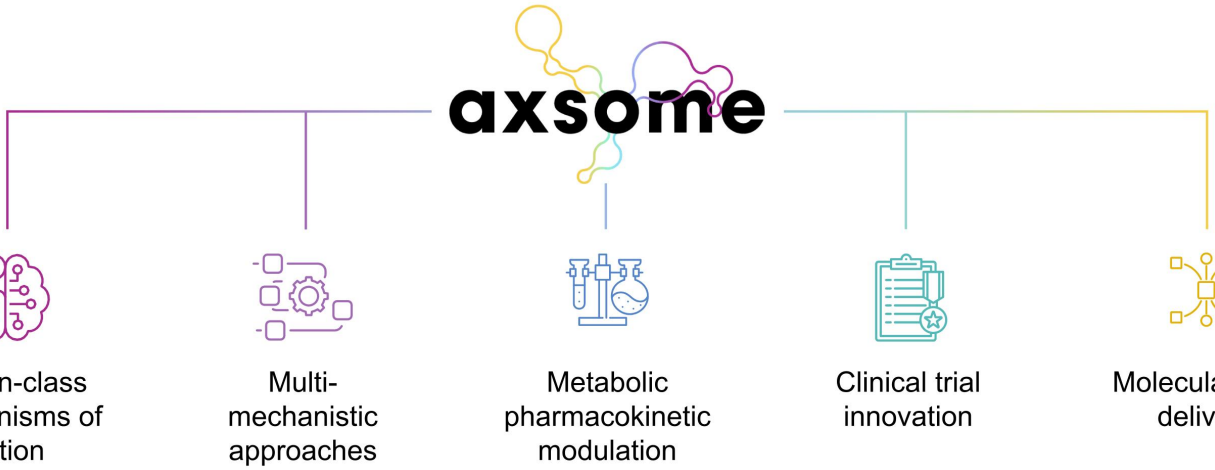
Major Depressive Disorder		Alzheimer's Disease Agitation		Smoking Cessation		ADHD		Binge Eating Disorder	
21M+	People in the U.S. live with MDD	4M+	people with Alzheimer's disease experience agitation	34M+	adults in the U.S. currently smoke cigarettes	22M+	adults and children in the U.S. live with ADHD	7M+	people in the U.S. experience BED in their lifetime
	of patients fail to achieve remission from initial therapy	1	FDA-approved product	~70%	of smokers say they want to quit		of adult ADHD patients do not receive any type of treatment	2-3x	more likely to have psychiatric and medical comorbidities

Neurology

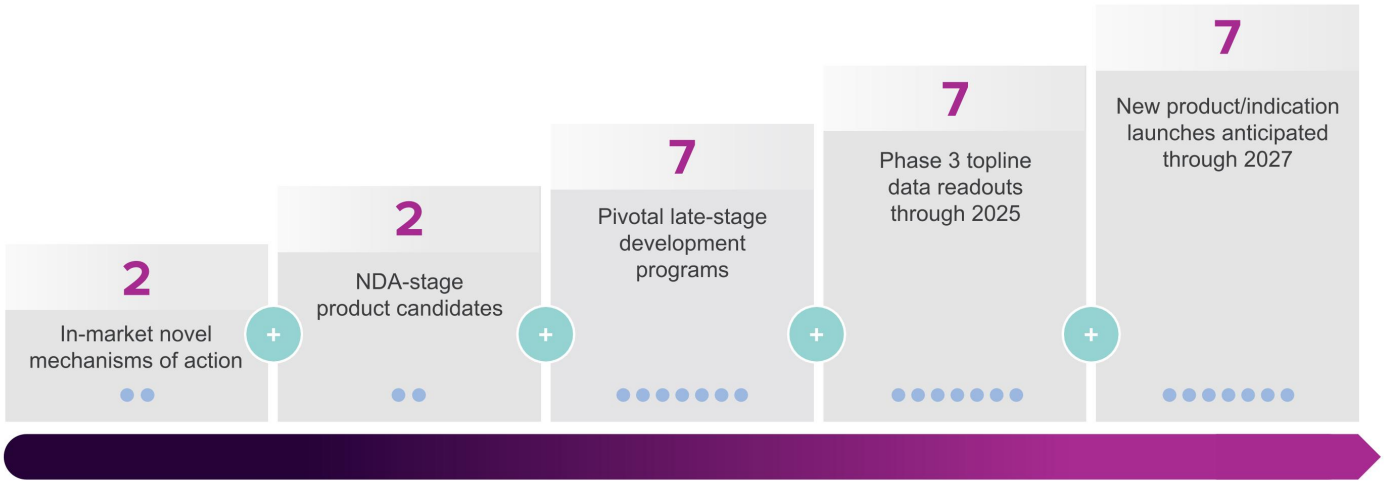
Obstructive Sleep Apnea		Migraine		Narcolepsy		Fibromyalgia		Shift Work Disorder	
22M+	U.S. adults are affected by OSA	39M+	adults in the U.S. suffer from migraine	185K	people in the U.S. are affected by narcolepsy	17M+	people in the U.S. have fibromyalgia	15M+	working Americans suffer from shift work disorder
~80%	of patients remain undiagnosed	>70%	of migraine sufferers are not fully satisfied with their current treatment	~70%	of patients suffer from cataplexy	>15	years since the last FDA-approved therapeutic	0	new medications approved in nearly two decades

