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 02, 2026

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 2, 2026, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 30, 2026, 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 2, 2026, 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 2, 2026.
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 2, 2026

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 2026 Financial Results and Provides Business Update

Total 3Q 2026 net product revenue of $259.7 million, representing 52% year-over-year growth

AUVELITY® 3Q 2026 net product sales of $207.6 million, representing 53% year-over-year growth

SUNOSI® 3Q 2026 net product revenue of $48.2 million, representing 47% year-over-year growth

SYMBRAVO® 3Q 2026 net product sales of $3.9 million, representing 88% year-over-year growth

SUMMIT Phase 3 trial of AXS-05 for smoking cessation initiated

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

NEW YORK, November 2, 2026 (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 2026 and provided a general business update.

“Axsome delivered 52% year-over-year total revenue growth in the third quarter, surpassing a one-billion-dollar annual run rate. We expect sustained momentum driven by strong underlying demand for Auvelity in major depressive disorder, and continued acceleration of new patient initiations in Alzheimer’s disease agitation,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. “Our industry-leading neuroscience pipeline continued to advance, leading to multiple anticipated regulatory and clinical trial milestones in the coming quarters. Our commercial and research and development performance positions us to continue to deliver innovation targeting significant unmet needs in brain health, with the potential to improve the lives of millions of patients.”

Third Quarter 2026 Financial Highlights

- Total net product revenue was $259.7 million for the third quarter of 2026, representing 52% year-over-year growth. Total net product revenue for the comparable period in 2025 was $171.0 million.
- AUVELITY net product sales were $207.6 million for the third quarter of 2026, representing 53% year-over-year growth. AUVELITY net product sales for the comparable period in 2025 were $136.1 million.
- SUNOSI net product revenue was $48.2 million for the third quarter of 2026, representing 47% year-over-year growth, which consisted of $38.5 million in net product sales, $1.2 million in royalty revenue associated with SUNOSI sales in out-licensed territories, and $8.5 million in milestone revenue. SUNOSI net product revenue for the comparable period in 2025 was $32.8 million, which consisted of $31.6 million in net product sales and $1.2 million in royalty revenue.
- SYMBRAVO net product sales were $3.9 million for the third quarter of 2026, representing 88% year-over-year growth. SYMBRAVO net product sales for the comparable period in 2025 were $2.1 million.
- Total cost of revenue was $17.8 million for the third quarter of 2026. Total cost of revenue for the comparable period in 2025 was $11.9 million.
- Research and development (R&D) expenses were $50.6 million for the third quarter of 2026, compared to $40.2 million for the comparable period in 2025. The increase primarily reflects costs for the ongoing clinical programs for solriamfetol, AXS-14, and AXS-05.

- Selling, general, and administrative (SG&A) expenses were $203.1 million for the third quarter of 2026, compared to $150.2 million for the comparable period in 2025. The increase primarily reflects commercialization activities for AUVELITY and SYMBRAVO.
- Net loss for the third quarter of 2026 was $12.9 million, or $(0.25) per share, compared to a net loss of $47.2 million, or $(0.94) per share, for the comparable period in 2025. The net loss in the third quarter of 2026 includes $26.4 million in stock-based compensation expense.
- Cash and cash equivalents totaled $313.9 million at September 30, 2026, compared to $322.9 million at December 31, 2025.
- Shares of common stock outstanding were 52,576,839 at September 30, 2026.

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 a first-in-class oral N-methyl-D-aspartate (NMDA) receptor antagonist and sigma-1 receptor agonist approved in the U.S. for the treatment of major depressive disorder in adults, and for the treatment of agitation associated with dementia due to Alzheimer's disease.

- Approximately 302,000 total prescriptions were written for AUVELITY in the third quarter of 2026, representing year-over-year and quarter-over-quarter increases of 40% and 14%, respectively. New-to-brand prescriptions, representing new AUVELITY patient starts, increased by 44% year-over-year and 21% quarter-over-quarter.
- Third quarter AUVELITY new-to-brand and total prescriptions among patients aged 65 years and older increased by 211% and 101%, respectively, compared to the third quarter of 2025. Third quarter AUVELITY new-to-brand and total prescriptions among patients aged 65 years and older increased by 99% and 43%, respectively, compared to the second quarter of 2026.
- Payer coverage for AUVELITY across all channels is currently at approximately 89% of all lives covered. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 82% and 100%, respectively.

SUNOSI

SUNOSI is the first and only dopamine and norepinephrine reuptake inhibitor (DNRI) approved for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy.

- Approximately 64,400 prescriptions were written for SUNOSI in the U.S. in the third quarter of 2026, a 15% increase compared to the same period in 2025, and a 6% increase compared to the second quarter of 2026.
- Payer coverage for SUNOSI across all channels is at approximately 82% of all lives covered, including approximately 97% of commercial lives and 59% of government lives.

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.

- Approximately 25,000 prescriptions were written for SYMBRAVO in the third quarter of 2026, a 382% increase compared to the same period in 2025, and a 7% increase compared to the second quarter of 2026.
- Payer coverage for SYMBRAVO across all channels is at approximately 57% of all lives covered, including approximately 56% of commercial lives and 57% of government lives.

Development Pipeline

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

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome's novel, oral, investigational NMDA receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for smoking cessation.

- **Smoking Cessation:** In August 2026, Axsome initiated the SUMMIT study, a Phase 3, randomized, double-blind, active- and placebo-controlled, multicenter trial to assess the efficacy and safety of AXS-05 for the treatment of smoking cessation. The Company anticipates topline results from the SUMMIT Phase 3 trial in the second half of 2027.

Solriamfetol

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

- **Attention Deficit Hyperactivity Disorder:** Axsome is conducting the FOCUS-2 and FOCUS-3 Phase 3, randomized, double-blind, placebo-controlled, multicenter trials evaluating the efficacy and safety of solriamfetol as a treatment for children and adolescents in ADHD, respectively. The Company anticipates topline results from both studies in the second half of 2027.
- **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. Target enrollment in the trial has been reached, and the Company anticipates topline results in the first quarter of 2027.
- **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 SUSTAIN in the second half of 2027.
- **Major Depressive Disorder:** Axsome is conducting the CLARITY study, a Phase 3, double-blind, placebo-controlled, multicenter, randomized withdrawal trial evaluating the efficacy and safety of solriamfetol for the treatment of MDD with EDS symptoms. The Company anticipates completion of enrollment in CLARITY in the first half of 2027.

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's NDA for AXS-12 for the treatment of cataplexy in narcolepsy is currently under review by the FDA. The PDUFA target action date is May 1, 2027.

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 is the SS-enantiomer of reboxetine.

- **Fibromyalgia:** Axsome is conducting the FORWARD study, a Phase 3, double-blind, placebo-controlled, multicenter, randomized withdrawal trial evaluating the efficacy and safety of AXS-14 for the management of fibromyalgia. The Company anticipates completion of enrollment in the FORWARD Phase 3 trial in the third quarter of 2027.

AXS-17

AXS-17 is Axsome's novel oral $GABA_A$ receptor α2,3 subtype-selective positive allosteric modulator (PAM) being developed for the treatment of epilepsy.

- **Epilepsy:** Axsome plans to initiate clinical trials of AXS-17 in epilepsy in the first half of 2027.

AXS-20

AXS-20 (balipodect) is Axsome's novel oral, potent, and selective phosphodiesterase 10A (PDE10A) inhibitor being developed for the treatment of schizophrenia.

- **Schizophrenia:** Axsome plans to initiate a pivotal Phase 3 trial of AXS-20 in schizophrenia in the first half of 2027.

