

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): August 10, 2026

Axsome Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37635
(Commission File Number)

45-4241907
(IRS Employer
Identification No.)

One World Trade Center, 29th Floor
New York, New York
(Address of Principal Executive Offices)

10007
(Zip Code)

Registrant's Telephone Number, Including Area Code: (212) 332-3241

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.0001 Per Share	AXSM	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2026, Axsome Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended June 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 August 10, 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 August 10, 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: August 10, 2026

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

**Axsome Therapeutics Reports Second Quarter 2026 Financial Results and Provides Business Update**

Total 2Q 2026 net product revenue of \$218.4 million, representing 46% year-over-year growth

AUVELITY® 2Q 2026 net product sales of \$180.3 million, representing 51% year-over-year growth

SUNOSI® 2Q 2026 net product revenue of \$35.8 million, representing 20% year-over-year growth

SYMBRAVO® 2Q 2026 net product sales of \$2.3 million

AUVELITY launched for treatment of agitation associated with dementia due to Alzheimer's disease in June 2026

NDA submission for AXS-12 for cataplexy in narcolepsy accepted by the FDA with PDUFA target action date of May 1, 2027

FOCUS-2 and FOCUS-3 Phase 3 trials of solriamfetol in children and adolescents with ADHD initiated

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

NEW YORK, August 10, 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 second quarter of 2026 and provided a general business update.

"The second quarter was highly productive for Axsome. Our commercial business grew robustly, driven by strong underlying demand for our products, and we made important regulatory and clinical progress across our innovative neuroscience pipeline," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "We expect our commercial momentum to build over the balance of the year, in particular with anticipated continued Auvelity growth in Alzheimer's disease agitation and major depressive disorder. With a focus on commercial execution and advancement of our broad late-stage neuroscience pipeline targeting high unmet needs, novel indications, first-in-class mechanisms of action, and best-in-class product profiles, Axsome is well positioned to deliver substantial value to patients and shareholders."

Second Quarter 2026 Financial Highlights

- Total net product revenue was \$218.4 million for the second quarter of 2026, representing 46% year-over-year growth. Total net product revenue for the comparable period in 2025 was \$150.0 million.
- AUVELITY net product sales were \$180.3 million for the second quarter of 2026, representing 51% year-over-year growth. AUVELITY net product sales for the comparable period in 2025 were \$119.6 million.
- SUNOSI net product revenue was \$35.8 million for the second quarter of 2026, representing 20% year-over-year growth, which consisted of \$33.8 million in net product sales, \$1.5 million in royalty revenue associated with SUNOSI sales in out-licensed territories, and \$0.5 million in milestone revenue. SUNOSI net product revenue for the comparable period in 2025 was \$30.0 million, which consisted of \$28.9 million in net product sales and \$1.1 million in royalty revenue.
- SYMBRAVO net product sales were \$2.3 million for the second quarter of 2026, representing 461% year-over-year growth. SYMBRAVO was launched in June 2025 and had net product sales of \$0.4 million for the second quarter of 2025.
- Total cost of revenue was \$13.6 million for the second quarter of 2026. Total cost of revenue for the comparable period in 2025 was \$13.4 million.

- Research and development (R&D) expenses were \$46.2 million for the second quarter of 2026, compared to \$49.5 million for the comparable period in 2025. The decrease primarily reflects lower costs for AXS-05 and AXS-14.
- Selling, general, and administrative (SG&A) expenses were \$208.1 million for the second quarter of 2026, compared to \$130.3 million for the comparable period in 2025. The increase primarily reflects commercialization activities for AUVELITY, including the sales force expansion and launch activities for the Alzheimer's disease agitation indication, and commercialization activities for SYMBRAVO.
- Net loss for the second quarter of 2026 was \$51.3 million, or \$(0.99) per share, compared to a net loss of \$48.0 million, or \$(0.97) per share, for the comparable period in 2025. The net loss in the second quarter of 2026 includes \$27.1 million in stock-based compensation expense.
- Cash and cash equivalents totaled \$319.9 million at June 30, 2026, compared to \$322.9 million at December 31, 2025.
- Shares of common stock outstanding were 52,299,889 at June 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 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.

- Axsome launched AUVELITY in Alzheimer's disease agitation in June 2026.
- New-to-brand prescriptions, representing new AUVELITY patient starts, increased 126% among patients ≥65 years of age during the first eight weeks following the Alzheimer's disease agitation launch compared to the same period in the prior quarter. New-to-brand prescriptions are considered a leading indicator of growth, reflecting expanding adoption in this patient segment. These early trends have been accompanied by positive prescriber feedback and recognition of AUVELITY's differentiated profile in Alzheimer's disease agitation.
- Overall new-to-brand prescriptions in the second quarter of 2026 increased 26% compared to the first quarter of 2026, reflecting the early impact of the sales force expansion which was completed in the second quarter. Approximately 266,000 total prescriptions were written for AUVELITY in the second quarter of 2026, representing year-over-year and quarter-over-quarter increases of 34% and 12%, respectively.
- 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 DNRI approved for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy.

- Approximately 61,000 prescriptions were written for SUNOSI in the U.S. in the second quarter of 2026, a 14% increase compared to the same period in 2025, and an 8% increase compared to the first quarter of 2026.
- Payer coverage for SUNOSI across all channels is at approximately 82% of all lives covered, including approximately 96% 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 23,500 prescriptions were written for SYMBRAVO in the second quarter of 2026, a 30% increase compared to the first 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.
- The previously announced expansion of the SYMBRAVO sales force is substantially complete. Our expanded sales team of approximately 150 sales representatives will enable broader reach within the primary care market and deeper engagement with headache specialists and neurologists nationwide.

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 N-methyl-D-aspartate (NMDA) receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for smoking cessation.

- **Smoking Cessation:** Axsome is on track to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in the third quarter of 2026.

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 EDS symptoms, binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** In June and July 2026, Axsome initiated the FOCUS-3 and FOCUS-2 Phase 3, randomized, double-blind, placebo-controlled, multicenter trials evaluating the efficacy and safety of solriamfetol as a treatment for adolescents and children with ADHD, respectively. The primary endpoint in both studies is the change from baseline to week 6 in the ADHD Rating Scale (ADHD-RS-5) total score.
- **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.

- **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 the fourth quarter of 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 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 submission for AXS-12 for the treatment of cataplexy in narcolepsy was accepted by the FDA and assigned a PDUFA target action date of 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.

AXS-17

AXS-17 is Axsome's novel oral GABA_A receptor α 2,3 subtype-selective positive allosteric modulator (PAM) being developed for the treatment of epilepsy.

- **Epilepsy:** Phase 2 trial-enabling activities for AXS-17 in epilepsy are underway.