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

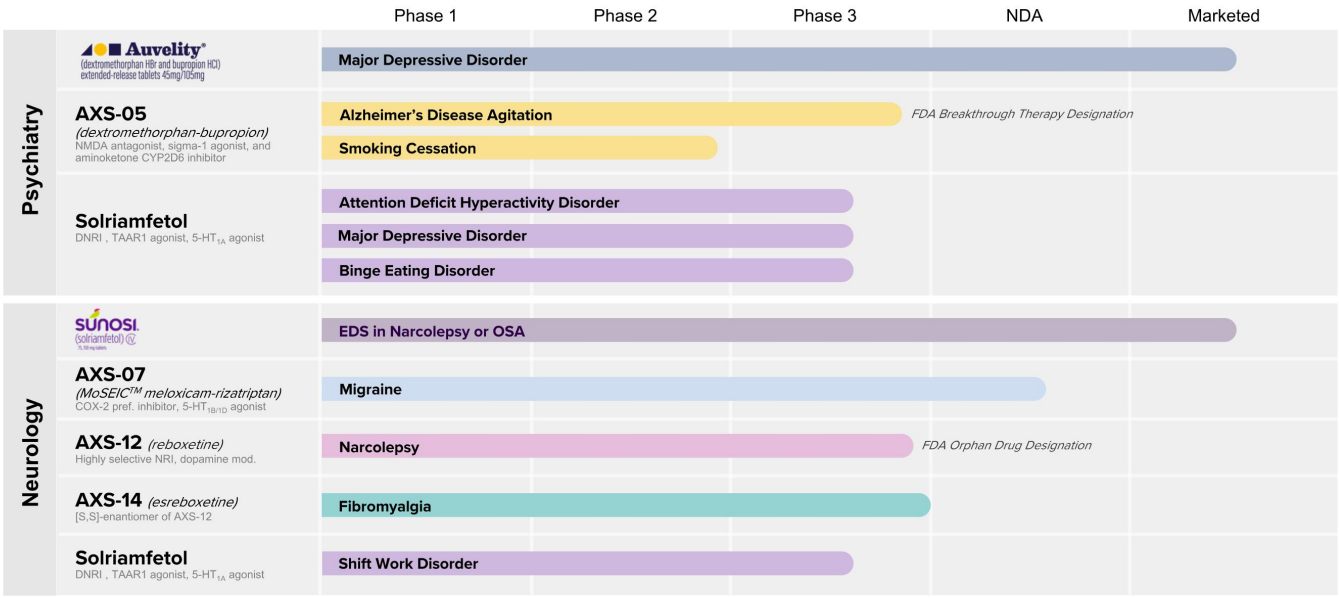
…And lead in innovation to expand the therapeutic possibilities for CNS conditions



Multiple value-creating opportunities to enable robust, long-term growth through 2040s and beyond



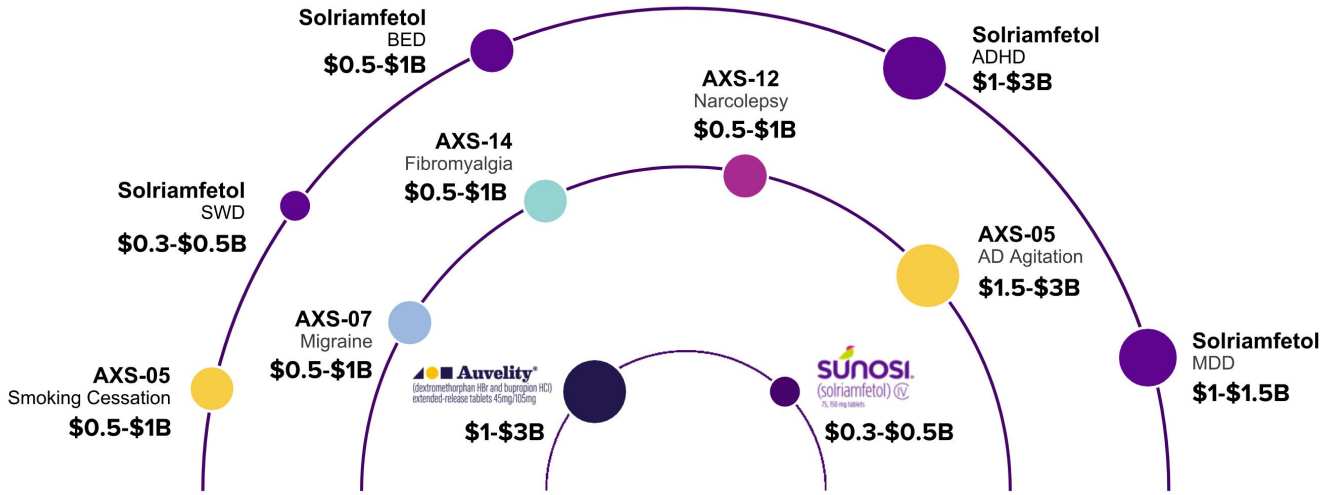
Advancing an industry-leading neuroscience pipeline



NMDA = N-methyl-D-aspartate; COX-2 = Cyclooxygenase-2; 5-HT = 5-Hydroxytryptamine; NE = Norepinephrine; CYP2D6 = Cytochrome P450 Family 2 Subfamily D Member 6; MoSEIC = Molecular Solubility Enhanced Inclusion Complex; TAAR1 = Trace amine-associated receptor 1; DNRI = dopamine-norepinephrine reuptake inhibitor

Please see full Prescribing Information for Auvelity at www.Auvelity.com; Please see full Prescribing Information for Sunosi at www.Sunosi.com

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



3Q 2024 highlights

Poised to deliver ≥3 FDA approvals through 2025/2026 and 7 new product/indication launches through 2027

Strong Commercial Execution

- Total net product revenue of $104.8M represents 81% YoY growth vs. 3Q 2023
  - Auvelity: $80.4M
  - Sunosi: $24.4M
- Strong demand for Auvelity and Sunosi expected to continue into next year

Leading CNS Innovation

- AXS-07 PDUFA goal date of January 31, 2025
- NDA submission for AXS-14 in fibromyalgia anticipated November 2024
- Topline results from both ADVANCE-2 and ACCORD-2 Ph 3 trials of AXS-05 in AD agitation on track for 4Q 2024
- Topline results from FOCUS and PARADIGM Ph 3 trials of solriamfetol in ADHD and MDD, respectively, anticipated 1Q 2025
- Topline results from ENCORE Ph 3 trial of AXS-12 in narcolepsy on track for 4Q 2024

Capital Allocation Excellence

- $327.3M cash and cash equivalents as of September 30, 2024
- Current cash expected to fund operations into cash flow positivity

