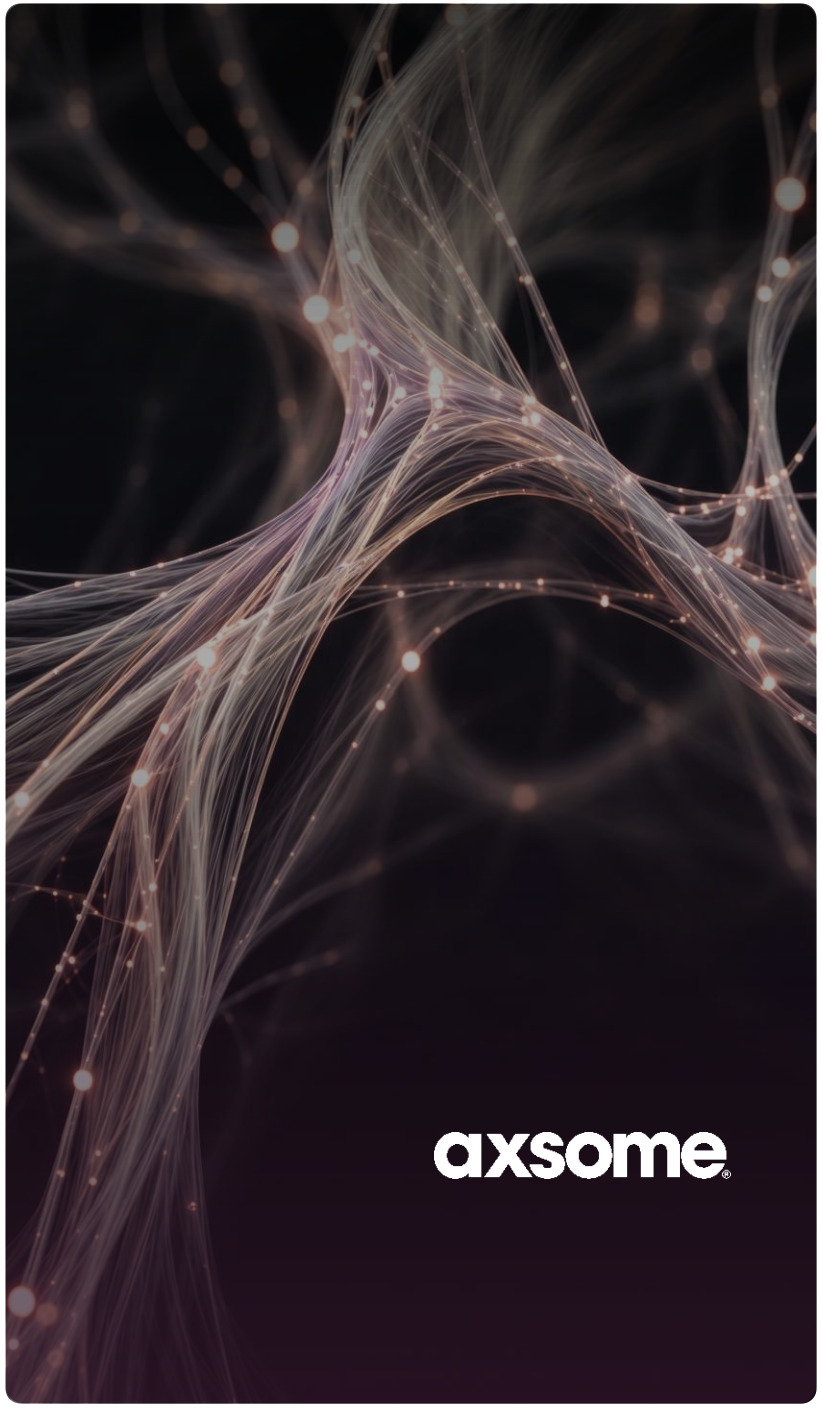


Advancing the frontiers of brain health



axsome®

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

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) (IV)

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)

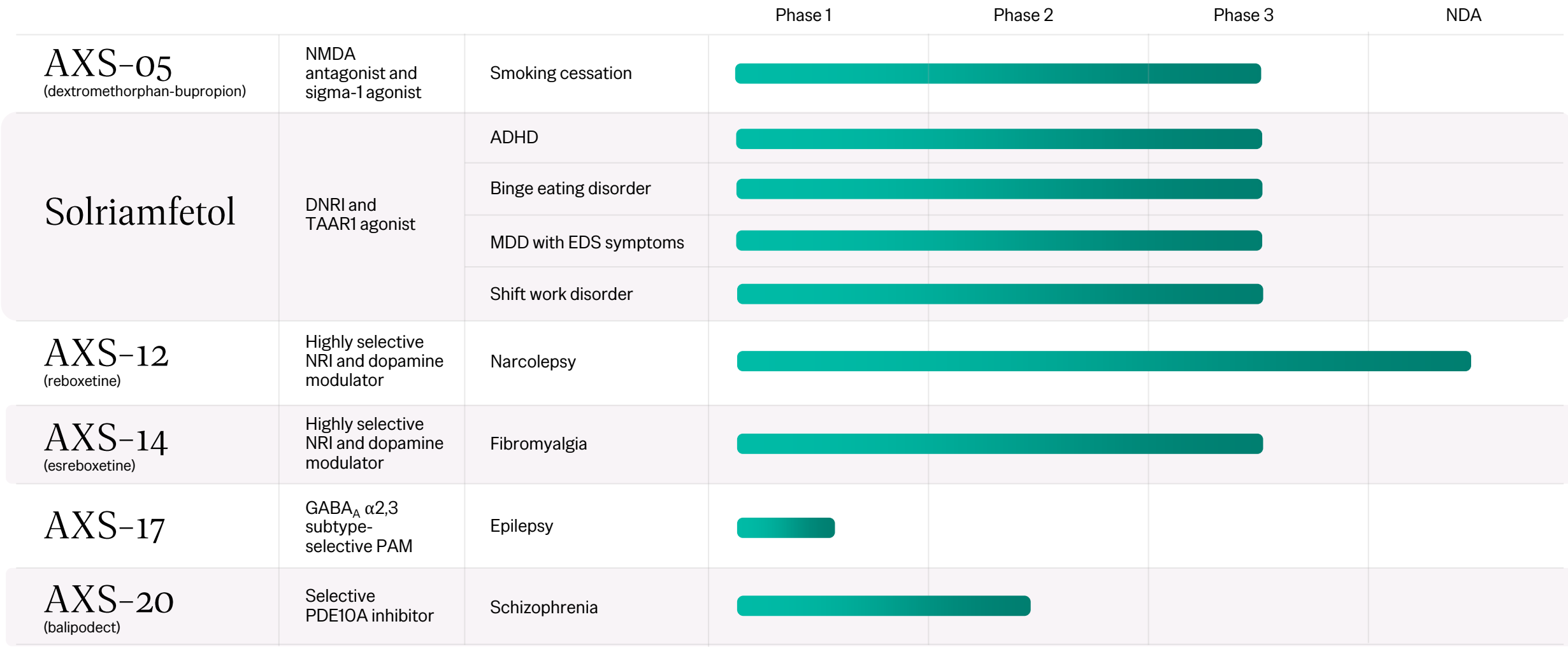
SUSTAIN Phase 3 topline results (2H 2027)

AXS-20 Phase 3 initiation (1H 2027)

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

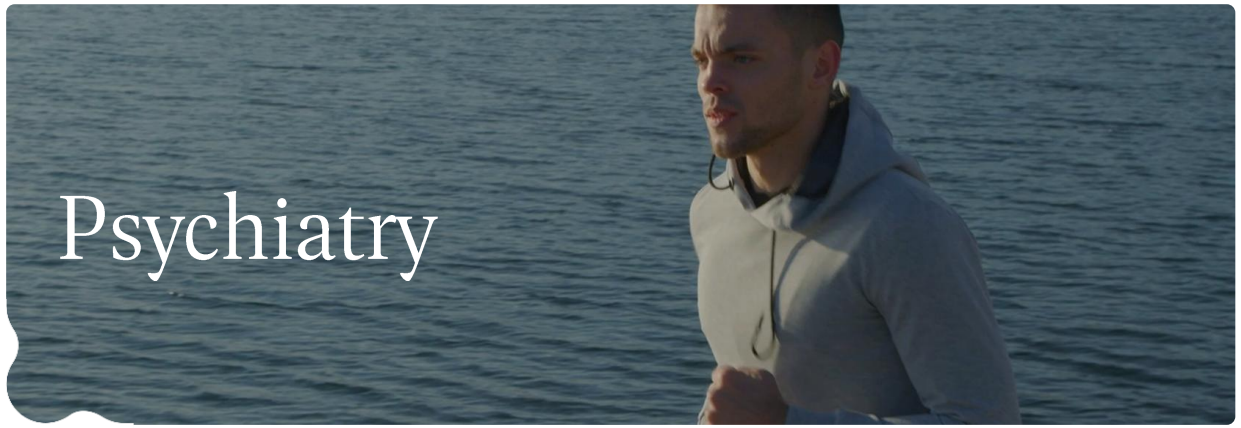
*AXS-12: cataplexy in narcolepsy, ENGAGE: solriamfetol in binge eating disorder, FOCUS-2/3: solriamfetol in children and adolescents with ADHD, SUMMIT: AXS-05 in smoking cessation, SUSTAIN: solriamfetol in shift work disorder, AXS-20: schizophrenia, AXS-17: epilepsy

Industry-leading neuroscience pipeline with deep stratification



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]		

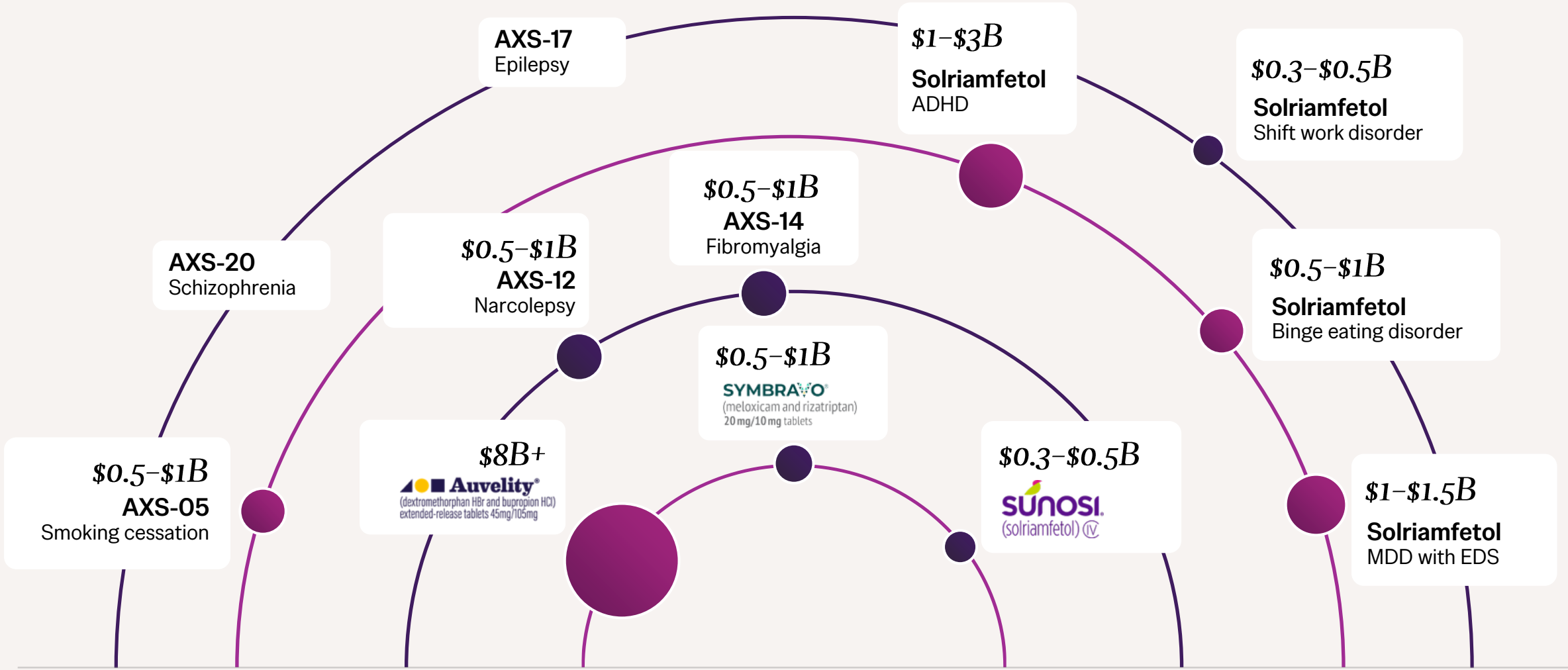
Narcolepsy	185K	people in the U.S. are affected by narcolepsy[8]	~70%	of patients suffer from cataplexy[9]
Fibromyalgia	17M+	people in the U.S. have fibromyalgia[10]	>50%	of patients discontinue treatment in the first year[11]
Shift work disorder	15M+	working Americans may be impacted[12-14]	0	new medications 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]