AXS-20

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

- **Schizophrenia:** Phase 3 trial-enabling activities for AXS-20 in schizophrenia are underway.
- **Tourette Syndrome:** Axsome plans to evaluate AXS-20 as a potential treatment for Tourette syndrome.

Anticipated Milestones

- **Clinical Trial Initiations and Progress:**
 - Phase 2/3 trial of AXS-05 in smoking cessation, initiation (3Q 2026)
- **Clinical Trial Topline Results:**
 - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (4Q 2026)
 - Phase 3 SUSTAIN trial of solriamfetol in shift work disorder (2027)
- **Regulatory and Commercial:**
 - AXS-12 for 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 second 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)

	June 30, 2026 (Unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 319,850	\$ 322,933
Accounts receivable, net	277,459	224,464
Inventories, net	37,883	27,938
Prepaid and other current assets	21,377	13,651
Total current assets	656,569	588,986
Equipment, net	874	562
Right-of-use asset - operating lease	19,157	20,858
Goodwill	12,042	12,042
Intangible asset, net	37,358	40,519
Non-current inventory and other assets	35,447	26,838
Total assets	<u>\$ 761,447</u>	<u>\$ 689,805</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 78,969	\$ 65,537
Accrued expenses and other current liabilities	299,632	232,853
Operating lease liability, current portion	646	434
Contingent consideration, current	11,199	10,012
Short-term borrowings	70,000	70,000
Total current liabilities	460,446	378,836
Contingent consideration, non-current	69,135	77,540
Loan payable, long-term	117,958	117,746
Operating lease liability, long-term	21,574	23,182
Finance lease liability, long-term	9,030	4,206
Total liabilities	678,143	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, 52,299,889 and 50,882,766 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively)	5	5
Additional paid-in capital	1,505,116	1,394,251
Accumulated deficit	(1,421,817)	(1,305,961)
Total stockholders' equity	83,304	88,295
Total liabilities and stockholders' equity	<u>\$ 761,447</u>	<u>\$ 689,805</u>

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

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Revenues:				
Product sales, net	\$ 216,355	\$ 148,959	\$ 405,755	\$ 269,317
Royalty revenue and milestone revenue	2,020	1,083	3,823	2,188
Total revenues	218,375	150,042	409,578	271,505
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	13,564	13,448	28,289	23,237
Research and development	46,227	49,541	98,904	94,326
Selling, general and administrative	208,137	130,280	393,133	251,067
Gain in fair value of contingent consideration	(1,496)	(8,102)	(906)	(6,590)
Intangible asset amortization	1,589	1,589	3,161	3,161
Total operating expenses	268,021	186,756	522,581	365,201
Loss from operations	(49,646)	(36,714)	(113,003)	(93,696)
Interest expense, net	(1,540)	(1,834)	(2,725)	(4,265)
Loss on debt extinguishment	—	(10,385)	—	(10,385)
Loss before income taxes	(51,186)	(48,933)	(115,728)	(108,346)
Income tax benefit (expense)	(128)	960	(128)	960
Net loss	\$ (51,314)	\$ (47,973)	\$ (115,856)	\$ (107,386)
Net loss per common share, basic and diluted	\$ (0.99)	\$ (0.97)	\$ (2.25)	\$ (2.18)
Weighted average common shares outstanding, basic and diluted	51,799,708	49,442,001	51,500,690	49,158,159

Investors:

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2Q 2026 Financial Results

| August 10, 2026

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
to improve the brain health of
millions of individuals



Positioned for significant and durable growth

3 marketed products	6 novel product candidates	10 pipeline indications	Psychiatry + Neurology Singular CNS portfolio
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COMMERCIAL PORTFOLIO

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

SUNOSI
(solriamfetol) (TV)

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

MDD | AD agitation
Expanding franchise

EDS in OSA or narcolepsy
Continued growth

Migraine
Launch phase

BROAD PIPELINE



Psychiatry

Smoking cessation
ADHD
Binge eating disorder
MDD with EDS symptoms
Schizophrenia



Neurology

Narcolepsy
Fibromyalgia
Shift work disorder
Epilepsy
Tourette syndrome



2Q 2026 performance

COMMERCIAL GROWTH

Total product revenue

\$218.4M (+46% YoY)

- Completed AUVELITY sales force expansion to ~630 representatives
- Launched AUVELITY in Alzheimer's disease agitation in June

PIPELINE PROGRESS

- NDA submission for AXS-12 for cataplexy in narcolepsy accepted by the FDA
- Initiated FOCUS-2 and FOCUS-3 Phase 3 trials of solriamfetol in children and adolescent with ADHD
- Clinical trials ongoing in five indications of high unmet need
- Phase 2 trial-enabling activities for AXS-17 in epilepsy underway
- Phase 3 trial-enabling activities for AXS-20 in schizophrenia underway

UPCOMING MILESTONES

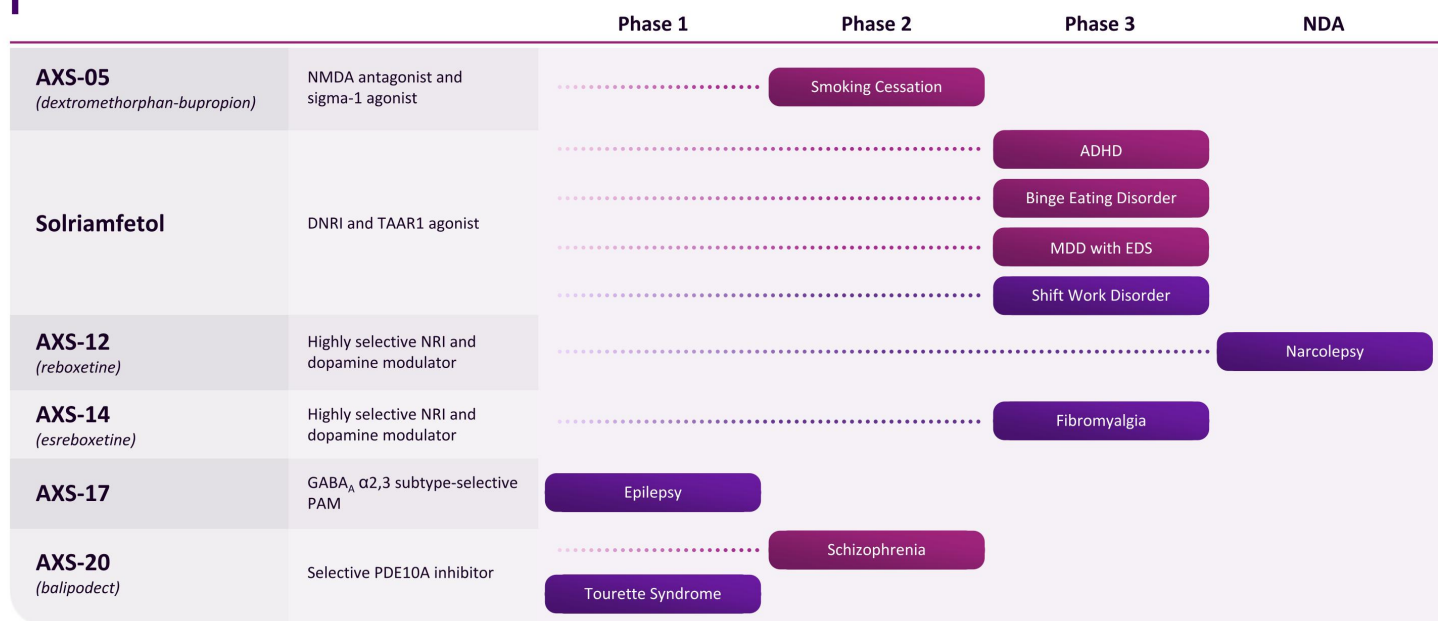
- AXS-12 PDUFA target action (May 1, 2027)
- Initiation of pivotal Phase 2/3 trial of AXS-05 in smoking cessation (3Q 2026)
- Topline results of the ENGAGE Phase 3 trial of solriamfetol in binge eating disorder (4Q 2026)
- Topline results of the SUSTAIN Phase 3 trial of solriamfetol in shift work disorder (2027)



