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): June 13, 2023

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 June 13, 2023, 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: June 13, 2023

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

nasdaq: axsm

Exhibit 99.1

Corporate Presentation

June 2023

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 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; 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, 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 COVID-19; 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.

Rapidly Growing, CNS-Focused Biopharma

2 Marketed Products

5 Late-stage Product Candidates

6 New Target Indications

140 Million Potential Patients Targeted

Leading CNS Portfolio

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) CV 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)	Attention Deficit Hyperactivity Disorder (ADHD)				

AXS-05, AXS-07, AXS-12, AXS-14, and solriamfetol for ADHD 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
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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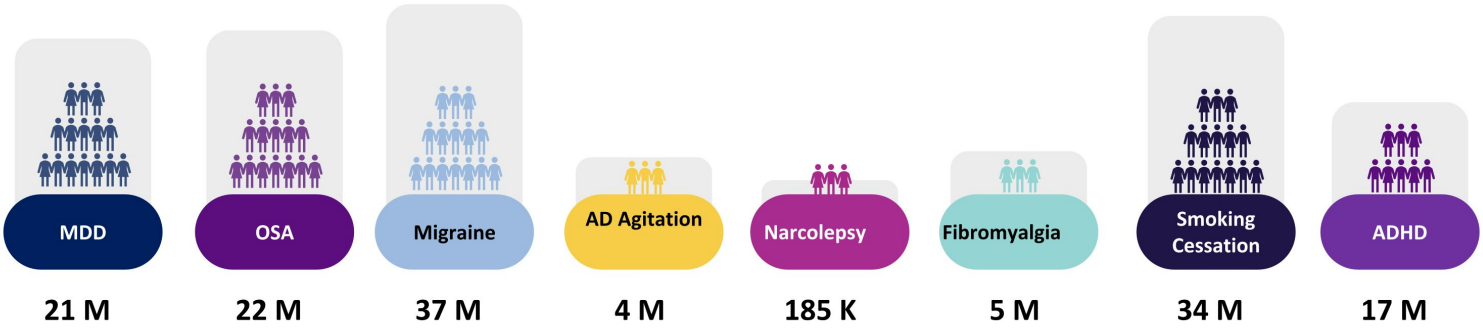
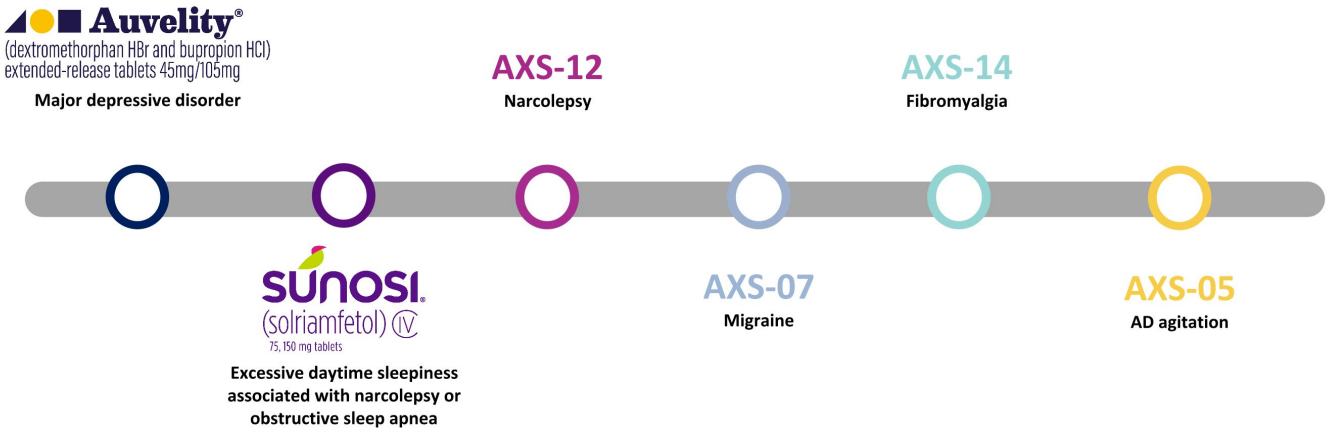
Marketed and Late-stage CNS Portfolio with Potential to Impact the Lives of >140M U.S. Patients



Abbreviations:
MDD = Major Depressive Disorder; OSA = Obstructive Sleep Apnea; AD = Alzheimer's Disease; ADHD = Attention Deficit Hyperactivity Disorder

