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): February 20, 2024

Axsome Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37635**	**45-4241907**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One World Trade Center, 22nd Floor	
New York, New York	**10007**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

Emerging growth company ☐

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

Item 8.01 Other Events.

On February 20, 2024, the Company updated its corporate presentation and posted such corporate presentation to the Company's website. The updated corporate presentation is filed as Exhibit 99.1 hereto and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	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: February 20, 2024

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

nasdaq: axsm

Corporate Presentation

February 2024

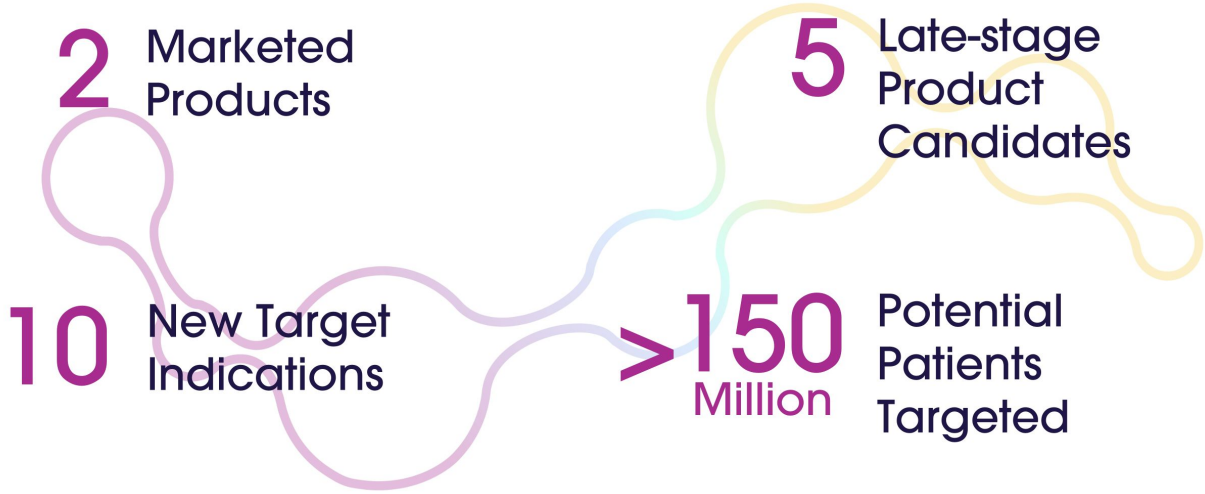
Forward Looking Statements & Safe Harbor

Certain information contained in this presentation may include “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company’s statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the continued commercial success of our Sunosi® and Auvelity® products and the success of our efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our 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 our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates, including statements regarding the timing of any NDA submission; whether issues identified by FDA in the complete response letter may impact the potential approvability of the Company’s NDA for AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment for the MOMENTUM clinical trial; the Company’s ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company’s research and development programs and collaborations; the success of the Company’s license agreements; the acceptance by the market of the Company’s products and product candidates, if approved; the Company’s anticipated capital requirements, including the amount of capital required for the continued commercialization of Sunosi and Auvelity and for the Company’s commercial launch of its other product candidates, if approved, and the potential impact on the Company’s anticipated cash runway; unforeseen circumstances or other disruptions to normal business operations arising from or related to geo-political conflicts or a global pandemic and other factors, including general economic conditions and regulatory developments, not within the Company’s control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

This presentation contains statements regarding the Company’s observations based upon the reported clinical data. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about the Company's industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, these projections, assumptions and estimates are necessarily subject to a high degree of uncertainty and risk.

Axsome, Auvelity, Sunosi, and MoSEIC, are trademarks or registered trademarks of Axsome Therapeutics, Inc. or its affiliates. Except as with respect to Auvelity and Sunosi for their approved indications, the development products referenced herein have not been approved by the FDA.

We are a Rapidly Growing, CNS-Focused Biopharma



axsome

Building an Industry-Leading Neuroscience Portfolio for 10 Serious Neurology and Psychiatry Conditions

Product	MOA	Phase 1	Phase 2	Phase 3	NDA	Marketed
Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	NMDA receptor antagonist and sigma-1 receptor agonist, aminoketone CYP2D6 inhibitor	Major Depressive Disorder (MDD)				
SUNOSI® (solriamfetol) (C-V) 75, 150 mg tablets	Dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI)	Excessive Daytime Sleepiness (EDS) Associated with Narcolepsy or Obstructive Sleep Apnea (OSA)				
AXS-05	NMDA receptor antagonist and sigma-1 receptor agonist, aminoketone CYP2D6 inhibitor	Alzheimer's Disease Agitation (ADA) — FDA Breakthrough Therapy Designation				
		Smoking Cessation				
AXS-07	MoSEIC™ COX-2 pref. inhibitor + 5-$HT_{1B/1D}$ agonist	Migraine				
AXS-12	Highly selective NE reuptake inhibitor	Narcolepsy — FDA Orphan Drug Designation				
AXS-14	Enantiomerically purified highly selective NE reuptake inhibitor	Fibromyalgia				
solriamfetol	Dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) and TAAR1 agonist	Attention Deficit Hyperactivity Disorder (ADHD)				
		Major Depressive Disorder (MDD)				
		Binge Eating Disorder (BED)				
		Shift Work Disorder (SWD)				

AXS-05, AXS-07, AXS-12, AXS-14, and solriamfetol for ADHD , BED, MDD, and SWD are not approved by the FDA, and their safety and effectiveness have not been established
Abbreviations: CNS = Central Nervous System; MOA = Mechanism of Action; NMDA = N-Methyl-D-aspartate; COX-2 = Cyclooxygenase-2; 5-HT = 5-Hydroxytryptamine; NE = Norepinephrine; CYP2D6 = Cytochrome P450 Family 2 Subfamily D Member 6; MoSEIC = Molecular Solubility Enhanced Inclusion Complex; TAAR1 = Trace amine-associated receptor 1 Please see full Prescribing Information for Auvelity at www.Auvelity.com. Please see full Prescribing Information for Sunosi at www.Sunosi.com.