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Leading neuroscience pipeline with deep stratification



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.
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Advancing new frontiers across 10 serious CNS conditions

PSYCHIATRY

Smoking cessation

34M+ adults in the U.S. smoke cigarettes¹ ~70% of smokers say they want to quit²

ADHD

22M+ people in the U.S. live with ADHD³ >90% of pediatric ADHD persist into adulthood⁴

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 EDS⁶ 0 FDA-approved treatments

Schizophrenia

~3.7M people in the U.S. have schizophrenia and related psychotic disorders⁷

NEUROLOGY

Narcolepsy

185K people in the U.S. are affected by narcolepsy⁸ ~70% of patients suffer from cataplexy⁹

Fibromyalgia

17M+ people in the U.S. have fibromyalgia¹⁰ >50% of patients discontinue treatment in the first year¹¹

Shift work disorder

15M+ working Americans may be impacted¹²⁻¹⁴ 0 new medications approved since 2007

Epilepsy

~3.4M people in the U.S. live with epilepsy¹⁵ >1/3 of patients don't respond to treatment¹⁶

Tourette syndrome

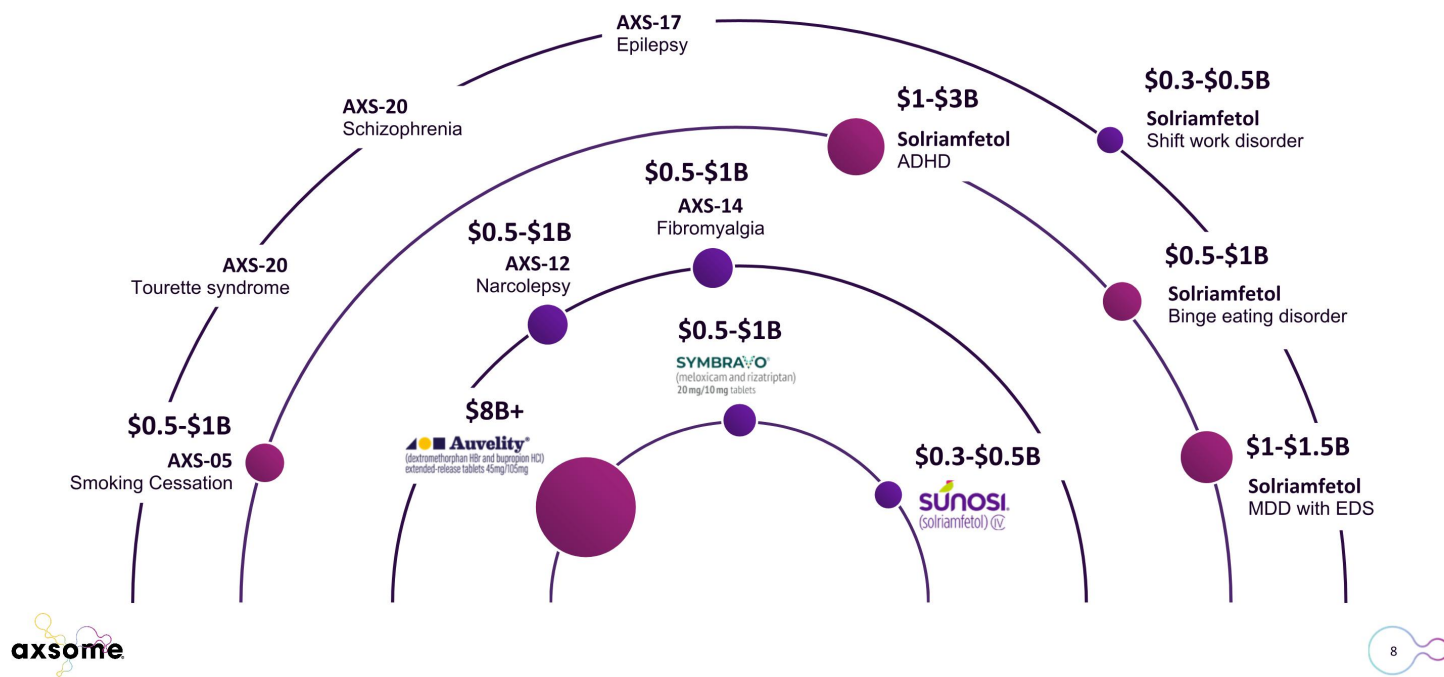
~0.6% of children in the U.S. may suffer from Tourette syndrome¹⁷



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; 17. Tourette Syndrome. CDC 2025
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Singular CNS portfolio with >\$18B in annual peak sales potential



Financial Highlights

2Q 2026 financial summary

\$ millions	2Q 2026	2Q 2025	% Change
Net Product Revenue	\$218.4	\$150.0	46%
AUVELITY	\$180.3	\$119.6	51%
SUNOSI*	\$35.8	\$30.0	20%
SYMBRAVO	\$2.3	\$0.4	461%
R&D Expense	\$46.2	\$49.5	-7%
SG&A Expense	\$208.1	\$130.3	60%



