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

July 13, 2016
Date of report (Date of earliest event reported)

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.)

25 Broadway, 9th Floor **New York, New York**	**10004**
(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 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))

Item 7.01. Regulation FD Disclosure

On July 13, 2016, Herriot Tabuteau, M.D., the Chief Executive Officer of Axsome Therapeutics, Inc. (the "Company"), will present at the Cantor Fitzgerald 2nd Annual Healthcare Conference to provide an overview of the Company's business and late-stage clinical product candidates, AXS-02 and AXS-05. Attached as Exhibit 99.1 to this Current Report on Form 8-K is a copy of the materials to be used in connection with this presentation.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation

SIGNATURES

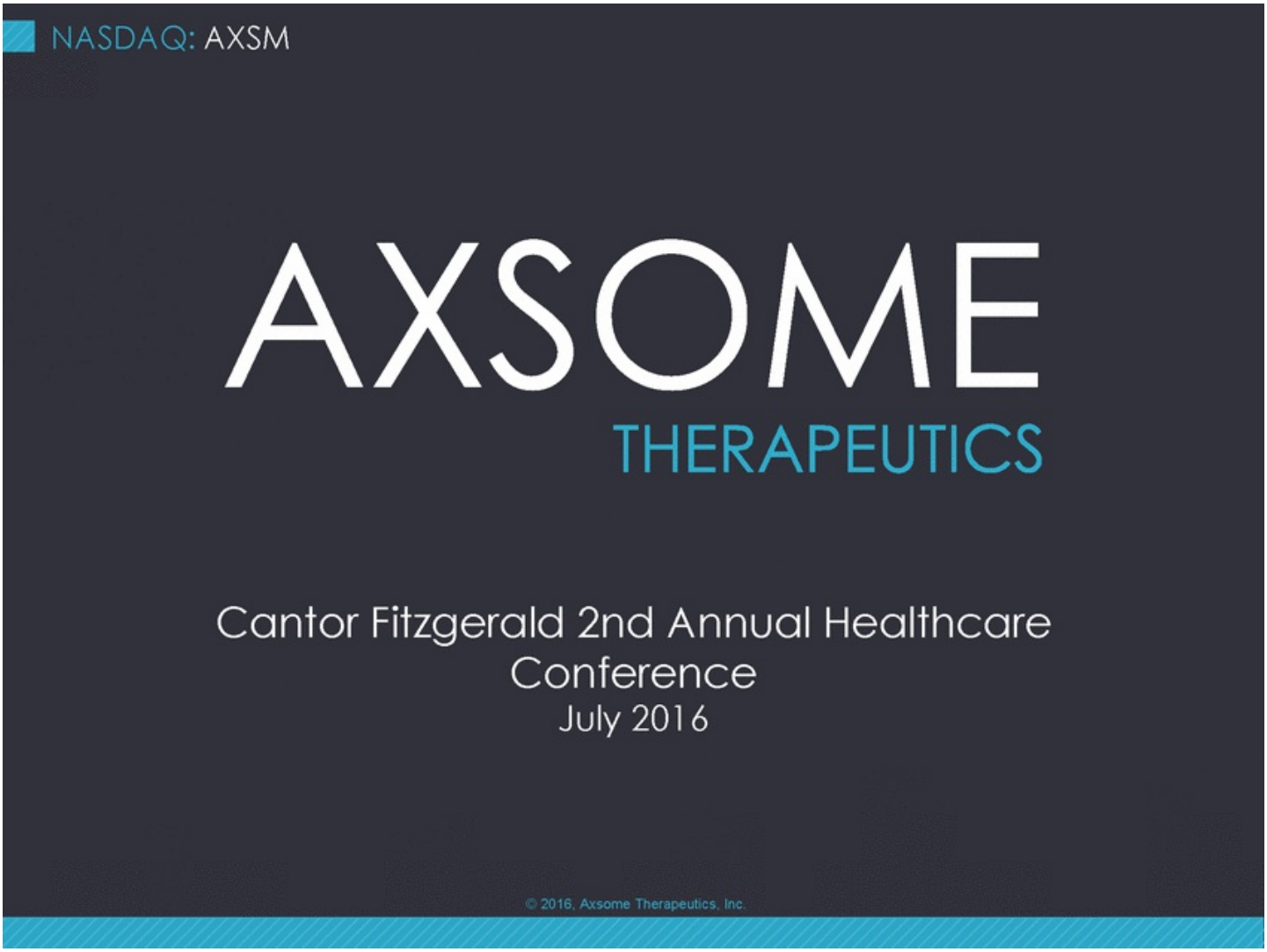
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Axsome Therapeutics, Inc.

Dated: July 13, 2016

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

Exhibit 99.1


NASDAQ: AXSM
AXSOME
THERAPEUTICS
Cantor Fitzgerald 2nd Annual Healthcare Conference
July 2016
© 2016, Axsome Therapeutics, Inc.

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 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 and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the Company's ability to obtain additional capital necessary to fund its operations; the Company's ability to generate revenues in the future; 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; the enforceability of the Company's license agreements; the acceptance by the market of the Company's product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. 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 circumstance.

