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 03, 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, 29th 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 3, 2025, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 30, 2025 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 3, 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 November 3, 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: November 3, 2025

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 2025 Financial Results and Provides Business Update

Total 3Q 2025 net product revenue of $171.0 million, representing 63% year-over-year growth

AUVELITY® 3Q 2025 net product sales of $136.1 million, representing 69% year-over-year growth

SUNOSI® 3Q 2025 net product revenue of $32.8 million, representing 35% year-over-year growth

SYMBRAVO® 3Q 2025 net product sales of $2.1 million

sNDA for AXS-05 in Alzheimer's disease agitation submitted to the FDA

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

NEW YORK, November 3, 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 third quarter of 2025 and provided a general business update.

"Axsome posted strong revenue growth in the third quarter driven by contributions from all three of our marketed products," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "Our broad development pipeline continues to advance, and we recently submitted our supplemental NDA for AXS-05 for the treatment of Alzheimer's disease agitation, a serious condition affecting millions of patients in the U.S., and a critical unmet medical need. With robust commercial performance and pipeline execution, Axsome is well positioned to continue delivering substantial and sustained growth and transformative new medicines for patients living with serious CNS disorders."

Financial Highlights

- Total net product revenue was $171.0 million for the third quarter of 2025, representing 63% year-over-year growth, and 14% sequential growth compared to the second quarter of 2025. Total net product revenue for the third quarter of 2024 was $104.8 million.
- AUVELITY net product sales were $136.1 million for the third quarter of 2025, representing 69% year-over-year growth, and 14% sequential growth compared to the second quarter of 2025. AUVELITY net product sales for the third quarter of 2024 were $80.4 million.
- SUNOSI net product revenue was $32.8 million for the third quarter of 2025, representing 35% year-over-year growth, and 9% sequential growth compared to the second quarter of 2025. SUNOSI net product revenue for the third quarter of 2025 consisted of $31.6 million in net product sales and $1.2 million in royalty revenue associated with SUNOSI sales in out-licensed territories. SUNOSI net product revenue for the third quarter of 2024 was $24.4 million, which consisted of $23.4 million in net product sales and $1.0 million in royalty revenue.
- SYMBRAVO net product sales were $2.1 million for the third quarter of 2025, the first full quarter of commercialization following its launch in June 2025.
- Total cost of revenue was $11.9 million for the third quarter of 2025. Total cost of revenue for the comparable period in 2024 was $8.4 million.
- Research and development (R&D) expenses were $40.2 million for the third quarter of 2025, compared to $45.4 million for the comparable period in 2024. The decrease was primarily related to the completion of trials for solriamfetol in ADHD and MDD, which was partially offset by higher costs related to AXS-07.

- Selling, general, and administrative (SG&A) expenses were $150.2 million for the third quarter of 2025, compared to $95.6 million for the comparable period in 2024. The increase was primarily related to commercialization activities for AUVELITY, including the sales force expansion and direct-to-consumer advertising campaign, and the commercial launch of SYMBRAVO.
- Net loss for the third quarter of 2025 was $47.2 million, or $(0.94) per share, compared to a net loss of $64.6 million, or $(1.34) per share, for the comparable period in 2024. The net loss in the third quarter of 2025 includes $23.1 million of stock-based compensation expense and a $13.2 million non-cash charge for contingent consideration.
- Cash and cash equivalents totaled $325.3 million at September 30, 2025, compared to $315.4 million at December 31, 2024.
- Shares of common stock outstanding were 50,307,834 at September 30, 2025.

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

AUVELITY is the first and only rapid-acting oral NMDA receptor antagonist and sigma-1 receptor agonist approved in the U.S. for the treatment of major depressive disorder.

- Approximately 209,000 prescriptions were written for AUVELITY in the third quarter of 2025, representing an increase of 46% compared to the same period in 2024, and an increase of 9% compared to the second quarter of 2025.
- Payer coverage for AUVELITY across all channels is currently at approximately 85% of all lives covered. The proportions of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 75% and 100%, respectively.
- Effective August 1, 2025, Axsome contracted with a third large group purchasing organization (GPO) for potential formulary coverage of AUVELITY. Pharmacy benefit managers and health plans under this GPO are now able to make coverage decisions for AUVELITY based on the contracted terms. Axsome has now contracted with each of the three largest GPOs for AUVELITY.

SUNOSI

SUNOSI is the first and only dopamine and norepinephrine reuptake inhibitor approved for the treatment of excessive daytime sleepiness in narcolepsy or obstructive sleep apnea.

- Approximately 53,000 prescriptions were written for SUNOSI in the U.S. in the third quarter of 2025, representing an increase of 12% compared to the same period in 2024, and an increase of 5% compared to the second quarter of 2025.
- Payer coverage for SUNOSI across all channels remains at approximately 83% of all lives covered. The proportions of lives covered for SUNOSI in the commercial and government channels are approximately 95% and 60%, respectively.

SYMBRAVO

SYMBRAVO is an oral, rapidly absorbed, multi-mechanistic, COX-2 preferential inhibitor and 5-$HT_{1B/1D}$ agonist approved in the U.S. for the acute treatment of migraine with or without aura in adults.

- The third quarter of 2025 was the first full quarter of sales for SYMBRAVO, which became commercially available in June 2025. Approximately 5,000 prescriptions were reported for SYMBRAVO in the third quarter of 2025.
- Payer coverage for SYMBRAVO across all channels is at approximately 52% of all lives covered as of October 1. The proportions of lives covered in the commercial and government channels are approximately 48% and 56%, respectively.
- Effective August 1, 2025, Axsome has contracted with a second large group purchasing organization (GPO) for potential formulary coverage of SYMBRAVO. Pharmacy benefit managers and health plans under this GPO are now able to make coverage decisions for SYMBRAVO based on the contracted terms. Axsome has now contracted with two of the three largest GPOs for SYMBRAVO.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of innovative, late-stage, product candidates addressing 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 submitted a supplemental NDA (sNDA) to the FDA for AXS-05 in Alzheimer's disease agitation. The Company plans to announce the FDA's decision on acceptance of the filing.
- **Smoking Cessation:** Axsome plans to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in the fourth quarter of 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) with excessive daytime sleepiness (EDS), binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome plans to initiate a Phase 3 trial of solriamfetol in children and adolescents with ADHD in the fourth quarter of 2025.
  The Company has completed the FOCUS Phase 3 trial evaluating the efficacy and safety of solriamfetol in adults with ADHD. In the trial, solriamfetol met the primary and key secondary endpoints and demonstrated rapid, substantial, and statistically significant reductions in ADHD symptoms and overall disease severity compared to placebo.
- **Major Depressive Disorder with Excessive Daytime Sleepiness:** Axsome plans to initiate a Phase 3 trial of solriamfetol in MDD patients with EDS in the fourth 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 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.

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 plans to submit an NDA to the FDA for AXS-12 for the treatment of cataplexy in narcolepsy in the fourth quarter 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 initiate a Phase 3, fixed-dose, 12-week, placebo-controlled trial of AXS-14 in fibromyalgia in the fourth quarter of 2025.

Anticipated Milestones

- **Regulatory and Commercial:**
    - AXS-12 for narcolepsy, NDA submission (4Q 2025)
- **Clinical Trial Topline Results:**
    - 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:**
    - Phase 2/3 trial of AXS-05 in smoking cessation, initiation (4Q 2025)
    - Phase 3 trial of solriamfetol in ADHD in pediatric patients, initiation (4Q 2025)
    - Phase 3 trial of solriamfetol in MDD with EDS, initiation (4Q 2025)
    - Phase 3 trial of AXS-14 in fibromyalgia, initiation (4Q 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 2025 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, excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea, and migraine, 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. For more information, please visit us at www.axsome.com and follow us on LinkedIn and X.