Anticipated Milestones

- **Clinical Trial Initiations:**
    - Phase 1B trial of AXS-17 in epilepsy (1H 2027)
    - Phase 3 trial of AXS-20 in schizophrenia (1H 2027)
- **Clinical Trial Topline Results:**
    - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (1Q 2027)
    - Phase 3 SUSTAIN trial of solriamfetol in shift work disorder (2H 2027)
    - Phase 3 FOCUS-2 trial of solriamfetol in children with ADHD (2H 2027)
    - Phase 3 FOCUS-3 trial of solriamfetol in adolescents with ADHD (2H 2027)
    - Phase 3 SUMMIT trial of AXS-05 in smoking cessation (2H 2027)
- **Regulatory and Commercial:**
    - AXS-12 for cataplexy in narcolepsy, PDUFA target action (May 1, 2027)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its third quarter 2026 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, agitation associated with dementia due to Alzheimer’s disease, excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea, and migraine, as well as multiple novel product candidates 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, 2026 (Unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 313,859	$ 322,933
Accounts receivable, net	343,114	224,464
Inventories, net	42,579	27,938
Prepaid and other current assets	25,084	13,651
Total current assets	724,636	588,986
Equipment, net	943	562
Right-of-use asset - operating lease	18,284	20,858
Goodwill	12,042	12,042
Intangible asset, net	35,751	40,519
Non-current inventory and other assets	35,117	26,838
Total assets	$ 826,773	$ 689,805
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 96,075	$ 65,537
Accrued expenses and other current liabilities	331,756	232,853
Operating lease liability, current portion	663	434
Contingent consideration, current	11,225	10,012
Short-term borrowings	70,000	70,000
Total current liabilities	509,719	378,836
Contingent consideration, non-current	63,610	77,540
Loan payable, long-term	118,069	117,746
Operating lease liability, long-term	20,748	23,182
Finance lease liability, long-term	9,193	4,206
Total liabilities	721,339	601,510
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, 52,576,839 and 50,882,766 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively)	5	5
Additional paid-in capital	1,540,123	1,394,251
Accumulated deficit	(1,434,694)	(1,305,961)
Total stockholders' equity	105,434	88,295
Total liabilities and stockholders' equity	$ 826,773	$ 689,805

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

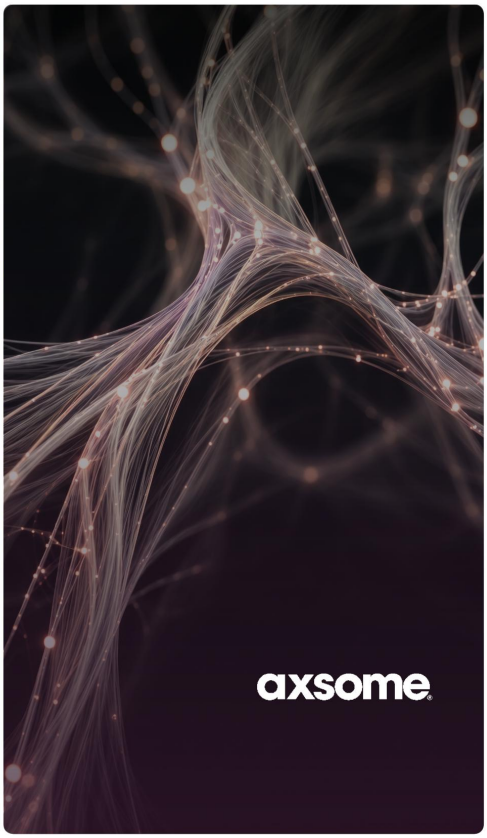
	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Revenues:				
Product sales, net	$ 249,951	$ 169,784	$ 655,706	$ 439,101
Royalty revenue and milestone revenue	9,740	1,208	13,563	3,396
Total revenues	259,691	170,992	669,269	442,497
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	17,804	11,912	46,093	35,149
Research and development	50,617	40,162	149,521	134,488
Selling, general and administrative	203,111	150,235	596,244	401,302
Loss (Gain) in fair value of contingent consideration	(2,380)	13,185	(3,286)	6,595
Intangible asset amortization	1,607	1,607	4,768	4,768
Total operating expenses	270,759	217,101	793,340	582,302
Loss from operations	(11,068)	(46,109)	(124,071)	(139,805)
Interest expense, net	(1,721)	(1,120)	(4,446)	(5,385)
Loss on debt extinguishment	—	—	—	(10,385)
Loss before income taxes	(12,789)	(47,229)	(128,517)	(155,575)
Income tax benefit (expense)	(88)	—	(216)	960
Net loss	$ (12,877)	$ (47,229)	$ (128,733)	$ (154,615)
Net loss per common share, basic and diluted	$ (0.25)	$ (0.94)	$ (2.48)	$ (3.13)
Weighted average common shares outstanding, basic and diluted	52,445,193	50,021,851	51,818,984	49,449,220

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Advancing the frontiers of brain health



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.

axsome

Our mission

We develop medicines through novel therapeutic approaches to improve the lives of people with serious brain disorders



Positioned for significant and durable growth

3	6	10	Psychiatry & Neurology
marketed products	novel product candidates	pipeline indications	Singular CNS portfolio

COMMERCIAL PORTFOLIO

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

MDD | **AD agitation**

$8B+ peak sales potential

SUNOSI® (solriamfetol) (V)

EDS in OSA or narcolepsy

$300M–$500M peak sales potential

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

Migraine

$500M–$1B peak sales potential

BROAD PIPELINE

Psychiatry

- Smoking cessation
- ADHD
- Binge eating disorder
- MDD with EDS symptoms
- Schizophrenia

Neurology

- Narcolepsy
- Fibromyalgia
- Shift work disorder
- Epilepsy

3Q 2026 results

COMMERCIAL GROWTH

Net product revenue

$259.7M

(+52% YoY)

>$1 billion annualized revenue run rate

Accelerating prescription growth for Alzheimer's disease agitation, building on continued momentum in MDD

PIPELINE PROGRESS

AXS-12 NDA under FDA review for cataplexy in narcolepsy

Initiated SUMMIT Phase 3 trial of AXS-05 in smoking cessation

ENGAGE Phase 3 trial of solriamfetol in binge eating disorder target enrollment reached

7 ongoing Phase 3 trials targeting large and underserved CNS conditions

UPCOMING MILESTONES*

AXS-12 PDUFA target action (May 1, 2027)

ENGAGE Phase 3 topline results (1Q 2027)

FOCUS-2 and FOCUS-3 Phase 3 topline results (2H 2027)

SUMMIT Phase 3 topline results (2H 2027)

SUSTAIN Phase 3 topline results (2H 2027)

AXS-20 Phase 3 initiation (1H 2027)

AXS-17 Phase 1b initiation (1H 2027)

*AXS-12: cataplexy in narcolepsy, ENGAGE: solriamfetol in binge eating disorder, FOCUS-2/3: solriamfetol in children and adolescents with ADHD, SUMMIT: AXS-05 in smoking cessation, SUSTAIN: solriamfetol in shift work disorder, AXS-20: schizophrenia, AXS-17: epilepsy

Industry-leading neuroscience pipeline with deep stratification

			Phase 1	Phase 2	Phase 3	NDA
AXS-05 (dextromethorphan-bupropion)	NMDA antagonist and sigma-1 agonist	Smoking cessation				
Solriamfetol	DNRI and TAAR1 agonist	ADHD				
		Binge eating disorder				
		MDD with EDS symptoms				
		Shift work disorder				
AXS-12 (reboxetine)	Highly selective NRI and dopamine modulator	Narcolepsy				
AXS-14 (esreboxetine)	Highly selective NRI and dopamine modulator	Fibromyalgia				
AXS-17	$GABA_A$ α2,3 subtype-selective PAM	Epilepsy				
AXS-20 (balipodect)	Selective PDE10A inhibitor	Schizophrenia				

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; GABA = gamma-aminobutyric acid;
Please see full Prescribing Information for AUVELITY, SUNOSI, and SYMBRAVO at www.AUVELITY.com, www.SUNOSI.com, and www.SYMBRAVO.com, respectively.