Key achievements to date with catalyst-rich path ahead

	2024	4Q 2024	2025 & 2026
Regulatory	✓ NDA resubmission for AXS-07 in migraine accepted for review by the FDA (3Q 2024)	• NDA submission for AXS-14 in fibromyalgia (November 2024)	• AXS-07 PDUFA goal date (January 31, 2025)
Clinical Trial Topline Results	✓ Positive topline results from SYMPHONY Ph 3 trial of AXS-12 in narcolepsy (1Q 2024)	• ADVANCE-2 Ph 3 trial of AXS-05 in Alzheimer's disease agitation (4Q 2024) • ACCORD-2 Ph 3 trial of AXS-05 in Alzheimer's disease agitation (4Q 2024) • ENCORE Ph 3 trial of AXS-12 in narcolepsy (4Q 2024) • EMERGE Ph 3 trial of AXS-07 in CGRP non-responders (4Q 2024)	• 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 (2025) • 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)

3Q 2024 financial summary

$ millions	3Q 2024	3Q 2023	% change	YTD 2024	YTD 2023	% change
Net product revenue	$104.8	$57.8	81%	$266.9	$133.3	100%
Auvelity net product sales	$80.4	$37.7	113%	$198.8	$81.0	145%
Sunosi net product revenue†	$24.4	$20.1	21%	$68.1	$52.3	30%
R&D expense	$45.4	$28.8	58%	$132.1	$67.1	97%
SG&A expense	$95.6	$83.2	15%	$298.1	$236.3	26%

3Q = three months ended September 30; YTD = nine months ended September 30; †Includes royalty revenue associated with sales in out-licensed territories and excludes a one-time upfront license payment received from Pharmanovia in 1Q 2023

3Q 2024 commercial highlights

Auvelity

- Net product sales of ***$80.4M*** represents 113% YoY growth vs. 3Q 2023
- ***~140,000*** new patients and ***>28,000*** 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)

Sunosi

- Net product revenue of ***$24.4M*** represents 21% YoY growth vs. 3Q 2023
- ***>76,000*** new patients and ***>13,000*** 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

axsome

Commercial Products

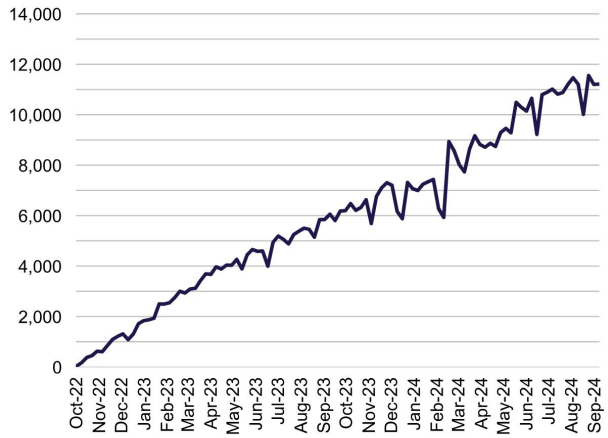
axsome

Auvelity – novel and differentiated oral treatment for major depressive disorder in adults[1,2]

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

- 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]

Weekly TRx Launch to Date

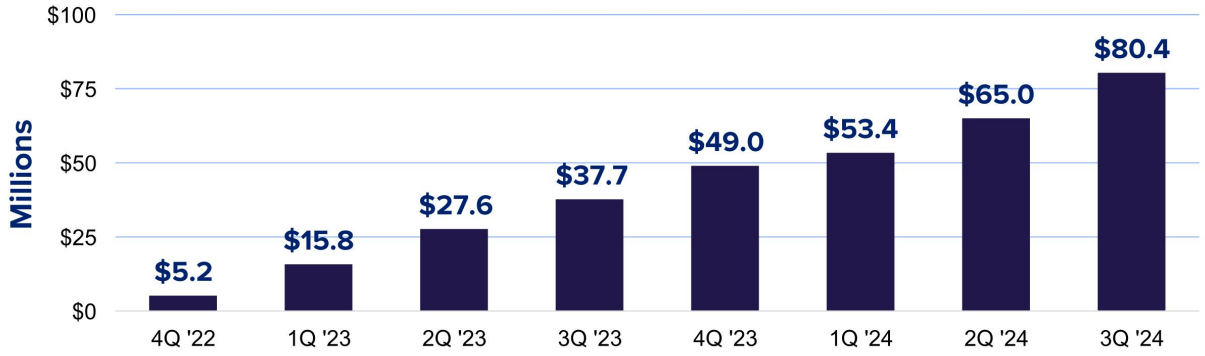


Source: Symphony METYS

TRx = total prescriptions; 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)

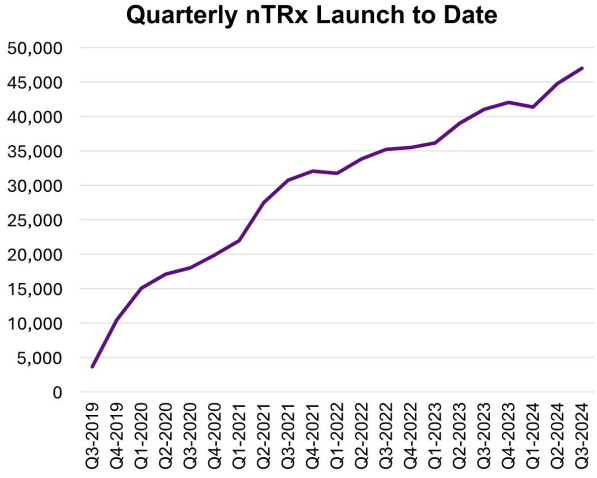
Auvelity quarterly net sales performance



3Q 2024 net sales of $80.4M represents ***113%*** year-over-year growth vs. 3Q 2023