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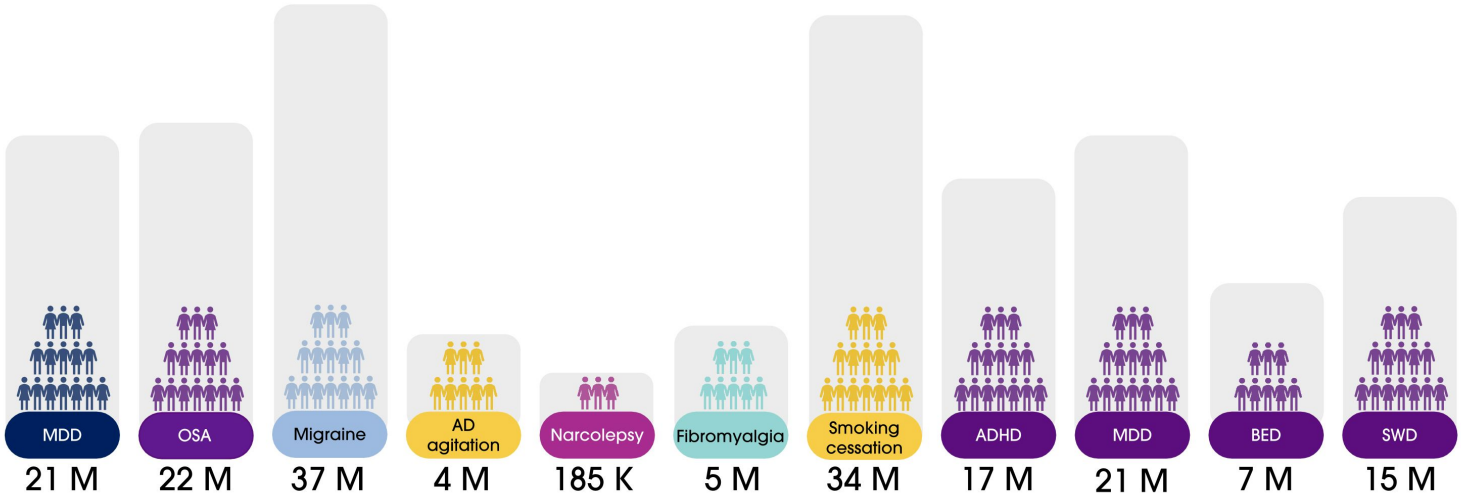
On a Mission to Deliver Novel Therapies with the Potential to Meaningfully Improve People's Lives



>150 Million patients targeted with countless additional lives impacted including physicians, caregivers, and loved ones

Abbreviations:
MDD = Major Depressive Disorder; OSA = Obstructive Sleep Apnea; AD = Alzheimer's Disease; ADHD = Attention Deficit Hyperactivity Disorder; BED = Binge Eating Disorder; SWD = Shift Work Disorder

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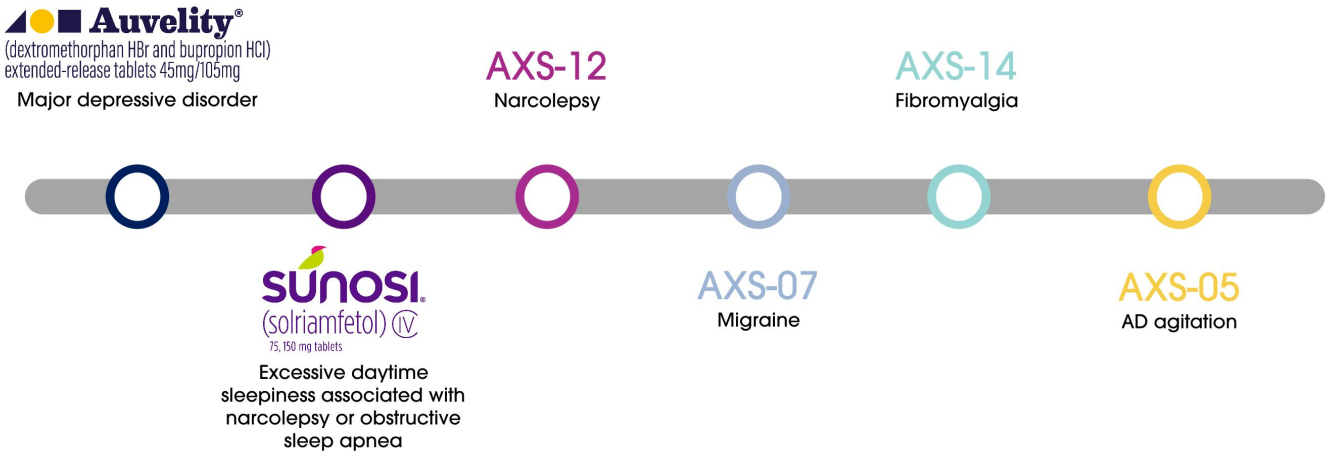
With Multiple Near-Term Value-Drivers Including Potentially Six Marketed Indications by 2025



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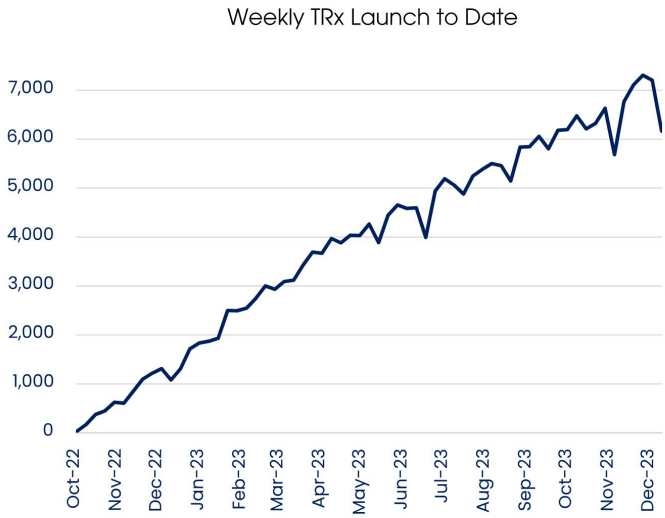
Marketed Products

Treating adult patients living with major depressive disorder

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

- Rapid acting NMDA receptor antagonist and sigma-1 receptor agonist for MDD[1-2*]
- New differentiated oral approach to treat MDD that is different from other oral antidepressants approved[1-3]
- Rapid symptom improvement starting at Week 1, sustained at Week 6 vs placebo[1]
- Rapid remission as early as Week 2, sustained and increased vs control through Week 6[4]



Source: Symphony METYS

Abbreviations: TRx = total prescriptions; NMDA = N-Methyl-D-aspartate; MDD = major depressive disorder