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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;

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



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Financial highlights

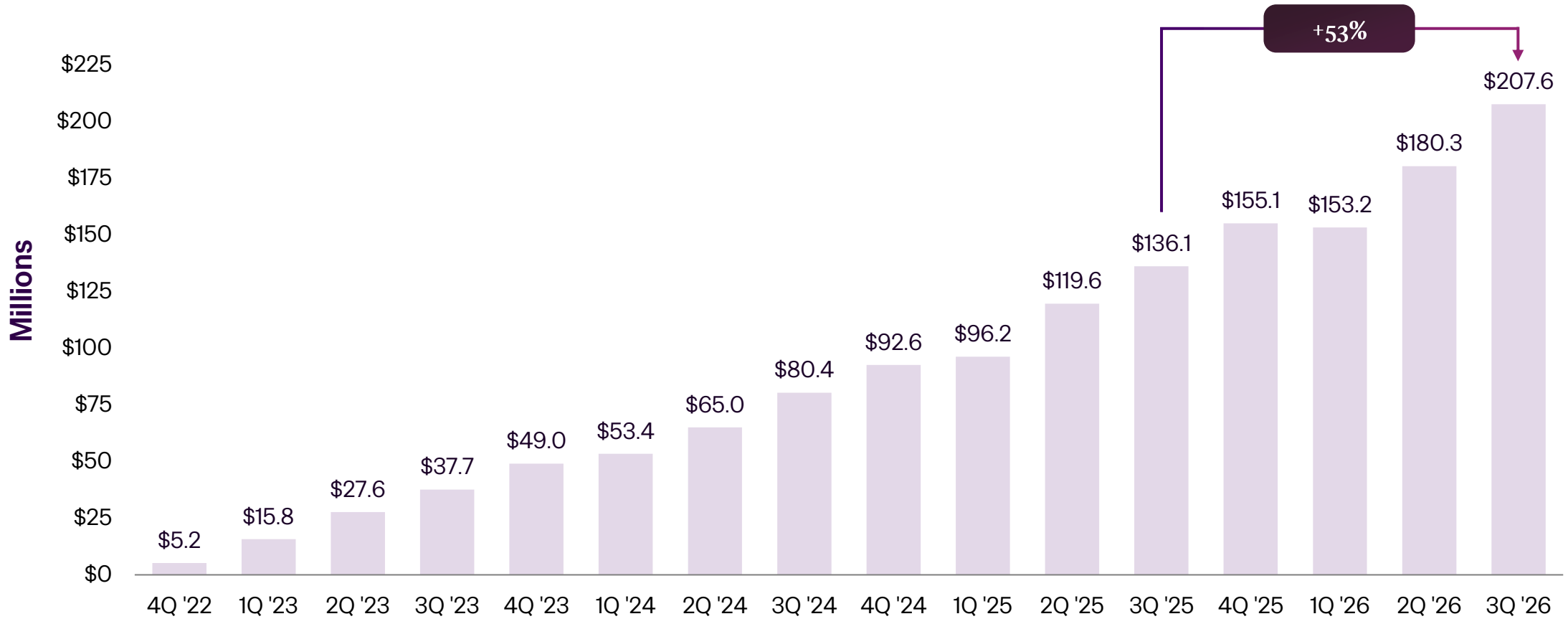
3Q 2026 financial performance

$ 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

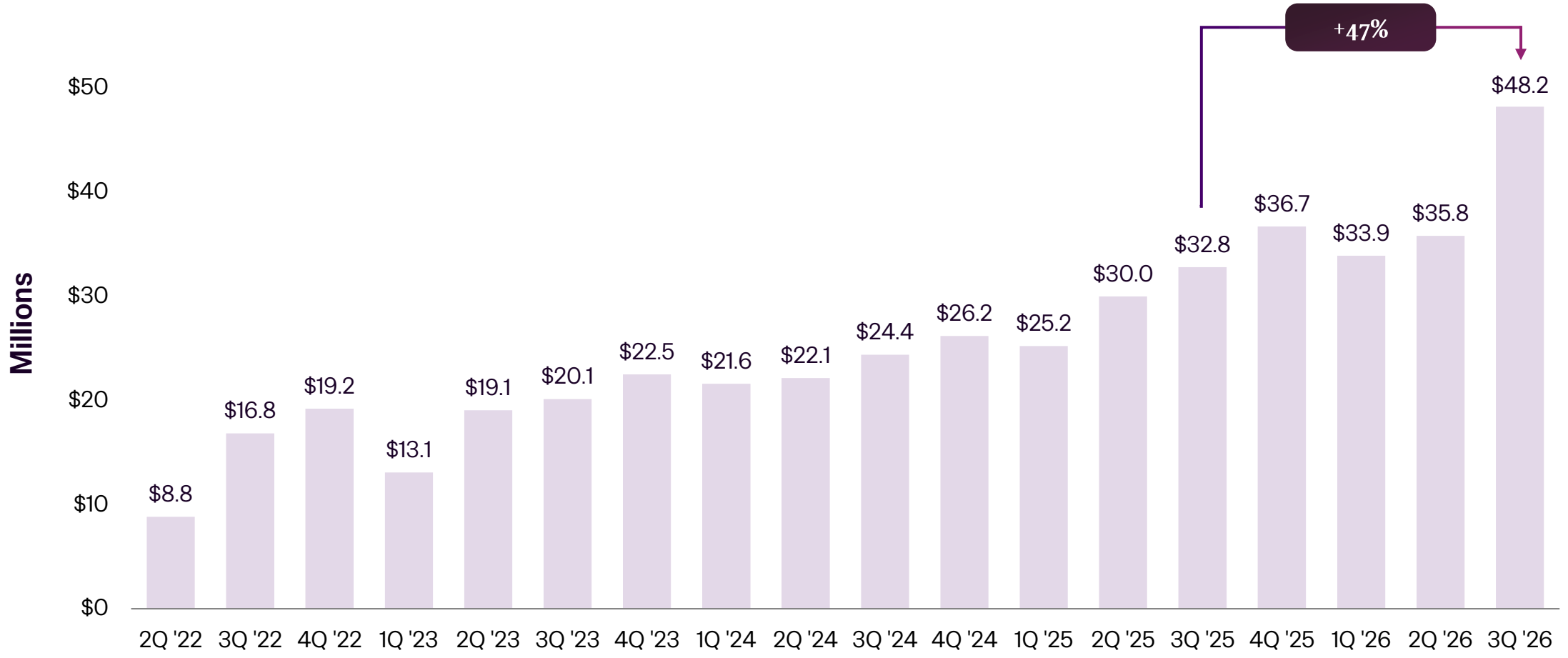
AUVELITY® quarterly net revenue performance

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)

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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

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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]