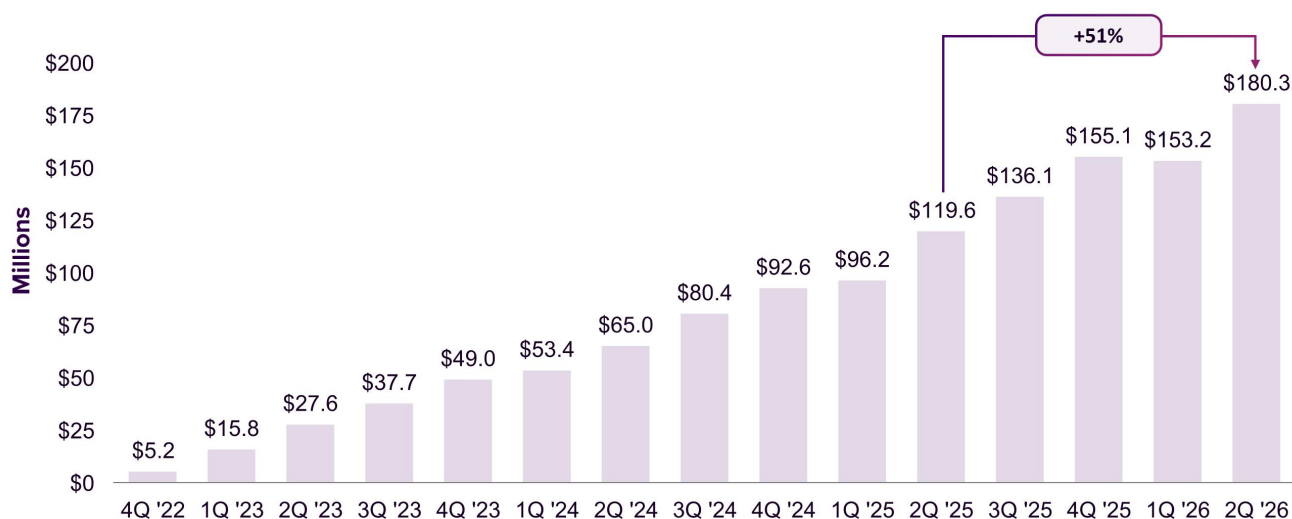
2Q = three months ended June 30; *Includes royalty revenue associated with sales in out-licensed territories and milestone revenue

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AUVELITY® quarterly net revenue performance

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

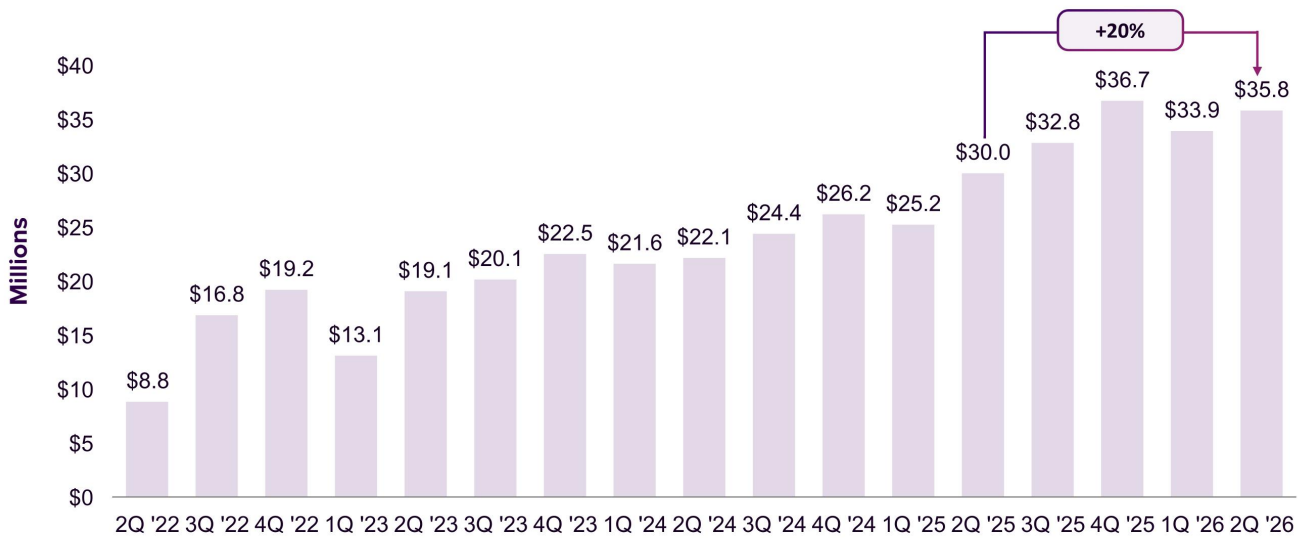


AUVELITY 2Q 2026 net produce revenue of \$180.3M (51% YoY growth)



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SUNOSI® quarterly net revenue performance



SUNOSI 2Q 2026 net produce revenue of \$35.8M (20% YoY growth)

Financial snapshot



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

Cash Balance: (as of June 30, 2026)	\$319.9M
Debt (Face Value): (as of June 30, 2026)	\$190M
Market Cap: (as of August 7, 2026)	\$11.0B
Shares Outstanding: (as of June 30, 2026)	52.3M
Options, RSUs, and Others Outstanding*:	8.1M



*Includes 5.9M options, 2.0M RSUs, and 0.2M others as of June 30, 2026

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Commercial Update

Well-positioned for accelerating commercial growth

HIGHLIGHTS / GROWTH DRIVERS		PEAK SALES POTENTIAL
 (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	• Launched AUVELITY in Alzheimer's disease agitation in June • Expanded sales force of ~630 representatives • Acceleration in new patient starts and new prescriber activation • Strong early NBRx growth trend among 65+ patients just weeks into launch	\$8B+
 (solriamfetol) (V)	• Consistent growth driven by durable demand	\$0.3B-\$0.5B
 (meloxicam and rizatriptan) 20 mg/10 mg tablets	• Strong underlying demand growth • Improvements in market access	\$0.5B-\$1B

~\$9.5B total commercial opportunity across marketed products



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 label¹



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 relapse¹



Distinct safety/tolerability profile with no new boxed warning; most common adverse reactions were dizziness and dyspepsia¹