Advancing new frontiers across 10 serious CNS conditions



Smoking cessation	34M+	adults in the U.S. smoke cigarettes[1]	~70%	of smokers say they want to quit[2]
ADHD	22M+	people in the U.S. live with ADHD[3]	>90%	of childhood ADHD persists into adulthood[4]
Binge eating disorder	7M+	people impacted in the U.S.[5]	1	FDA-approved treatment
MDD with EDS symptoms	~50%	of MDD patients have concomitant EDS[6]	0	FDA-approved treatments
Schizophrenia	~3.7M	people in the U.S. have schizophrenia and related psychotic disorders[7]		

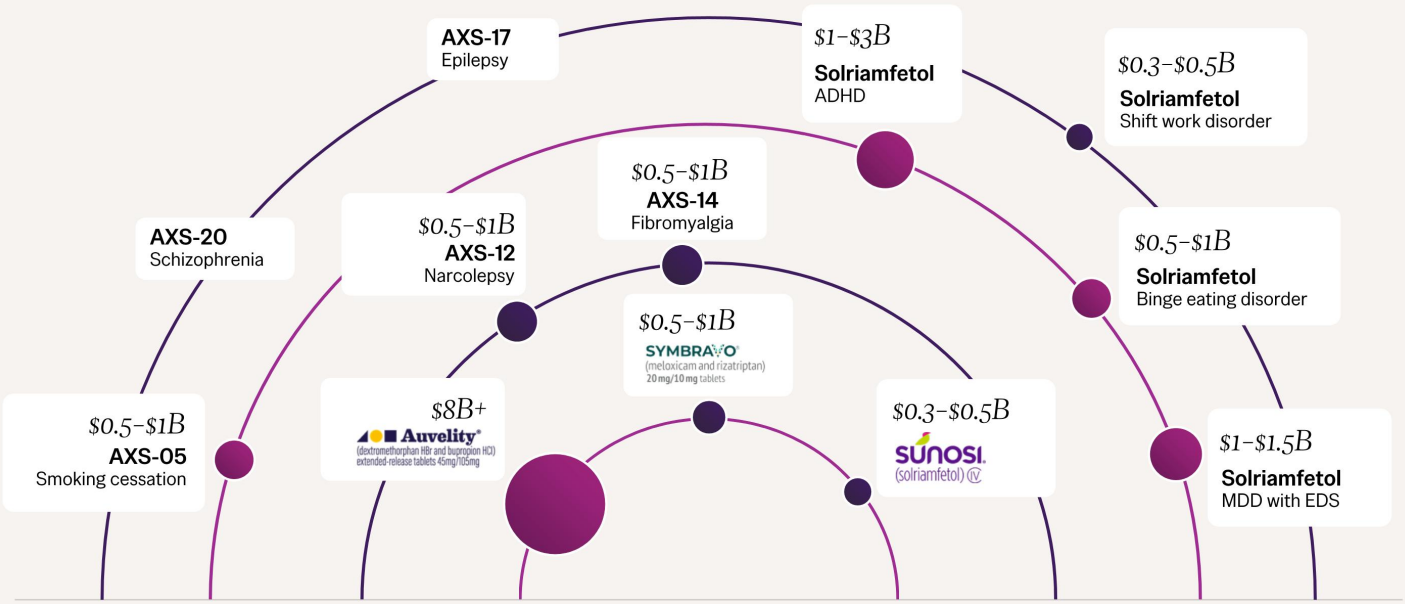
Narcolepsy	185K	people in the U.S. are affected by narcolepsy[8]	~70%	of patients suffer from cataplexy[9]
Fibromyalgia	17M+	people in the U.S. have fibromyalgia[10]	>50%	of patients discontinue treatment in the first year[11]
Shift work disorder	15M+	working Americans may be impacted[12-14]	0	new medications approved since 2007
Epilepsy	~3.4M	people in the U.S. live with epilepsy[15]	>1/3	of patients don't respond to treatment[16]



1. U.S. Department of Health and Human Services 2020; 2. Hughes JR, et al. 2004; 3. Facts About ADHD in Adults. CDC 2024; 4. Sibley MH, et al. 2022; 5. Hudson JI, et al. 2007; 6. Hein M, et al. 2019; 7. Ringeisen H, et al. 2023; 8. Narcolepsy Network 2024; 9. Swick TJ. 2015; 10. Vincent, et al. 2013; 11. Liu Y, et al. 2016; 12. Sateia MJ. 2014; 13. Alterman T, et al. 2013; 14. Wickwire EM. 2017; 15. Epilepsy CDC 2025; 16. Chen Z, et al. 2018;

Psychiatry | Neurology

Singular CNS portfolio with >$18B in annual peak sales potential



axsome

Financial highlights

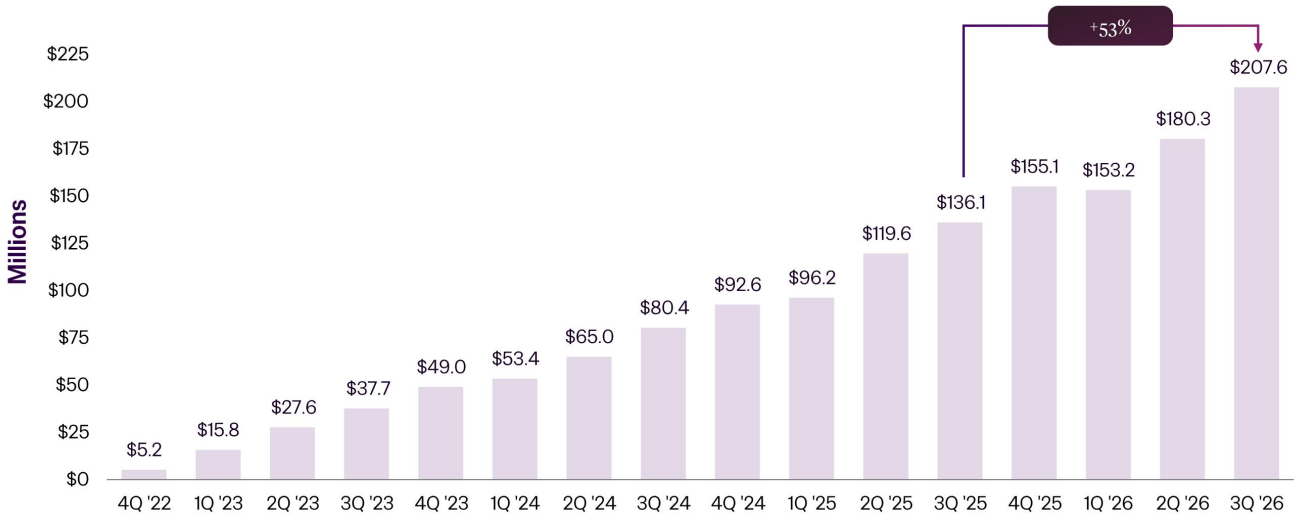
3Q 2026 financial performance

$ millions	3Q 2026	3Q 2025	% Change
Net product revenue	$259.7	$171.0	52%
AUVELITY	$207.6	$136.1	53%
SUNOSI*	$48.2	$32.8	47%
SYMBRAVO	$3.9	$2.1	88%
R&D expense	$50.6	$40.2	26%
SG&A expense	$203.1	$150.2	35%

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

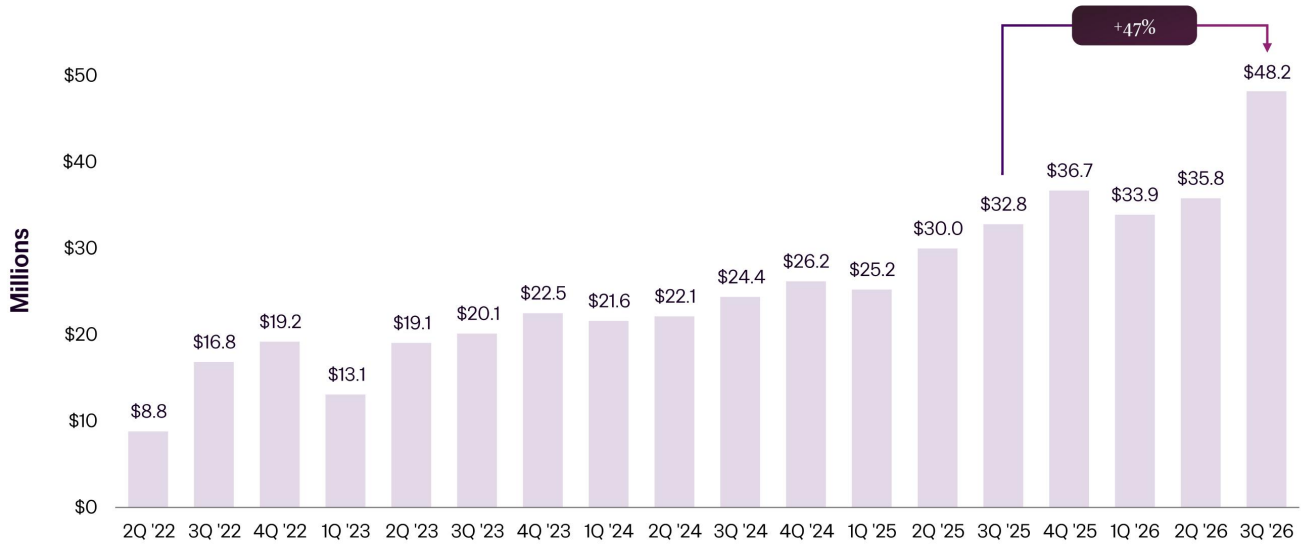
AUVELITY® quarterly net revenue performance