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 Company's ability to successfully resolve any intellectual property litigation, and even if such disputes are settled, whether the applicable federal agencies will approve of such settlements; 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 circumstances.

Axsome Therapeutics, Inc.
Selected Consolidated Financial Data

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

	September 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 325,272	$ 315,353
Accounts receivable, net	196,507	142,001
Inventories, net	23,774	15,732
Prepaid and other current assets	19,789	11,978
Total current assets	565,342	485,064
Equipment, net	605	584
Right-of-use asset - operating lease	21,654	5,383
Goodwill	12,042	12,042
Intangible asset, net	42,126	46,894
Non-current inventory and other assets	27,481	18,531
Total assets	$ 669,250	$ 568,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 54,227	$ 71,997
Accrued expenses and other current liabilities	225,632	147,987
Operating lease liability, current portion	736	1,835
Contingent consideration, current	9,695	8,285
Short-term borrowings	70,000	—
Total current liabilities	360,290	230,104
Contingent consideration, non-current	89,870	91,680
Loan payable, long-term	117,642	180,710
Operating lease liability, long-term	23,041	6,046
Finance lease liability, long-term	4,680	2,943
Total liabilities	595,523	511,483
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, 50,307,834 and 48,667,587 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively)	5	5
Additional paid-in capital	1,351,124	1,179,797
Accumulated deficit	(1,277,402)	(1,122,787)
Total stockholders' equity	73,727	57,015
Total liabilities and stockholders' equity	$ 669,250	$ 568,498

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,	
	2025	2024	2025	2024
Revenues:				
Product sales, net	$ 169,784	$ 103,736	$ 439,101	$ 264,352
Royalty revenue	1,208	1,026	3,396	2,575
Total revenues	170,992	104,762	442,497	266,927
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	11,912	8,437	35,149	22,789
Research and development	40,162	45,388	134,488	132,071
Selling, general and administrative	150,235	95,564	401,302	298,088
Loss in fair value of contingent consideration	13,185	16,391	6,595	17,139
Intangible asset amortization	1,607	1,606	4,768	4,785
Total operating expenses	217,101	167,386	582,302	474,872
Loss from operations	(46,109)	(62,624)	(139,805)	(207,945)
Interest expense, net	(1,120)	(1,978)	(5,385)	(4,359)
Loss on debt extinguishment	—	—	(10,385)	—
Loss before income taxes	(47,229)	(64,602)	(155,575)	(212,304)
Income tax benefit	—	—	960	—
Net loss	$ (47,229)	$ (64,602)	$ (154,615)	$ (212,304)
Net loss per common share, basic and diluted	$ (0.94)	$ (1.34)	$ (3.13)	$ (4.45)
Weighted average common shares outstanding, basic and diluted	50,021,851	48,140,519	49,449,220	47,703,508

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3Q 2025
Corporate Presentation

November 3, 2025

Forward looking statements & safe harbor

Certain matters discussed in this presentation 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 Company's ability to successfully resolve any intellectual property litigation, and even if such disputes are settled, whether the applicable federal agencies will approve of such settlements; 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 presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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.

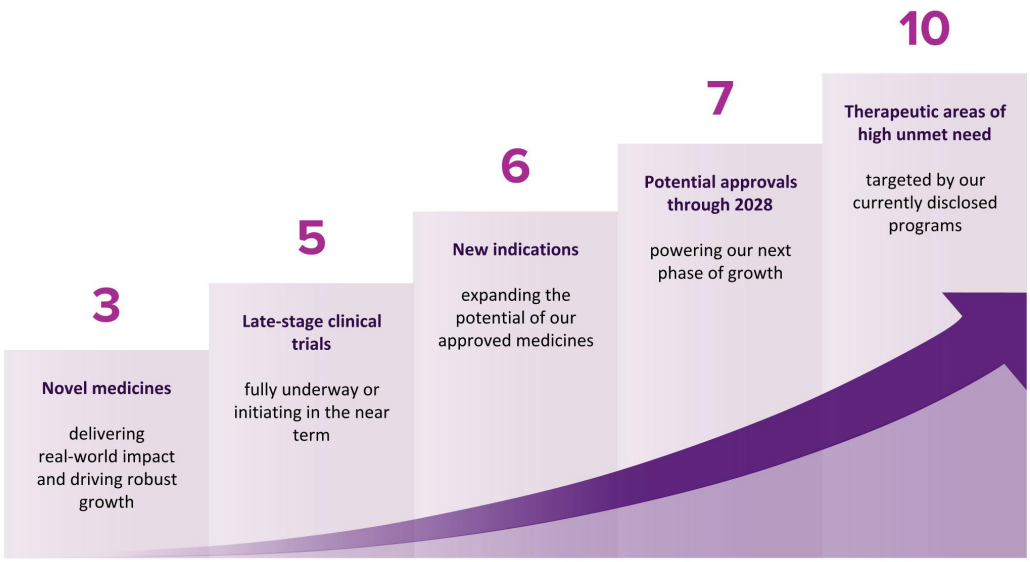
Our Mission

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

axsome

How we drive innovation in brain health

Positioned to deliver compounding growth and enduring value



>$16B
peak sales potential

>150M
Patients impacted

Robust intellectual property portfolio with patent protection through the **2040s**

3Q 2025 performance

Execution

$171.0M (+63% YoY)

Total net product revenue

Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	SUNOSI® (solriamfetol) (V)	SYMBRAVO® (meloxicam and rizatriptan) 20 mg/10 mg tablets
$136.1M (+69% YoY)	$32.8M (+35% YoY)	$2.1M

Innovation

- sNDA for AXS-05 in Alzheimer's disease agitation submitted to the FDA
- NDA submission for AXS-12 for cataplexy in narcolepsy anticipated 4Q 2025
- Phase 3 trial of solriamfetol in children and adolescents with ADHD anticipated 4Q 2025
- Advancing multiple additional innovative late-stage programs in binge eating disorder, shift work disorder, depression associated with excessive daytime sleepiness, fibromyalgia, and smoking cessation

Discipline

$325.3M

Cash and cash equivalents†

50.3M

Shares outstanding†

axsome

†As of September 30, 2025

Strategic focus across high-impact CNS conditions

Therapeutic areas driving today's growth

Major depressive disorder

- 21M+ people in the U.S. live with MDD[1]
- ~2/3 of patients fail to achieve remission from initial therapy[2]

Obstructive sleep apnea

- 22M+ U.S. adults are affected by OSA[3]
- ~80% of patients remain undiagnosed[4]

Migraine

- 39M+ U.S. adults experience migraine[5]
- >80% of patients discontinue their acute migraine treatment in the first 12 months[6]

Priority development areas poised for substantial value creation

Alzheimer's disease agitation

- 5M+ U.S. individuals with Alzheimer's experience agitation[7]
- 1 FDA-approved treatment

Narcolepsy

- 185K people in the U.S. are affected by narcolepsy[8]
- ~70% of patients suffer from cataplexy[9]

Fibromyalgia

- 17M+ people in the U.S. have fibromyalgia[10]
- >50% of patients discontinue treatment in the first year[11]

Growth opportunities expanding long-term value potential

Attention deficit hyperactivity disorder

- 22M+ people in the U.S. live with ADHD[12]
- >90% of patients diagnosed in childhood continue to exhibit symptoms into adulthood[13]

Binge eating disorder

- 7M+ people impacted in the U.S.[14]
- 1 FDA-approved treatment

Shift work disorder

- 15M+ working Americans may be impacted[15-17]
- 0 new medications approved since 2007