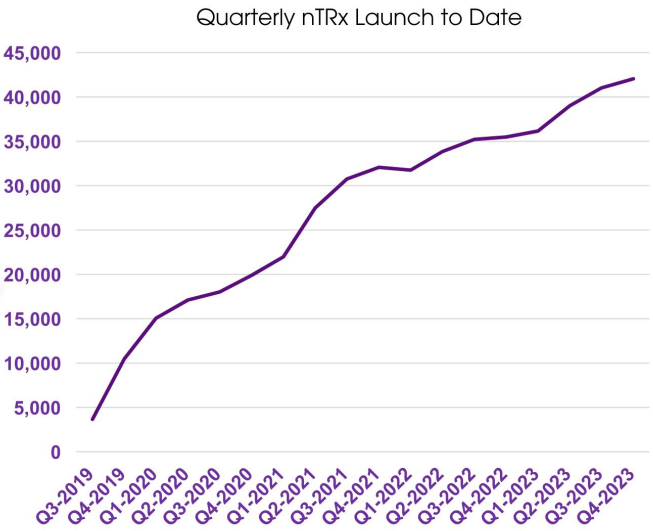
1. Auvelity [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY 2. FDA Depression Medicines. https://www.fda.gov/media/132665/download. Accessed March 21, 2022. 3. Thomas D, and Wessel C. The state of innovation in highly prevalent chronic diseases volume I: Depression therapeutics. December 2017. https://www.bio.org/sites/default/files/legacy/bioorg/docs/BIO_HPCD_Series-Depression_2018-01-03.pdf. Accessed March 21, 2022. 4. Iosifescu DV et al. J Clin Psychiatry. 2022;83(4):21m1434

* AUVELITY is a combination of dextromethorphan, an uncompetitive NMDA receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor

axsome

Improving wakefulness in adult patients with EDS associated with narcolepsy or OSA

- First and only DNRI indicated 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]



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

Abbreviations: nTRx = normalized total prescriptions; EDS = excessive daytime sleepiness; OSA = obstructive sleep apnea; DNRI = dopamine-norepinephrine reuptake inhibitor

1. SUNOSI [Prescribing Information]. Axsome Therapeutics, Inc., New York, NY: 2. Schweitzer PK et al. Am J Resp Crit Care Med. 2019;199(11):1421-1431.

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Development Pipeline

AXS-05

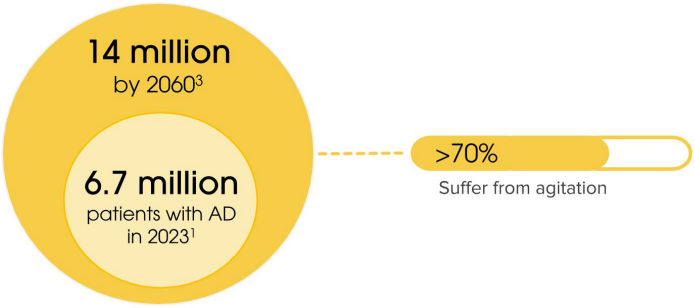
(dextromethorphan-bupropion)

a new approach to treating multiple CNS conditions

Alzheimer's Disease Agitation: High Unmet Medical Need, Novel Approach

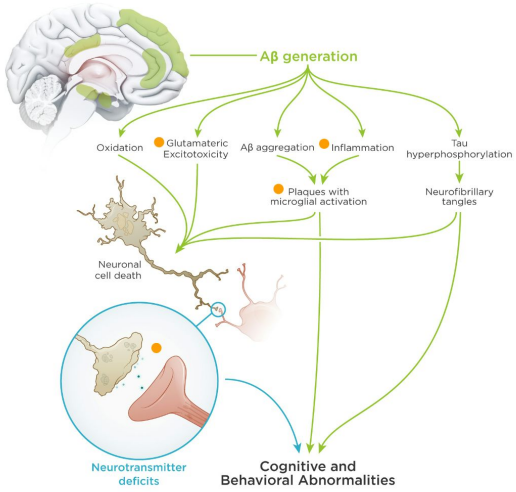
AXS-05

- Agitation is seen in up to 70% of Alzheimer's disease patients[1,2]



- Associated with accelerated cognitive decline, earlier nursing home placement, increased mortality risk[4,5]
- High unmet medical need for safe and effective options
- AXS-05 pharmacology relevant to implicated disease pathways

Brain regions implicated in AD agitation[6]



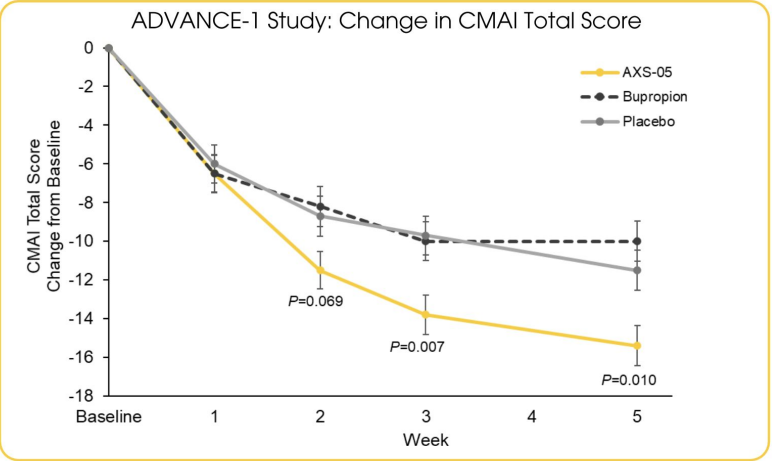
AXS-05 pharmacological actions[7,8]

1. Alzheimer's Association. 2023 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2023;19(4). 2. Tractenberg R, et al. J Neuropsychiatry Clin Neurosci. 2002;14:11-18. 3. Alzheimers Dement. 2021 Mar;17(3):327-406. 4. Porsteinsson AP, et al. Expert Opin Pharmacother. 2017; 18:6, 611-620. 5. Lee D et al Expert Opin. On Pharm. 2023, https://doi.org/10.1080/14656566.2023.2195539 6. Rosenberg PB, et al. Mol Aspects Med. 2015;0: 25–37. 7. Stahl SM. CNS Spectr. 2019;24:461-466. 8. Cheng W, et al. Mol Med Rep. 2015 Feb;11(2):1132-8

Alzheimer's Disease Agitation: Clinical Results and Program Status

AXS-05

- Primary endpoints met in two controlled trials:
  - ADVANCE-1 Phase 2/3, parallel group trial
  - ACCORD Phase 3, randomized withdrawal trial
- ADVANCE-2 Phase 3 trial ongoing, topline results expected 2H 2024
- FDA Breakthrough Therapy Designation received