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

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



ACCELERATING PRESCRIBER GROWTH

~69,000

Unique writers since launch

+21%

QoQ growth in activated new writers



GROWING PATIENT ADOPTION

+26%

QoQ NBRx growth

>350,000

Patients treated since launch

~266,000

TRx in 2Q 2026



STRONG MARKET ACCESS

~89%

Total covered lives

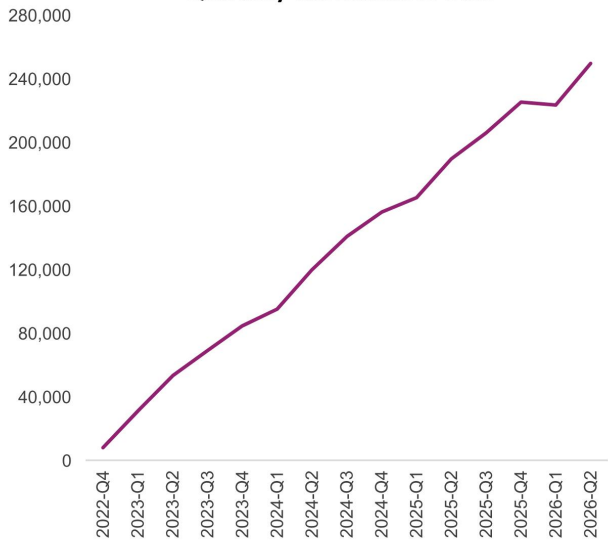
~82%

Commercial covered lives

~100%

Medicare and Medicaid covered lives

Quarterly TRx Launch to Date



Source: Symphony METYS

First and only dopamine and norepinephrine reuptake inhibitor for EDS associated with narcolepsy or OSA¹



First and only wakefulness promoting agent proven to improve wakefulness through 9 hours¹



90% of patients reported feeling better with SUNOSI 150 mg²



Improvements in cognitive functioning vs. placebo demonstrated in clinical trials



EDS = Excessive daytime sleepiness; OSA = Obstructive sleep apnea; DNRI = Dopamine-norepinephrine reuptake inhibitor
1. SUNOSI [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY; 2. Schweitzer PK, et al. 2019

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Durable demand continues to drive growth



EXPANDING PRESCRIBER REACH

>17,000

Unique writers since launch



STEADY PATIENT GROWTH

~109,000

Patients treated since launch

~61,000

TRx in 2Q 2026



BROAD PAYER COVERAGE

~82%

Total covered
lives

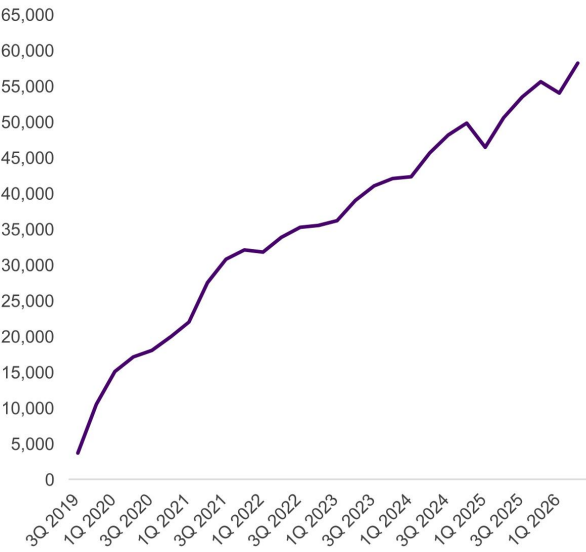
~96%

Commercial
covered lives

~59%

Medicare and Medicaid
covered lives

Quarterly nTRx Launch to Date



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

Novel, oral, rapidly-absorbed, multi-mechanistic approach for the acute treatment of migraine¹



Single, oral dose provided rapid migraine pain freedom and return to normal functioning within 2 hours¹



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

© Axsome Therapeutics, Inc.

Prescription growth driven by increasing demand

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



PRESCRIBER GROWTH

~4,700

Unique writers since launch



PATIENT GROWTH

~19,500

Patients treated since launch

~23,500

TRx in 2Q 2026



ESTABLISHED MARKET ACCESS

~57%

Total covered
lives

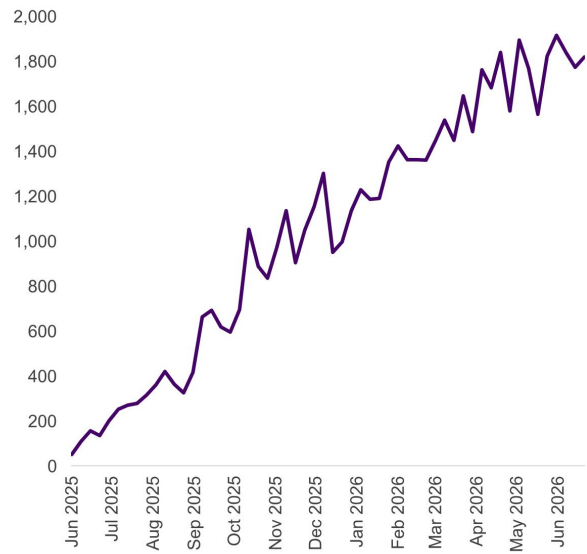
~56%

Commercial
covered lives

~57%

Medicare and Medicaid
covered lives

Weekly TRx Launch to Date



Source: Symphony METYS



TRx = Total prescriptions

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Development Pipeline

AXS-05 for smoking cessation

70% of smokers
want to quit²



Only 3-5% who attempt to quit without
assistance are successful for 6-12 months²



~34M adults in the U.S. smoke
cigarettes, ~50% of whom live
with a smoking-related
disease¹



Single largest cause of
preventable disease and death in
the U.S., accounting for nearly 1
in 5 deaths¹



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. 2004

Solriamfetol

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

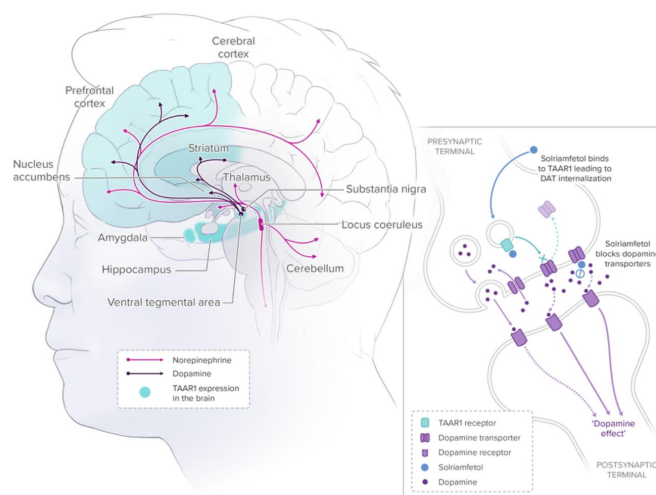
Solriamfetol was initially developed as a **dopamine and norepinephrine reuptake inhibitor (DNRI)** with wake-promoting effects