MDD with excessive daytime sleepiness

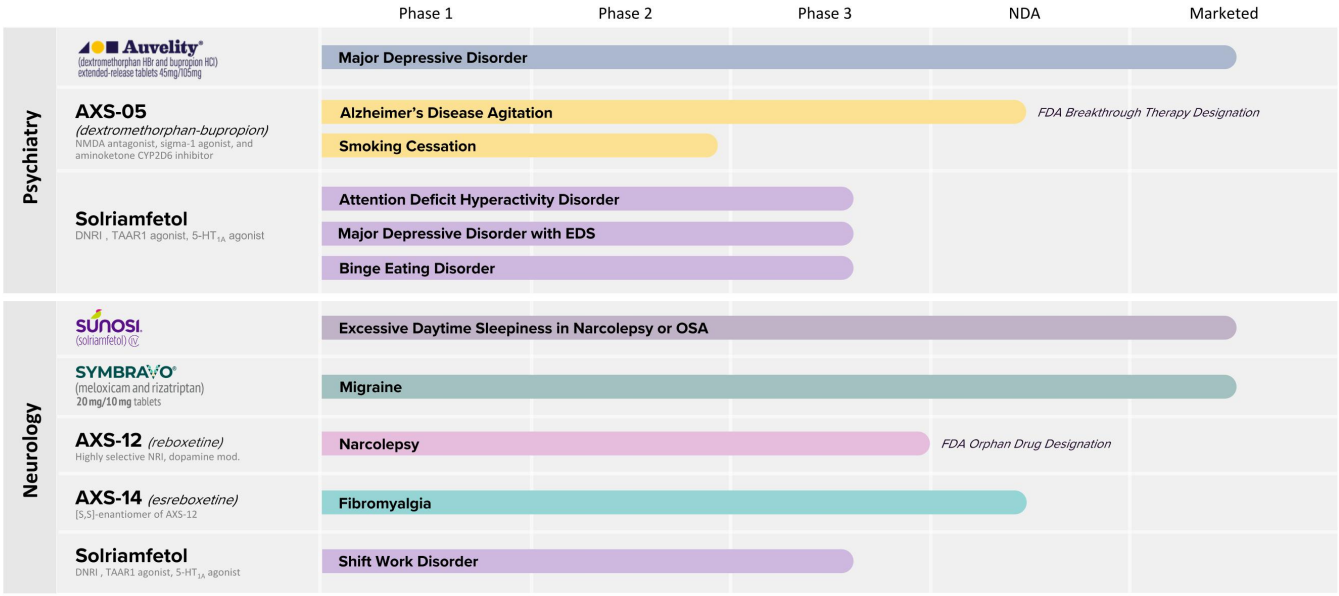
- ~50% of MDD patients have concomitant EDS[18]
- 0 FDA-approved treatments

Smoking cessation

- 34M+ adults in the U.S. smoke cigarettes[19]
- ~70% of smokers say they want to quit[20]

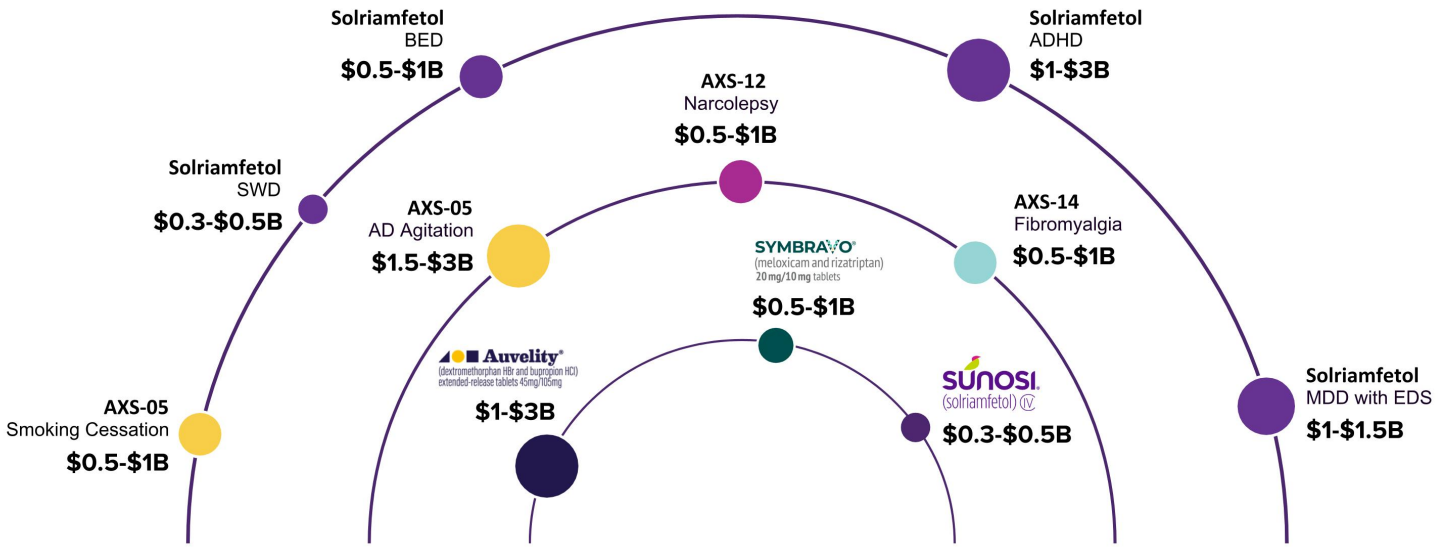
1. Major Depression. *NIMH* 2023; 2. Rush AJ, et al. *Am J sychiatry* 2006; 3. Benjafield AV, et al. *Lancet Respir Med.* 2020; 4. Watson N, et al. *Sleep* 2025; 5. American Migraine Foundation 2023; 6. Symphony Health Claims, New to Brand Patients 2022-2023; 7. 2025 Alzheimer's Disease Facts and Figures; 8. "About Narcolepsy." Narcolepsy Network 2024; 9. Swick TJ.*Nat Sci Sleep* 2015; 10. Vincent, et al. *Arthritis Care Res (Hoboken)* 2013; 11. Liu Y, et al. *J Manag Care Spec Pharm.* 2016; 12. Facts About ADHD in Adults. CDC 2024; 13. Sibley MH, et al.*Am J Psychiatry* 2022; 14. Hudson JI, et al. *Biol Psychiatry* 2007; 15. Sateia MJ. *Chest* 2014; 16. Alterman T, et al. *Am J Ind Med.* 2013; 17. Wickwire EM. *Chest* 2017; 18. Hein M, et al. *J Affect Disord.* 2019; 19. U.S. Department of Health and Human Services 2020; 20. Hughes JR, et al. *Addiction* 2004

Advancing a diversified late-stage pipeline of potential first-in-class, best-in-class therapeutics



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.