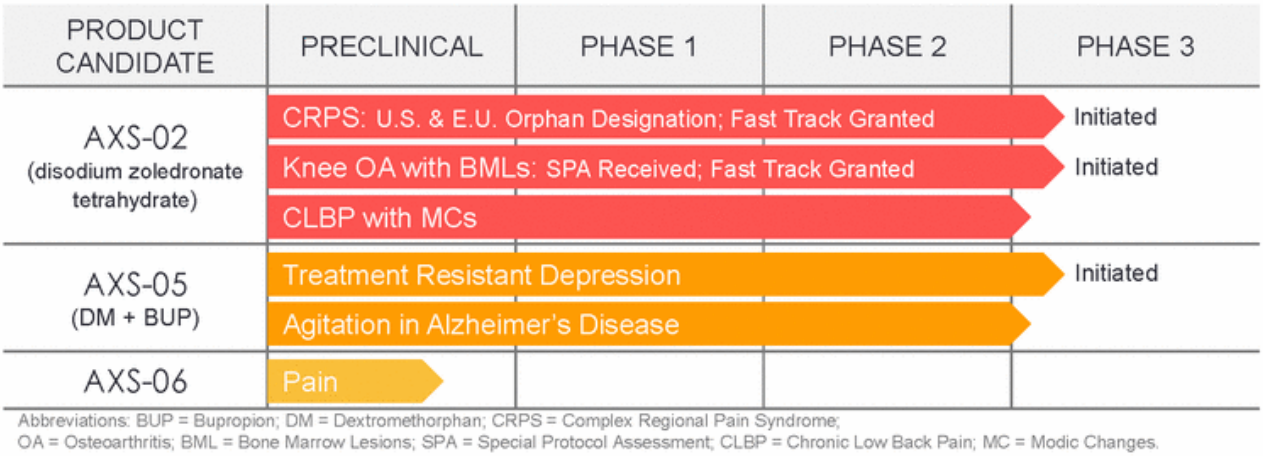
This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we 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.

Developing novel therapies for CNS disorders.

Axsome is addressing growing markets, where current treatment options are limited or inadequate, by leveraging well-characterized compounds to create novel therapeutics to meet unmet medical needs and improve the lives of patients.

Our Candidates and Pipeline

- Two differentiated Phase 3-stage assets targeting significant and growing markets:
  - AXS-02: oral, non-opioid, long-acting, potentially first-in-class therapeutic for chronic pain
  - AXS-05: novel therapeutic combination with multiple mechanisms for CNS disorders
- Phase 3 trials initiated in two indications with AXS-02: CRPS, Knee OA.
- Phase 3 trial in TRD initiated with AXS-05.
- Novel indications, positive proofs of concept.
- Patent protection to 2034.
- Worldwide rights.



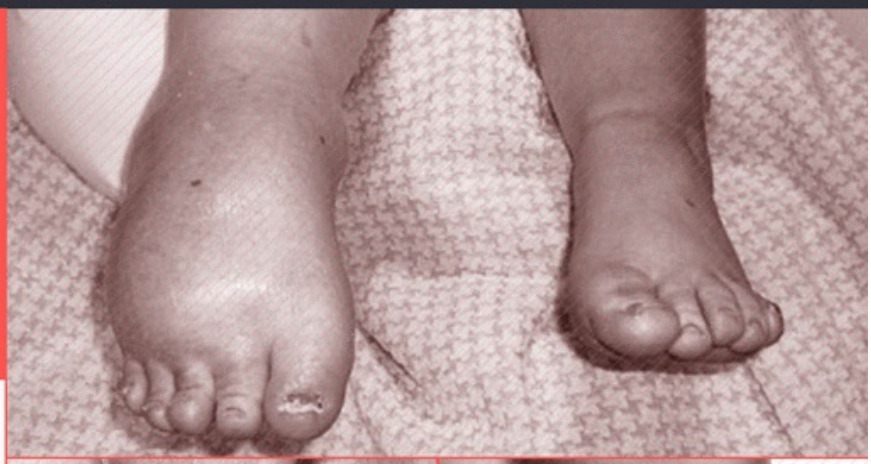
Abbreviations: BUP = Bupropion; DM = Dextromethorphan; CRPS = Complex Regional Pain Syndrome; OA = Osteoarthritis; BML = Bone Marrow Lesions; SPA = Special Protocol Assessment; CLBP = Chronic Low Back Pain; MC = Modic Changes.

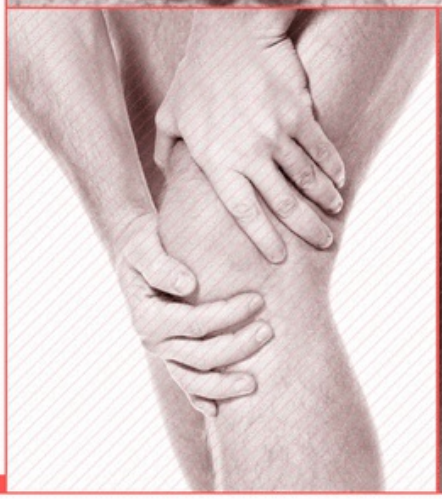
AXS-02

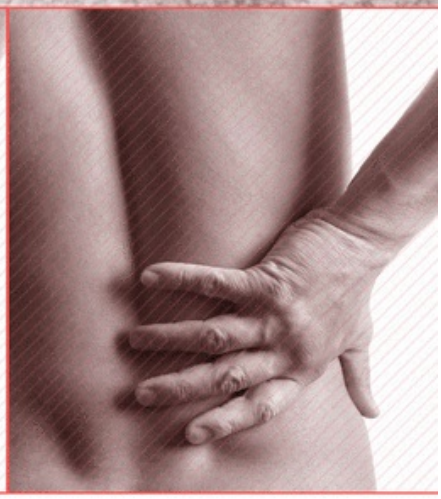
Disodium Zoledronate Tetrahydrate

Novel therapy for chronic pain:

- Complex Regional Pain Syndrome (CRPS)
- Knee Osteoarthritis (OA) with Bone Marrow Lesions (BMLs)
- Chronic Low Back Pain (CLBP) with Modic Changes (MCs)

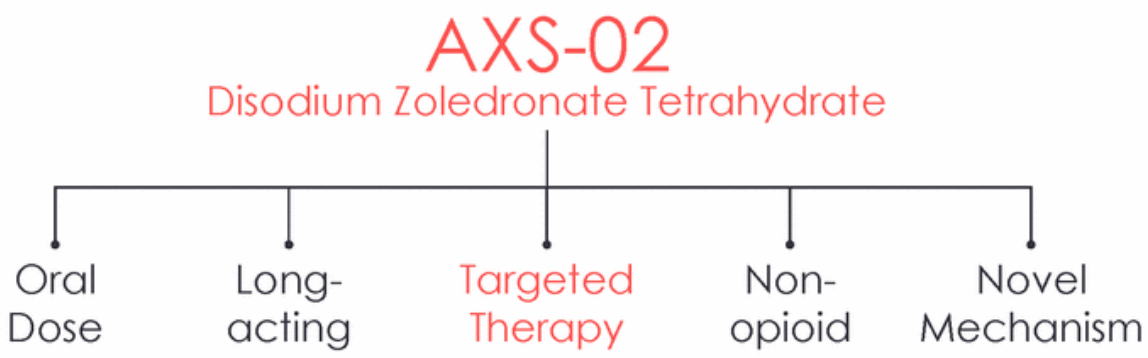






CRPS image source: Voet C, et al. *F1000Reseach.* 2014;3:97.

Chronic Pain:
Differentiated Therapy



IP Overview

- 25 issued patents – protection through 2034.
- Drug delivery, pharmacokinetic, composition of matter, and method of use claims.
- U.S. Orphan Drug Designation (7 years exclusivity).
- E.U. Orphan Medicinal Product Designation (10 years exclusivity, 12 years with PIP).

Chronic Pain:
Therapy via Multiple Mechanisms of Action

AXS-02
Disodium Zoledronate Tetrahydrate

Inhibits bone-resorbing osteoclasts

- ▼Decreased bone resorption.
- ▼Farnesyl pyrophosphate synthase (FPPS).[1]

Downregulates acid-sensing* ion channels

- ▼ASIC1a expression.
- ▼ASIC activation.[2]
- ▼TRPV1 activation.[2,3]

Reduces pro-inflammatory cytokine production

- ▼TNFα production.[4]
- ▼IL-6 production.[5]
- ▼IL-8 production.[6]

Anti-angiogenic

- ▼Angiogenesis.[7]
- ▼c-FOS expression.[2]

* Acid is a well known cause of pain.

1. Green JR, Rogers MJ. *Drug Dev Res*. 2002;55:210-24. 2. Nagae M, et al. *Bone*. 2006;39:1107-15. 3. Abe Y, et al. *J Bone Miner Metab*. 2015;33:125–134. 4. Wolf AM, et al. *Haematologica*. 2006;91:1165-71. 5. Derenne S, et al. *Bone Miner Res*. 1999;14:2048-56. 6. Stathopoulos GT, et al. *Am J Respir Crit Care Med*. 2008;178:50-9. 7. Misso G, et al. *Cancer Biol Ther*. 2012;13:1491-500.

Chronic Pain:
Lead Indications and Market Potential

Complex Regional Pain Syndrome (CRPS)

- Localized bone resorption.[1,2]
- Increased pro-inflammatory cytokines.[3]

80,000 new cases per year in the U.S.[4]

Knee Osteoarthritis (OA) with Bone Marrow Lesions (BMLs)

- BMLs are associated with pain in knee OA.[5]
- BMLs: Increased bone turnover; Decreased bone mineral density.[6,7]

7M patients in the U.S.[11-14,16]

Chronic Low Back Pain (CLBP) with Modic Changes (MCs)

- MCs are associated with low back pain.[8]
- MCs: Increased bone turnover, pro-inflammatory cytokines, vascular density.[9,10]

1.6M patients in the U.S.[11,12,15,16]