Potentially Marketed Indications by 2025



Marketed Products

Treating adult patients living with major depressive disorder

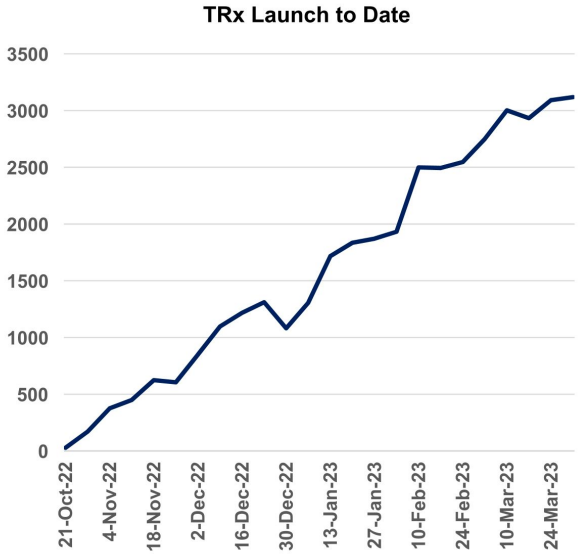
Auvelity®
(dextromethorphan HBr and bupropion HCl)
extended-release tablets 45mg/105mg

First and only oral rapid acting NMDA receptor antagonist for MDD[1-2]

New approach to treat MDD that is different from other oral antidepressants approved in more than 60 years[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

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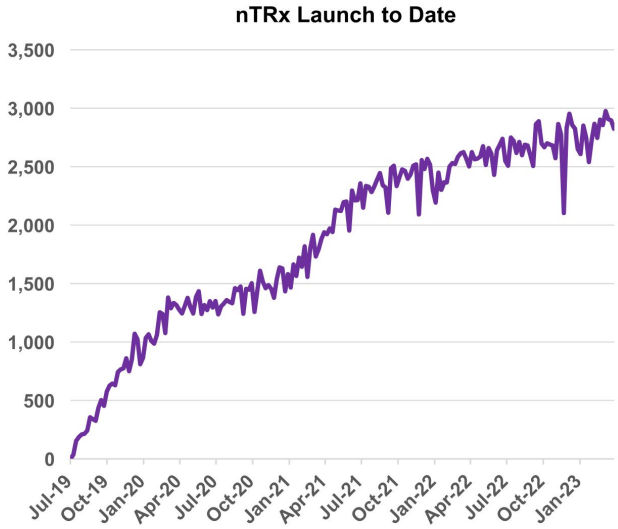
Improving wakefulness in adult patients with EDS associated with narcolepsy or OSA

- 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

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AXS-05

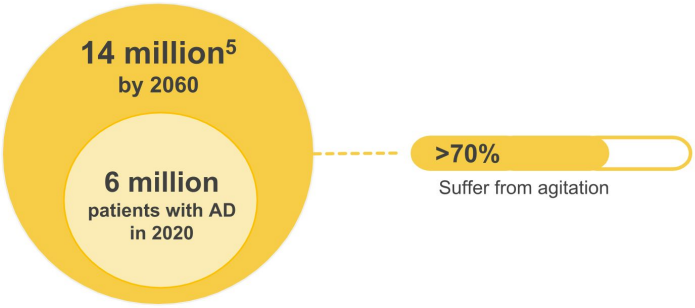
(dextromethorphan-bupropion)

a new approach to treating multiple CNS conditions

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

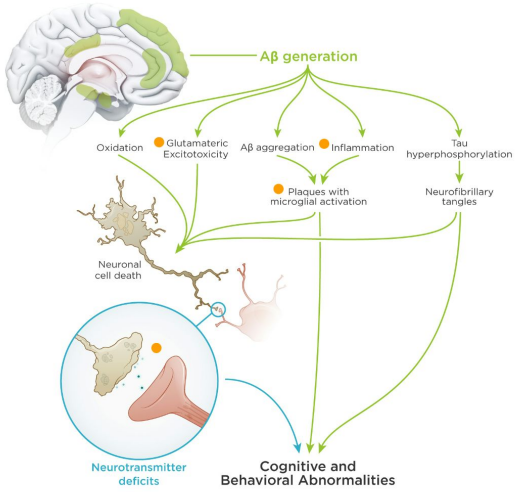
AXS-05

- 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[3,4]
- High unmet medical need for safe and effective options
- AXS-05 pharmacology relevant to implicated disease pathways

Brain regions implicated in AD agitation[6]