Multiple differentiated paths to value creation with >$16B in combined peak sales potential



Continued execution with key upcoming milestones ahead

	2025	2025 & 2026
Regulatory & Commercial	✓ Commercial launch of SYMBRAVO in the U.S. (June 2025) ✓ sNDA for AXS-05 in Alzheimer's disease agitation submitted to the FDA	• NDA submission for AXS-12 for cataplexy in narcolepsy (4Q 2025)
Clinical Trial Topline Results	✓ Positive topline results from EMERGE Ph 3 trial of SYMBRAVO in oral CGRP non-responders (1Q 2025) ✓ Positive topline results from FOCUS Ph 3 trial of solriamfetol in ADHD in adults (1Q 2025) ✓ Topline results from 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		• Initiate Ph 3 trial of solriamfetol in ADHD in pediatric patients (4Q 2025) • Initiate Ph 3 trial of solriamfetol in MDD with EDS (4Q 2025) • Initiate Ph 3 trial of AXS-14 in fibromyalgia (4Q 2025) • Initiate Ph 2/3 trial of AXS-05 in smoking cessation (4Q 2025)

Shaping the frontier of differentiated innovation in brain health

axsome

3Q 2025 financial summary

$ millions	3Q 2025	3Q 2024	% Change	YTD 2025	YTD 2024	% Change
Net Product Revenue	$171.0	$104.8	63%	$442.5	$266.9	66%
AUVELITY Net Product Sales	$136.1	$80.4	69%	$352.0	$198.8	77%
SUNOSI Net Product Revenue†	$32.8	$24.4	35%	$88.0	$68.1	29%
SYMBRAVO Net Product Sales	$2.1	—	—	$2.5	—	—
R&D Expense	$40.2	$45.4	-11%	$134.5	$132.1	2%
SG&A Expense	$150.2	$95.6	57%	$401.3	$298.1	35%

3Q = three months ended September 30; †Includes royalty revenue associated with sales in out-licensed territories

Financial snapshot

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

Cash Balance: (as of September 30, 2025)	$325.3M
Debt (Face Value): (as of September 30, 2025)	$190M
Market Cap: (as of October 31, 2025)	$6.7B
Shares Outstanding: (as of September 30, 2025)	50.3M
Options, RSUs, and Warrants Outstanding*:	9.3M

*Includes 7.6 M options, 1.5 M RSUs, 0.08 M warrants, and 0.08 M ESPP as of September 30, 2025

Commercial Highlights

axsome

Commercial execution driving accelerating growth across our expanding CNS portfolio

Major depressive disorder

- Continued strong demand growth and broadening prescriber reach
- Expanding market presence through strategic commercial investments
- Building on strong market access to drive durable, long-term growth

EDS in narcolepsy or OSA

- Continued strong sequential performance
- Steady demand growth across narcolepsy and OSA markets
- High patient satisfaction driving durable utilization

Migraine with or without aura

- Foundational first full quarter supporting long-term growth potential
- Focused launch execution driving awareness and trial among clinicians
- Broadening patient access

~$5B combined peak sales potential

EDS = Excessive daytime sleepiness; OSA = Obstructive sleep apnea
Rx, sales, and revenue growth vs. comparable periods in 2024

First and only oral NMDA receptor antagonist and sigma-1 receptor agonist for MDD in adults[1,2]

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

- Only oral antidepressant with rapid-acting efficacy reflected in FDA label[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)

Continued strong demand and expanding market access driving further growth

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

~209,000 (+46% YoY)
Total prescriptions in 3Q 2025

+50%
NBRx growth in primary care since Q1 expansion

~250,000
New patients since launch

~46,000
Unique writers since launch

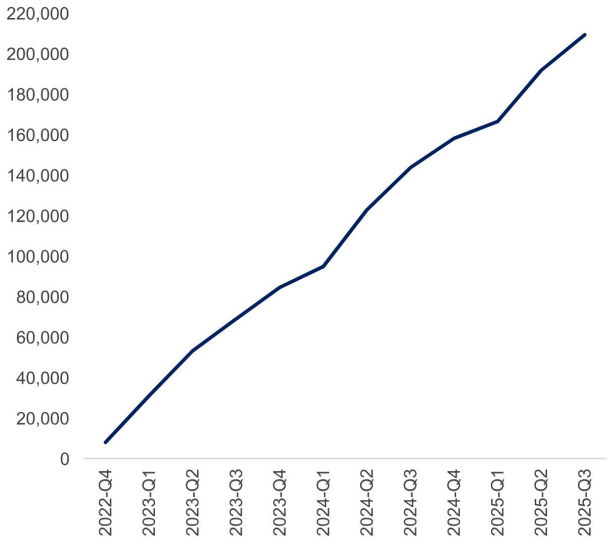
~75%
Covered commercial lives

~85%
Covered lives all channels

~50%
First-line or second-line use

~55%
Monotherapy use

Quarterly TRx Launch to Date

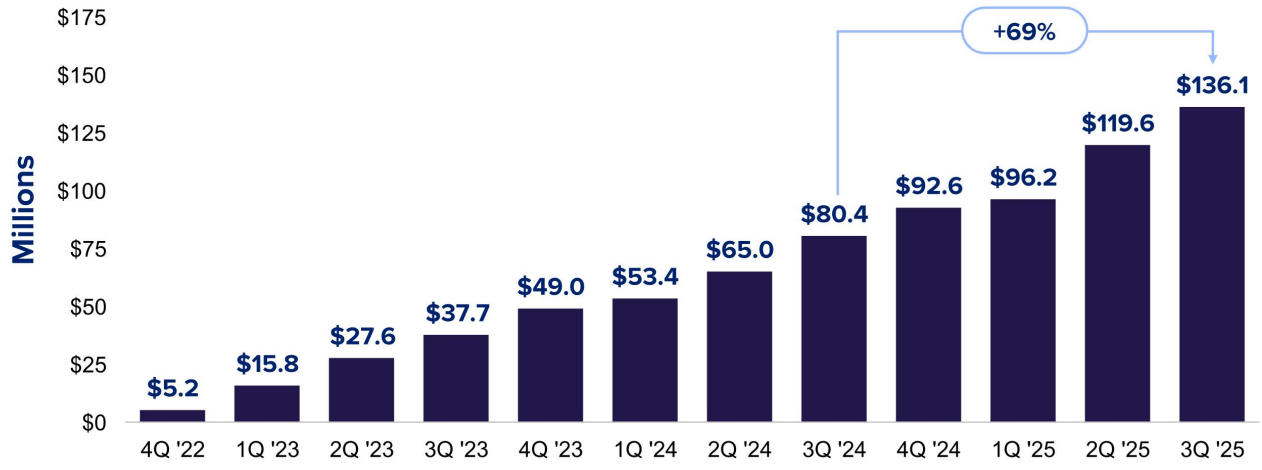


Source: Symphony METYS

TRx = Total prescriptions; NBRx = New-to-brand prescriptions

AUVELITY® quarterly net sales performance

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



3Q 2025 net product sales of **$136.1M** represents ***69%*** YoY growth

axsome

First and only dopamine and norepinephrine reuptake inhibitor for EDS associated with narcolepsy or OSA[1]

SUNOSI (solriamfetol) CIV

- 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

axsome

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)

Steady growth supported by durable demand and high patient satisfaction

~53,000 (+12% YoY)
Total prescriptions in 3Q 2025

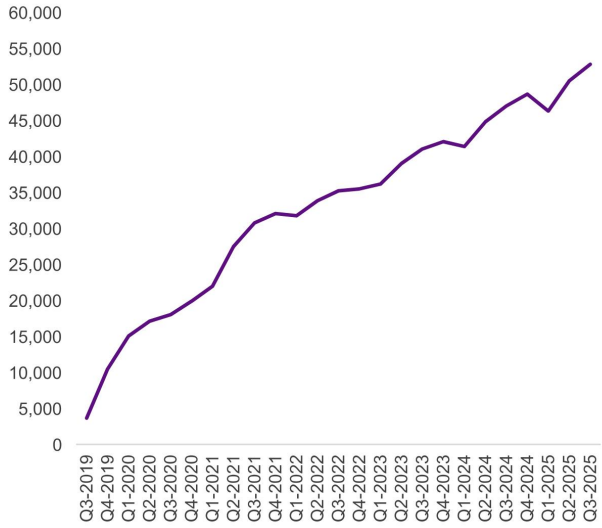
~94,000
New patients since launch

~15,100
Unique writers since launch

~83%
Covered lives all channels

>50%
Of patients who switch from or add on to their current treatment with SUNOSI come from other WPA agents