1. Capello ZJ, et al. *J Hand Surg Am*. 2012;37:288-296. **2.** Krämer HH, et al. *Pain*. 2014;155:889–895. **3.** Parkitny L, et al. *Neurology*. 2013;80:106-117. **4.** Moseley GL, et al. *J Pain*. 2014;15:16-23. **5.** Driban JB, et al. *Arthritis Res Ther*. 2013;15:R112. **6.** Hunter DJ, et al. *Arthritis Res Ther*. 2009;11:R11. **7.** Kazakia GJ, et al. *Osteoarthritis Cartilage*. 2013;21:94-101. **8.** Zhang Y, et al. *Eur Spine J*. 2008;17:1289-1299. **9.** Järvinen J, et al. *Spine: ISSLS Society Meeting Abstracts*. Oct. 2011(vol suppl, abstract GP127). **10.** Rahme R, Moussa R. *Am J Neuroradiol*. 2008;29:838–42. **11.** Lawrence RC, et al. *Arthritis Rheum*. 2008;58:26-35. **12.** Zhang Y, Jordan. *JM Clin Geriatr Med*. 2010;26:355–69. **13.** Tanamas SK, et al. *Rheumatology*. 2010;49:2413–19. **14.** Guermazi A, et al. *BMJ*. 2012;345:e5339. **15.** Jensen OK, et al. *Spine J*. Feb. 14, 2014;pii:S1529-9430(14)00214-9. **16.** U.S. Census Bureau, Population April 1, 2010 to July 1, 2013.

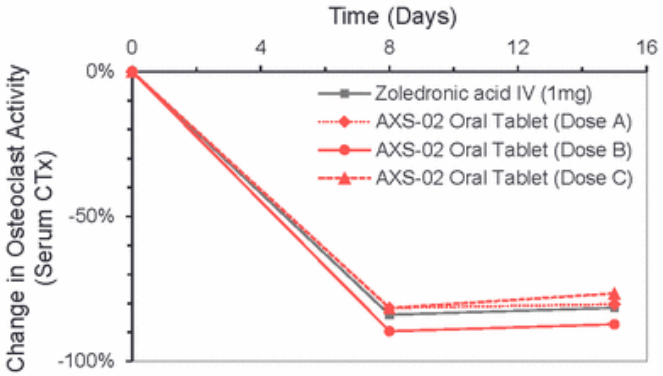
Chronic Pain:
Phase 1 Results and Oral Preference

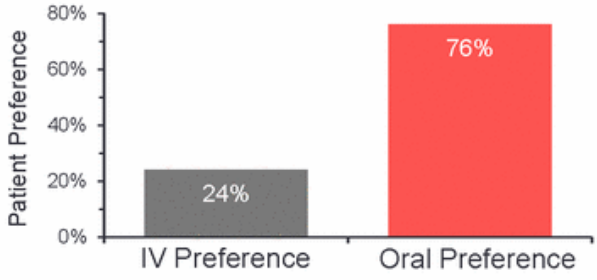
Phase 1 Summary

- Oral administration of AXS-02 resulted in rapid absorption of zoledronic acid.
- Significant plasma levels attained.
- Robust pharmacodynamics (PD) effects.
- PD relevant to targeted pain indications.
- AXS-02 was well tolerated.

Patient-stated Preference for Oral vs IV[1,2]

- Assessed in 6,097 patients treated 3 years with oral or IV bisphosphonates:
  - Oral: clodronate or ibandronate, daily
  - IV: zoledronic acid, monthly, then every 6 months
- Oral preference at randomization and therapy completion: 76%, 73% respectively.
- Potential safety advantage.

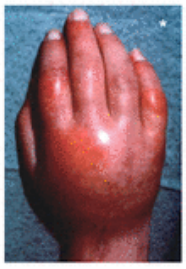




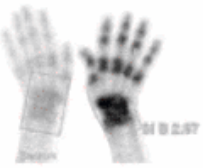
1. Gralow, et al. *J Clin Oncol.* 33, 2015 (suppl; abstr 503).
2. Gralow, et al. *J Clin Oncol.* 32.5, 2014 (suppl; abstr 558).

Chronic Pain:
CRPS Overview

- Severe, continuous, disabling pain in a limb:
  - Sensation described as burning, stabbing, grinding, throbbing
- Localized bone resorption,[1,2] increased pro-inflammatory cytokines.[3]
- Common pain meds (e.g., NSAIDs, opioids, gabapentin) are considered ineffective.[4]
- No approved drug = high unmet need.
- Phase 3 initiated – interim efficacy analysis anticipated around year-end 2016.
- Issued U.S. patents: protection into 2034 – uses of oral zoledronic acid for CRPS.



Bone scan: hands**



Dorsum

Orphan Disease

80,000 new cases per year in the U.S.[5]

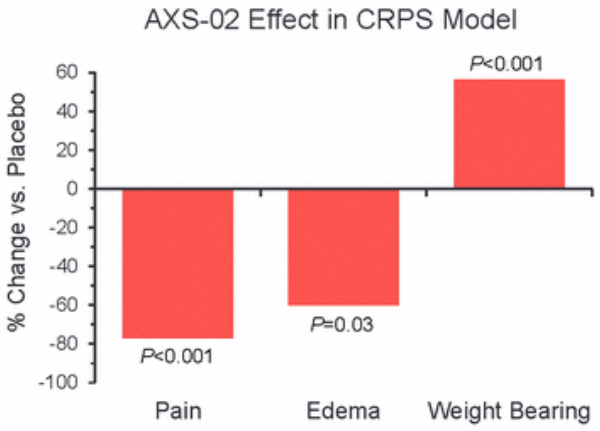
PRODUCT CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
AXS-02	CRPS: U.S. & E.U. Orphan Designation; Fast Track Granted			Initiated