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



AUVELITY 3Q 2026 net product revenue of $207.6M (53% YoY growth)

SUNOSI® quarterly net revenue performance



SUNOSI 3Q 2026 net product revenue of $48.2M (47% YoY growth)

axsome

Financial snapshot

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

Cash balance: (as of September 30, 2026)	$313.9M
Debt (face value): (as of September 30, 2026)	$190M
Market cap: (as of October 30, 2026)	$7.6B
Shares outstanding: (as of September 30, 2026)	52.6M
Options, RSUs, and Others outstanding:*	7.8M

*Includes 5.6M stock options, 2.0M RSUs, and 0.2M others as of September 30, 2026

axsome

Commercial update

Robust commercial portfolio positioned for significant further growth

	HIGHLIGHTS / GROWTH DRIVERS	PEAK SALES POTENTIAL*
Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	• Accelerating new-to-brand prescription growth • Broadening prescriber base and deepening utilization • Strong market access	$8B+
SUNOSI® (solriamfetol) (IV)	• Durable demand and high patient satisfaction • Multiple label expansion opportunities to expand addressable market	$0.3B–$0.5B
SYMBRAVO® (meloxicam and rizatriptan) 20 mg/10 mg tablets	• Expanding prescriber adoption • Broader payer coverage and improving access	$0.5B–$1B

~$9.5B total commercial opportunity across approved medicines

*In approved indications only

First and only oral NMDA antagonist and sigma-1 agonist for MDD and Alzheimer's disease agitation[1,2]

MAJOR DEPRESSIVE DISORDER

Only oral antidepressant with rapid-acting efficacy reflected in FDA label[1]

Rapid symptom improvement starting at week 1 and remission as early as week 2, sustained at week 6[1,3]

ALZHEIMER'S DISEASE AGITATION

Only approved treatment demonstrating substantial symptom improvement and statistically significantly longer time to relapse[1]

Distinct safety/tolerability profile with no new boxed warning; most common adverse reactions were dizziness and dyspepsia[1]



axsome

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 DV, et al. 2022

Continued momentum reflects underlying MDD growth and early impact from the sales force expansion

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

GROWING PRESCRIBER BASE

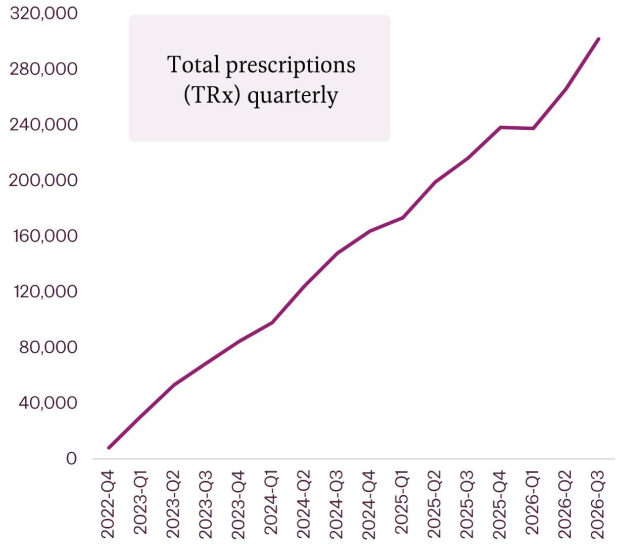
~77,000 Unique writers LTD	+19% QoQ growth in newly activated writers

ACCELERATING NEW PATIENT STARTS

+21% QoQ NBRx growth	>400,000 Patients treated LTD	~302,000 TRx in 3Q 2026

STRONG MARKET ACCESS

~89% Total covered lives	~82% Commercial covered lives	~100% Medicare and Medicaid covered lives

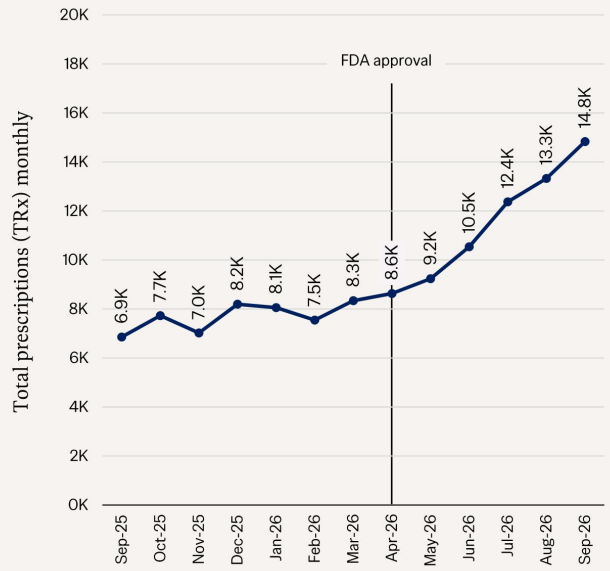


Source: Symphony METYS

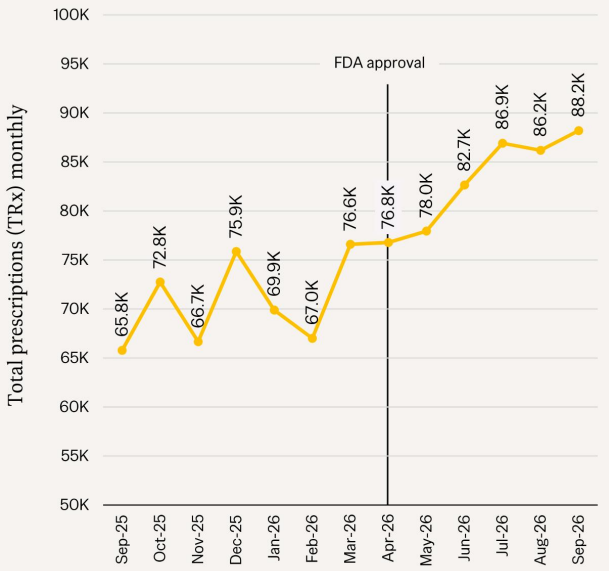
LTD = launch to date

Acceleration in prescription trends among patients aged 65+ following ADA label expansion, alongside continued growth for under 65

Auvelity TRx : 65+



Auvelity TRx : Under 65

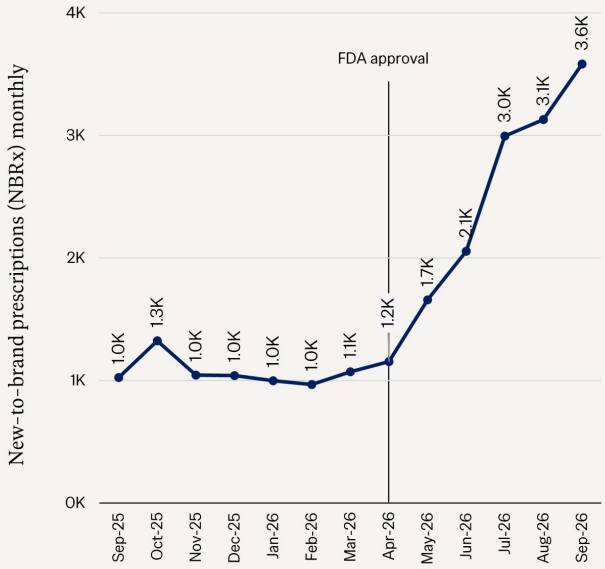


axsome

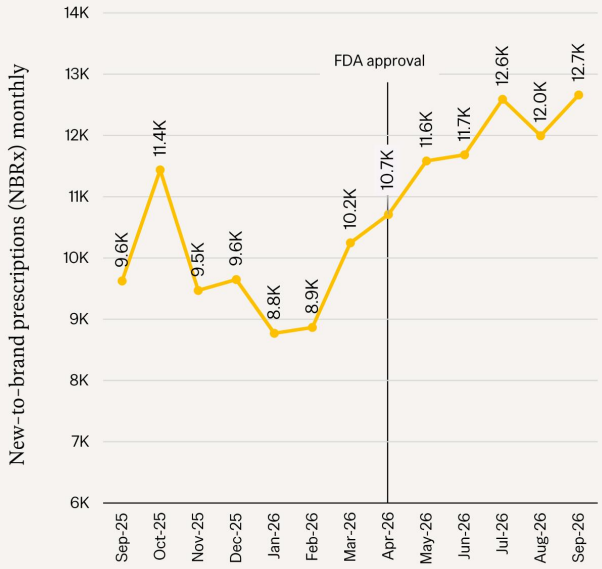
AUVELITY was approved by the FDA for the treatment of agitation associated with dementia due to Alzheimer's disease on April 30, 2026