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

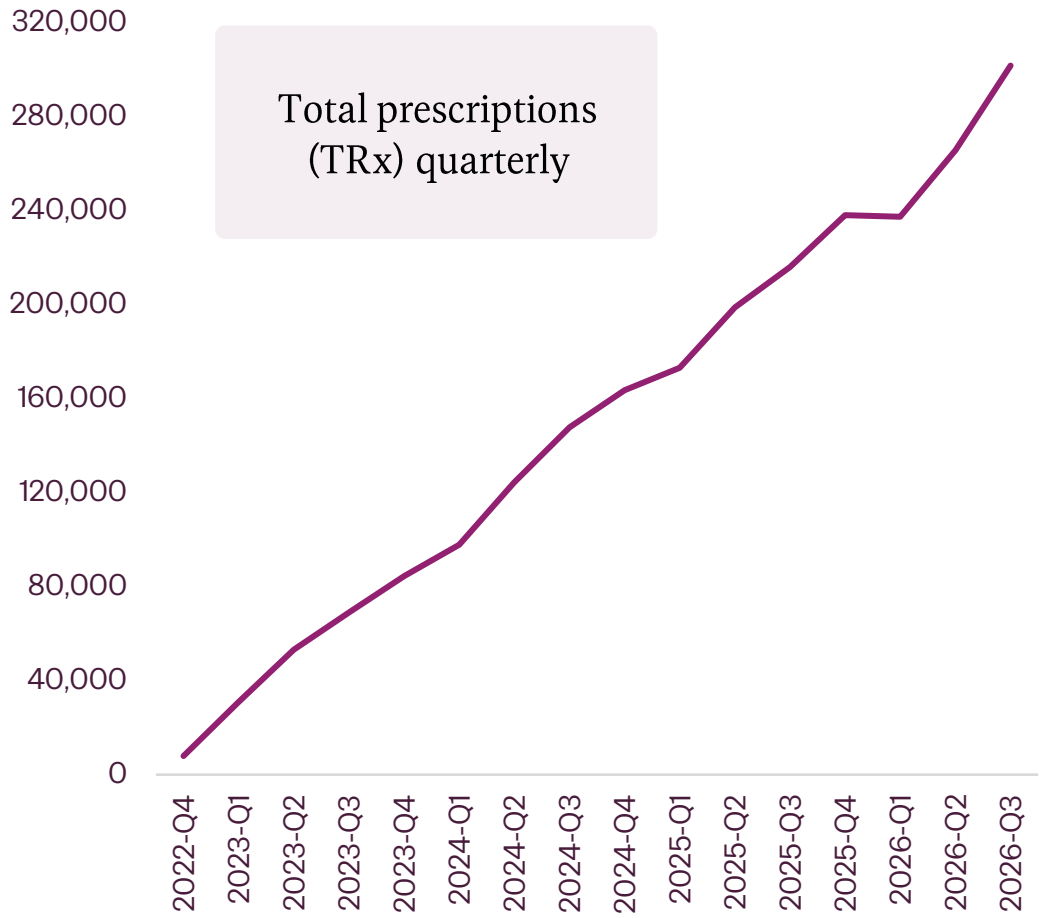
~302,000
TRx in 3Q 2026

STRONG MARKET ACCESS

~89%
Total covered lives

~82%
Commercial covered lives

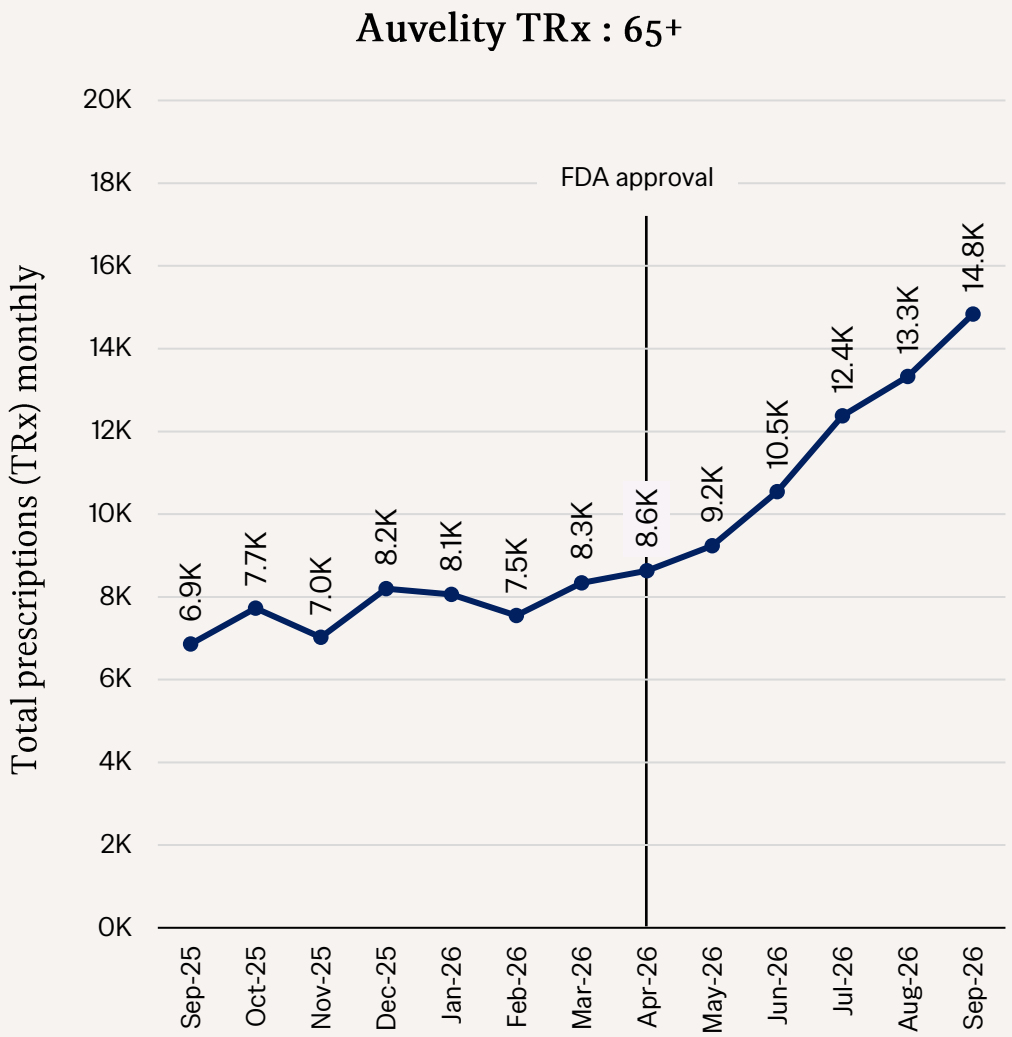
~100%
Medicare and Medicaid covered lives

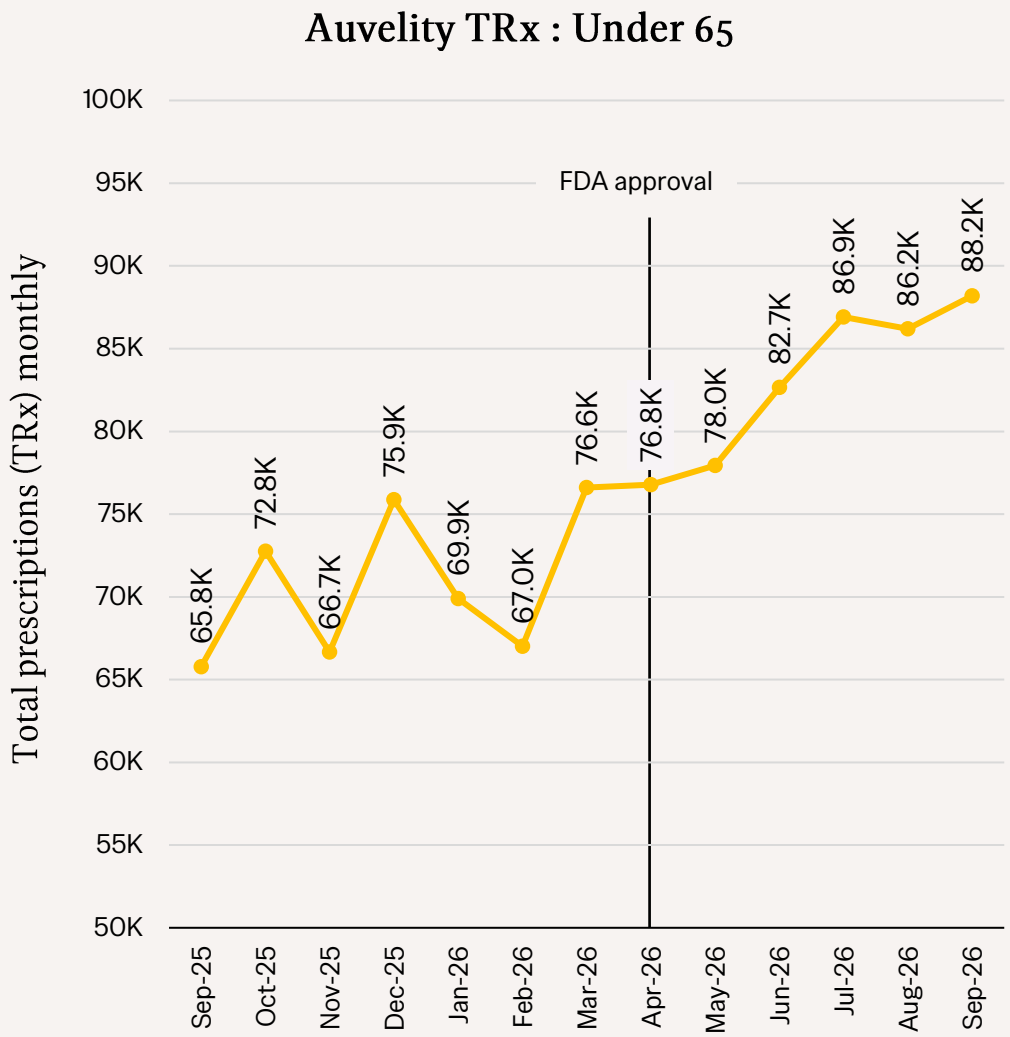


Source: Symphony METYS

LTD = launch to date

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

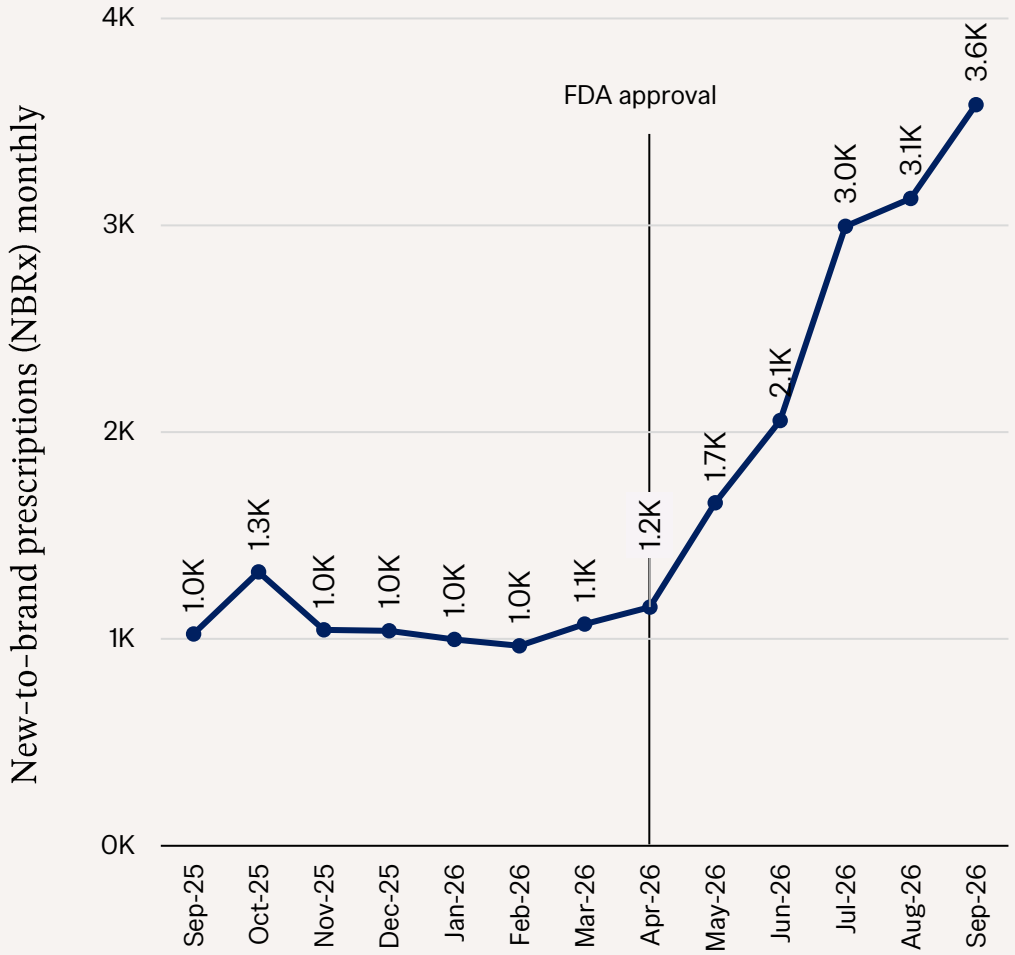




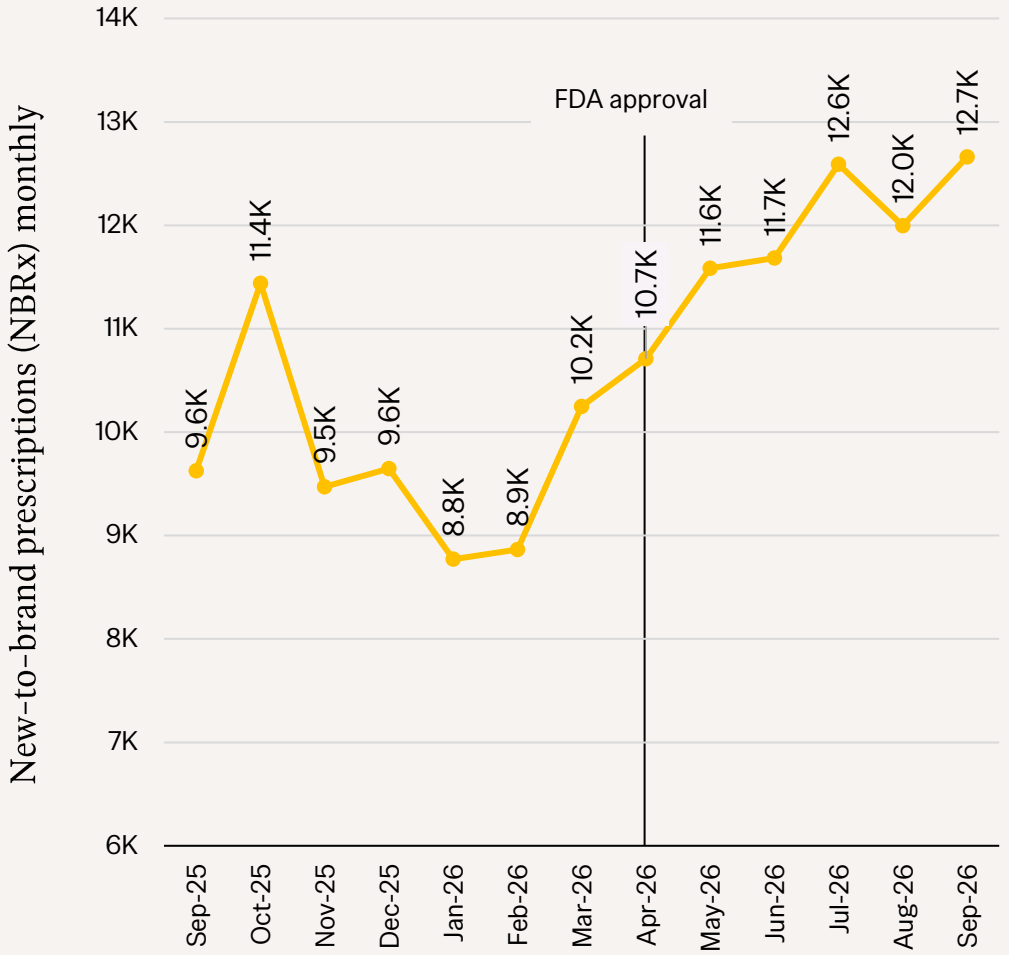
AUVELITY was approved by the FDA for the treatment of agitation associated with dementia due to Alzheimer's disease on April 30, 2026