* Goebel A, Complex regional pain syndrome in adult. *Rheumatology (Oxford)*. 2011;50(10):1739-1750, by permission of Oxford University Press.
** Sampath S, et al. *Indian J Nucl Med*.2013;Jan-Mar;28(1):11–16.
1. Capello ZJ, et al. *J Hand Surg Am*. 2012;37:288-296. 2. Krämer HH, et al. *Pain*. 2014;155:889–895.
3. Parkitny L, et al. *Neurology*. 2013;80:106-117. 4. Bruehl S. *Anesthesiology*. 2010;113:713-725. 5. Moseley GL, et al. *J Pain*. 2014;15:16-23.

Chronic Pain:
CRPS Preclinical and Clinical Rationale

Preclinical:

- Well validated CRPS model replicates: Inciting trauma, clinical presentation, natural history, and pathologic changes.
- Oral administration of AXS-02: Significant pain and edema reduction; improved weight bearing.



Clinical:

- Clinical Trials: 5 randomized, double-blind, placebo-controlled trials, with 4 different bisphosphonates.[1-5]
- Pain reduction: Mean 54% reduction in VAS pain scores (range 33% to 66%) during double-blind phases.
- Statistical significance: $p<0.0001$, $p=0.001$, $p<0.01$, $p<0.05$, $p=0.048$.
- Potency of bisphosphonates: 1/1000 to 1/20 potency of AXS-02.[6]

1. Adami S. et al. *Ann Rheum Dis.* 1997;56:201-204. **2.** Varenna M. et al. *J Rheumatol.* 2000;27:1477-1483. **3.** Robinson JN, et al. *Pain Med.* 2004;5:276-280. **4.** Manicourt DH, et al. *Arthritis Rheum.* 2004;50:3690-3697. **5.** Varenna M. et al. *Rheumatology (Oxford).* 2013;52:534-542. **6.** Green JR, Rogers MJ. *Drug Dev Res.* 2002;55:210-224.

Chronic Pain:
CRPS Phase 3 Design

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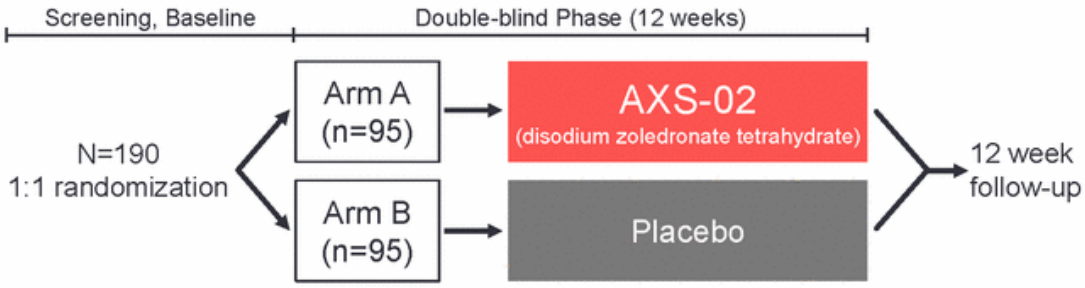
CRPS Treatment Evaluation 1 Study

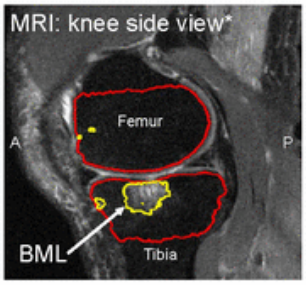
A Phase 3 trial to assess the efficacy and safety of AXS-02 in the treatment of pain associated with CRPS type 1.



- **Primary Endpoint:** Change in pain intensity from baseline to week 12, measured using the 0-10 Numerical Rating Scale (NRS).
- **Key Inclusion Criteria:**
  - Male or female ≥18 years old, recently diagnosed with CRPS type 1
  - Average NRS pain intensity score of ≥5
- **Dosage:** Once per week for six weeks; no drug for last six weeks.
- **Interim analysis:** When half of patients have completed double-blind phase.

Chronic Pain:
Knee OA with BMLs Overview

- Bone marrow lesions (BMLs) on MRI are associated with pain in knee osteoarthritis (OA).[1]
- BMLs are regions of increased bone turnover, and reduced mineral density.[2,3]
- Zoledronic acid inhibits bone resorption and increases mineral density.
- Phase 2 results: Zoledronic acid reduced pain and BML size in patients with knee osteoarthritis.
- Phase 3 initiated under Special Protocol Assessment (SPA).
- Issued U.S. patents: protection into 2034 – uses of zoledronic acid for knee pain.