Sunosi – 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

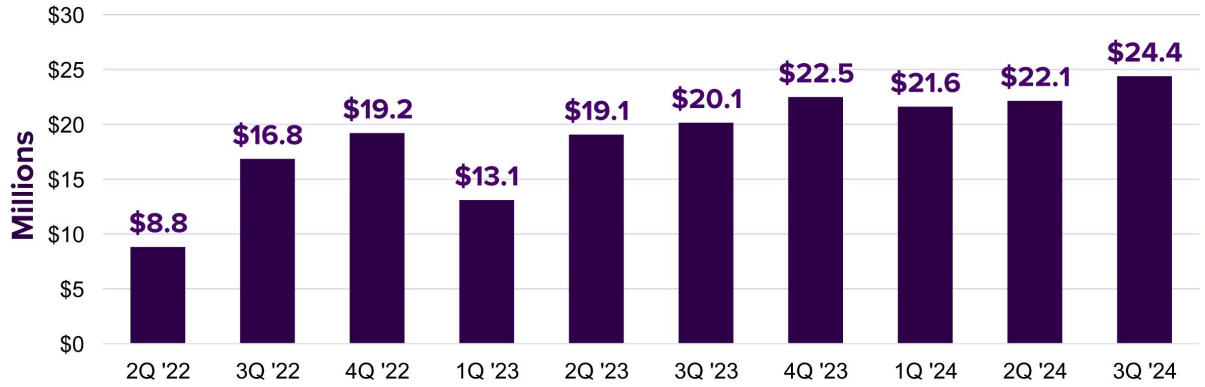


Source: Symphony METYS. nTRx normalizes number of pills in each Trx for 30-day period.

nTRx = normalized total prescriptions; 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)

Sunosi quarterly net revenue performance



3Q 2024 net revenue of $24.4M represents ***21%*** year-over-year growth vs. 3Q 2023

Development Pipeline

axsome

AXS-05 (dextromethorphan-bupropion)

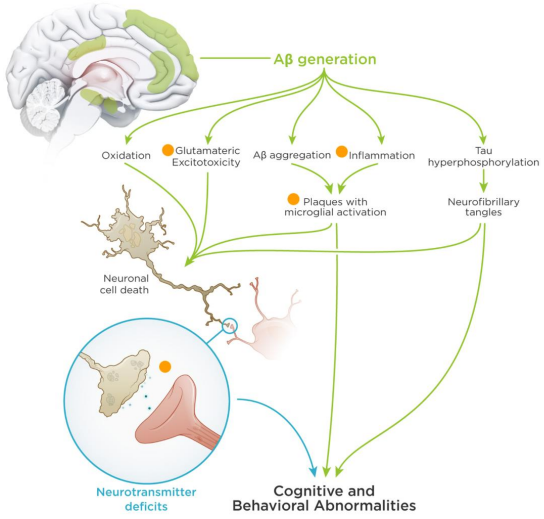
Potentially first-in-class, best-in-class treatment for Alzheimer's disease agitation

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]

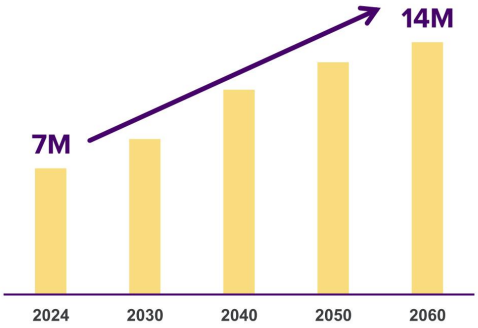


AXS-05 pharmacological actions[5,6]

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)

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]

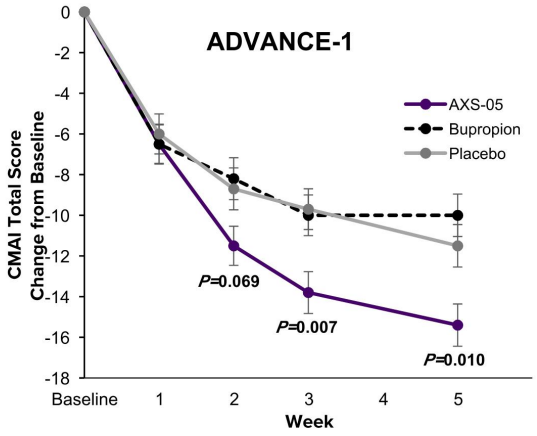
Agitation is reported in ***~70%*** of people with AD and is characterized by emotional distress, verbal and physical aggressiveness, disruptive irritability, and disinhibition[1,2]

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

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

Clinically meaningful improvements in symptoms of agitation

Primary endpoint: Change from baseline in CMAI total score at week 5



FDA Breakthrough Therapy designation received June 2020

Rapid and substantial reduction in agitation with separation as early as Week 2 and statistically significant improvement at Week 3

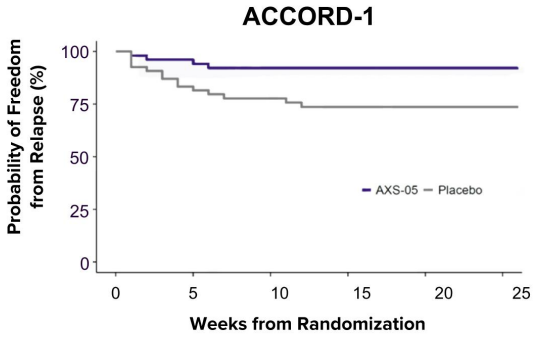
Significantly greater percentage of patients on AXS-05 achieved a clinical response (≥30% reduction in CMAI) vs. placebo (p=0.005)

Well tolerated with ***low and similar*** TEAE-related discontinuation rates between AXS-05 and placebo groups

axsome

Substantial and statistically significant increase in time to relapse

Primary endpoint: Time from randomization to relapse of AD agitation symptoms



Hazard Ratio for Time to Relapse	
Hazard Ratio (95% CI)	0.275 (0.091-0.836)
***P*-value**	0.014

AXS-05 ***significantly delayed*** time to relapse and ***prevented more*** relapses of agitation symptoms vs. placebo