Continued NBRx acceleration to drive compounding TRx growth

Auvelity NBRx : 65+



Auvelity NBRx : Under 65



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

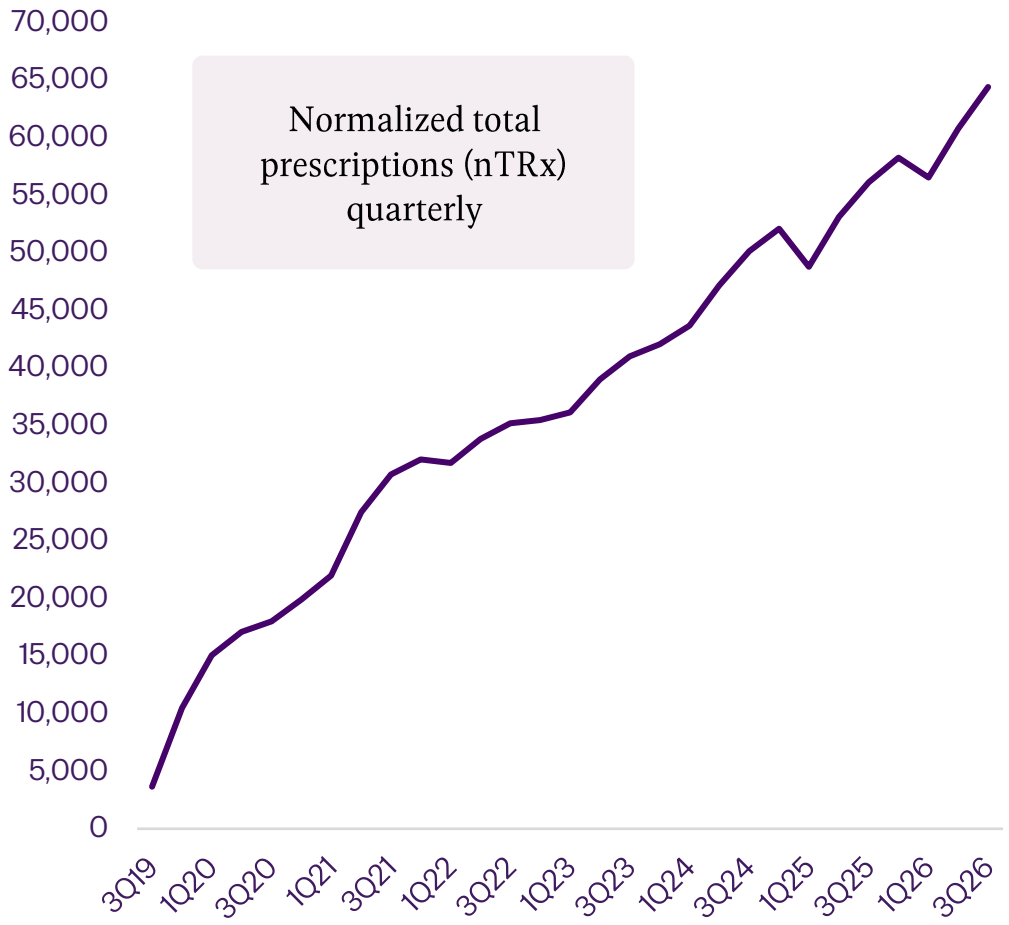
~64,400
TRx in 3Q 2026

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

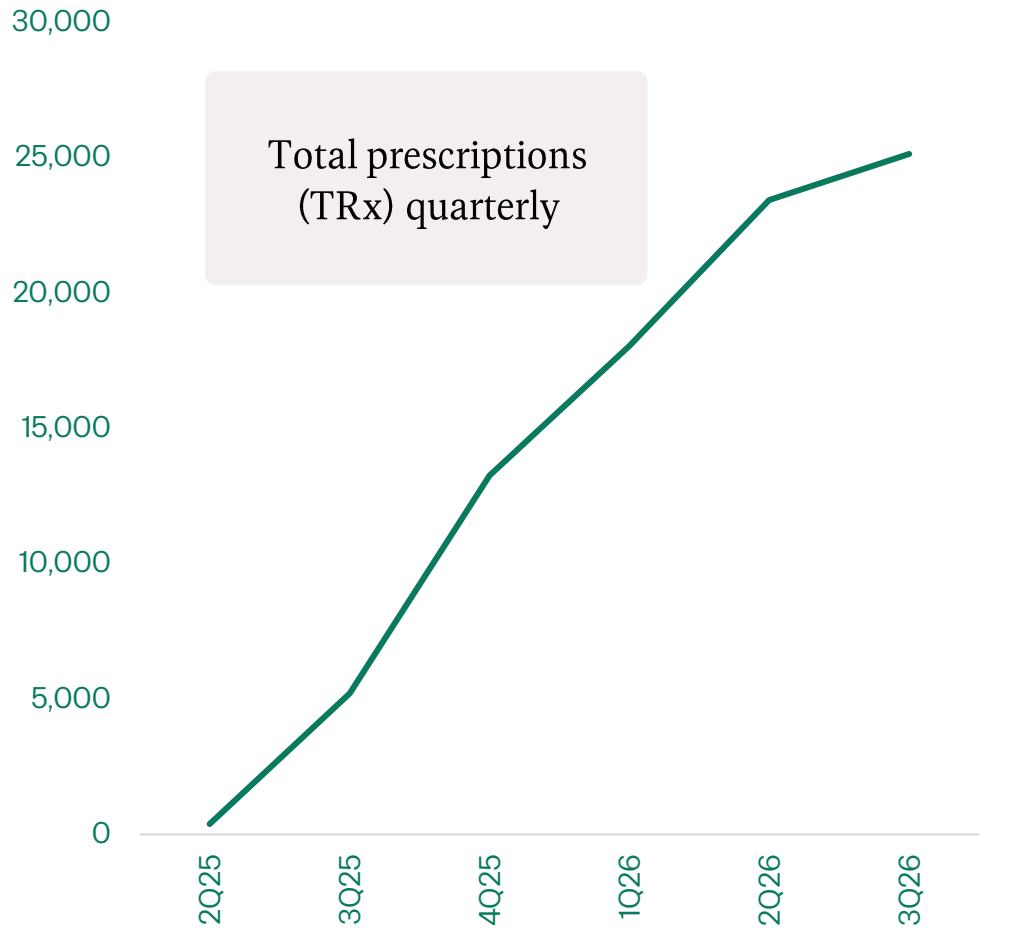
>25,000
TRx in 3Q 2026

MARKET ACCESS

~57%
Total covered lives

~56%
Commercial covered lives

~57%
Medicare and Medicaid covered lives



Source: Symphony METYS

LTD = launch to date

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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]

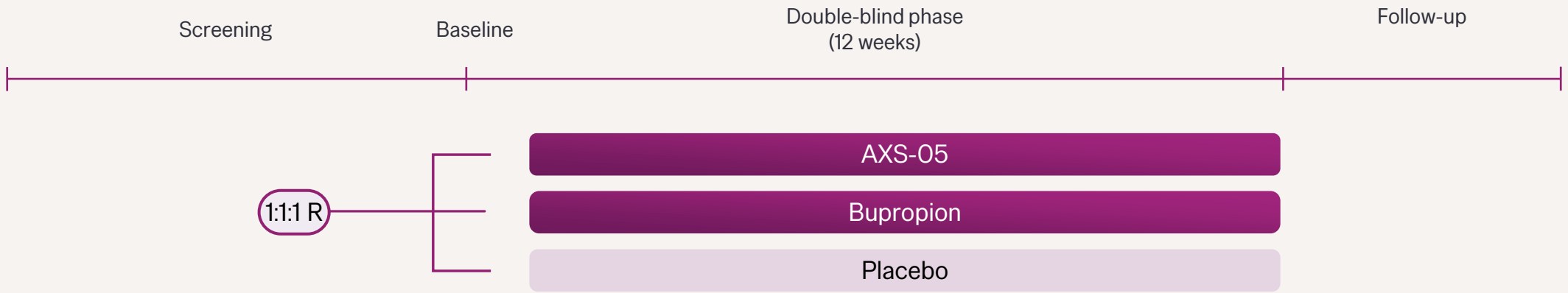


Associated with over $300 billion in annual costs in the U.S.[1]