7M patients in the U.S.[4-9]

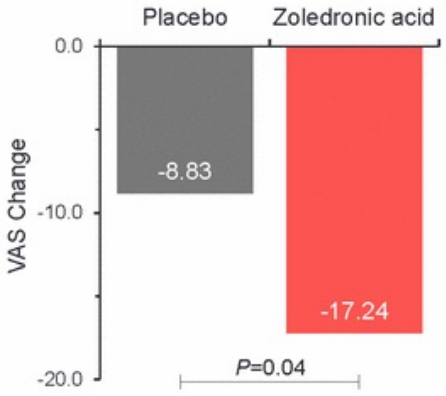
PRODUCT CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
AXS-02	Knee OA with BMLs: SPA Received; Fast Track Granted			Initiated

* MRI showing BML in medial tibia from Driban, et al. *Arthritis Res Ther*. 2013;15:R112.

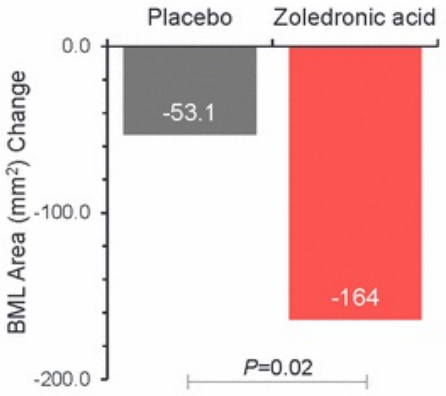
1. Driban JB, et al. *Arthritis Res Ther*. 2013;15:R112. **2.** Hunter DJ, et al. *Arthritis Res Ther*. 2009;11:R11. **3.** Kazakia GJ, et al. *Osteoarthritis Cartilage*. 2013;21:94-101. **4.** Lawrence RC, et al. *Arthritis Rheum*. 2008;58:26-35. **5.** Zhang Y, Jordan. *JM Clin Geriatr Med*. 2010;26:355–69. **6.** Tanamas SK, et al. *Rheumatology*. 2010;49:2413–19. **7.** Guermazi A, et al. *BMJ*. 2012;345:e5339. **8.** Jensen OK, et al. *Spine J*. Feb. 14, 2014;pii:S1529-9430(14)00214-9. **9.** U.S. Census Bureau, Population April 1, 2010 to July 1, 2013.

Chronic Pain:
Knee OA with BMLs Phase 2 Results

Change in Pain Intensity at 6 Mos

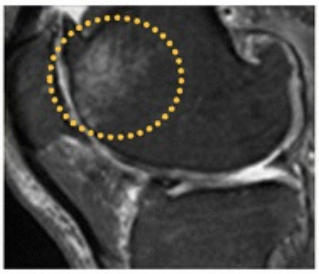


Change in BML Size at 6 Mos

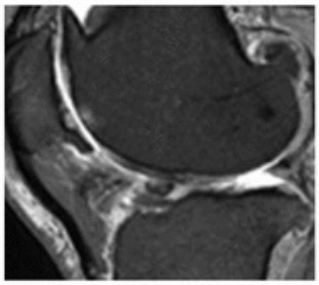


BML at Baseline and Post Zoledronic Acid Treatment

Baseline



6 Months Post Treatment



- Randomized, double-blind, placebo-controlled trial (N=59):
  - Placebo (n=28), zoledronic acid IV (n=31)
- Primary endpoints:
  - Pain intensity measured using 100-mm VAS
  - BML size on MRI

Laslett LL, et al. *Ann Rheum Dis*. 2012;71:1322-8.
MRI images courtesy of Prof. Graeme Jones.

Chronic Pain:
Knee OA with BMLs Phase 3 Design

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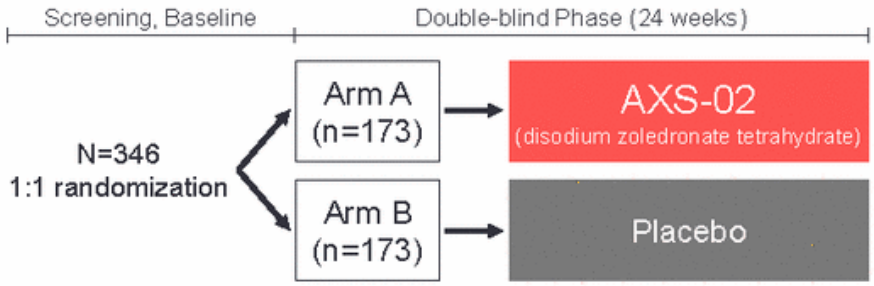
Clinical Knee OA Symptom Treatment 1 Study

A Phase 3 trial to assess the efficacy and safety of AXS-02 in the treatment of pain of knee OA associated with BMLs.

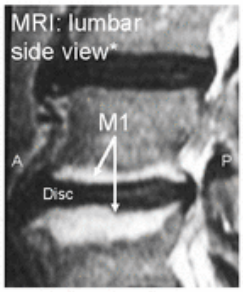
Special Protocol Assessment (SPA) received



- **Primary Endpoint:** Change in pain intensity from baseline to week 24, measured using the 0-10 Numerical Rating Scale (NRS).
- **Key Inclusion Criteria:**
  - Male at least 50 years of age or postmenopausal female, with knee OA and BMLs
  - Moderate or worse knee pain
- **Dosage:** Once per week for six weeks; no drug for remainder of double-blind phase.