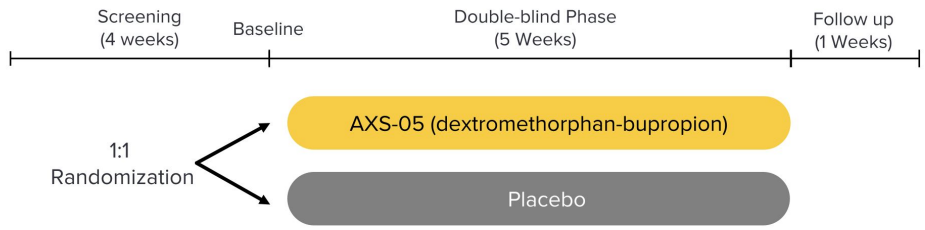


Abbreviations:
CMAI = Cohen Mansfield Agitation Inventory

Alzheimer's Disease Agitation: ADVANCE-2 Phase 3 Trial

AXS-05

A Phase 3 trial to assess efficacy and safety of AXS-05 as compared to placebo in the treatment of Alzheimer's disease agitation.



- Primary Endpoint: Efficacy of AXS-05 compared to placebo on the change from baseline in CMAI total score
- Key Inclusion Criteria:
  - Male or female 65-90 years old
  - Diagnosis of probable AD and of clinically significant agitation resulting from probable AD
- Target Enrollment: 350
- Topline Data: 2H 2024

Smoking Cessation

AXS-05

- Smoking is single largest cause of preventable death in the U.S.[1]
- AXS-05 represents a potentially new mechanism of action for smoking cessation
- Positive FDA Pre-IND meeting guidance received from the FDA – can proceed to pivotal Phase 2/3 trial
- Planned trial initiation in 2024

70% of smokers want to quit[2]

Only 3-5% who attempt to quit without assistance are successful for 6-12 months[2]

U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. 2014. 2. Hughes JR, et al. Addiction. 2004;99(1):29-38

AXS-07

(MoSEIC™ meloxicam-rizatriptan)

a multi-mechanistic approach to treating migraine

Migraine:
Significant Need for More Efficacious Treatments

AXS-07

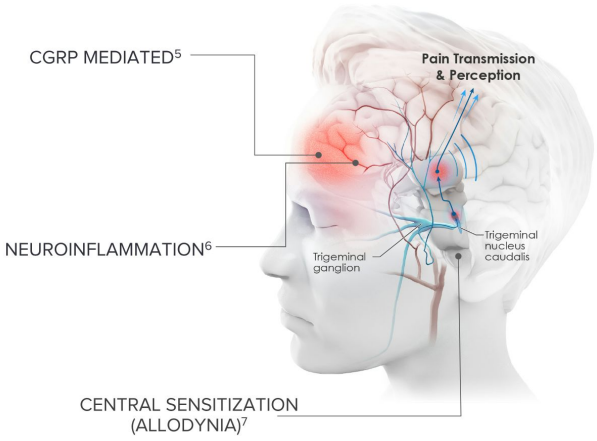
- Unmet need for improved efficacy in migraine: disability on par with dementia, quadriplegia, active psychosis[1,2]:

>37 million
in the U.S. suffer from migraine[3]

>70%
not fully satisfied with current treatment

~80%
would try a new therapy

- $78 billion direct and indirect costs in the U.S. each year[4]
- Mechanisms of AXS-07 address multiple disordered physiological processes observed during migraine attacks

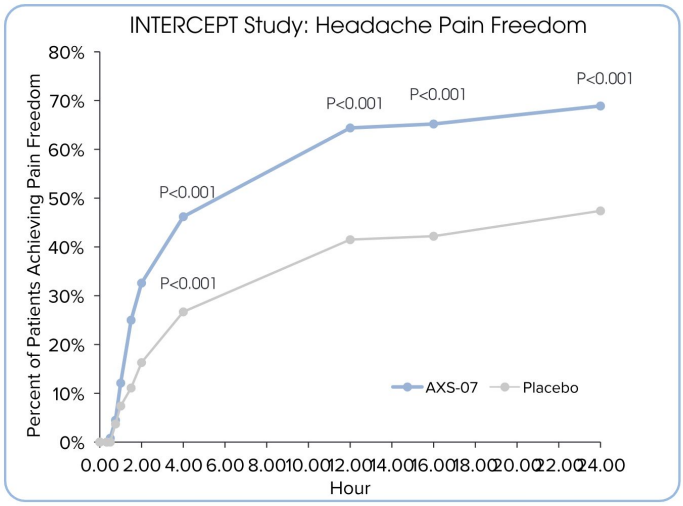


1. Menken et al. Arch Neurol. 2000;57:418-420. 2. Shapiro and Goadsby. Cephalalgia. 2007;27:991-4. 3. Pescador Ruschel MA, et al. Migraine Headache. [Updated 2023 Aug 23]. available from: https://www.ncbi.nlm.nih.gov/books/NBK560787/ 4. Gooch CL, Pracht E, Borenstein AR. The burden of neurological disease in the United States: A summary report and call to action. Ann Neurol. 2017 Apr; 81(4):479-484. 5. Geppetti et al. J Headache Pain. 2012; 13:103–111. 6. Changes measured in migraine patients. COX-2 data from Li et al. Med Sci Monit. 2017 Jan 3;23:24-28. PGE2 data from Sarchielli et al. Cephalalgia. 2000 Dec;20(10):907-18. 7. Change measured in migraine patient. Data from Burstein et al. Brain. 2000;123 (Pt 8):1703-9.