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

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

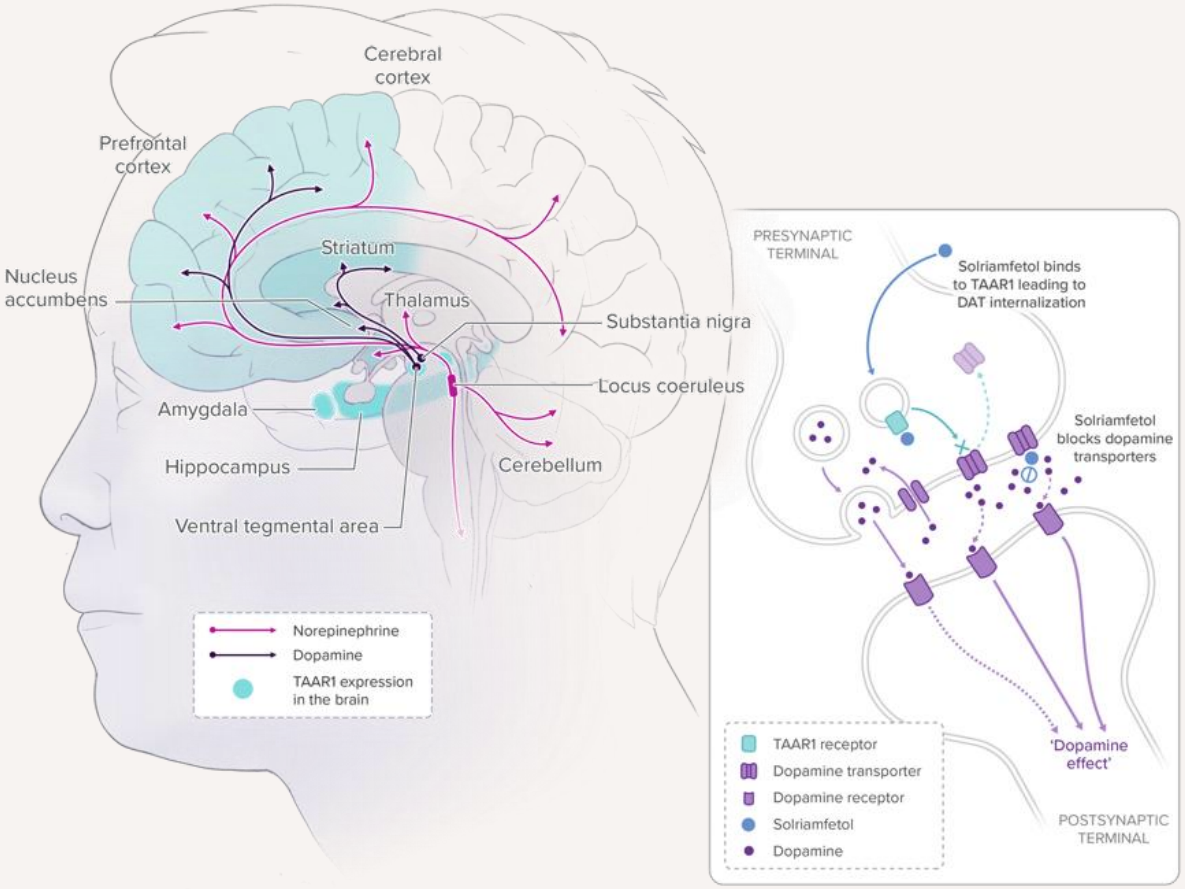
Topline results anticipated 2H 2027

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

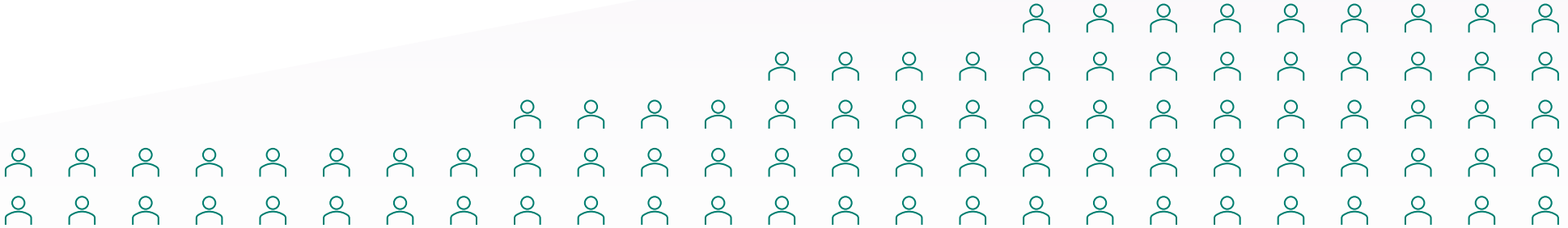
Preclinical and clinical evidence[1,2] suggests TAAR1 plays a role in neuropsychiatric conditions related to the dysregulation of monoaminergic transmission

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)



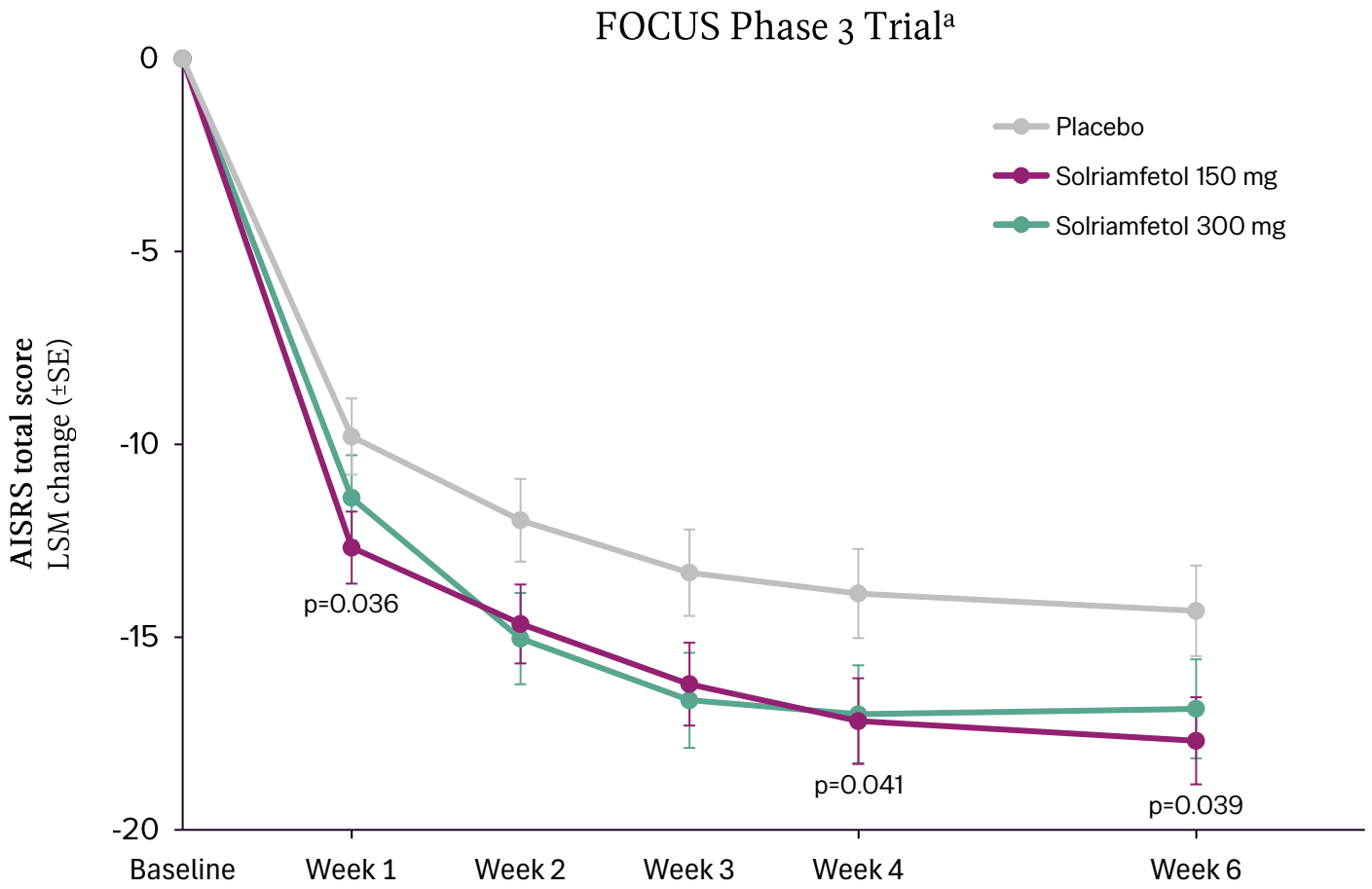
Characterized by a persistent pattern of inattention and/or hyperactive-impulsive behaviors[3]

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]

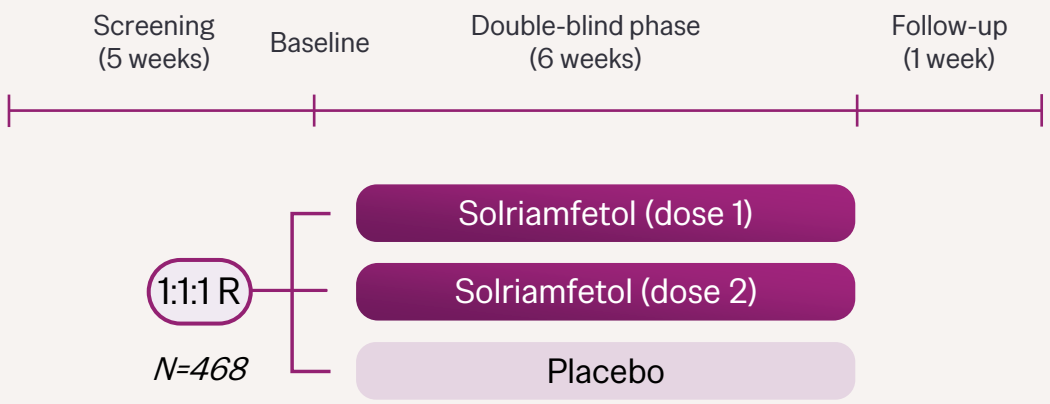
Significant improvements in overall ADHD severity vs. placebo (CGI-S, p=0.017)[c]

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



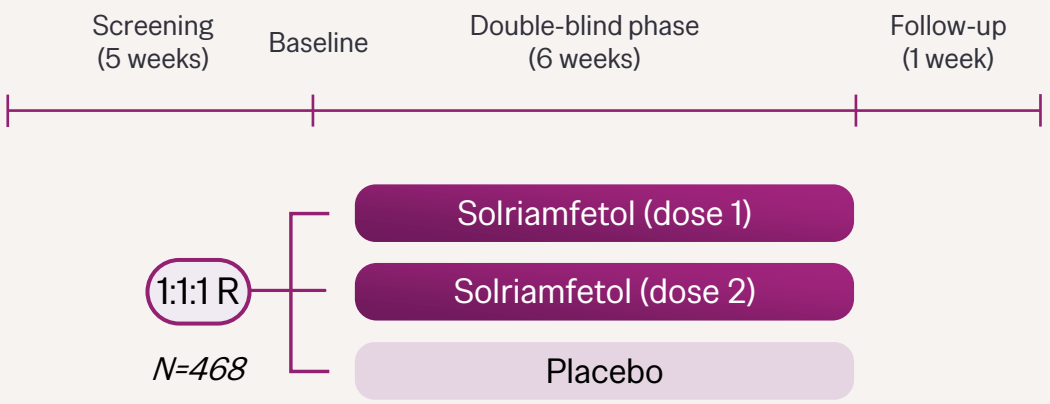
Key eligibility criteria

- 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

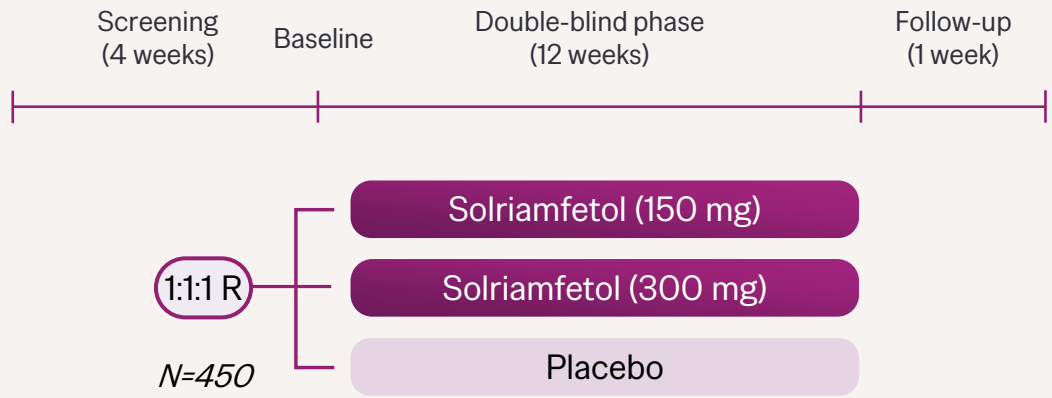
Solriamfetol for the treatment of binge eating disorder