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



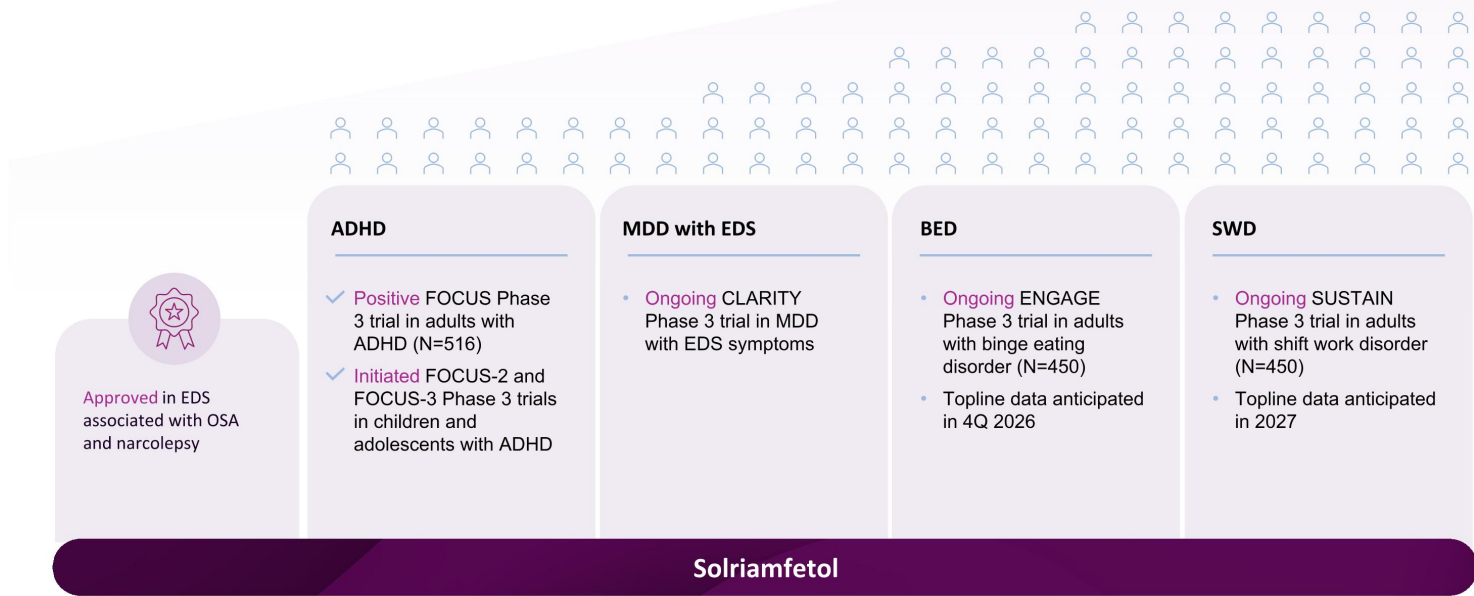
Multimodal activity of solriamfetol selectively inhibits the reuptake of dopamine and norepinephrine and exhibits agonist activity at TAAR1 receptors in the brain



1. Raony I, et al. 2022; 2. Half EF, et al. 2023

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Solriamfetol Phase 3 development programs



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

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Attention deficit hyperactivity disorder (ADHD)



Chronic neurobiological and developmental disorder affecting an estimated ~22M people in the U.S.¹, including ~7M children aged 3-17 years old²



Characterized by a persistent pattern of inattention and/or hyperactive-impulsive behaviors³

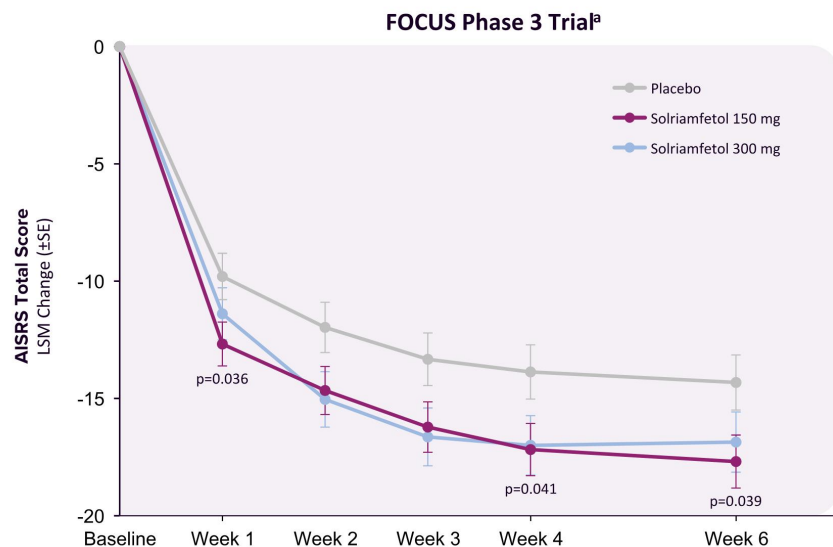


Associated with significant impairment in social, academic, and occupational functioning and development³



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

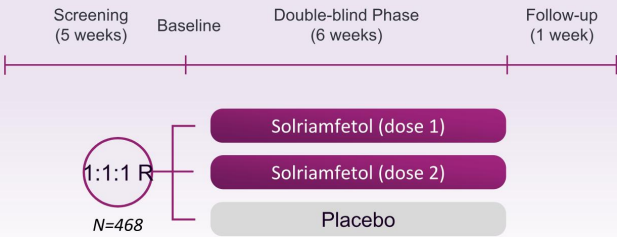


CMAI = Cohen-Mansfield Agitation Inventory; LSM = least-squares mean; SE = standard error; SR = sustained release
a. p-values shown for solriamfetol 150 mg p-values are nominal; b. Clinical response defined as ≥30% reduction in AISRS; c. solriamfetol 150 mg
Axsome Therapeutics, Inc. Data on file.

© Axsome Therapeutics, Inc.

Solriamfetol in ADHD pediatric Phase 3 trial designs

FOCUS-2 Phase 3 Trial



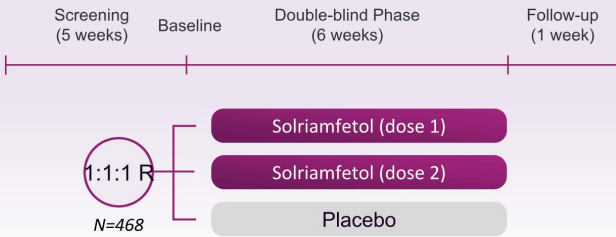
Key eligibility criteria

- 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



ADHD-RS-5 = ADHD Rating Scale

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MDD with excessive daytime sleepiness symptoms



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



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

CLARITY Phase 3 trial design

CLARITY Phase 3 Trial



Key eligibility criteria

- 18-65 years of age with diagnosis of MDD (DSM-5 criteria)
- Excessive daytime sleepiness symptoms

Primary endpoint

- Time from randomization to relapse of depressive symptoms



Binge eating disorder

>7 million people in the U.S. have BED¹



BED is 1.75x more common in women than in men¹



1. Hudson JI, et al. 2007; 2. Swanson SA, et al. 2011; 3. Kessler RM, et al. 2016; 4. McElroy SL, et al. 2020

Evaluating solriamfetol as a potential treatment for binge eating disorder

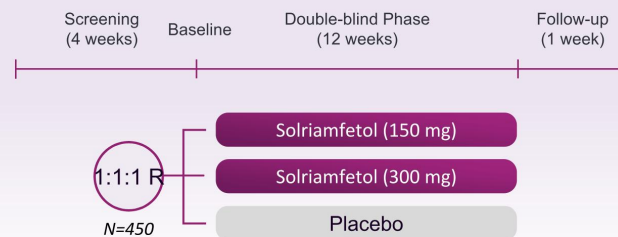


Solriamfetol inhibits the reuptake of dopamine and norepinephrine, neurotransmitters implicated in the pathophysiology of binge eating disorder¹⁻³



Pre-clinical and clinical data support potential effects of solriamfetol on appetite, food consumption, and weight^{4,5}

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



TAAAR1 = Trace amine-associated receptor 1

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.