Patients on AXS-05 were ***3.6x less likely*** to relapse vs. placebo

A ***majority of patients*** achieved a clinical response (≥30% reduction in CMAI) by week 3 and over 90% by week 7 in the open-label period

CMAI = Cohen-Mansfield Agitation Inventory

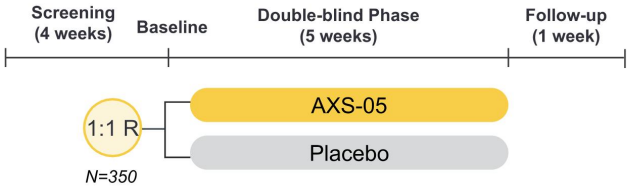
Comprehensive development program of AXS-05 in Alzheimer's disease agitation

Alzheimer's Disease Agitation				
ADVANCE-1 *Phase 2/3 (N=366)*	**ACCORD-1** *Phase 3 (N=108)*	**ADVANCE-2** *Phase 3 (N=350)*	**ACCORD-2** *Phase 3 (N=140)*	**OLE safety** *Phase 3*
✓ Two completed, **positive**, pivotal efficacy and safety trials in >450 patients with Alzheimer's disease agitation		⊕ • Two ongoing pivotal Phase 3 trials evaluating the efficacy and safety of AXS-05 vs. placebo • Ongoing open-label safety extension trial to support long-term safety database		
		ADVANCE-2 and ACCORD-2 Topline Data Anticipated 4Q 2024		

Ongoing pivotal Phase 3 trials evaluating the efficacy and safety of AXS-05 in Alzheimer's disease agitation

ADVANCE-2 Phase 3 Trial

Consistent trial design as the ADVANCE-1 Phase 2/3 trial



Key eligibility criteria

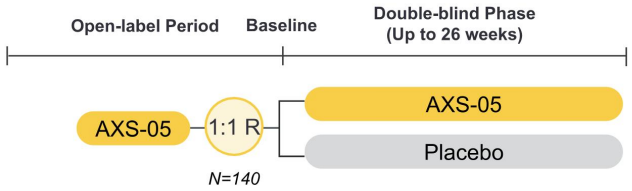
- 65-90 years of age with diagnosis of probable Alzheimer's disease (AD) and clinically significant agitation resulting from probable AD

Primary endpoint

- Change from baseline in CMAI total score

ACCORD-2 Phase 3 Trial

Consistent trial design as the ACCORD-1 Phase 3 trial



Key eligibility criteria

- 65-90 years of age with diagnosis of probable Alzheimer's disease (AD) and clinically significant agitation resulting from probable AD

Primary endpoint

- Time from randomization to relapse of agitation

CMAI = Cohen-Mansfield Agitation Inventory

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)

AXS-07 (MoSEIC™ meloxicam-rizatriptan)

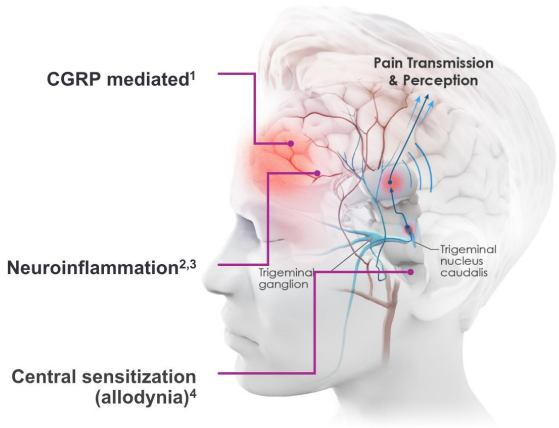
Unique multi-mechanistic approach targets four known pathways implicated in a migraine attack

MoSEIC™ meloxicam inhibits COX-2-mediated synthesis of prostaglandins (PGE_2), resulting in ***reduced neuroinflammation***

MoSEIC™ meloxicam decreases peripheral sensitization by reducing neuroinflammation, leading to the ***reversal of central sensitization***

Rizatriptan inhibits the release of CGRP by stimulating 5-HT_{1D} receptors on the pre-synaptic trigeminal nerve ending, resulting in ***reduced pain signal transmission***

Rizatriptan stimulates 5-HT_{1B} receptors on the post-synaptic arterial smooth muscle cell, resulting in ***reduced vasodilation***



1. Geppetti, P. et al. *J Headache Pain* (2012); 2. COX-2 data from Li, M.M. et al. *Med Sci Monit.* (2017); 3. PGE_2 data from Sarchielli, P. et al. *Cephalalgia* (2000); 4. Data from Burstein, R., Cutrer, M.F., & Yarnitsky, D. *Brain* (2000)

Migraine

>70% of patients are not fully satisfied with their current treatment and desire faster, more durable therapies[4,5]

Leading cause of disability among neurological disorders in the U.S., affecting approximately ***39M people***[1,2]

Characterized by recurrent attacks of ***pulsating, often severe and disabling head pain*** associated with nausea, sensitivity to light, and sensitivity to sound[3]

Associated with ***$78 billion*** in direct and indirect costs in the U.S. annually[6]

1. American Migraine Foundation (2023); 2. Steiner, T.J. et al. *J Headache Pain* (2020); 3. Headache Classification Committee of the International Headache Society (IHS) *Cephalagia* (2018); 4. Smelt, A.F.H. et al. *PLoS One* (2014); 5. Lipton, R.B. & Stewart, W.F. *Headache* (1999); 6. Gooch, C.L., Pracht, E., & Borenstein, A.R. *Ann Neurol.* (2017)

Differentiated efficacy and safety profile supported by three Phase 3 clinical trials

Migraine

MOMENTUM *Phase 3 (N=1594)*	INTERCEPT *Phase 3 (N=302)*	MOVEMENT (OLE) *Phase 3 (N=706)*
✓ Two **completed**, positive, registrational efficacy and safety trials in >1,800 patients with migraine ✓ **Rapid, substantial, and sustained** pain relief vs. controls in short-term trials ✓ AXS-07 **well tolerated** in open-label extension trial with substantially consistent safety profile as short-term trials		