Migraine:
Clinical Results and Program Status

AXS-07

- Rapid and sustained efficacy as compared to placebo and active comparator rizatriptan, in three positive Phase 3 trials:
  - MOMENTUM trial, in patients with history of inadequate response, vs. placebo and rizatriptan
  - INTERCEPT trial, in early treatment, vs. placebo
  - MOVEMENT trial, long-term open-label treatment, up to 12 months
- Class 2 NDA resubmission anticipated in the first half of 2024



AXS-12
(reboxetine)

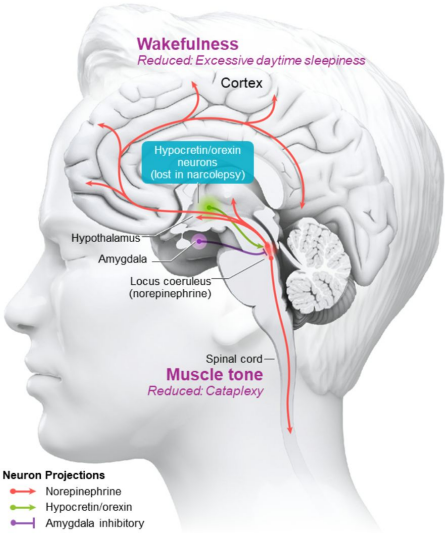
a potentially new treatment option for narcolepsy

Narcolepsy

AXS-12

- Narcolepsy is a debilitating disorder characterized by excessive daytime sleepiness and cataplexy, with limited treatment options

- Loss of excitatory hypocretin/orexin neurons in the brain lead to dysregulation of norepinephrine resulting[2]:
  - Loss of muscle tone while awake (cataplexy)
  - Decreased wakefulness during the day (EDS)
- AXS-12 (reboxetine) improves regulation of norepinephrine signaling in narcolepsy

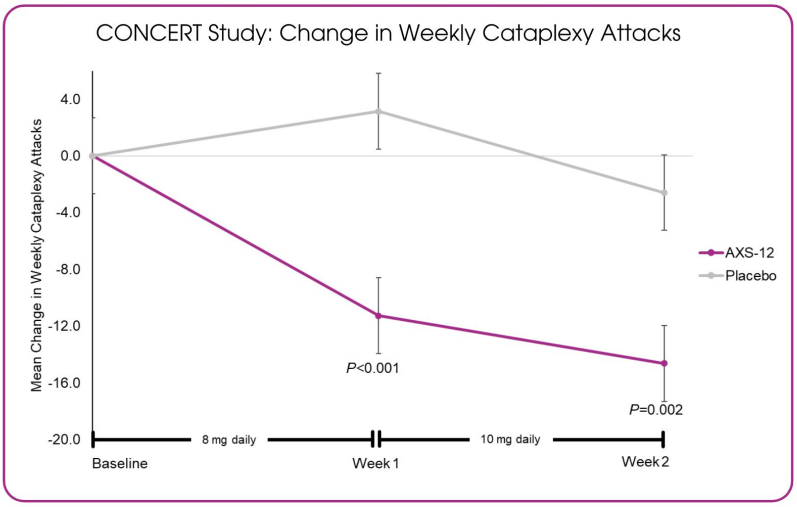


1. https://narcolepsynetwork.org/ accessed Feb 20, 2024 2. Szabo ST, et al. Sleep Medicine Reviews 43 (2019) 23-36

Narcolepsy:
Clinical Results and Program Status

AXS-12

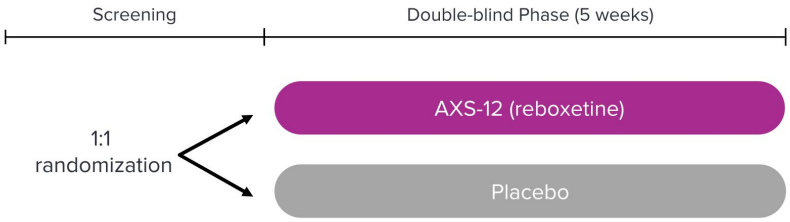
- Positive Phase 2 results with AXS-12
  - Significant reduction in cataplexy attacks
  - Significant improvement in excessive daytime sleepiness
  - Significant improvement in cognitive function
- SYMPHONY Phase 3 trial ongoing, topline results expected 1Q 2024



Narcolepsy:
SYMPHONY Phase 3 Trial

AXS-12

A Phase 3 trial to assess efficacy and safety of AXS-12 as compared to placebo in the treatment of cataplexy in narcolepsy.



- Primary Endpoint: Change in the frequency of cataplexy attacks
- Key Inclusion Criteria:
  - Male or female 15-75 years old
  - Primary diagnosis of narcolepsy with cataplexy
- Topline Data: 1Q 2024

AXS-14
(esreboxetine)

a potentially new treatment option for fibromyalgia

Fibromyalgia

AXS-14

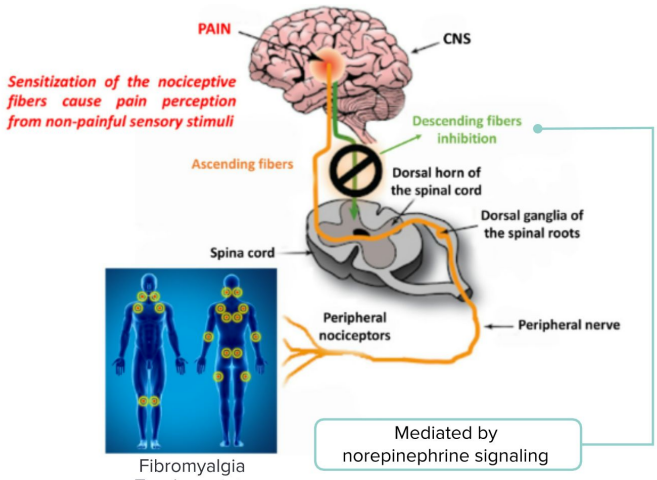
- Debilitating, chronic, CNS disorder characterized by widespread pain, fatigue, disturbed sleep, depression, and cognitive impairment; ~90% affected are women

5 million patients in the U.S.[1]

90% are women

- Limited treatment options with only 3 approved agents, variable efficacy, and do not address all symptoms
- AXS-14 (esreboxetine) increases descending norepinephrine inhibition of pain signaling

Pathways influencing pain sensitivity in fibromyalgia[2]



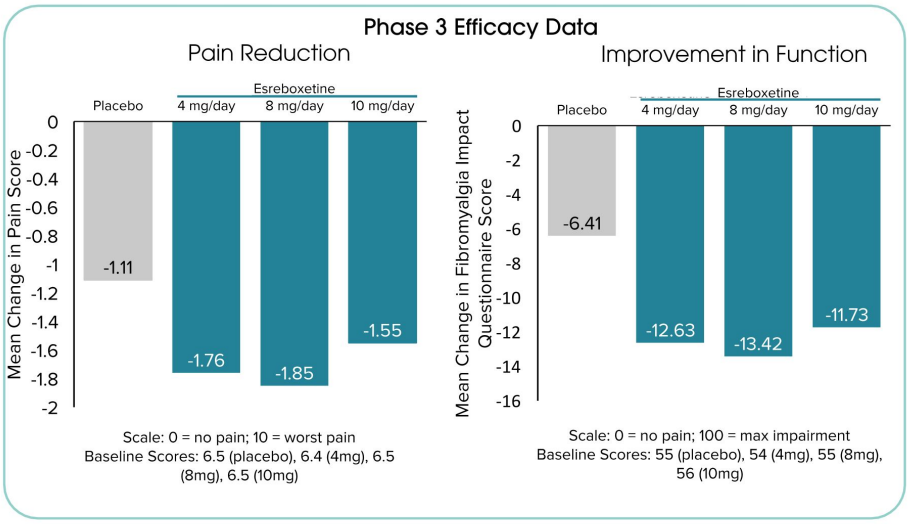
Fibromyalgia
Tender points

1. Decision Resources Group 2019 2. Adapted from Siracusa, R., et al. Fibromyalgia: Pathogenesis, Mechanisms, Diagnosis and Treatment Options Update. Int. J. Mol. Sci. 2021, 22, 3891.