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

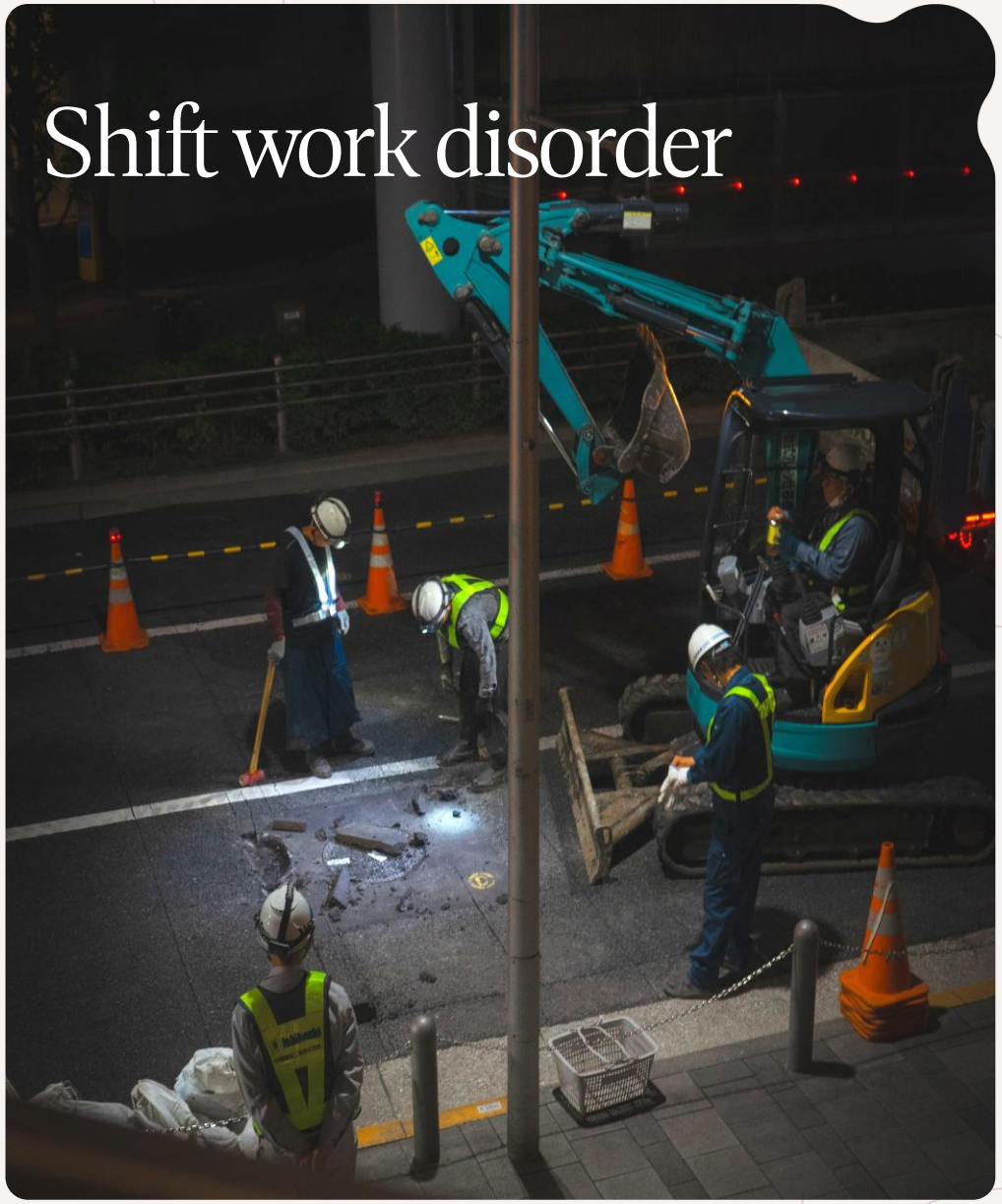
- 18–55 years of age with diagnosis of BED (DSM-5)

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]

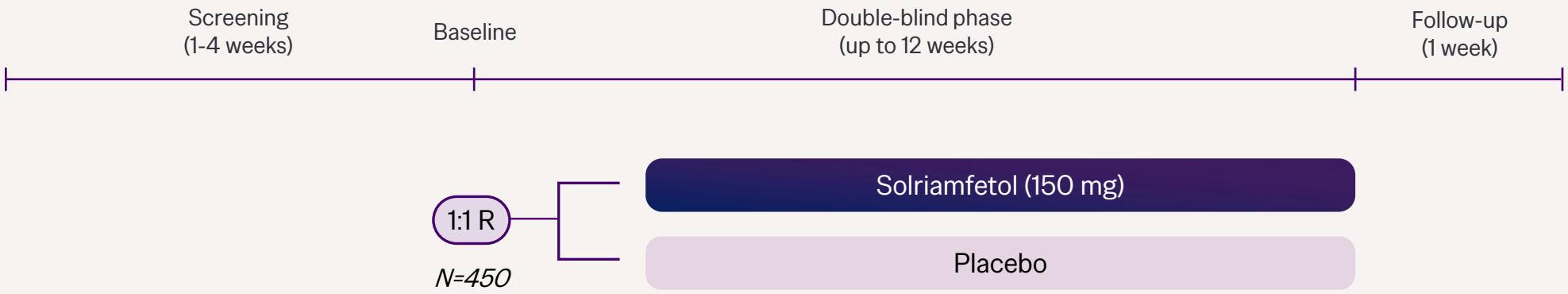
Shift work disorder (SWD) is a combination of excessive sleepiness during wakefulness and persistent insomnia during daytime sleep when working outside a 7 a.m. to 6 p.m. workday[1]

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]

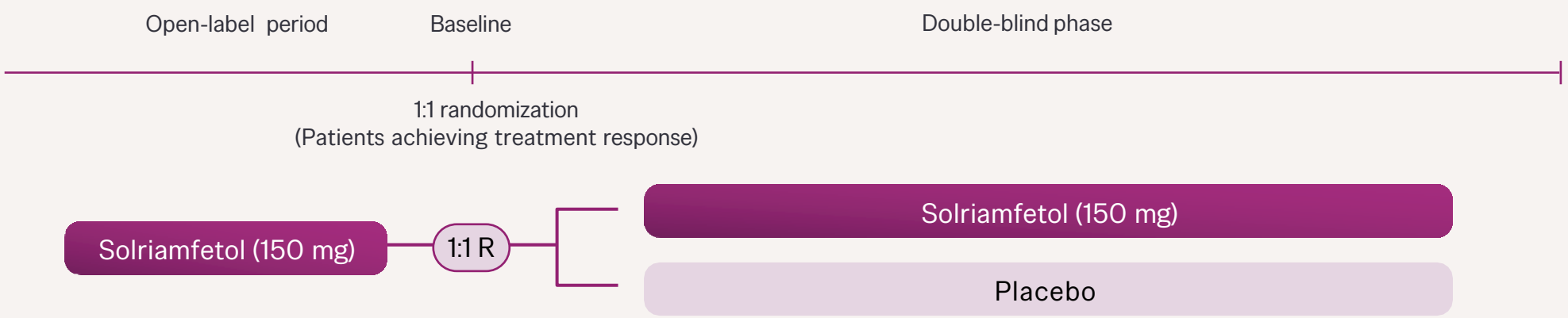
MDD patients with EDS have difficulty maintaining wakefulness, resulting in impaired daily functioning and increased safety risks

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)

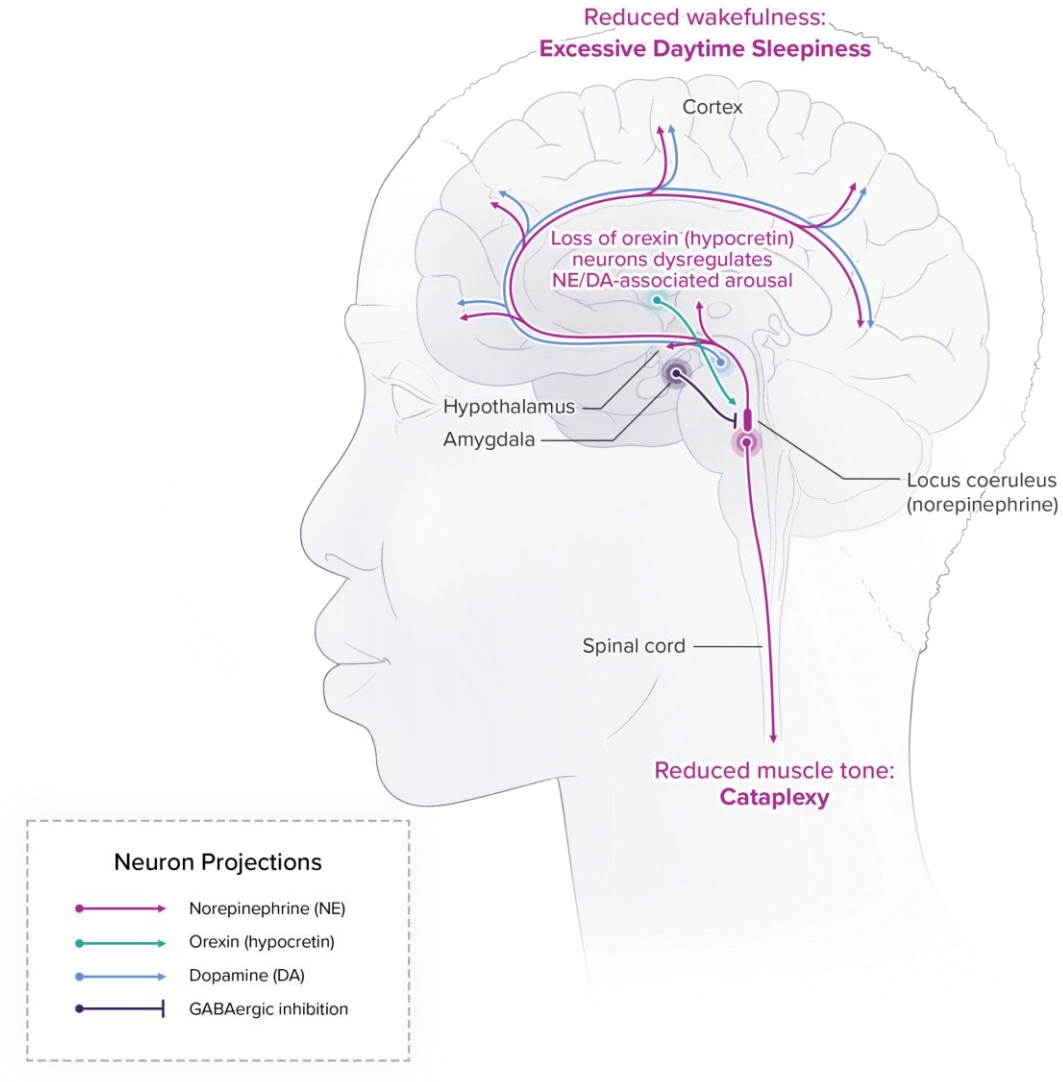
Novel pharmacological approach for the treatment of narcolepsy