PDUFA goal date of January 31, 2025

⊕

EMERGE
Phase 3 (N=100)

- Ongoing Phase 3 trial evaluating the efficacy and safety of AXS-07 (oral CGRP antagonist non-responders)

Topline Data Anticipated 4Q 2024

AXS-12 (reboxetine)

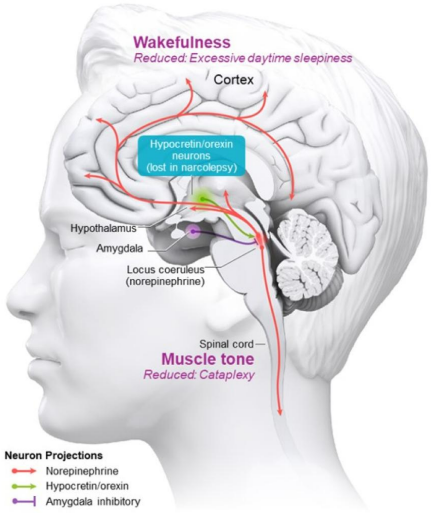
Novel pharmacological approach for the treatment of narcolepsy

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)

Narcolepsy

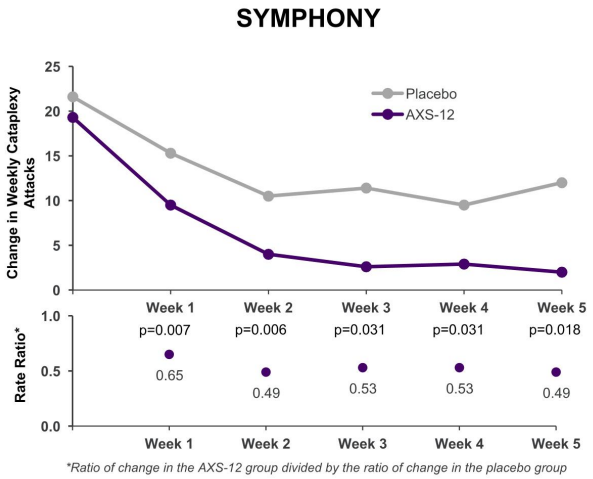
Rare and debilitating neurological condition that affects approximately ***185,000*** people in the U.S.[1]

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)

Statistically significant reductions in cataplexy and EDS in two completed clinical trials



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

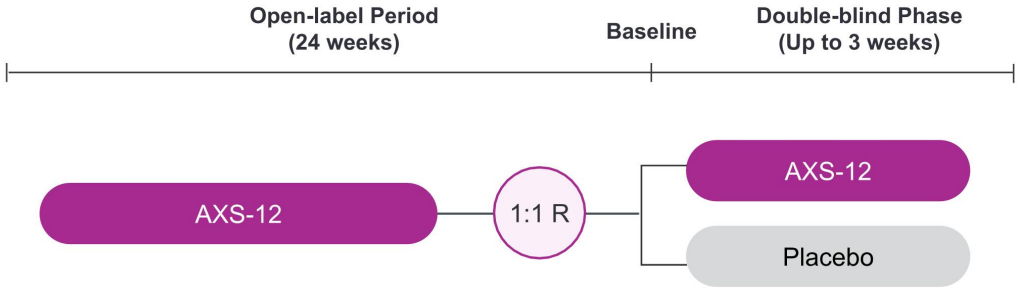
CONCERT (Phase 2)	SYMPHONY (Phase 3)
Efficacy and safety of AXS-12 vs. placebo in patients with narcolepsy with cataplexy	
2-week, randomized, double-blind, placebo-controlled crossover trial ✓ Statistically significant reduction in cataplexy attacks vs. placebo (p<0.001) ✓ Statistically significant improvements in excessive daytime sleepiness (EDS), cognitive function, and sleep quality	**5-week, randomized, double-blind, placebo-controlled trial** ✓ Statistically significant reduction in cataplexy attacks vs. placebo (p=0.018) with significantly more AXS-12 patients achieving remission of cataplexy (p<0.01) ✓ Statistically significant improvements in EDS, cognition, narcolepsy severity, and overall quality of life

Topline Results From the ENCORE Phase 3 Trial Anticipated 4Q 2024

EDS = excessive daytime sleepiness

ENCORE Phase 3 trial design

Two-period trial evaluating long-term efficacy and safety of AXS-12 in narcolepsy



Key eligibility criteria

- 15-75 years of age with diagnosis of narcolepsy type 1 with ≥7 cataplexy attacks/week or ≥14 in two weeks

Primary endpoint

- Change in average weekly frequency of cataplexy attacks

TEAE = treatment emergent adverse event

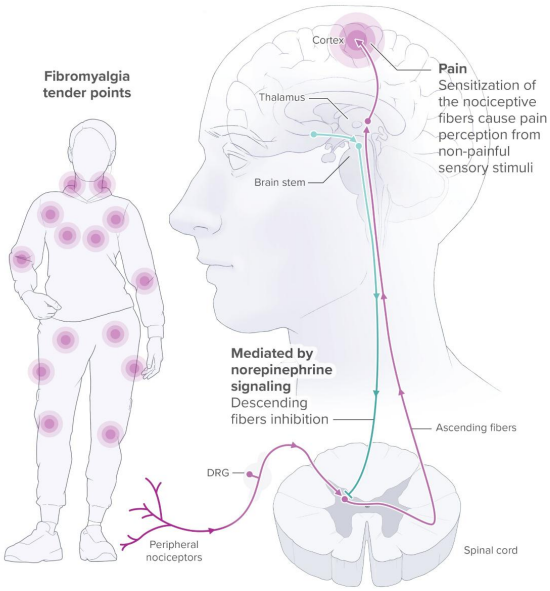
AXS-14 (esreboxetine)

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)