Continued NBRx acceleration to drive compounding TRx growth

Auvelity NBRx : 65+



Auvelity NBRx : Under 65



axsome

AUVELITY was approved by the FDA for the treatment of agitation associated with dementia due to Alzheimer's disease on April 30, 2026

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

First and only wakefulness promoting agent proven to improve wakefulness through 9 hours[1]

90% of patients reported feeling better with SUNOSI 150 mg[2]

Improvements in cognitive functioning vs. placebo demonstrated in clinical trials



EDS = Excessive daytime sleepiness; OSA = Obstructive sleep apnea

1. SUNOSI [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY; 2. Schweitzer PK, et al. 2019

Steady demand continues to drive durable growth

EXPANDING PRESCRIBER REACH

>17,500
Unique writers LTD

STEADY DEMAND GROWTH

~114,000
Patients treated LTD

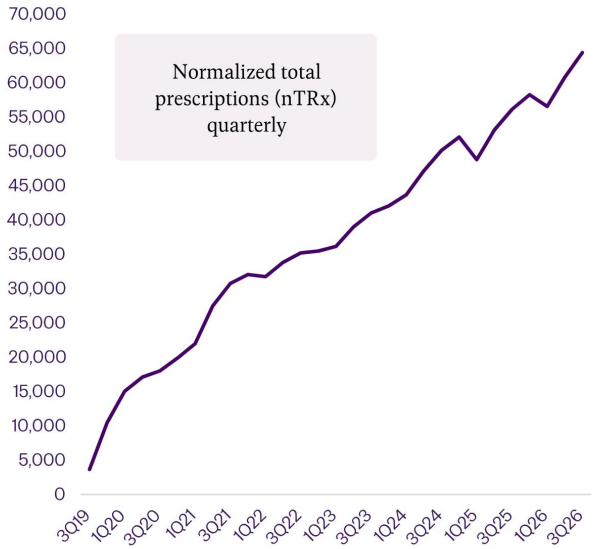
~64,400
TRx in 3Q 2026

BROAD PAYER COVERAGE

~82%
Total covered lives

~97%
Commercial covered lives

~59%
Medicare and Medicaid covered lives



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

LTD = launch to date

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

Single, oral dose provided rapid migraine pain freedom and return to normal functioning within 2 hours[1]

Superior efficacy demonstrated across a broad range of migraine severity (mild, moderate, severe)[1]

Harnesses Axsome's MoSEIC™ rapid absorption technology to target multiple pathways underlying a migraine attack



MoSEIC = Molecular Solubility Enhanced Inclusion Complex;

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

Expanding prescriber and patient adoption

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

PRESCRIBER GROWTH

~5,750
Unique writers LTD

PATIENT GROWTH

~24,900
Patients treated LTD

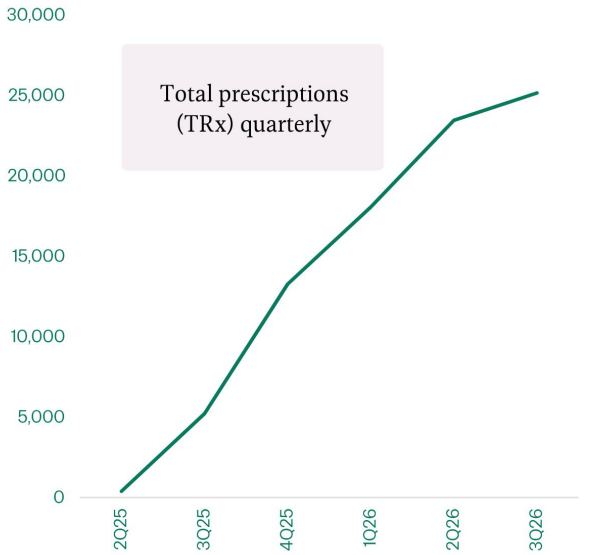
>25,000
TRx in 3Q 2026

MARKET ACCESS

~57%
Total covered lives

~56%
Commercial covered lives

~57%
Medicare and Medicaid covered lives



Source: Symphony METYS

LTD = launch to date

axsome

Development pipeline

Smoking cessation

70% of smokers want to quit[2]



Only 3-5% of smokers 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]



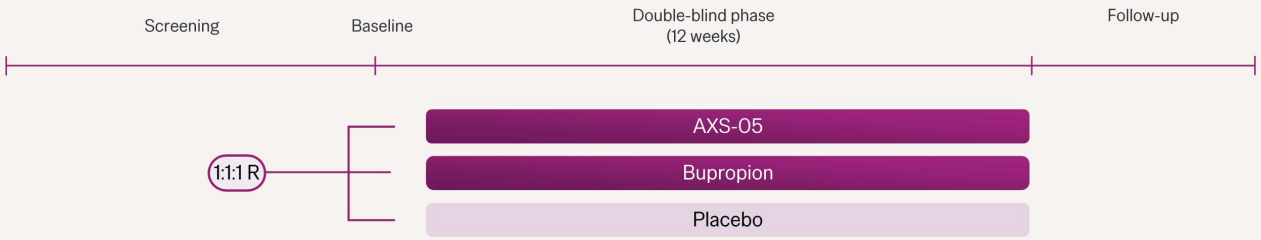
Single largest cause of preventable disease and death in the U.S., accounting for nearly 1 in 5 deaths[1]



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

Evaluating AXS-05 as a treatment for smoking cessation

SUMMIT Phase 3 trial



Key eligibility criteria

- 18–65 years of age

Primary endpoint

- Change from baseline in smoking abstinence

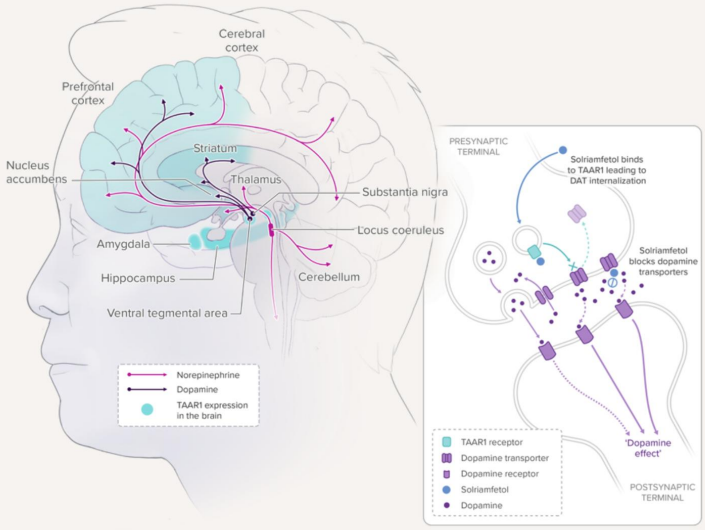
Topline results anticipated 2H 2027

Solriamfetol: Unique pharmacology 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

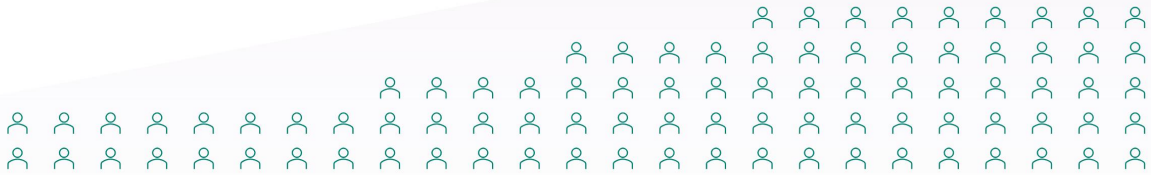
Preclinical and clinical evidence[1,2] suggests TAAR1 plays a role in neuropsychiatric conditions related to the dysregulation of monoaminergic transmission