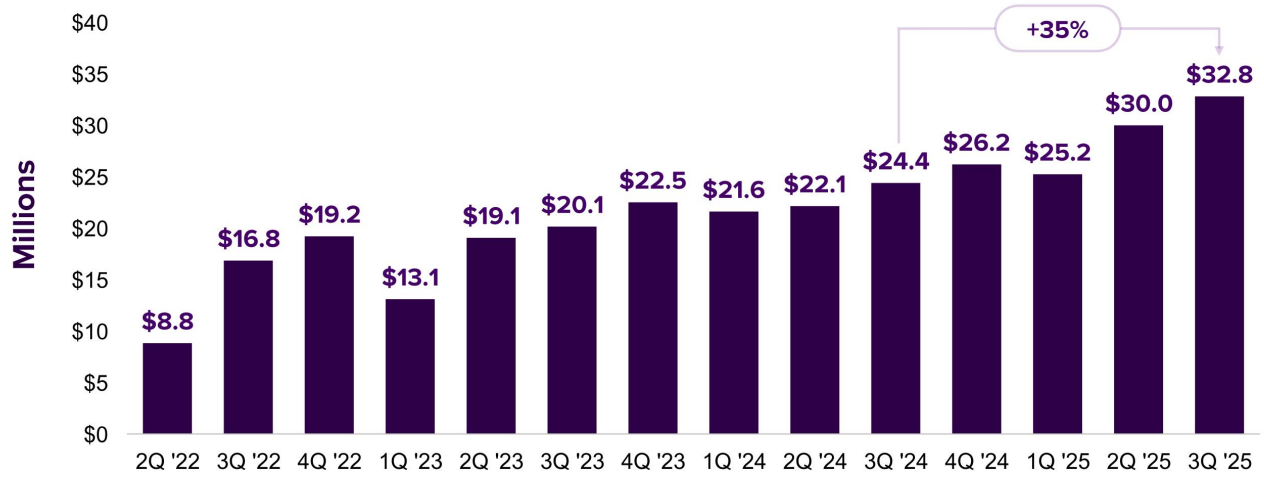
Quarterly nTRX Launch to Date



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

nTRx = Normalized total prescriptions

SUNOSI® quarterly net revenue performance



3Q 2025 net product revenue of **$32.8M** represents ***35%*** YoY growth

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

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

- 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 MoSEIC™ rapid absorption technology to target multiple pathways underlying a migraine attack

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

Establishing a strong foundation with growing clinician awareness and broader patient access

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

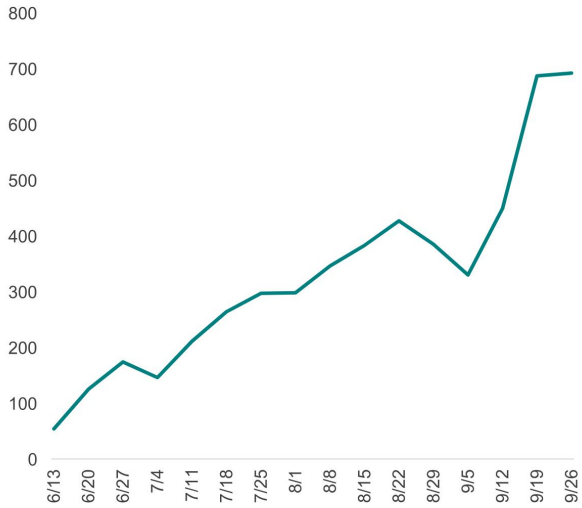
>5,000
Total prescriptions in 3Q 2025

>3,300
New patients in 3Q 2025

~48%
Covered commercial lives

~52%
Covered lives all channels

Weekly TRx Launch to Date



Source: Symphony METYS

axsome

TRx = Total prescriptions

Development Pipeline

axsome®

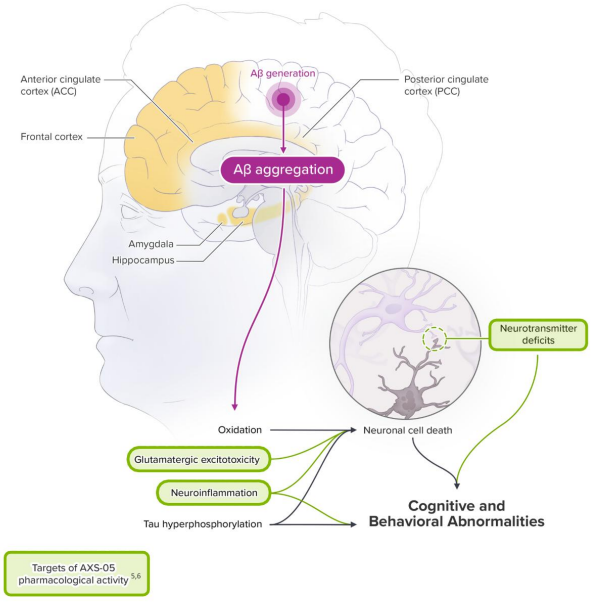
AXS-05 (dextromethorphan-bupropion)

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]

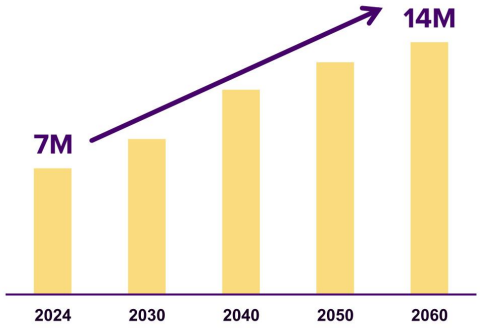
AXS-05 is believed to ***modulate the function*** of neurotransmitters and receptors implicated in Alzheimer's disease (glutamate, sigma-1, norepinephrine, and dopamine)[1-4]



1. Cummings JL, *N Engl J Med.* 2004; 2. Querfurth HW & LaFerla FM, *N Engl J Med.* 2010; 3. Porsteinsson AP & Antonsdottir IM, *Expert Opin Pharmacother.* 2017; 4. Rosenberg PB, Nowrangi MA, & Lyketsos CG, *Mol Aspects Med.* 2015; 5. Stahl SM, *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]



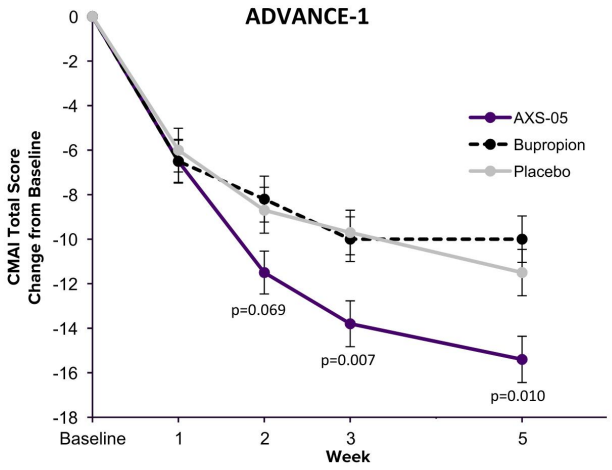
Alzheimer's disease (AD) is the most common form of dementia, affecting over ***7M*** people in the U.S.[1]

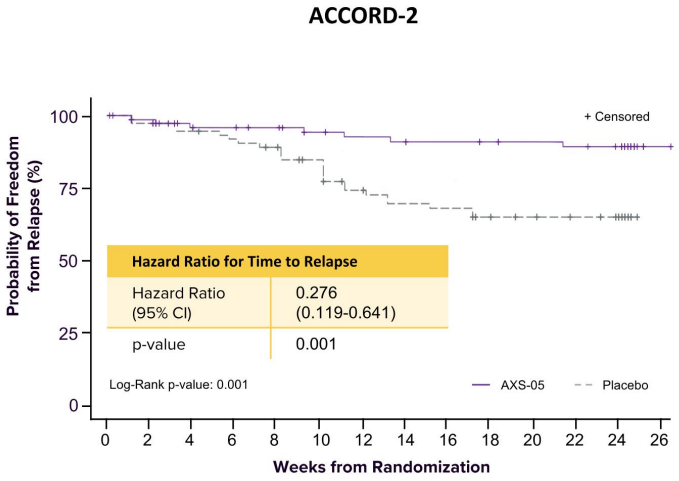
Agitation is one of the most common and debilitating neuropsychiatric symptoms affecting up to ***76%*** of people[1,2]