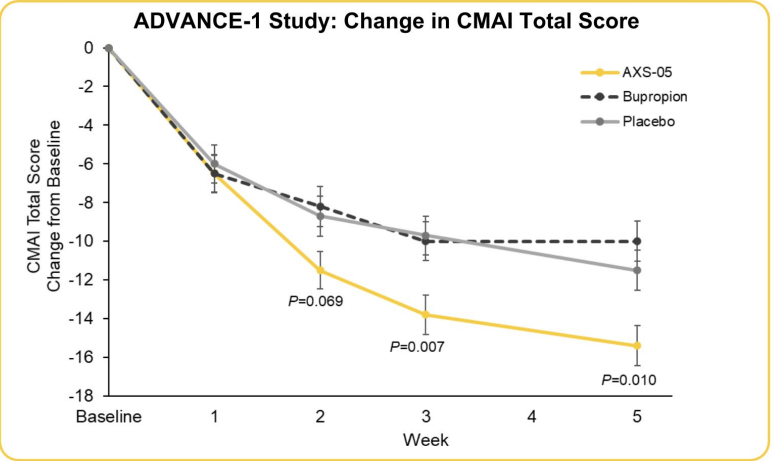
● **AXS-05 pharmacological actions[7,8]**

1. Alzheimer's Association. Alzheimer's Dement. 2020;16(3):391+. 2. Tractenberg R, et al. J Neuropsychiatry Clin Neurosci. 2002;14:11-18. 3. Porsteinsson AP, et al. Expert Opin Pharmacother. 2017; 18:6, 611-620. 4. Rabins PV et al. Alzheimer's Dement. 2013; 9:204-207. 5. Alzheimers Dement. 2021 Mar;17(3):327-406. 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

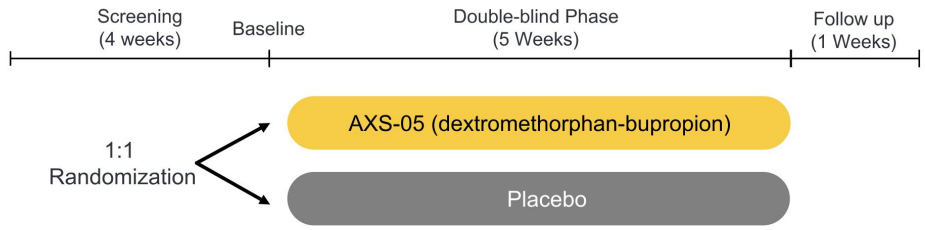
- Primary endpoints met in two controlled trials:
  - ADVANCE-1 Phase 2/3, parallel group trial
  - ACCORD Phase 3, randomized withdrawal trial
- ADVANCE-2 Phase 3 trial ongoing, with expected completion by 1H 2024
- FDA Breakthrough Therapy Designation received



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:** 1H 2024

Smoking Cessation

AXS-05

Fast Facts

- Smoking is single largest cause of preventable death in the U.S.[1]
- 70% of smokers want to quit[2]
- Only 3-5% who attempt to quit without assistance are successful for 6-12 months[2]

AXS-05 Key Updates

- 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 4Q 2023

Abbreviations: NMDA = N-methyl D-aspartate

1. 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

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AXS-07

(MoSEIC™ meloxicam-rizatriptan)

a multi-mechanistic approach to treating migraine

Migraine:
Significant Need for More Efficacious Treatments

AXS-07

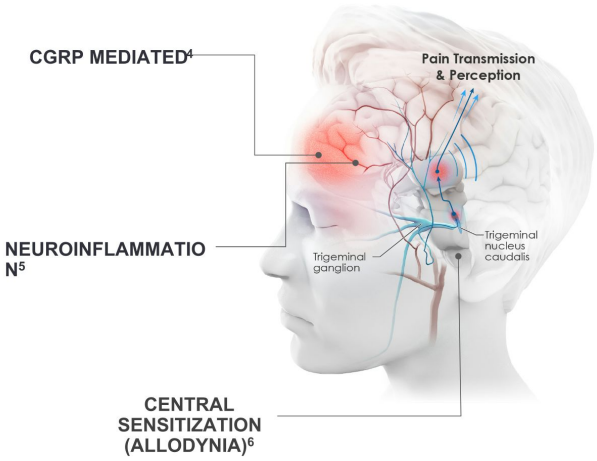
- Unmet need for improved efficacy in migraine: disability on par with dementia, quadriplegia, active psychosis[1,2]:

>37 million in the U.S. suffer from migraine

>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[3]



- 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. 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.
4. Geppetti et al. J Headache Pain. 2012; 13:103–111. 5. 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. 6. Change measured in migraine patient. Data from Burstein et al. Brain. 2000;123 (Pt 8):1703-9.