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. 2022; 2. Halff EF, et al. 2023; TAAR1 = Trace amine–associated receptor 1

Solriamfetol Phase 3 development programs



Approved in EDS associated with OSA and narcolepsy

ADHD

- ✓ Positive FOCUS Phase 3 trial in adults with ADHD (N=516)
- Topline data from FOCUS-2 and FOCUS-3 Phase 3 trials in children and adolescents with ADHD anticipated in 2H 2027

MDD with EDS

- Ongoing CLARITY Phase 3 trial in MDD with EDS symptoms

BED

- Topline data from ENGAGE Phase 3 trial in adults with binge eating disorder anticipated in 1Q 2027

SWD

- Ongoing SUSTAIN Phase 3 trial in adults with shift work disorder (N=450)
- Topline data anticipated in 2H 2027

Evaluating solriamfetol across four additional indications

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



Solriamfetol has the potential to treat a broad range of psychiatric and neurological conditions

Approved indication

- Excessive daytime sleepiness (EDS) in OSA and narcolepsy

Potential label expansion programs

- ADHD: ~22M patients
- Binge eating disorder: ~7M patients
- Major depressive disorder with EDS symptoms: ~10.5M patients
- Shift work disorder: ~15M patients

Attention-deficit/hyperactivity disorder (ADHD)



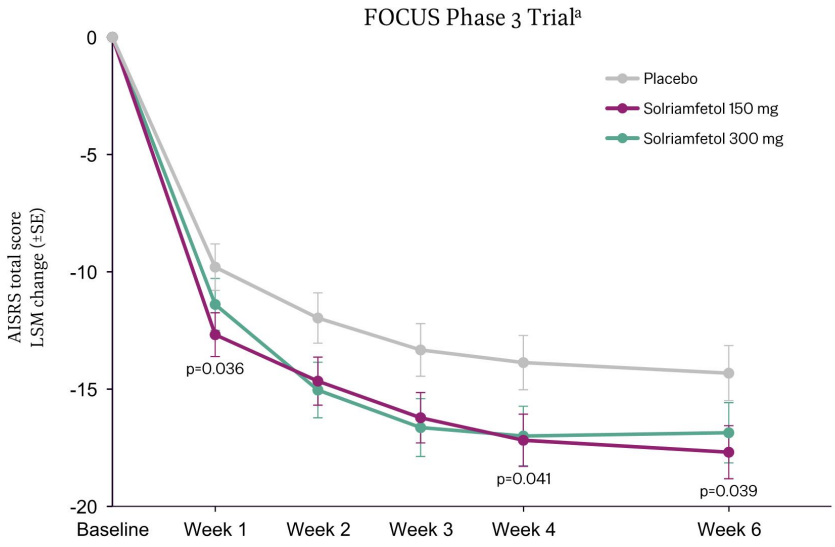
Characterized by a persistent pattern of inattention and/or hyperactive-impulsive behaviors[3]

Chronic neurobiological and developmental disorder affecting an estimated ~22M people in the U.S.[1], including ~7M children aged 3-17 years[2]

Associated with significant impairment in social, academic, and occupational functioning and development[3]

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

Statistically significant improvements in ADHD symptoms with solriamfetol treatment



Primary endpoint:
Change from baseline in AISRS total score at Week 6

17.7–point

reduction in the AISRS total score at Week 6 with solriamfetol vs. 14.3-point reduction with placebo (p=0.039)[b]

Significantly greater percentage of patients receiving solriamfetol achieved a clinical response[b] vs. placebo (p=0.024)[c]

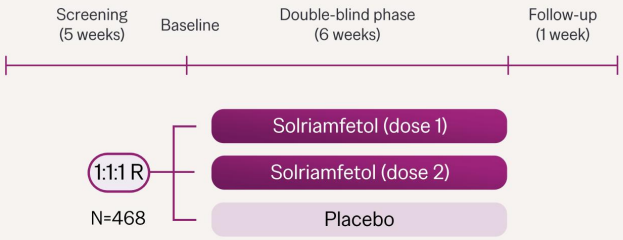
Significant improvements in overall ADHD severity vs. placebo (CGI-S, p=0.017)[c]

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

AISRS = Adult ADHD Investigator Symptom Rating Scale; LSM = least-squares mean; SE = standard error; SR = sustained release; CGI-S = Clinical Global Impression–Severity scale
a. p-values shown for solriamfetol 150 mg are nominal; b. Clinical response defined as ≥30% reduction in AISRS; c. solriamfetol 150 mg;
Axsome Therapeutics, Inc. Data on file.

Solriamfetol Phase 3 program in pediatric ADHD

FOCUS-2 Phase 3 trial



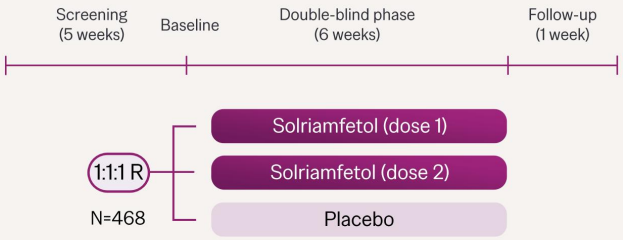
Key eligibility criteria

- 6 to <12 years of age with diagnosis of ADHD (DSM-5)

Primary endpoint

- Change from baseline in ADHD-RS-5 total score

FOCUS-3 Phase 3 trial



Key eligibility criteria

- 12 to <18 years of age with diagnosis of ADHD (DSM-5)

Primary endpoint

- Change from baseline in ADHD-RS-5 total score

Topline results anticipated 2H 2027

ADHD-RS-5 = ADHD Rating Scale

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 U.S.[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. 2007; 2. Swanson SA, et al. 2011; 3. Kessler RM, et al. 2016; 4. McElroy SL, et al. 2020

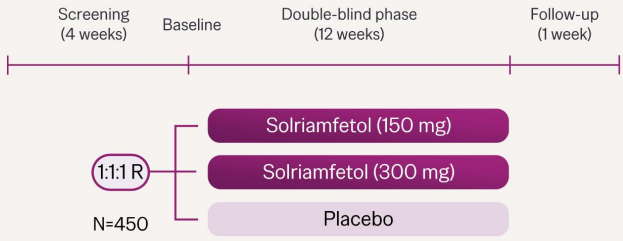
Solriamfetol for the treatment of binge eating disorder

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

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

Topline results anticipated 1Q 2027

ENGAGE Phase 3 trial



Key eligibility criteria

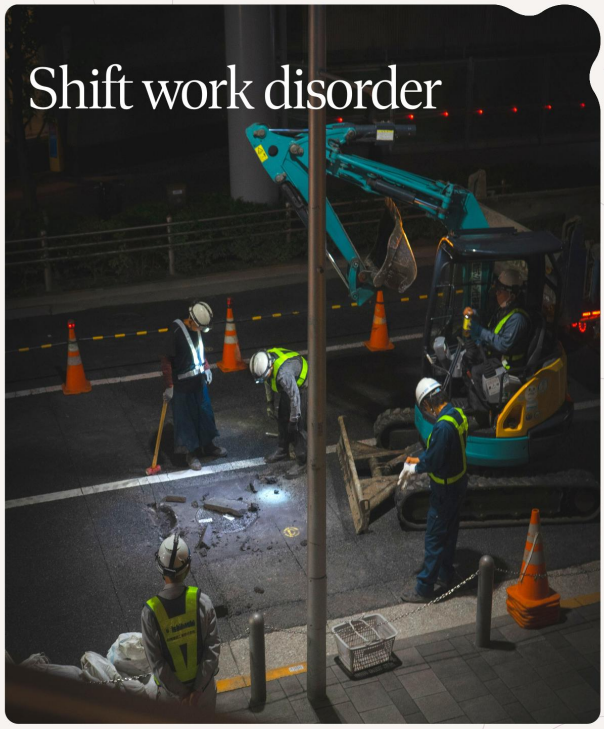
- 18–55 years of age with diagnosis of BED (DSM-5)

Primary endpoint

- Change from baseline in days with binge eating episodes

1. Giel KE, et al. 2022; 2. Bello NT, Hajnal A. 2010; 3. Pruccoli J, et al. 2021; 4. Malhotra A, et al. 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 U.S. workers works an alternate shift[2]