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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 shift²



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. workday¹



Shift work has long been associated with multiple serious health complaints and a 23% greater risk of sustaining a work-related injury⁴⁻⁵



No new medications approved since 2007 and considerable residual sleepiness reported when medication is used⁶

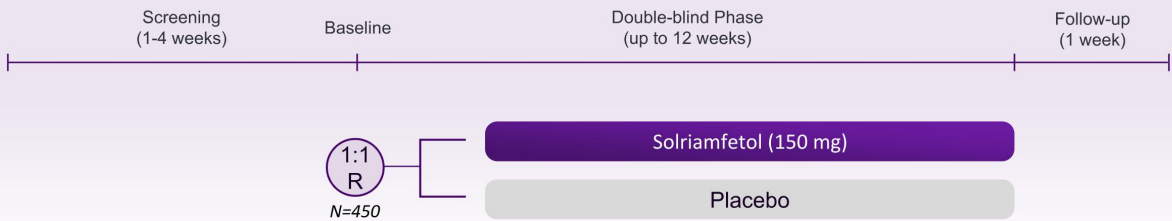


1. Sateia MJ. 2014; 2. Alterman T, et al. 2013; 3. Wickwire EM. 2017; 4. Smith L, et al. 1994; 5. Akerstedt T, Wright KP. 2009; 6. Czeisler CA, et al. 2005

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Evaluating solriamfetol as a potential treatment for 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



MWT = Maintenance of Wakefulness Test

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AXS-12 (reboxetine)

Novel pharmacological approach for the treatment of narcolepsy

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

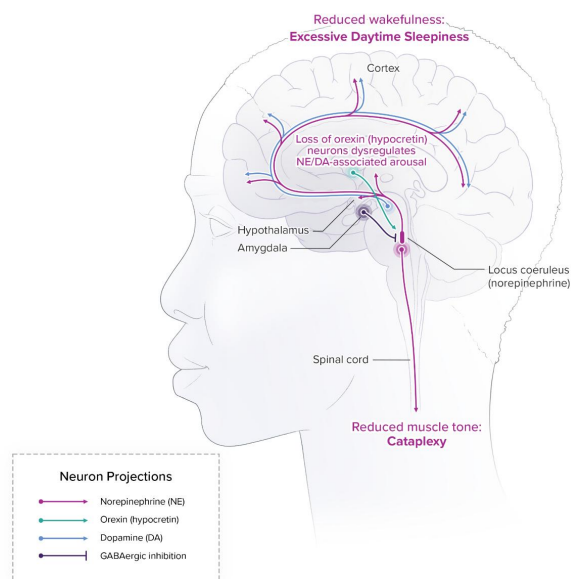


The loss of orexin input inhibits the production of these neurotransmitters^{1,2}

- Decreased norepinephrine signaling is thought to contribute to **cataplexy**, **EDS**, and **cognitive impairment**^{1,4-7}
- Decreased dopamine signaling is thought to contribute to **EDS** and **cognitive impairment**^{1,4}



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



1. Szabo 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

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Narcolepsy



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



Characterized by cataplexy, excessive daytime sleepiness (EDS), hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep²⁻⁴



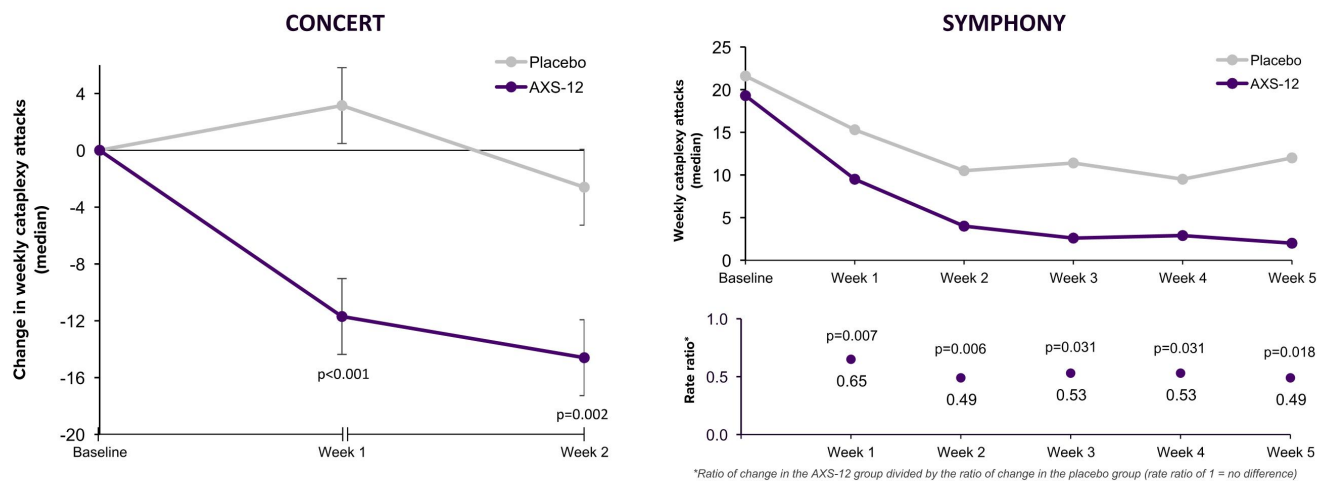
Up to 70% of patients suffer from cataplexy, or the sudden reduction or loss of muscle tone while awake⁵



1. Narcolepsy Network 2024; 2. Sateia MJ. 2014; 3. Narcolepsy. NINDS 2024; 4. España RA, Scammell TE. 2011; 5. Swick TJ. 2015

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Rapid and robust reductions in cataplexy with AXS-12 treatment



NDA for AXS-12 for cataplexy in narcolepsy accepted by the FDA with PDUFA target action date of May 1, 2027



AXS-14 (esreboxetine)

Novel pharmacological approach for the management of fibromyalgia (FM)