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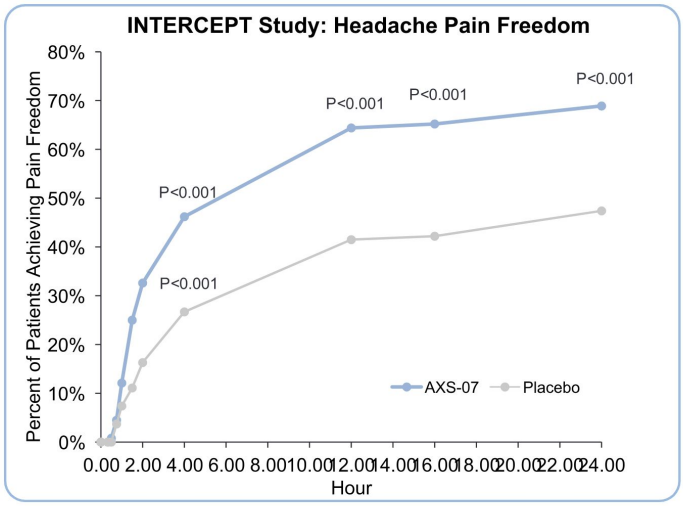
Migraine:
Clinical Results and Program Status

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 second half of 2023



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AXS-12
(reboxetine)

a potentially new treatment option for narcolepsy

Narcolepsy

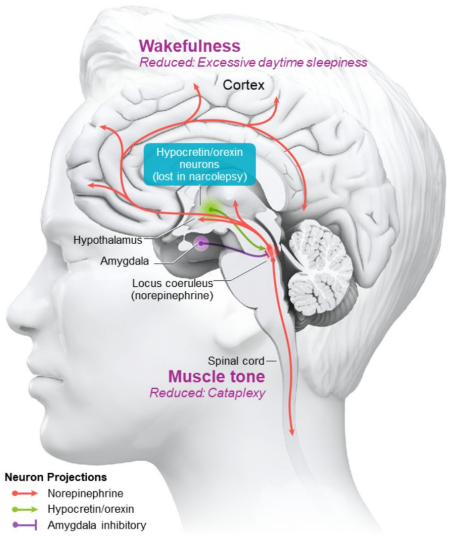
AXS-12

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

185,000
patients in the U.S.

70%
suffer from cataplexy

- Loss of excitatory hypocretin/orexin neurons in the brain lead to dysregulation of norepinephrine resulting[1]:
  - Loss of muscle tone while awake (cataplexy)
  - Decreased wakefulness during the day (EDS)
- AXS-12 (reboxetine) improves regulation of norepinephrine signaling in narcolepsy