AD agitation is characterized by emotional distress, verbal and physical aggressiveness, disruptive irritability, and disinhibition[1,2]

1. 2025 Alzheimer's Disease Facts and Figures; 2. Trachtenberg et al. *J Neuropsychiatry Clin Neurosci.* 2002

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





Supplemental New Drug Application (sNDA) submitted to the FDA

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]

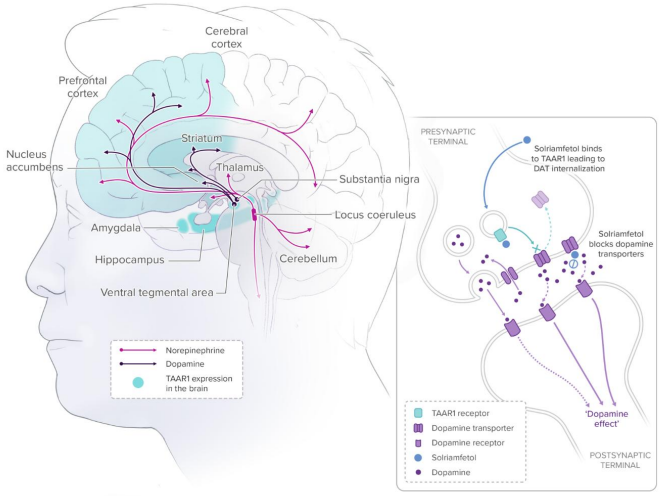
1. U.S. Department of Health and Human Services 2020; 2. Hughes JR, et al. Addiction 2004

Unique pharmacology of solriamfetol supports potential utility in a broad range of CNS conditions

Solriamfetol was initially developed as a dopamine and norepinephrine reuptake inhibitor (DNRI) with ***wake-promoting effects***

Preclinical and clinical evidence[1,2] suggest TAAR1 plays a role in neuropsychiatric conditions related to the ***dysregulation of monoaminergic transmission***

Multimodal activity of solriamfetol ***selectively inhibits*** the reuptake of dopamine and norepinephrine and exhibits ***agonist activity*** at TAAR1 receptors in the brain



1. Raony I, et al. *Prog Neuropsychopharmacol Biol Psychiatry* 2022; 2. Halff EF, et al. *Trends Neurosci.* 2023

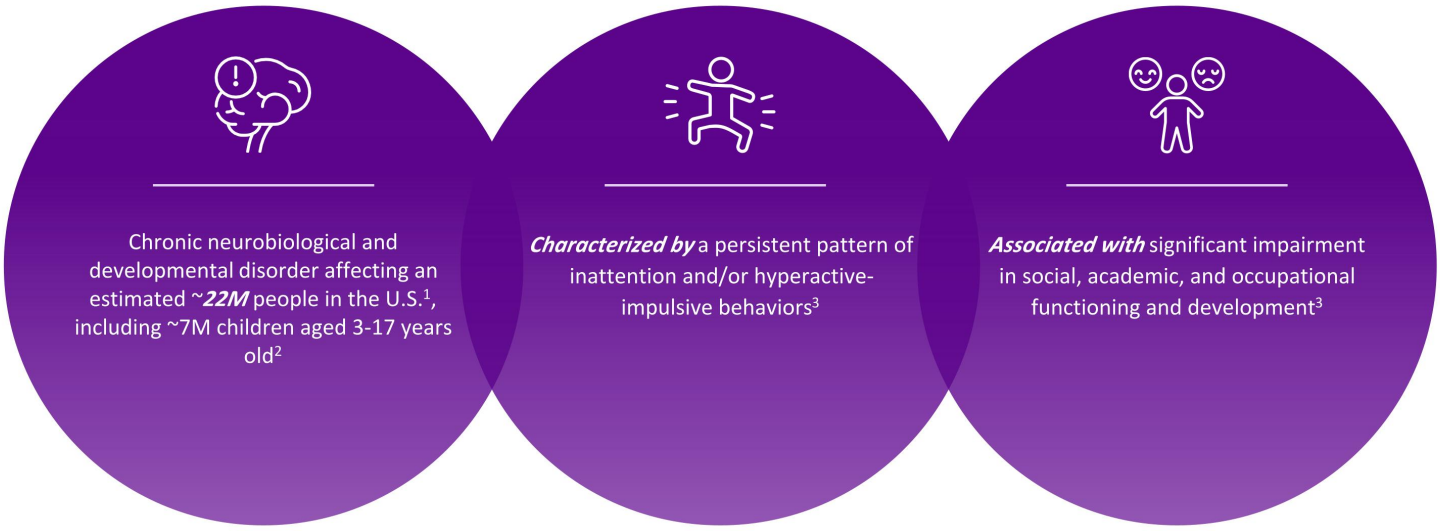
Solriamfetol Phase 3 development programs

Solriamfetol

ADHD	MDD	BED	SWD
FOCUS *Phase 3 (N=516)*	**PARADIGM** *Phase 3 (EDS subgroup n=51)*	**ENGAGE** *Phase 3 (N=450)*	**SUSTAIN** *Phase 3 (N=450)*
✓ Substantial and statistically significant improvements in ADHD symptoms and disease severity • Initiation of Phase 3 pediatric trial anticipated in 4Q 2025	✓ Numerically greater improvements in depressive symptoms in prespecified subgroup of patients with severe EDS • Initiation of Phase 3 trial in MDD with EDS anticipated in 4Q 2025	• 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
Complete	***Complete***	***Topline data 2026***	***Topline data 2026***

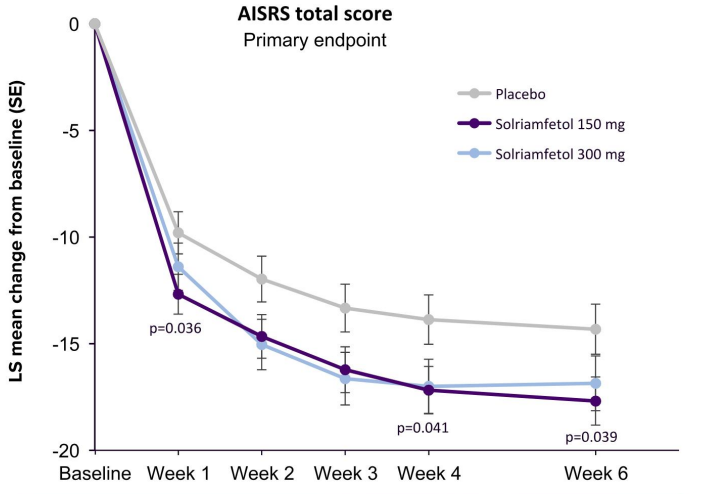
ADHD = Attention deficit hyperactivity disorder; MDD = Major depressive disorder; BED = Binge eating disorder; SWD = Shift work disorder

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

Significant improvements in ADHD symptoms with solriamfetol treatment in FOCUS Phase 3 trial in adult patients



Initiation of Phase 3 pediatric trial anticipated in 4Q 2025

Substantial reduction in the AISRS score of 17.7 points at Week 6, representing a ***45% improvement*** in ADHD symptoms from baseline (p=0.039, solriamfetol 150 mg)