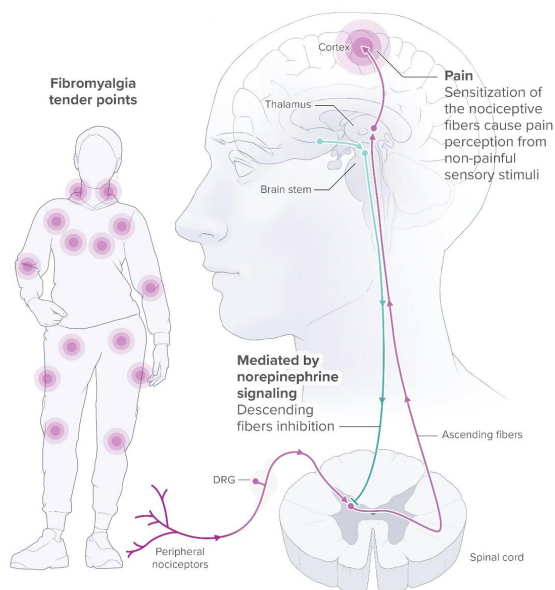
Fibromyalgia pain is thought to be partially caused by **dysregulated signaling** in the descending analgesic system



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



AXS-14 is a 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. 2021

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Fibromyalgia

An estimated ~17 million people in the U.S. are impacted by fibromyalgia¹



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 wellbeing, financial burden, and reduced quality of life^{2,3}

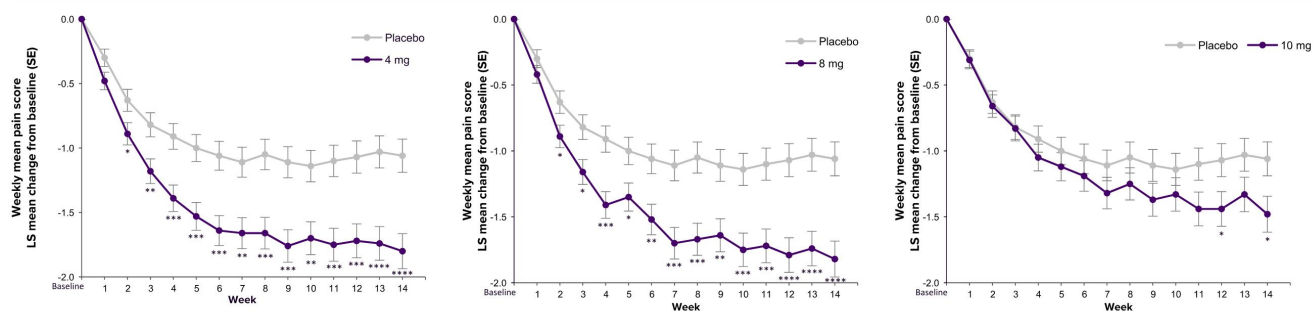


1. Vincent, et al. 2013; 3. Choy E, et al. 2010; 3. Arnold LM, et al. 2008; 4. Bair MJ, Krebs EE. 2020; 5. Clauw DJ. 2024

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

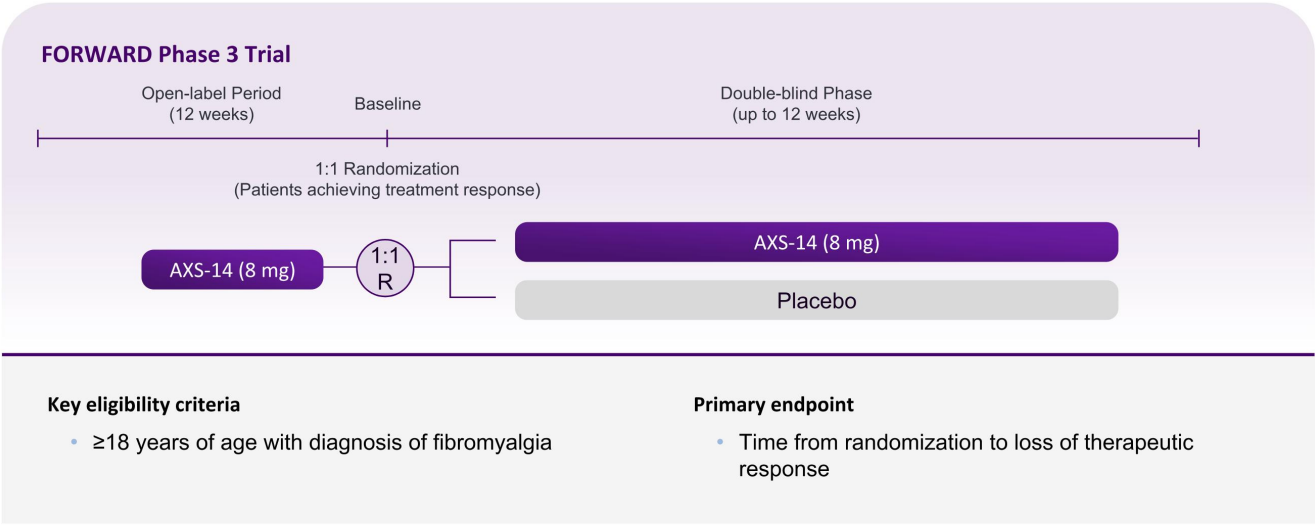
FORWARD Phase 3 trial ongoing



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

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FORWARD Phase 3 trial design



AXS-17

Novel oral GABA_A receptor $\alpha 2,3$ 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



Despite currently available treatment options, <1/3 of patients do not respond to treatment²



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



Phase 2 trial-enabling activities underway



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

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AXS-20

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

Schizophrenia

- Demonstrated a favorable safety and tolerability profile in clinical studies in >360 individuals to date
- Completed a proof-of-concept Phase 2 trial in patients with schizophrenia
- Phase 3 trial-enabling activities for AXS-20 in schizophrenia underway

~3.7M people in the U.S. have schizophrenia and related psychotic disorders¹

Tourette syndrome

- Evaluating AXS-20 as a potential treatment for Tourette syndrome

1 out of every 162 children in the U.S. may suffer from Tourette syndrome²



1. Ringeisen H, et al. 2023; 2. Tourette Syndrome. CDC 2025

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Strong intellectual property portfolio

Product	Highlights
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 6 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

Nick Pizzie, CPA, MBA
Chief Financial Officer

Mark Jacobson, MA
Chief Operating Officer

Hunter Murdock, JD
General Counsel

Ari Maizel
Chief Commercial Officer

Goldman Sachs **BANK OF AMERICA**

Pierre Fabre **IMMUCOR**
MERCK **Pfizer**

Stemline

AUROBINDO **SUN PHARMA**
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Herriot Tabuteau, MD
Chairman



Thank you