Fibromyalgia:
Clinical Data and Program Status

AXS-14

- Positive Phase 3 and Phase 2 efficacy results with AXS-14 in fibromyalgia:
  - Significant reduction in pain and improvement in function
- NDA submission planned for first half of 2024



Solriamfetol

a potentially differentiated option for the treatment of CNS disorders

Attention Deficit Hyperactivity Disorder

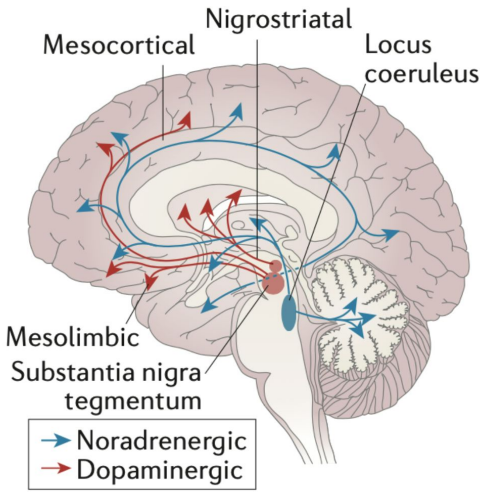
solriamfetol

- ADHD is a serious disorder characterized by inattention, hyperactivity or impulsivity

17.4 million
in the U.S. with ADHD

- Associated with significant impairment in social, academic, and occupational functioning or development
- Solriamfetol targets neurotransmitter pathways in the brain implicated in ADHD[3]

Neurotransmitter Pathways Implicated in ADHD[1]



1. Kessler RC, et al. The prevalence and correlates of adult ADHD in the United States: results from the National Comorbidity Survey Replication. Am J Psychiatry. 2006 Apr;163(4):716-23. 2. Bitsko RH, et al. Mental health surveillance among children—United States, 2013–2019. MMWR Suppl. 2022;71(2):1-48. 3. Faraone, S. V. et al. Attention-deficit/hyperactivity disorder. Nat. Rev. Dis. Primers. 2015

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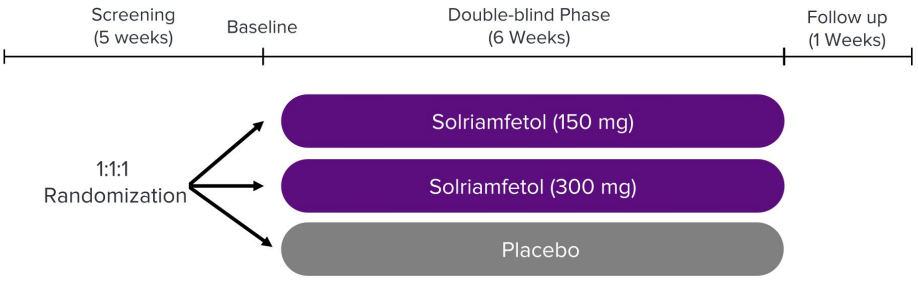
Attention Deficit Hyperactivity Disorder: FOCUS Phase 3 Trial

solriamfetol

A Phase 3 trial to assess efficacy and safety of solriamfetol as compared to placebo in the treatment of ADHD.



- Primary Endpoint: Change in the Adult ADHD Investigator Symptom Report Scale (AISRS)
- Key Inclusion Criteria:
  - Male or female 18-55
  - Primary diagnosis of ADHD (inattentive, hyperactive, or combined subtype) using DSM-5 criteria
- Target Enrollment: 450
- Topline Data: 2H 2024

axsome

Major Depressive Disorder

solriamfetol

- Major depression is one of the most common mental disorders in the United States[1]
- Solriamfetol is a dopamine and norepinephrine reuptake inhibitor, a TAAR1 and 5-HT_{1A} agonist
- The combination of monoamine reuptake inhibition and TAAR1/5-HT_{1A} agonism showed synergistic results in two mouse models of depression[3]

Approximately 1 in 5 individuals in the U.S. will experience MDD at some point in their life[2,*]

~21 million

adults in the U.S. had at least one major depressive episode in 2021[1]

1. "Major Depression" National Institute of Health, U.S. Dept. of Health and Human Services https://www.nimh.nih.gov/health/statistics/major-depression Accessed 21 Dec. 2023 2. Hasin DS et al. JAMA Psychiatry. 2018;75(4):336-346. 3. Treadway MT, et al. Biol Mood Anxiety Disord. 2014 Mar 7;4(1):5. doi: 10.1186/2045-5380-4-5. 3. Ren, Xia, et al. "The Potential Antidepressant Action of Duloxetine Co-Administered with the TAAR1 Receptor Agonist SEP-363856 in Mice." Molecules 27.9 (2022): 2755.

* According to a study of 36,309 adult participants surveyed in the 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions III.

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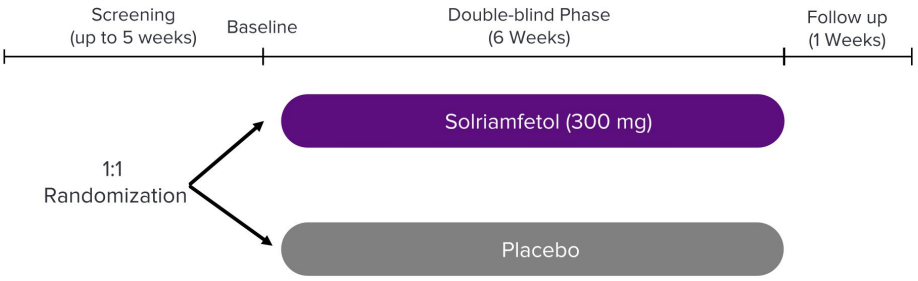
Major Depressive Disorder (MDD): Planned Phase 3 Trial

A Phase 3 trial to assess efficacy and safety of solriamfetol as compared to placebo in the treatment of MDD.