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

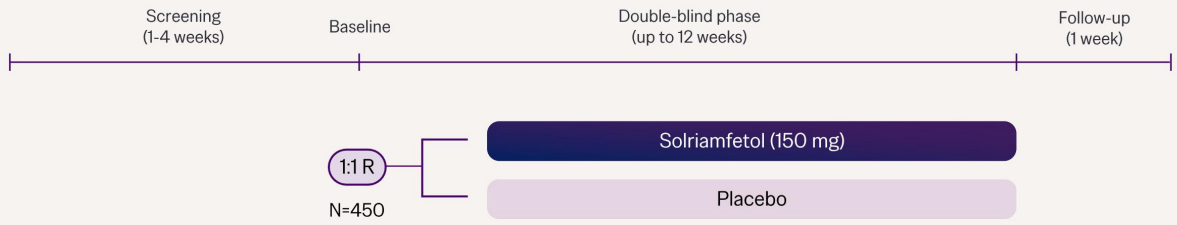
Shift work disorder (SWD) is a combination of excessive sleepiness during wakefulness and persistent insomnia during daytime sleep when working outside a 7 a.m. to 6 p.m. workday[1]

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

1. Sateia MJ. 2014; 2. Alterman T, et al. 2013; 3. Wickwire EM. 2017; 4. Smith L, et al. 1994; 5. Akerstedt T, Wright KP. 2009; 6. Czeisler CA, et al. 2005

Solriamfetol for the treatment of shift work disorder

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 MWT

Topline results anticipated 2H 2027

MWT = Maintenance of Wakefulness Test



MDD with excessive daytime sleepiness (EDS) symptoms

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

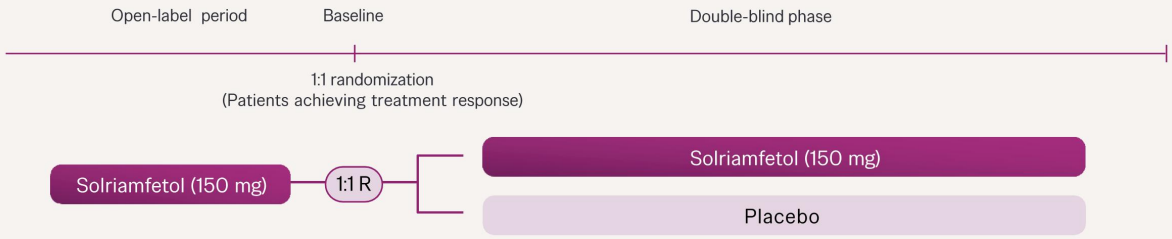
MDD patients with EDS have difficulty maintaining wakefulness, resulting in impaired daily functioning and increased safety risks

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

1. Rush AJ, et al. 2006; 2. Major Depression. NIMH 2023; 3. Hasin DS, et al. 2018; 4. Hein M, et al. 2019

Solriamfetol for the treatment of MDD with EDS symptoms

CLARITY Phase 3 trial



Key eligibility criteria

- 18–65 years of age with diagnosis of MDD (DSM-5 criteria)
- Symptoms of excessive daytime sleepiness

Primary endpoint

- Time from randomization to relapse of depressive symptoms

Enrollment completion anticipated 1H 2027

AXS-12 (reboxetine)

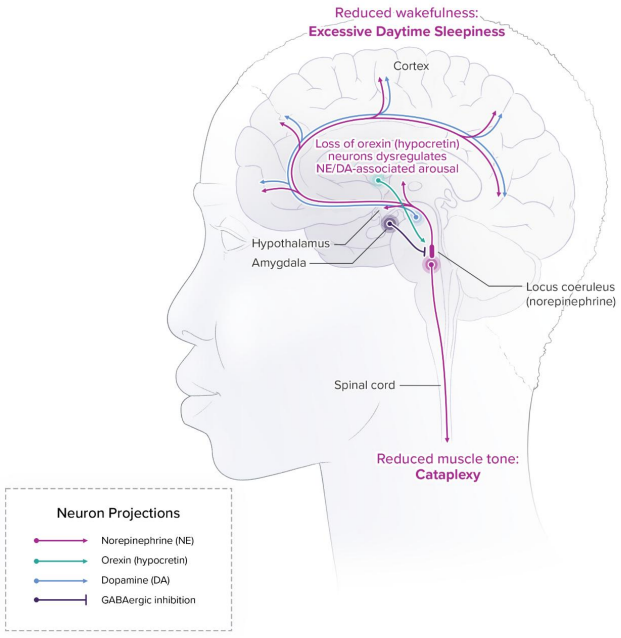
Novel pharmacological approach for the treatment of narcolepsy

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

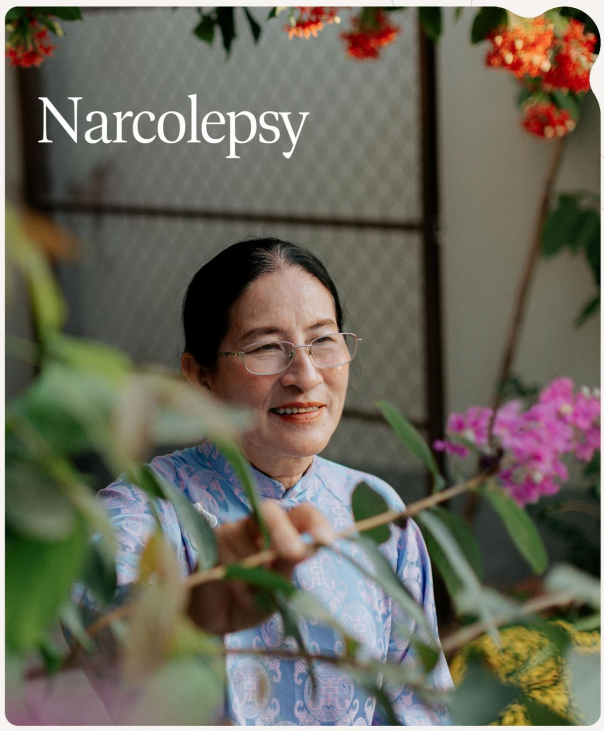
The loss of orexin input inhibits the production of these neurotransmitters[1,2]

- 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. 2019; 2. Krahn LE, Zee PC, Thorpy MJ. 2022; 3. Scammell TE. 2015; 4. Stahl SM, Grady MM. 2003; 5. Burgess CR, Peever JH. 2013; 6. Wu MF, et al. 1999; 7. Bruinstroop E, et al. 2012



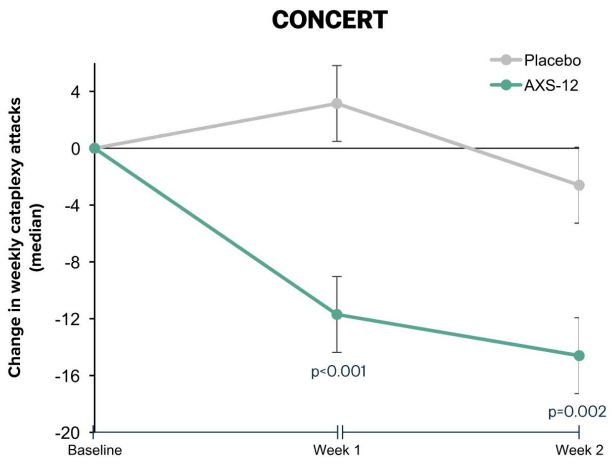
Rare and debilitating neurological condition that affects approximately 185,000 people in the U.S.[1]

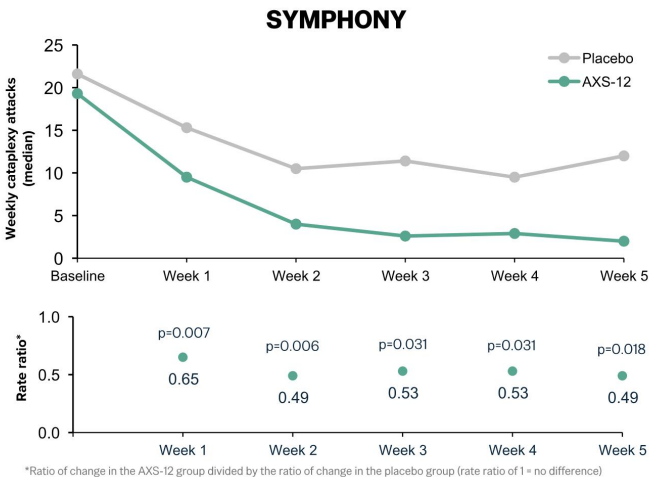
Characterized by cataplexy, excessive daytime sleepiness (EDS), hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep[2-4]