Significantly greater percentage of patients achieved a clinical response (≥30% reduction in AISRS) vs. placebo (p=0.024, solriamfetol 150 mg)

Improvements in severity of overall ADHD as measured by the CGI-S total score at Week 6 (p=0.017, solriamfetol 150 mg)

Well tolerated with a side effect profile ***consistent*** with the established safety profile of solriamfetol

1. p-values shown for solriamfetol 150 mg dose vs. placebo only (primary analysis)

Major depressive disorder

~2/3 of patients experience inadequate response to first-line treatment[1]

Major depressive disorder (MDD) is one of the most common mental disorders in the U.S., impacting ***~21M*** adults each year[2,3]

Approximately 50% of patients with MDD also experience excessive daytime sleepiness (EDS)[4], for which there are no approved treatments

Initiation of Phase 3 trial of solriamfetol in MDD patients with EDS anticipated in 4Q 2025

1. Rush AJ, et al. *Am J Psychiatry* 2006; 2. Major Depression. NIMH 2023; 3. Hasin DS, et al. JAMA Psychiatry 2018; 4. Hein M, et al. J Affect Disord. 2019

Binge eating disorder

>7 million people in the U.S. have BED[1]

BED is ***1.75x more common*** in women than in men[1]

Binge eating disorder (BED) is the most common eating disorder, affecting 2.8% of adults and 1.6% of adolescents in the US[1,2]

BED is thought to involve issues with food reward processing, impulse control, cognitive control, and appetite regulation[1,3]

Unmet medical need associated with a 2- to 3-fold increased risk of psychiatric and medical comorbidities[4]

1. Hudson JI, et al. *Biol Psychiatry* 2007; 2. Swanson SA, et al. *Arch Gen Psychiatry* 2011; 3. Kessler RM, et al. *Neurosci Biobehav Rev.* 2016; 4. McElroy SL, et al. *J Clin Psychiatry* 2020;

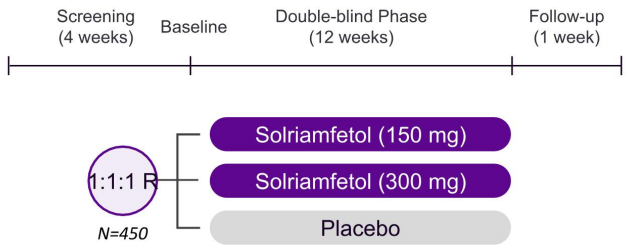
Ongoing Phase 3 trial of solriamfetol in patients with binge eating disorder

Solriamfetol inhibits the reuptake of dopamine and norepinephrine, neurotransmitters implicated in the pathophysiology of binge eating disorder[1-3]

Pre-clinical and clinical data support potential effects of solriamfetol on appetite, food consumption, and weight[4,5]

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 KE, et al. Nat Rev Dis Primer 2022; 2. Bello NT and Hajnal A. Pharmacol Biochem Behav. 2010; 3. Pruccoli J, et al. Int J Mol Sci. 2021; 4. Malhotra A, et al. Sleep Med. 2022; 5. SUNOSI [Prescribing Information]. Axsome Therapeutics, Inc. New York, NY.

Shift work disorder

~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]

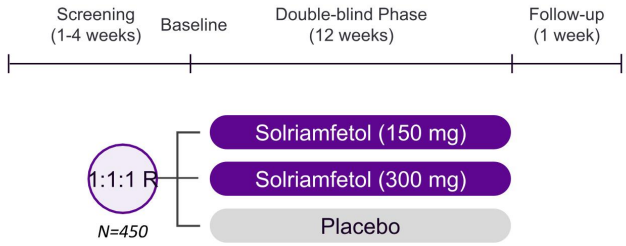
No new medications approved since 2007 and considerable residual sleepiness reported when medication is used[6]

1. Sateia MJ. Chest 2014; 2. Alterman T, et al. Am J Ind Med. 2013; 3. Wickwire EM. Chest 2017; 4. Smith L, et al. Lancet 1994; 5. Akerstedt T & Wright KP. Sleep Med Clin. 2009; 6. Czeisler CA, 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

- 18-65 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

AXS-12 (reboxetine)

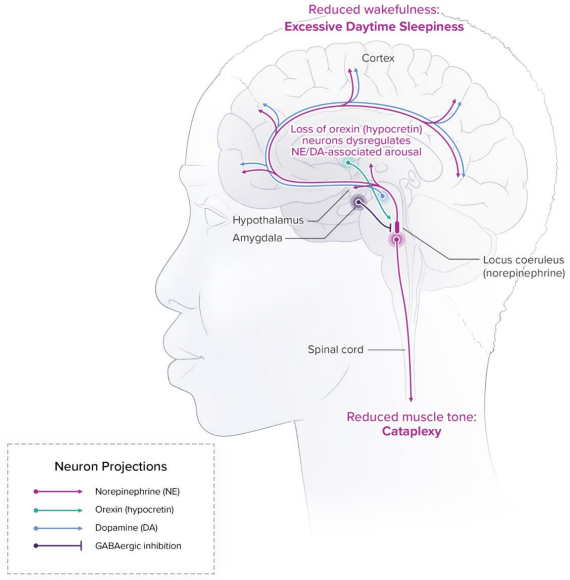
Novel pharmacological approach for the treatment of narcolepsy

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 ST, et al. *Sleep Med Rev.* 2019; 2. Krahn LE, Zee PC, & Thorpy MJ. *Adv Ther.* 2022; 3. Scammell TE. *N Engl J Med.* 2015; 4. Stahl SM & Grady MM. *J Clin Psychiatry* 2003; 5. Burgess CR & Peever JH. *Curr Biol.* 2013; 6. Wu MF, et al. *Neuroscience* 1999; 7. Bruinstroop E, et al. *J Comp Neurol.* 2012

Narcolepsy

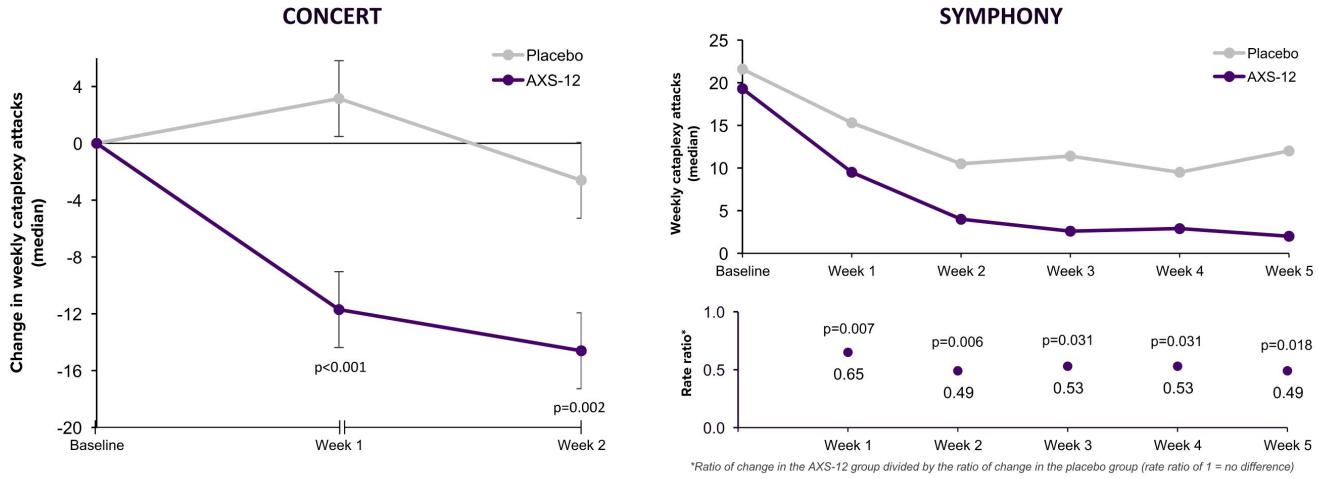
Rare and debilitating neurological condition that affects approximately ***185,000*** people in the U.S.[1]