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

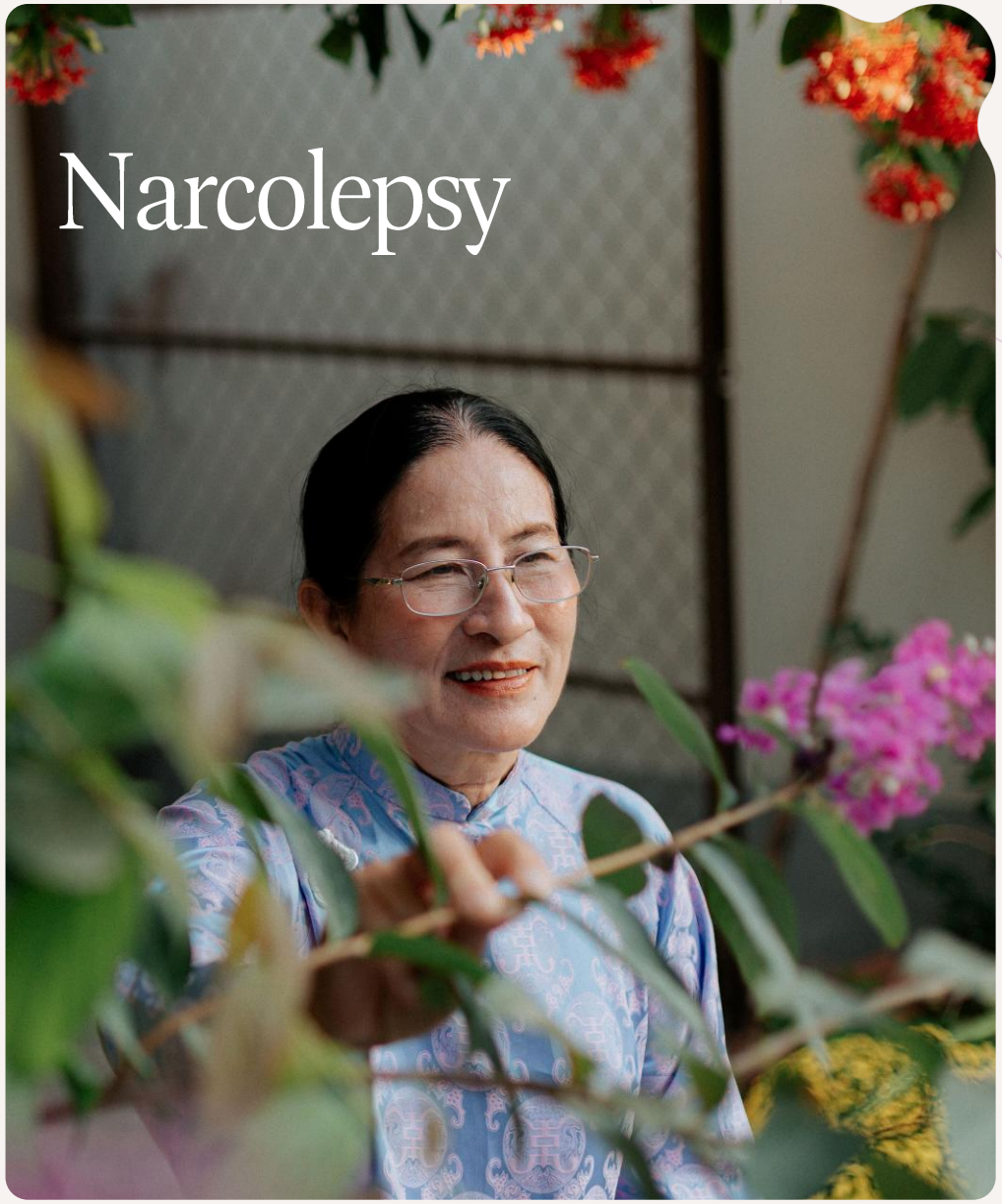
The loss of orexin input inhibits the production of these neurotransmitters[1,2]

- 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



Narcolepsy

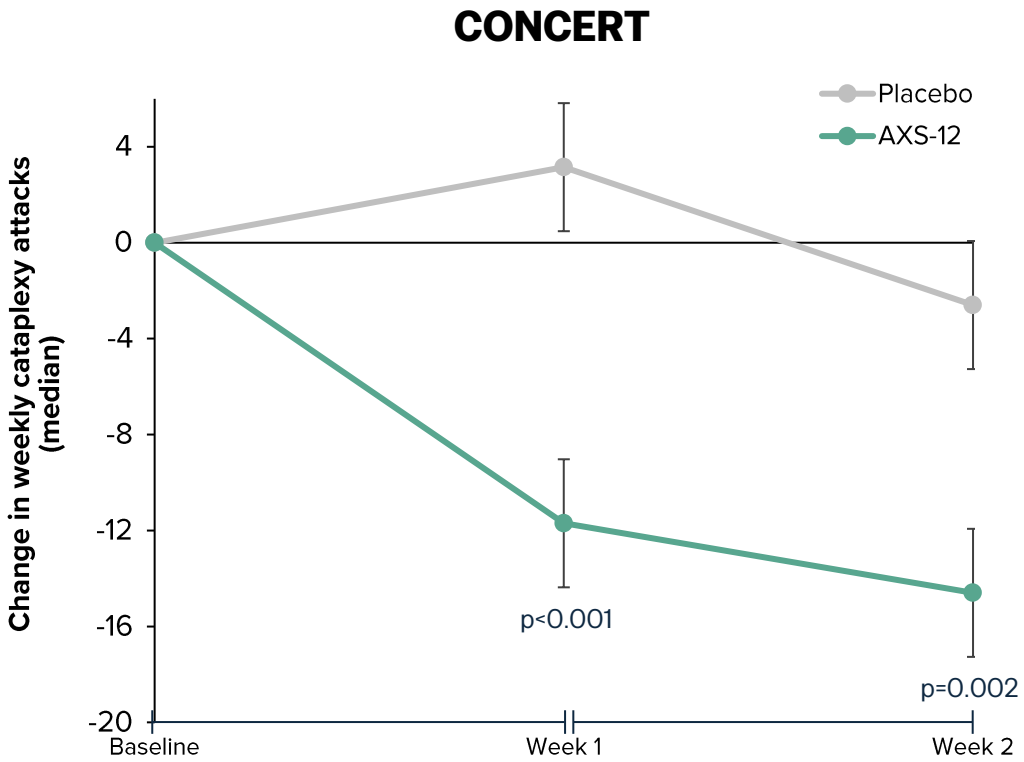
Rare and debilitating neurological condition that affects approximately 185,000 people in the U.S.[1]

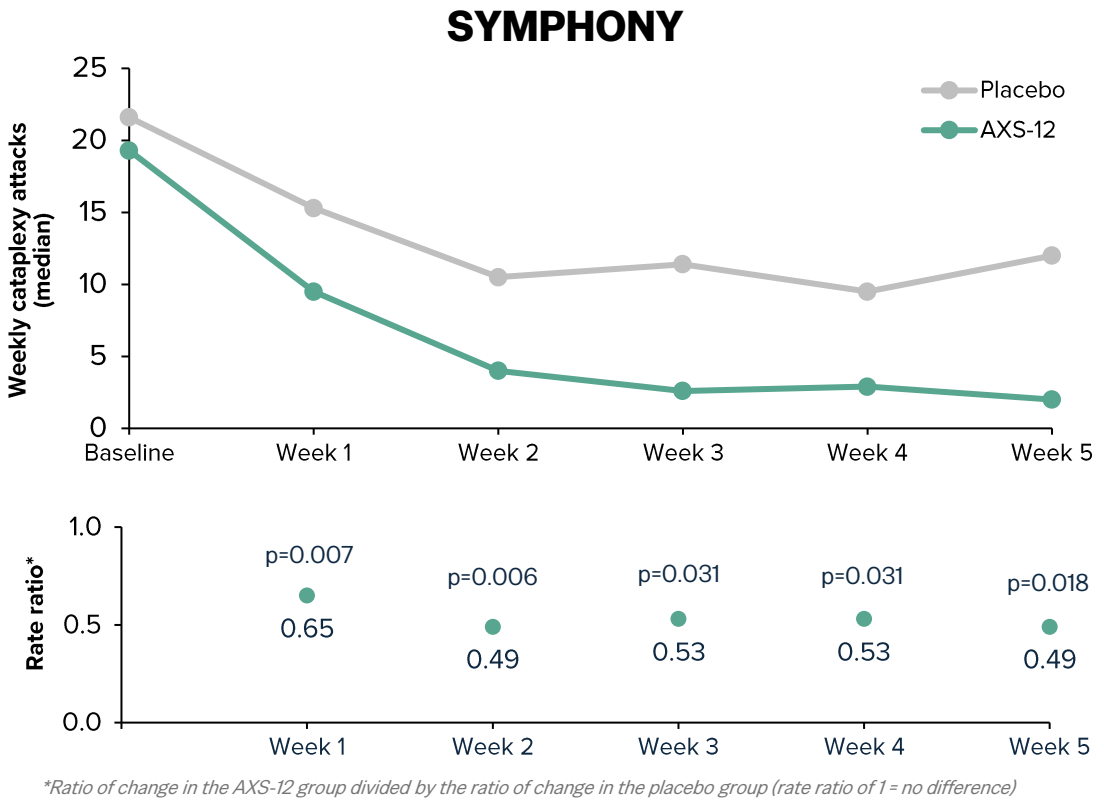
Characterized by cataplexy, excessive daytime sleepiness (EDS), hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep[2-4]

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

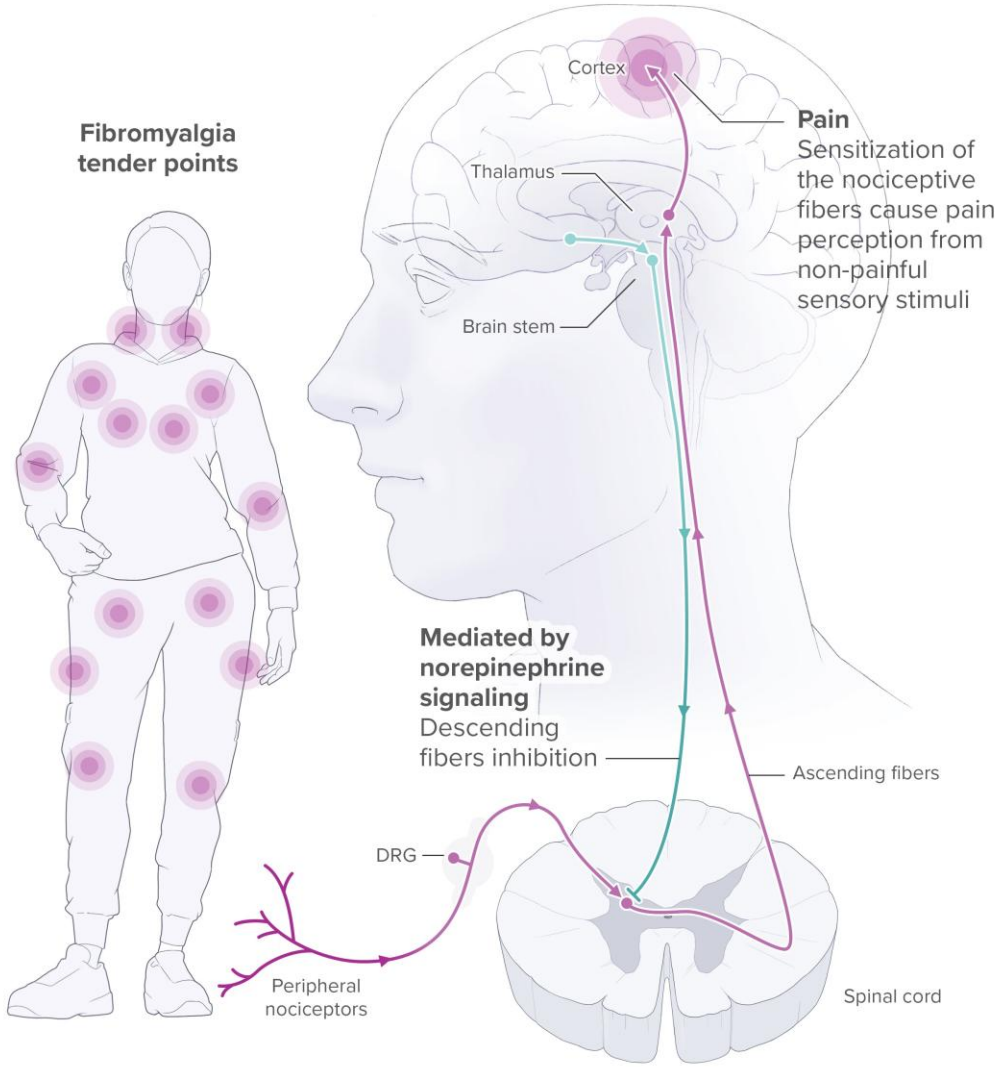
AXS-14 (esreboxetine)