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***

axsome

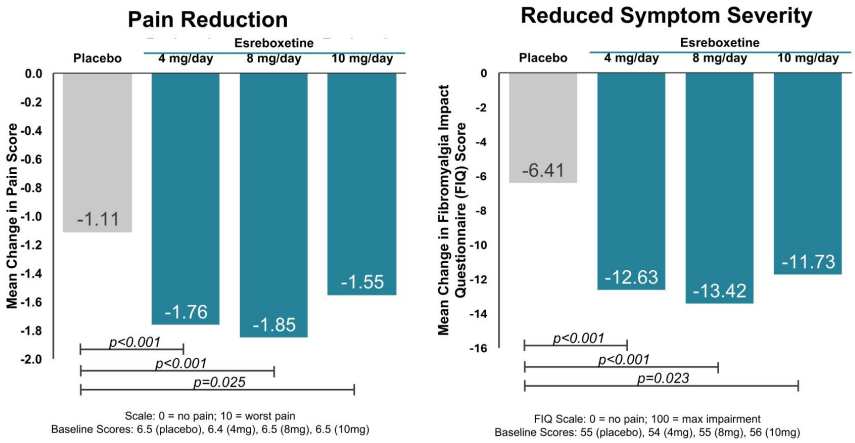
1. Vincent et al. *Arthritis Care Res (Hoboken)* (2013); 2. Bair, M.J. & Krebs, E.E. *Ann Intern Med.* (2020)

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

New Drug Application (NDA) Submission Anticipated November 2024

Phase 3 Efficacy Results
(N=1,122)



Solriamfetol Phase 3 development programs

Solriamfetol

ADHD

FOCUS
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

Topline Data Anticipated 1Q 2025

MDD

PARADIGM
Phase 3 (N=300)

- Efficacy and safety of solriamfetol vs. placebo in adults with major depressive disorder
- 6-week, double-blind, randomized, placebo-controlled, parallel group trial

Topline Data Anticipated 1Q 2025

BED

ENGAGE
Phase 3 (N=450)

- Efficacy and safety of solriamfetol vs. placebo in adults with binge eating disorder
- 12-week, double-blind, randomized, placebo-controlled, parallel group trial

Topline Data Anticipated 2025

SWD

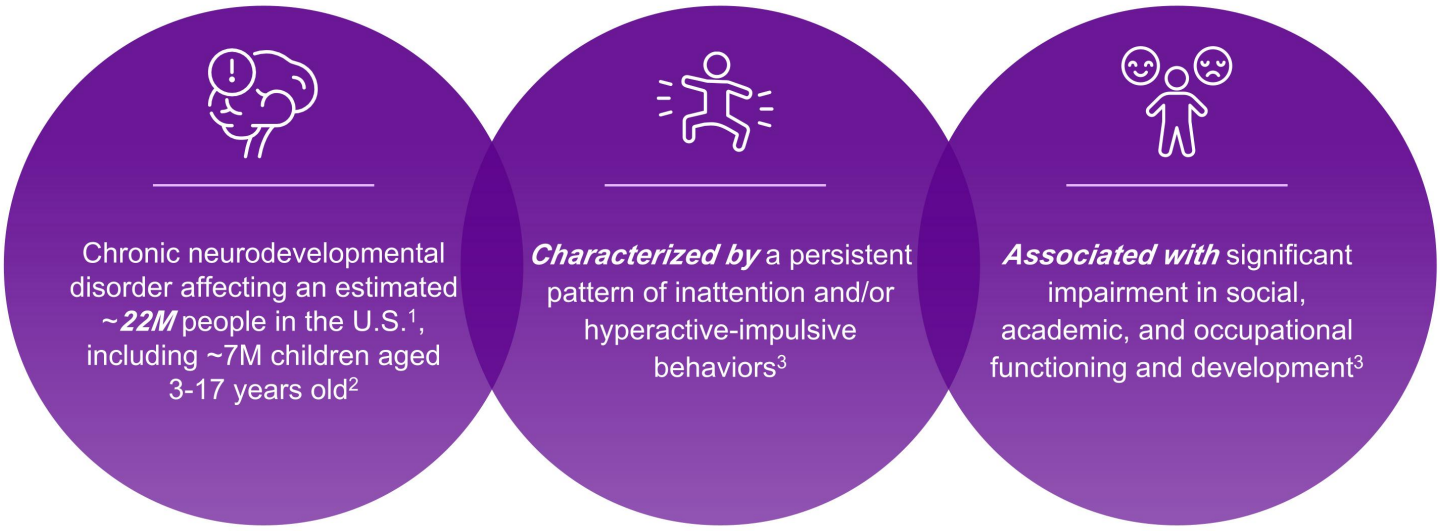
SUSTAIN
Phase 3 (N=450)

- Efficacy and safety of solriamfetol vs. placebo in adults with shift work disorder
- 6-week, double-blind, randomized, placebo-controlled, parallel group trial

Topline Data Anticipated 2026

ADHD = attention deficit hyperactivity disorder; MDD = major depressive disorder; BED = binge eating disorder; SWD = shift work disorder

Attention deficit hyperactivity disorder (ADHD)

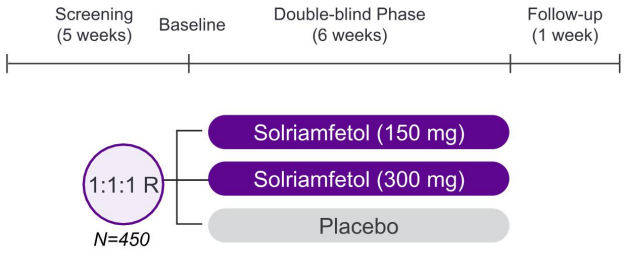


1. “Facts About ADHD in Adults.” CDC (2024); 2. “Data and Statistics on ADHD.” CDC (2024); 3. “Attention-Deficit/Hyperactivity Disorder.” NIMH (2024)