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 MJ. Chest 2014; 3. “Narcolepsy.” NINDS 2024; 4. España RA & Scammell TE. Sleep 2011; 5. Swick TJ. Nat Sci Sleep 2015

Rapid and robust reductions in cataplexy with AXS-12 treatment



*Ratio of change in the AXS-12 group divided by the ratio of change in the placebo group (rate ratio of 1 = no difference)

New Drug Application (NDA) submission on track for 4Q 2025

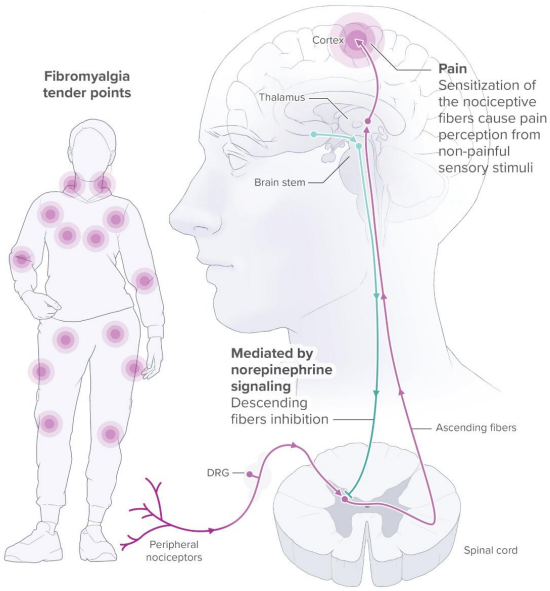
AXS-14 (esreboxetine)

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***

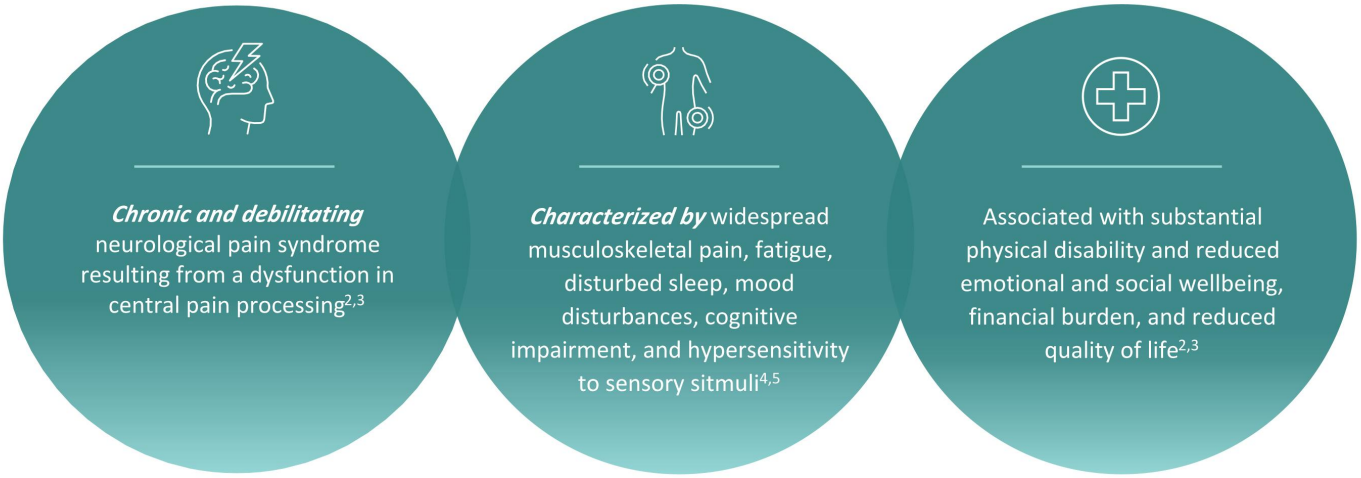
AXS-14 is a ***more potent*** and ***selective*** enantiomer of racemic reboxetine that inhibits the reuptake of norepinephrine, resulting in increased norepinephrine activity and decreased pain signaling



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

Fibromyalgia

An estimated ***~17 million*** people in the U.S. are impacted by fibromyalgia[1]



1. Vincent, et al. *Arthritis Care Res (Hoboken)* 2013; 3. Choy E, et al. *BMC Health Serv Res.* 2010; 3. Arnold LM, et al. *Patient Educ Couns.* 2008; 4. Bair MJ & Krebs EE. *Ann Intern Med.* 2020; 5. Clauw DJ. *Ann Rheum Dis.* 2024

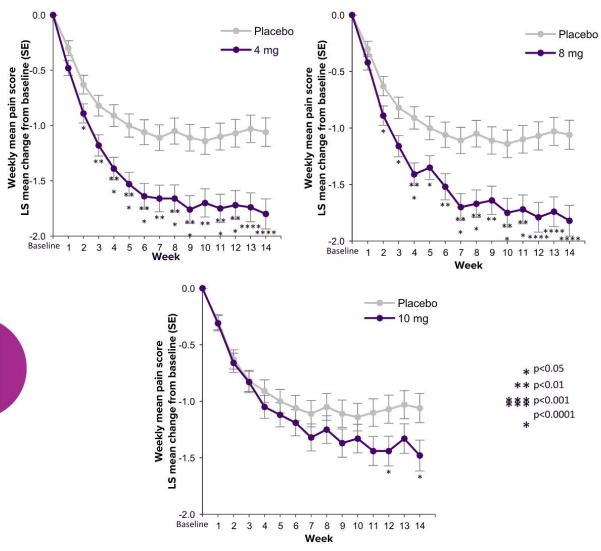
Rapid and robust efficacy demonstrated in Phase 2 and Phase 3 trials of AXS-14 in fibromyalgia

- Efficacy and safety of AXS-14 compared to placebo evaluated in >1,000 individuals with fibromyalgia across Phase 2 and Phase 3 clinical trials for up to 14 weeks
- Rapid and significant reductions in pain scores, improvements in patient-reported global functioning, fatigue, and overall symptom severity

Initiation of new Phase 3 trial anticipated in 4Q 2025

Pain reduction

Phase 3 efficacy results (N=1,122)



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 to at least 2043; Multiple pending • Proprietary drug product formulation and methods of treatment
SYMBRAVO® (meloxicam and rizatriptan) 20 mg/10 mg tablets	• Protected by a robust patent estate extending to at least 2041; Multiple pending • Proprietary MoSEIC™ formulation, drug product formulation, and methods of treatment
SUNOSI® (solriamfetol) (IV) 75, 150 mg tablets	• Protected by a robust patent estate extending to at least 2042; Multiple pending • Proprietary drug substance and drug product formulation
AXS-12	• Orphan Drug Designation • Claims extending to at least 2039 • 9 issued U.S. patents and 4 issued O.U.S. patents; Multiple pending • Proprietary drug substance, drug product formulation, and methods of treatment
AXS-05	• Claims extending to at least 2043 • >150 issued U.S. patents and >100 issued O.U.S. patents; Multiple pending • Proprietary drug product formulation and methods of treatment
AXS-14	• Multiple pending U.S. patents • Proprietary drug substance, drug product formulation, and methods of treatment

Leadership team

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Herriot Tabuteau, MD
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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Former SVP of Eli Lilly and President Lilly Oncology
Prior positions at BMS, Amgen and Schering-Plough

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

Herriot Tabuteau, MD
Chairman

Thank you