Novel pharmacological approach for the management of fibromyalgia

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

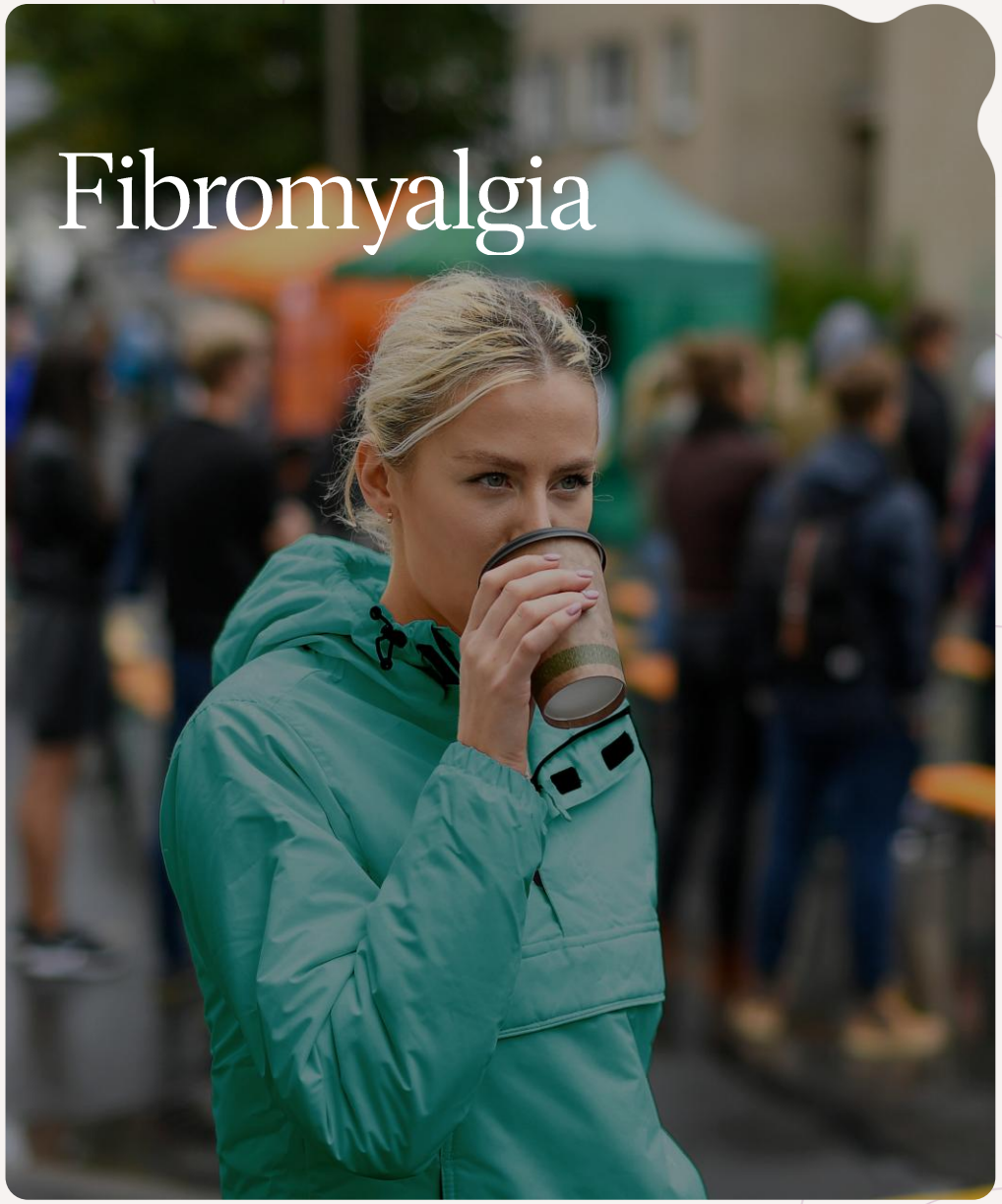
Norepinephrine, one of the key neurotransmitters in this pathway, has predominantly pain-inhibitory effects

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



Adapted from Siracusa, R. et al. 2021

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]

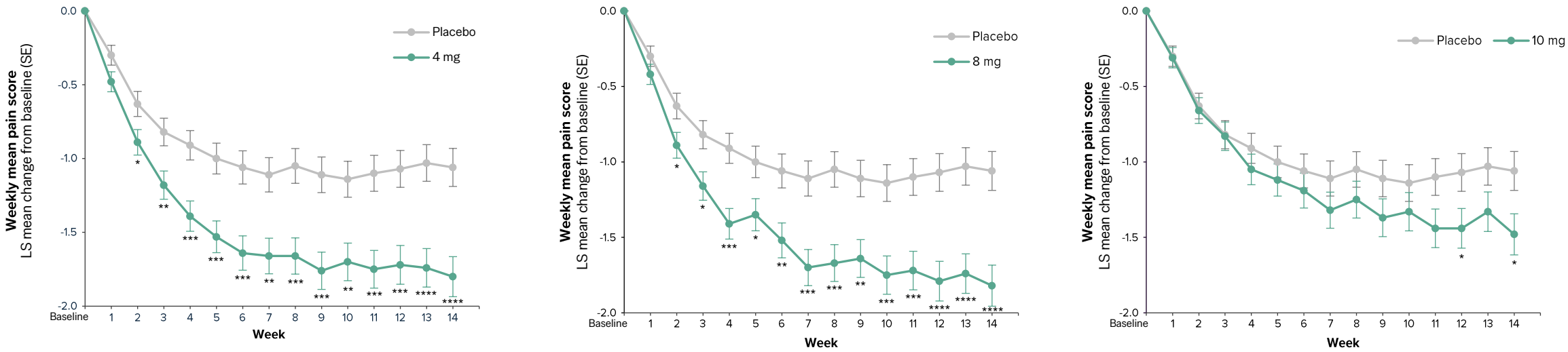
Associated with substantial physical disability and reduced emotional and social well-being, financial burden, and reduced quality of life[2,3]

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)

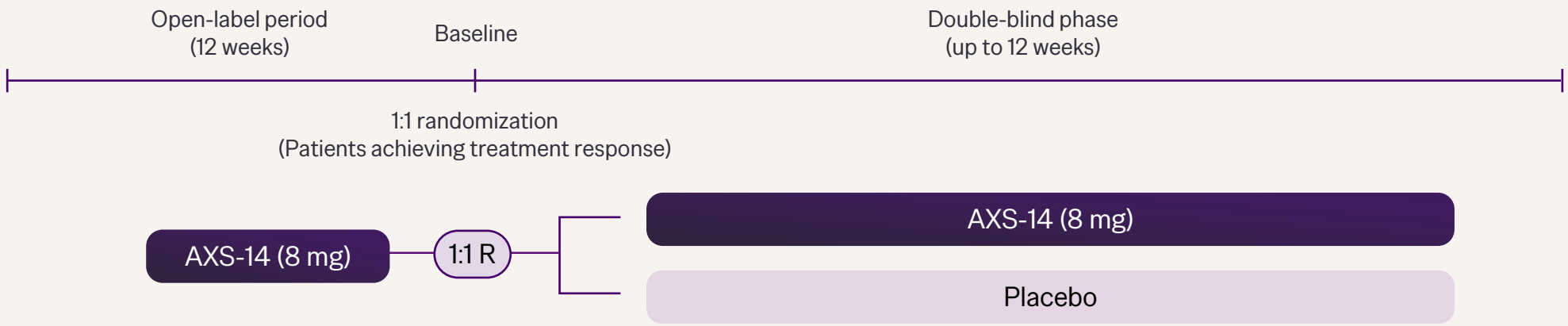


- Efficacy and safety of AXS-14 compared to placebo evaluated in >1,000 individuals with fibromyalgia across Phase 2 and Phase 3 clinical trials for up to 14 weeks
- Rapid and significant reductions in pain scores, improvements in patient-reported global functioning, fatigue, and overall symptom severity

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

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

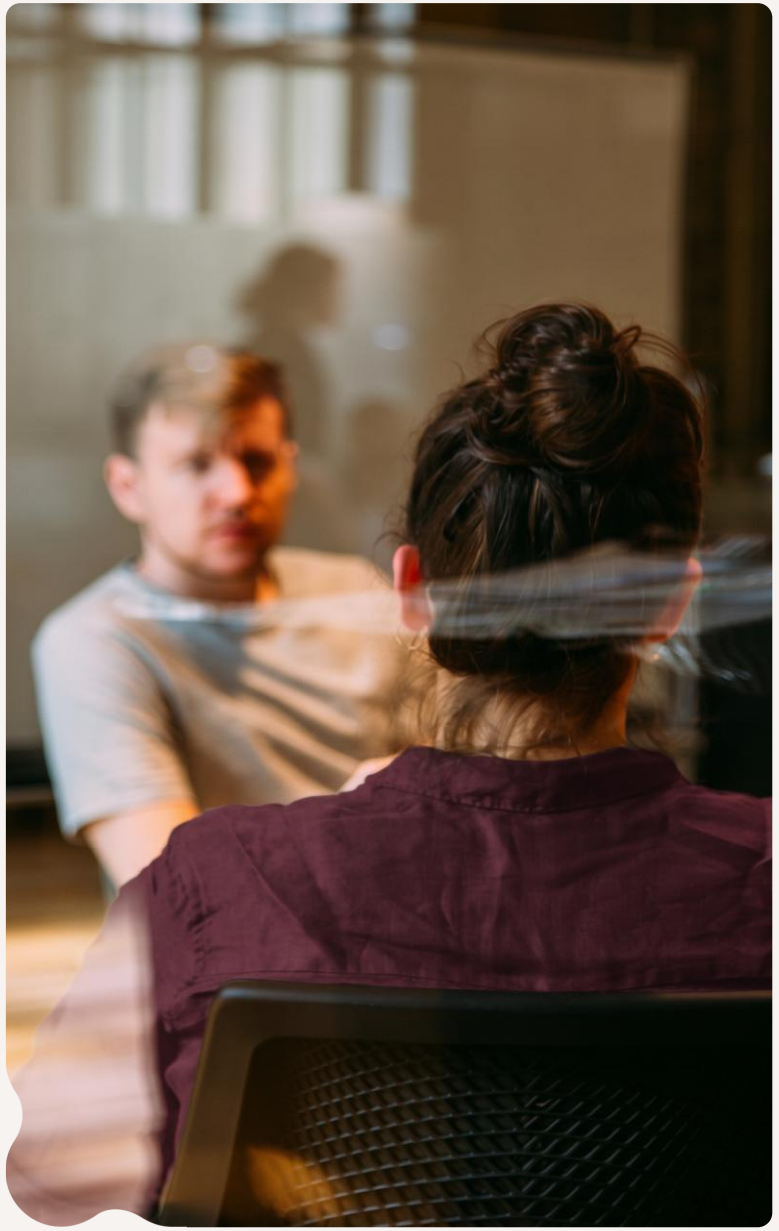
Roger Jeffs, PhD
CEO, LIQUIDIA CORPORATION
Former President, Co-CEO, Director United Therapeutics Corp.
Prior positions at Amgen and Burroughs Wellcome

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