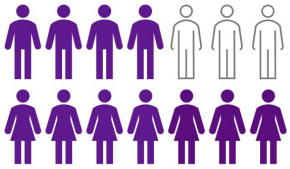


- Primary Endpoint: Change in the Montgomery-Åsberg Depression Rating Scale (MADRS)
- Key Inclusion Criteria:
  - Male or female 18-65 years old
  - Confirmed diagnosis of moderate to severe MDD
- Target Enrollment: 300

Binge Eating Disorder

solriamfetol

- Binge eating disorder (BED) is the most common eating disorder and is thought to involve issues with food reward processing, impulse control, and appetite regulation[1,2]
- Unmet medical need, associated with a 2- to 3-fold increased risk of psychiatric and medical comorbidities[3]
- Solriamfetol's dopamine, norepinephrine, and TAAR1 mechanisms appear relevant to the pathophysiology of BED[4-6]



BED is 1.75x more common in women than in men[2]

~7 million
people in the U.S. have BED[2]

Abbreviations: OFC = orbital frontal cortex; vmPFC = ventromedial prefrontal cortex; ACC = anterior cingulate cortex

1. Kessler RM, et al. Neurosci. Biobehav. Rev., vol. 63, pp. 223–238, Apr. 2016 2. Hudson JI, et al. Biol. Psychiatry, vol. 61, no. 3, pp. 348–358, Feb. 2007 3. McElroy SL et al. J. Clin. Psychiatry, vol. 81, no. 5, Sep. 2020 4. Giel KL et al. Nat. Rev. Dis. Primer, vol. 8, no. 1, Art. no. 1, Mar. 2022 5. Bello NT et al. Pharmacol. Biochem. Behav., vol. 97, no. 1, pp. 25–33, Nov. 2010 6. Pruccoli et al. Int. J. Mol. Sci., vol. 22, no. 20, p. 11086, Oct. 2021

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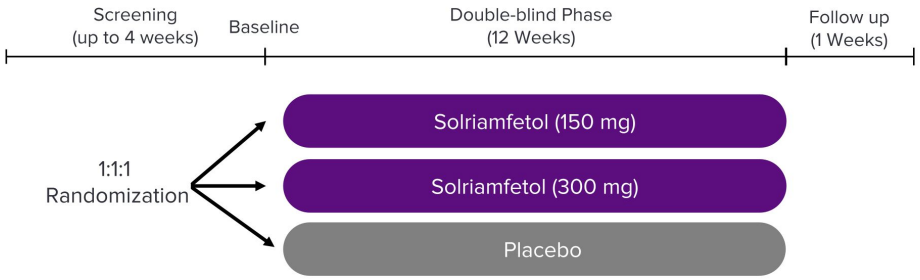
Binge Eating Disorder: Planned Phase 3 Trial

A Phase 3 trial to assess efficacy and safety of solriamfetol as compared to placebo in the treatment of BED.



- Primary Endpoint: Change from baseline in binge eating
- Key Inclusion Criteria:
  - Male or female 18-55 years old
  - Meets DSM-5 criteria for BED
- Target Enrollment: 450

Shift Work Disorder

solriamfetol

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

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

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

VTA: ventral tegmental area; LC: locus coeruleus; DR: dorsal raphe; BF: basal forebrain; LH: lateral hypothalamus; TMN: tuberomammillary nucleus; TC, thalamocortical relay neurons; LDT/PPT, laterodorsal tegmental and pedunculopontine nuclei. Refs: 1. Sateia, M. J. International Classification of Sleep Disorders, 3rd Edition (ICSD-3) Chest 146, 1387–1394 (2014) 2. Alterman, T. et al. Am. J. Ind. Med. 56, 647–659 (2013) 3. Wickwire, E. M., et al. Chest 151, 1156–1172 (2017) 4. Smith, L., et al. Lancet Lond. Engl. 344, 1137–1139 (1994) 5. Akerstedt, T. & Wright, K. P. Sleep Med. Clin. 4, 257–271 (2009) 6. Czeisler, C. A. et al. N. Engl. J. Med. 353, 476–486 (2005).

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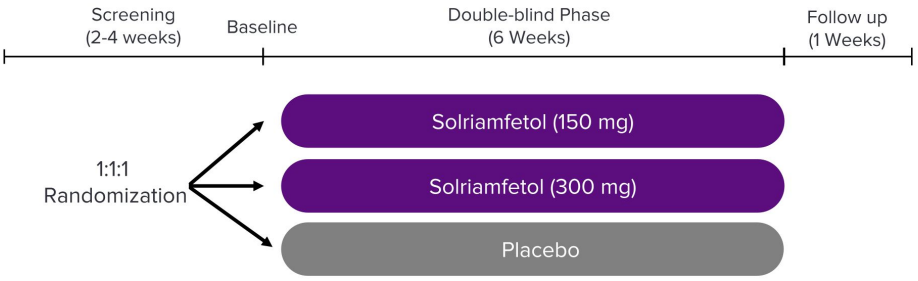
Shift Work Disorder: Planned Phase 3 Trial

A Phase 3 trial to assess efficacy and safety of solriamfetol as compared to placebo in the treatment of SWD.



- Primary Endpoint: Change from baseline in patient's disease status as measured by the CGI-C
- Key Inclusion Criteria:
  - Male or female 18-65 years old
  - Diagnosis of SWD based on the ICSD-2 or -3 criteria
- Target Enrollment: 450

Abbreviations:
CGI-C = Clinical Global Impressions of Change.