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

1. Narcolepsy Network 2024; 2. Sateia MJ. 2014; 3. Narcolepsy. NINDS 2024; 4. España RA, Scammell TE. 2011; 5. Swick TJ. 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)

PDUFA target action date: May 1, 2027

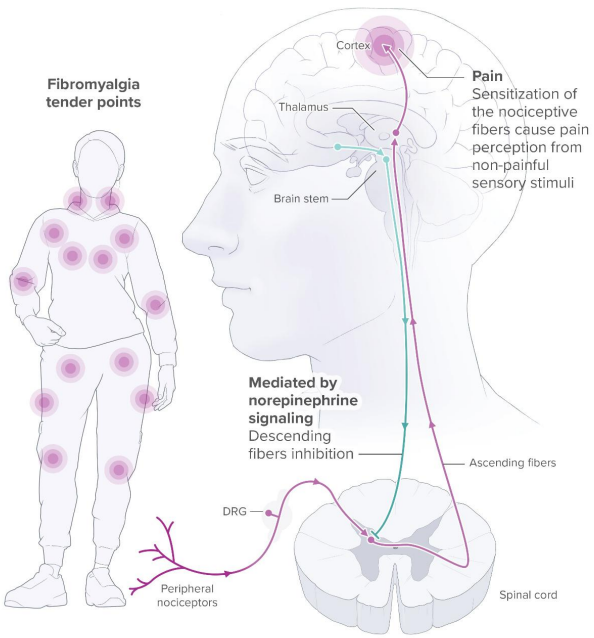
AXS-14 (esreboxetine)

Novel pharmacological approach for the management of fibromyalgia

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 potent and selective enantiomer of racemic reboxetine that inhibits the reuptake of norepinephrine, resulting in increased norepinephrine activity and decreased pain signaling





Fibromyalgia

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

Chronic and debilitating neurological pain syndrome resulting from a dysfunction in central pain processing[2,3]

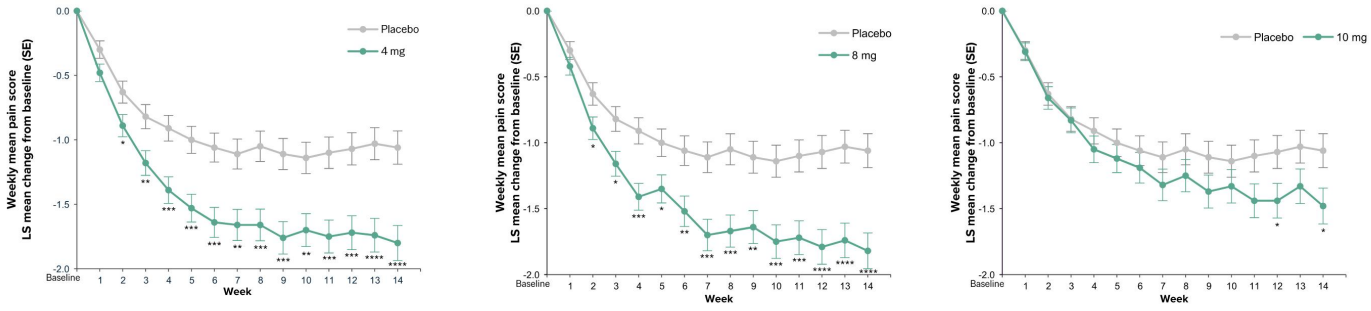
Characterized by widespread musculoskeletal pain, fatigue, disturbed sleep, mood disturbances, cognitive impairment, and hypersensitivity to sensory stimuli[4,5]

Associated with substantial physical disability and reduced emotional and social well-being, financial burden, and reduced quality of life[2,3]

1. Vincent, et al. 2013; 2. Choy E, et al. 2010; 3. Arnold LM, et al. 2008; 4. Bair MJ, Krebs EE. 2020; 5. Clauw DJ. 2024

Rapid and robust improvements in fibromyalgia symptoms with AXS-14 treatment

Pain reduction[a]
Phase 3 efficacy results (N=1,122)



- 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

a. p-values are defined as: *p<0.05, **p<0.01, ***p<0.001, ****p<0.0001

AXS-14 for the management of fibromyalgia

FORWARD Phase 3 trial



Key eligibility criteria

- ≥18 years of age with diagnosis of fibromyalgia

Primary endpoint

- Time from randomization to loss of therapeutic response

Enrollment completion anticipated 3Q 2027

AXS-17

Novel oral $GABA_A$ receptor α2,3 subtype-selective positive allosteric modulator (PAM) for epilepsy

Epilepsy is a chronic and debilitating neurological disorder affecting ~3.4M people in the U.S.[1]

AXS-17 was safe and well tolerated in clinical studies in >700 patients to date and demonstrated compelling anti-convulsant activity in preclinical seizure models

Despite currently available treatment options, >1/3 of patients do not respond to treatment[2]

Phase 1B initiation in epilepsy anticipated 1H 2027

1. Epilepsy. CDC 2025; 2. Chen Z, et al. 2018

AXS-20

Potential first-in-class selective PDE10A inhibitor for neuropsychiatric conditions

~3.7M people in the U.S. have schizophrenia and related psychotic disorders[1]

AXS-20 demonstrated a favorable safety and tolerability profile in clinical studies in >360 individuals to date

Completed proof-of-concept Phase 2 trial in patients with schizophrenia

Phase 3 initiation in schizophrenia anticipated 1H 2027

axsome

1. Ringeisen H, et al. 2023

Strong intellectual property portfolio

AUVELITY

- Protected by a robust patent estate extending to at least 2043, multiple pending
- Proprietary drug product formulation and methods of treatment

SUNOSI

- Protected by a robust patent estate extending to at least 2042, multiple pending
- Proprietary drug substance, drug product formulation, and methods of treatment

SYMBRAVO

- Protected by a robust patent estate extending to at least 2045, multiple pending
- Proprietary MoSEIC™ formulation, drug product formulation, and methods of treatment

AXS-12

- Orphan Drug Designation
- Claims extending to at least 2039; 10 issued U.S. patents and 7 issued O.U.S. patents, multiple pending
- Proprietary drug substance, drug product formulation, and methods of treatment

AXS-14

- Claims extending to at least 2045; 1 issued U.S. patent, multiple pending
- Proprietary drug substance, drug product formulation, and methods of treatment

Leadership team

Management

Herriot Tabuteau, MD
FOUNDER & CEO
Goldman Sachs
Bank of America

Nick Pizzie, CPA, MBA
CHIEF FINANCIAL OFFICER
Pierre Fabre – Merck
Pfizer - Immucor

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

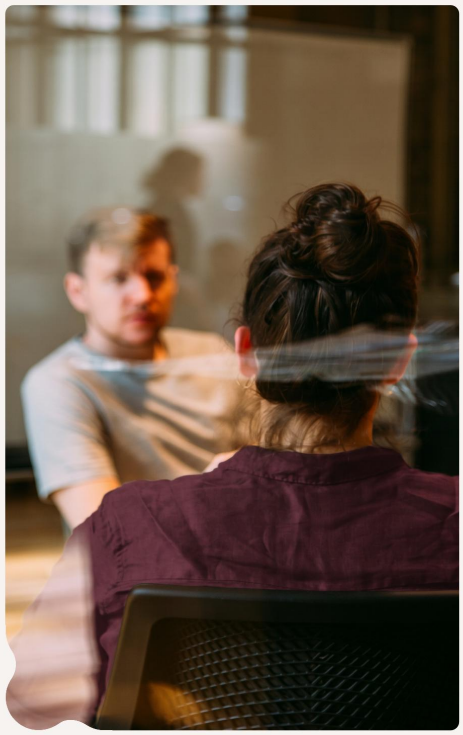
Roger Jeffs, PhD
CEO, LIQUIDIA CORPORATION
Former President, Co-CEO, Director United Therapeutics Corp.
Prior positions at Amgen and Burroughs Wellcome

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

Herriot Tabuteau, MD
CHAIRMAN



axsome

Thank you.



We develop medicines through novel therapeutic approaches to improve the lives of people with serious brain disorders