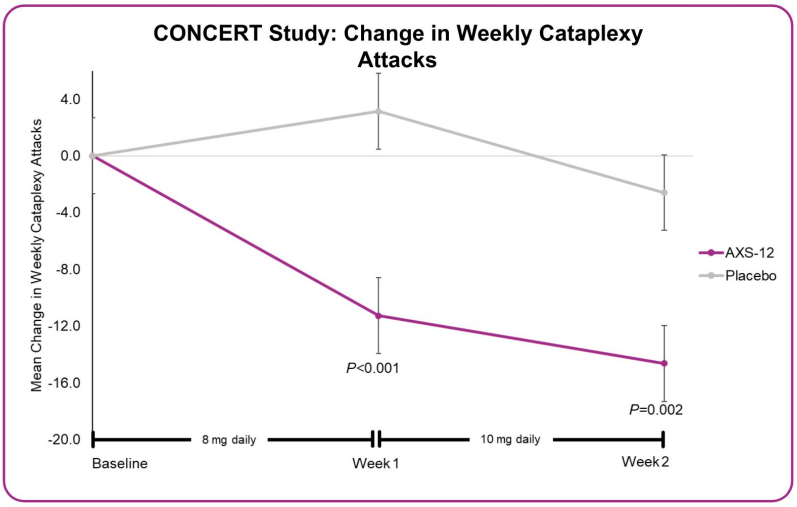


1. Szabo ST, et al. *Sleep Medicine Reviews* 43 (2019) 23-36

Narcolepsy:
Clinical Results and Program Status

AXS-12

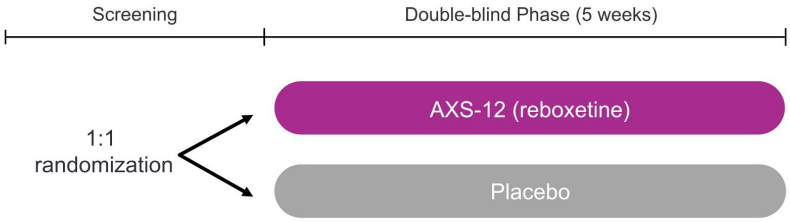
- Positive Phase 2 results with AXS-12
  - Significant reduction in cataplexy attacks
  - Significant improvement in excessive daytime sleepiness
  - Significant improvement in cognitive function
- SYMPHONY Phase 3 trial ongoing, with completion of enrollment expected in 3Q 2023



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.



- **Objective:** Evaluate the safety and efficacy of AXS-12 compared to placebo
- **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
- **Completion of Enrollment:** expected in 3Q 2023

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AXS-14
(esreboxetine)

a potentially new treatment option for fibromyalgia

Fibromyalgia

AXS-14

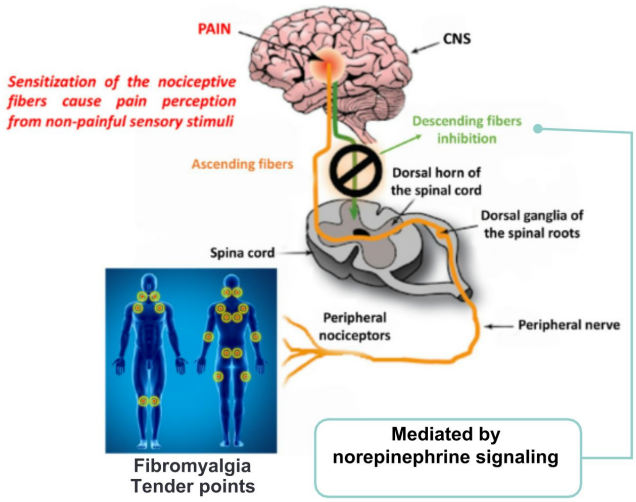
- Debilitating, chronic, CNS disorder characterized by widespread pain, fatigue, disturbed sleep, depression, and cognitive impairment; ~90% affected are women

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]



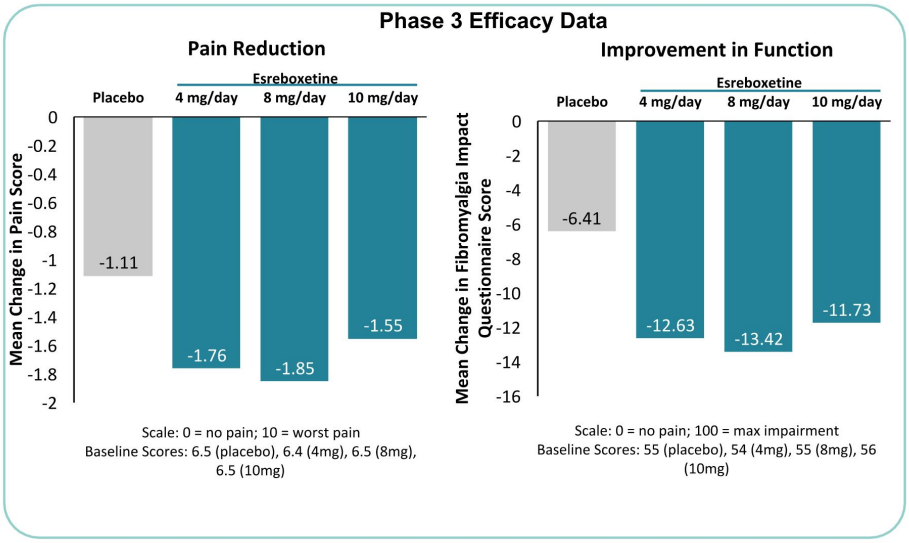
Fibromyalgia
Tender points

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 second half 2023



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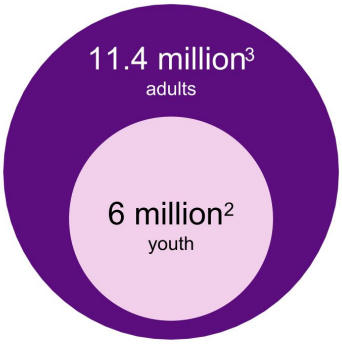
Solriamfetol