Chronic Pain:
CLBP with MCs Overview

- Modic changes (MCs) type 1 (M1) on MRI are associated with chronic low back pain (CLBP).[1]
- Increased bone turnover on bone scan is seen in M1 lesions.[2]
- Increased pro-inflammatory cytokines, and vascular density seen in M1 lesions.[3]
- Zoledronic acid reduces bone turnover, suppresses the production of inflammatory mediators, and is anti-angiogenic.
- Phase 2 results: Zoledronic acid reduced pain in patients with CLBP.
- Phase 3 initiation planned.
- Issued U.S. patents: protection into 2034 – uses of oral zoledronic acid for low back pain.



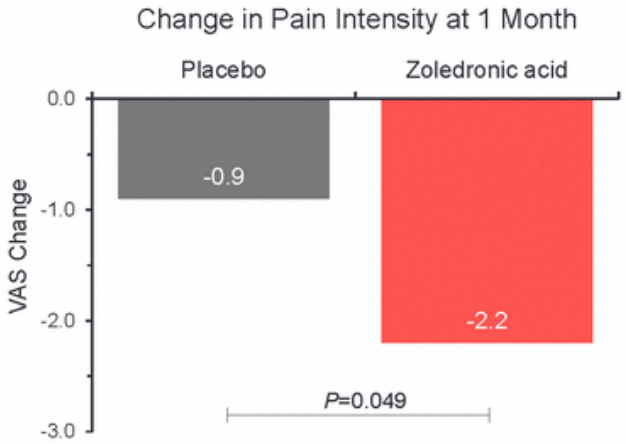
1.6M patients in the U.S.[4-7]

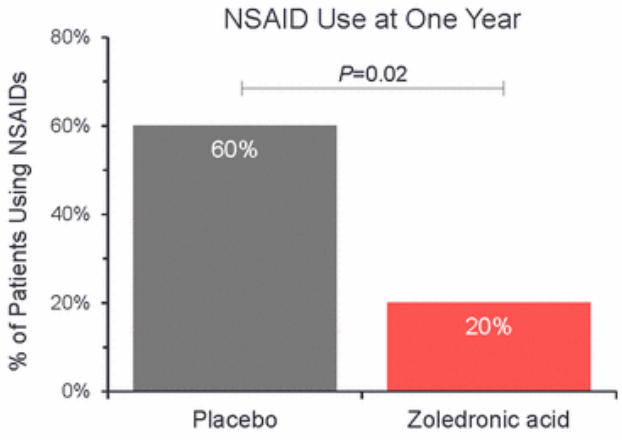
PRODUCT CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
AXS-02	CLBP with MCs			

* MRI showing modic type 1 lesions from Luoma K. et al. *European Congress of Radiology (ECR)*. 2014;Poster B-0458.

1. Zhang Y, et al. *Eur Spine J*. 2008;17:1289-1299. **2.** Järvinen J, et al. *Spine: ISSLS Society Meeting Abstracts*. Oct. 2011;Volume Suppl, Abstract GP127. **3.** Rahme R, Moussa R. *Am J Neuroradiol*. 2008;29:838–42. **4.** Lawrence RC, et al. *Arthritis Rheum*. 2008;58:26-35. **5.** Zhang Y, Jordan. *JM Clin Geriatr Med*. 2010;26:355–69. **6.** Jensen OK, et al. *Spine J*. Feb. 14, 2014;pii:S1529-9430(14)00214-9. **7.** U.S. Census Bureau, Population April 1, 2010 to July 1, 2013.

Chronic Pain:
CLBP with MCs Phase 2 Results





- Randomized, double-blind, placebo-controlled trial (N=40):
  - Placebo (n=20), zoledronic acid IV (n=20)
- Primary endpoint: Pain intensity measured using 10-cm VAS.

Axsome data on file.

AXS-05

Dextromethorphan (DM) + Bupropion (BUP)

Novel therapy for CNS disorders:

- Treatment Resistant Depression (TRD)
- Agitation in Alzheimer's Disease (AD)

CNS Disorders:
Mechanisms of Action

	Pharmacodynamic Synergy		
Mechanism of Action	DM	BUP	AXS-05 DM+BUP
NMDA Receptor Antagonist	✓		✓
Sigma-1R Agonist	✓		✓
Norepinephrine Reuptake Inhibitor	✓	✓	✓
Serotonin Reuptake Inhibitor	✓		✓
Dopamine Reuptake Inhibitor		✓	✓
Nicotinic ACh Receptor Antagonist		✓	✓