CNS portfolio with potential to generate total U.S. peak sales of up to $16.5B

Program		Launch Year	Est. Peak U.S. Sales	Key Highlights
Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	major depressive disorder	2022	$1- $3B	• Rapid and substantial efficacy, as early as week 1[1] • New differentiated oral approach to treat MDD different from other oral ADTs
SUNOSI (solriamfetol) CV	EDS associated with OSA and narcolepsy	2022	$0.3 - $0.5B	• First and only wakefulness promoting agent to improve wakefulness through 9 hours[5] • First FDA approved dual-acting DNRI to treat EDS in OSA or narcolepsy
AXS-05	Alzheimer's disease agitation	2025 est.	$1.5 - $3B	• Rapid and substantial effect, as early as Week 2, with no associated cognitive impairment or sedation
	smoking cessation	TBD	$0.5 - $1B	• Represents a potentially new mechanism of action for smoking cessation • Planned Phase 2/3 trial initiation
AXS-07	migraine	2025 est.	$0.5 - $1B	• Rapid and consistent relief with reduced symptom recurrence
AXS-12	narcolepsy	2025 est.	$0.5 - $1B	• Improved cataplexy, EDS, and cognitive function
AXS-14	fibromylagia	2025 est.	$0.5 - $1B	• Reduced pain with improved function with effect on fatigue
Solriamfetol	major depressive disorder	TBD	$1 – 1.5B	• Phase 3 trial planned to start in 1Q 2024
	attention deficit hyperactivity disorder	TBD	$1 - 3B	• Phase 3 trial ongoing; topline data expected in 2H 2024
	binge eating disorder	TBD	$0.5 - $1B	• Phase 3 trial planned to start in 1Q 2024
	shift work disorder	TBD	$0.3 - $0.5B	• Phase 3 trial planned to start in 1Q 2024

ADTs: approved antidepressant therapies
Please see full Prescribing Information for Auvelity at www.Auvelity.com. Please see full Prescribing Information for Sunosi at www.Sunosi.com.
Auvelity and Sunosi referencess are on Slides 8 and 9, respectively.

Strong Intellectual Property and Barriers to Entry

Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	• Protected by a robust patent estate extending out to at least 2043; Multiple pending • Proprietary drug product formulation
SUNOSI® (solriamfetol) CIV 75, 150 mg tablets	• Protected by a robust patent estate extending out to at least 2042; >27 Issued U.S. Patents and >62 Issued O-U.S. Patents; Multiple pending • Proprietary drug substance and drug product formulation
AXS-05	• >130 Issued U.S. Patents and >86 Issued O-U.S. Patents Claims extending to at least 2034-43; Multiple pending • Proprietary drug product formulation
AXS-07	• >97 Issued U.S. Patents and >128 Issued O-U.S. Patents Claims extending to at least 2038; Multiple pending • Proprietary MoSEIC™ formulation and drug product formulation
AXS-12	• Orphan Drug Designation • 6 issued U.S. Patents and 1 issued O-U.S. Patent; • Claims extending to at least 2039 • Proprietary drug substance and drug product formulation
AXS-14	• Pending U.S. patents • Proprietary drug substance and drug product formulation

Financial Snapshot

Cash Balance: (as of Dec. 31, 2023)	$ 386.2 M
Debt (Face Value): (as of Dec. 31, 2023)	$ 180 M
Market Cap: (as of February 16, 2024)	$ 4.4 B
Shares Outstanding: (as of December 31, 2023)	47.4 M
Options, RSUs, and Warrants Outstanding[1]:	9.3 M

[1] Consists of 8.46 M options, 0.8 M RSUs, and 0.080 M warrants

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

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
EVP, Head of Commercial

Lori Englebert, MBA
EVP, Product Strategy

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
Former CFO
Bird Rock Bio, Inc.
Former COO of the Global Healthcare Group at UBS

Mark Coleman, MD
Director of Clinical Services
National Spine and Pain Centers
Diplomat of the American Board of Anesthesiology

Susan Mahony, PhD
Former SVP of Eli Lilly and President Lilly Oncology
Prior positions at BMS, Amgen and Shering-Plough

Herriot Tabuteau, MD
Chairman

Anticipated Upcoming Clinical and Regulatory Milestones

Regulatory and Commercial

AXS-07	Migraine NDA, planned resubmission – 1H 2024
AXS-14	Fibromyalgia NDA, planned submission – 1H 2024

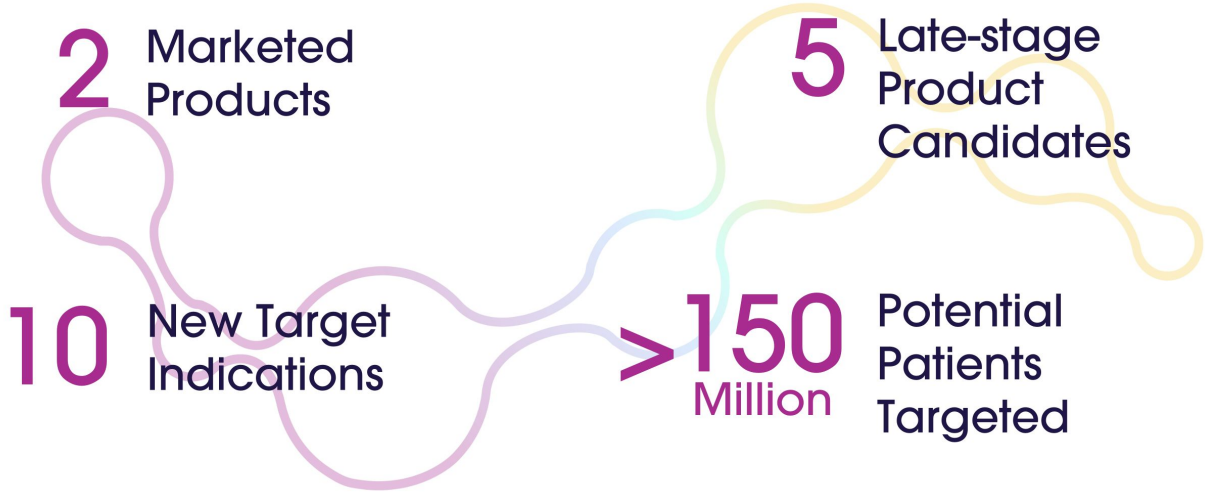
Clinical Trial Topline Results

AXS-12	SYMPHONY Phase 3 trial in narcolepsy – 1Q 2024
AXS-05	ADVANCE-2 Phase 3 trial in Alzheimer's disease agitation – 2H 2024
solriamfetol	FOCUS Phase 3 trial in adult ADHD – 2H 2024

Clinical Trial Initiations

solriamfetol	Phase 3 trial in major depressive disorder – 1Q 2024
solriamfetol	Phase 3 trial in binge eating disorder – 1Q 2024
solriamfetol	Phase 3 trial in shift work disorder – 1Q 2024
AXS-05	Phase 2/3 trial in smoking cessation – 2024

Rapidly Growing, CNS-Focused Biopharma



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thank you

for more information, please contact:

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chief operating officer
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mjacobson@axsome.com
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