a potentially differentiated option for the treatment of ADHD

Attention Deficit Hyperactivity Disorder

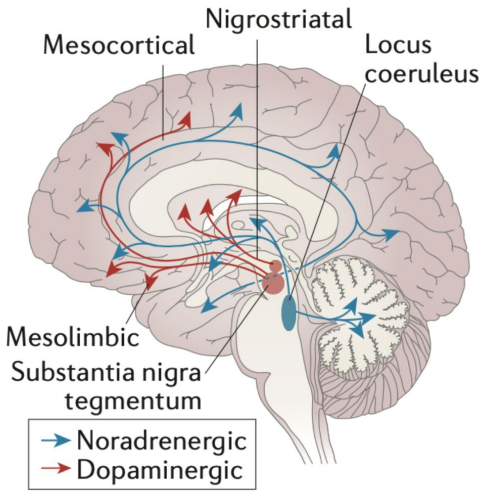
solriamfetol

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



17.4 million
in the U.S. with ADHD

Neurotransmitter Pathways Implicated in ADHD[1]



- Associated with significant impairment in social, academic, and occupational functioning or development
- Solriamfetol targets neurotransmitter pathways in the brain implicated in ADHD[1]

1. Faraone, S. V. et al. *Attention-deficit/hyperactivity disorder. Nat. Rev. Dis. Primers.* 2015 2. Bitsko RH, et al. Mental health surveillance among children—United States, 2013–2019. MMWR Suppl. 2022;71(2):1-48. 3. 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.

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CNS portfolio with potential to generate total U.S. peak sales of up to $11.5B

Program		Launch Year	Est. Peak U.S. Sales	Key Highlights
Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets 45mg/105mg	MDD	2022	$1- $3B	• Rapid and substantial efficacy, as early as week[1] • First oral antidepressant with a new MOA in 60 years[1-4]
SUNOSI (solriamfetol) (R) 75, 150 mg tablets	EDS associated with OSA and narcolepsy	2022	$300 - $500M	• 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
AXS-05	Smoking Cessation	TBD	$0.5 - $1B	• Represents a potentially new mechanism of action for smoking cessation • Planned Phase 2/3 trial initiation in 4Q 2023
AXS-07	Migraine	2024 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	ADHD	TBD	$1B	• Planned Phase 3 trial initiation 2Q 2023

Auvelity and Sunosi refs are on Slides 8 and 9, respectively. 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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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 2040 / allowed claims out to 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 2040; Multiple pending • Proprietary drug substance and drug product formulation
AXS-05	• >120 Issued U.S. Patents and >70 Issued O-U.S. Patents Claims extending to at least 2034-43; Multiple pending • Proprietary drug product formulation
AXS-07	• >85 Issued U.S. Patents and >103 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 • 5 issued U.S. patents • 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 March 31, 2023)	**$ 247 M**
Debt (Face Value): (as of March 31, 2023)	**$ 150 M**
Market Cap: (as of May 8, 2023)	**$ 3.3 B**
Shares Outstanding: (as of March 31, 2023)	**43.5 M**
Options, RSUs, and Warrants Outstanding[1]:	**8.9 M**

[1] Consists of 8.04 M options, 0.79 M RSUs, and 0.070 M warrants

- Cash, along with remaining committed capital from the $350 million term loan facility, is sufficient to fund anticipated operations into 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

Lori Englebert, MBA
EVP, Commercial & Business Dev.

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

Herriot Tabuteau, MD
Chairman

Anticipated Upcoming Clinical and Regulatory Milestones

Regulatory and Commercial

AXS-07	Migraine NDA, planned resubmission – 2H 2023
AXS-14	Fibromyalgia NDA, planned submission – 4Q 2023

Clinical Trial Readouts

AXS-12	SYMPHONY Phase 3 trial in narcolepsy, completion of enrollment – 3Q 2023
AXS-05	ADVANCE-2 Phase 3 trial in Alzheimer's disease agitation, topline data – 1H 2024

Clinical Trial Initiations

solriamfetol	Phase 3 trial in ADHD, initiation – 2Q 2023
AXS-05	Phase 2/3 trial in smoking cessation, initiation – 4Q 2023

Rapidly Growing, CNS-Focused Biopharma

2 Marketed Products

5 Late-stage Product Candidates

6 New Target Indications

140 Million Potential Patients Targeted

thank you

for more information, please contact:

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