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

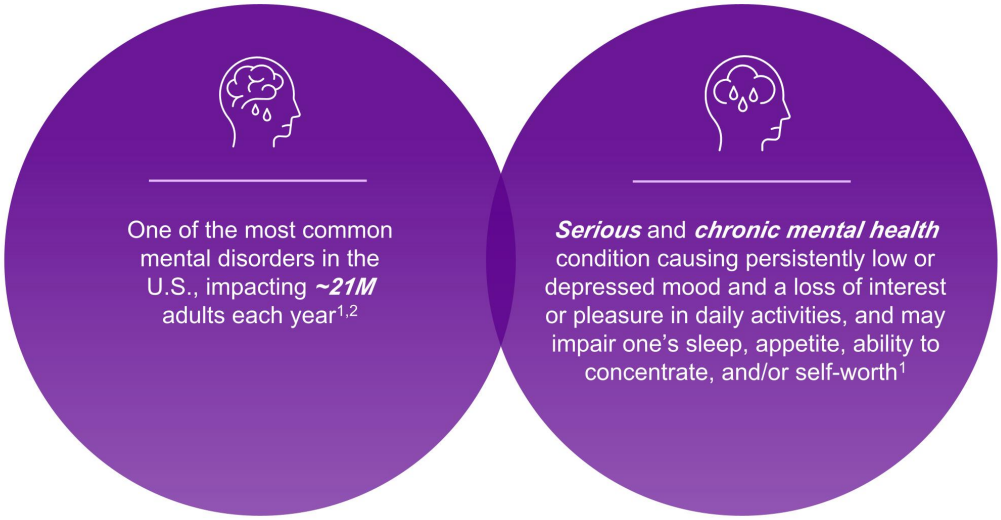
- Change from baseline in AISRS score

AISRS = Adult ADHD Investigator Symptom Report Scale

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

Major depressive disorder (MDD)

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



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

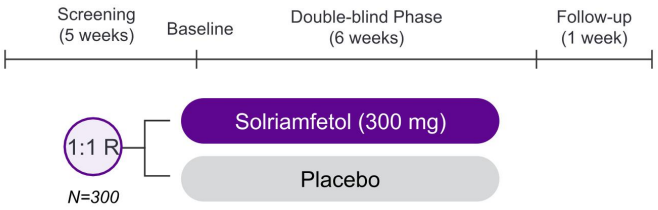
Evaluating solriamfetol as a potential treatment for MDD

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

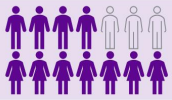
- Change from baseline in MADRS score

EDS = excessive daytime sleepiness; MADRS = Montgomery-Åsberg Depression Rating Scale

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

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]

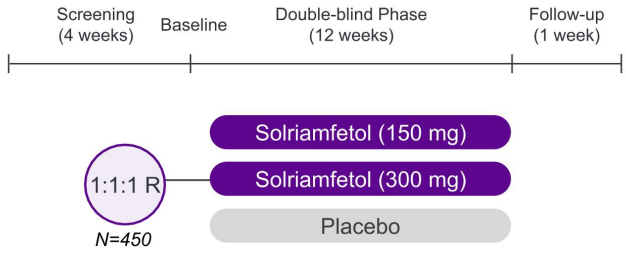
1. Kessler, R.M. et al. *Neurosci Biobehav Rev*. (2016); 2. Hudson, J.I. et al. *Biol Psychiatry* (2007); 3. McElroy, S.L. et al. *J Clin Psychiatry* (2020); 4. Giel, KL. et al. *Nat Rev Dis Primer* (2022); 5. Bello, N.T. & Hajnal, A. *Pharmacol Biochem Behav*. (2010); 6. Pruccoli et al. *Int J Mol Sci*.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

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 2025

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

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)

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]

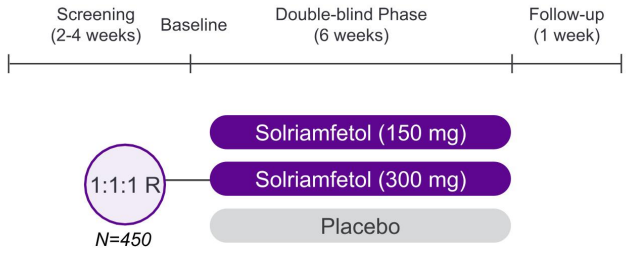
No new medications approved since 2007 and considerable residual sleepiness reported when medication is used[6]

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)

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

- 18-55 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 Impressions of Change

Strong intellectual property and barriers to entry

Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	• Protected by a robust patent estate extending out to at least 2043; Multiple pending • Proprietary drug product formulation
AXS-07	• >98 issued U.S. patents and >129 issued O.U.S. patents • Claims extending to at least 2038; Multiple pending • Proprietary MoSEIC™ formulation and drug product formulation
SUNOSI® (solriamfetol) (V) 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 1 issued O.U.S. patent • Claims extending to at least 2039 • Proprietary drug substance and drug product formulation
AXS-05	• >135 issued U.S. patents and >92 issued O.U.S. patents • Claims extending to at least 2034-43; Multiple pending • Proprietary drug product formulation
AXS-14	• Pending U.S. patents • Proprietary drug substance and drug product formulation

Financial snapshot

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

Cash Balance: (as of September 30, 2024)	$327.3 M
Debt (Face Value): (as of September 30, 2024)	$180 M
Market Cap: (as of November 11, 2024)	$4.4 B
Shares Outstanding: (as of September 30, 2024)	48.4 M
Options, RSUs, and Warrants Outstanding†:	9.5 M

†Consists of 8.5 M options, 0.9 M RSUs, 0.08 M warrants, and 0.07 ESPP as of September 30, 2024

Leadership team

Management

Herriot Tabuteau, MD
Founder & CEO
Goldman Sachs · BANK OF AMERICA

Nick Pizzie, CPA, MBA
Chief Financial Officer
Pierre Fabre · IMMUCOR · MERCK · Pfizer

Mark Jacobson, MA
Chief Operating Officer
Stemline

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

Ari Maizel
Chief Commercial Officer
abbvie · Allergan · Johnson&Johnson

Board of Directors

Roger Jeffs, PhD
CEO, Liquidia Corporation
Former President, Co-CEO, Director United Therapeutics Corp.
Prior positions at Amgen and Burroughs Wellcome

Mark Saad
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

Thank you

November 2024