DM = Dextromethorphan; BUP = Bupropion. ✓Present

CNS Disorders:
Mechanisms of Action and Relevant Indications

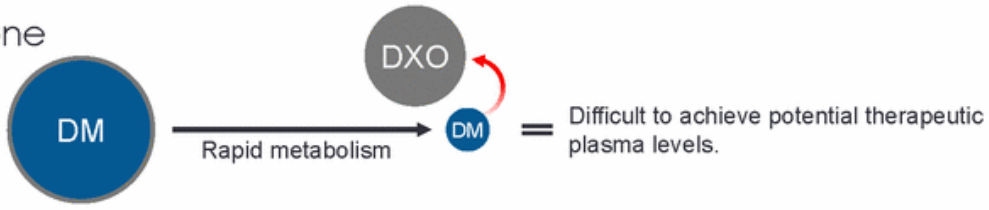
Mechanism of Action	Pharmacodynamic Synergy: DM	BUP	AXS-05 DM+BUP	Relevant Indications[1]: ADHD	Anxiety	Alzheimer's	Depression	Fibromyalgia	OCD	Pain	Smoking cessation	Related Agents[2]
NMDA Receptor Antagonist	✓		✓			■	■			■		• Ketamine • Memantine (Namenda®)
Sigma-1R Agonist	✓		✓			■	■		■			• Fluvoxamine (Luvox®) • Donepezil (Aricept®)
Norepinephrine Reuptake Inhibitor	✓	✓	✓				■	■		■		• Duloxetine (Cymbalta®) • Venlafaxine (Effexor®)
Serotonin Reuptake Inhibitor	✓		✓		■		■		■			• Escitalopram (Lexapro®) • Fluoxetine (Prozac®) • Sertraline (Zoloft®)
Dopamine Reuptake Inhibitor		✓	✓	■			■				■	• Bupropion (Wellbutrin®)
Nicotinic ACh Receptor Antagonist		✓	✓	■			■				■	• Bupropion (Wellbutrin®)

DM = Dextromethorphan; BUP = Bupropion. ✓ Present ■ Relevant

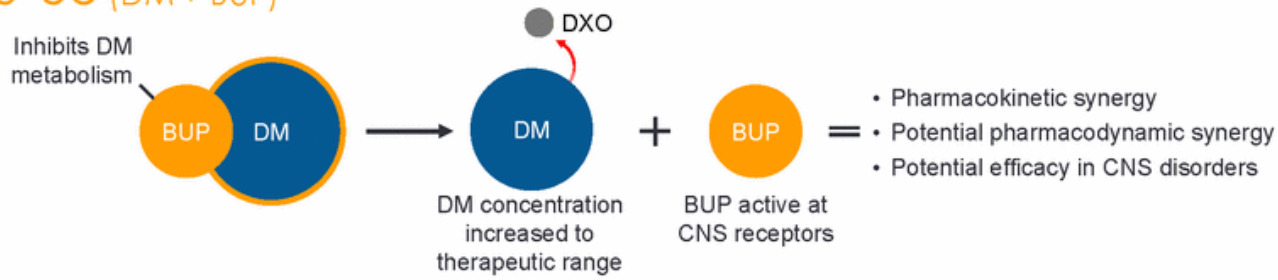
1. Indications listed are associated with the mechanism of action and are not related to either DM or BUP, unless specifically noted. 2. Agents do not contain DM or BUP, unless specifically noted.

CNS Disorders:
Novel Therapy for CNS Disorders

DM Alone



AXS-05 (DM + BUP)



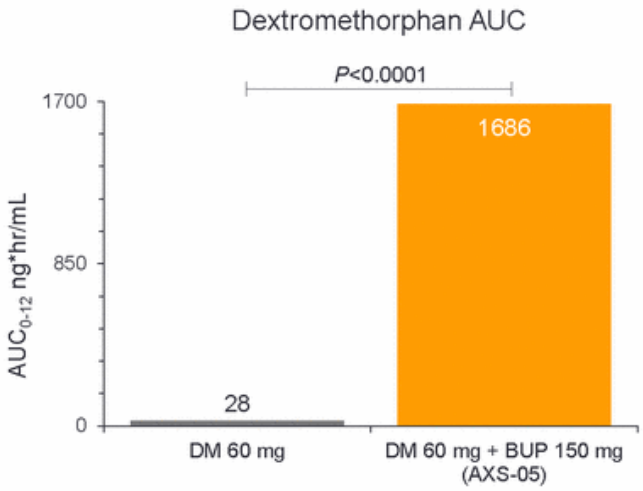
DM = Dextromethorphan; DXO = Dextrorphan; BUP = Bupropion.

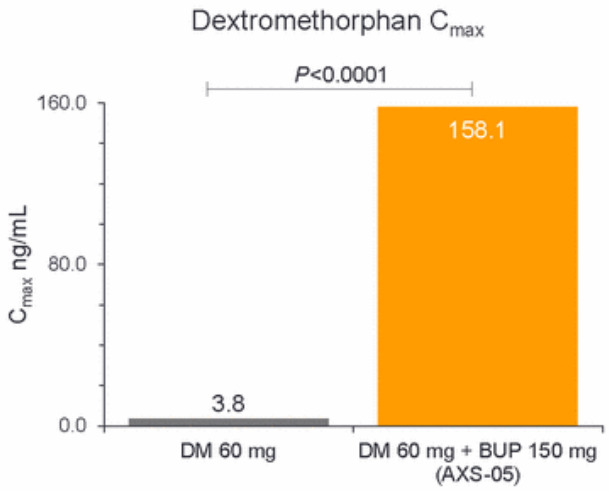
- Two Phase 1 trials with AXS-05 completed:
  - Significant increase in DM plasma levels.
- Phase 3 in TRD initiated.

IP Overview

- 8 issued patents – protection through 2034.

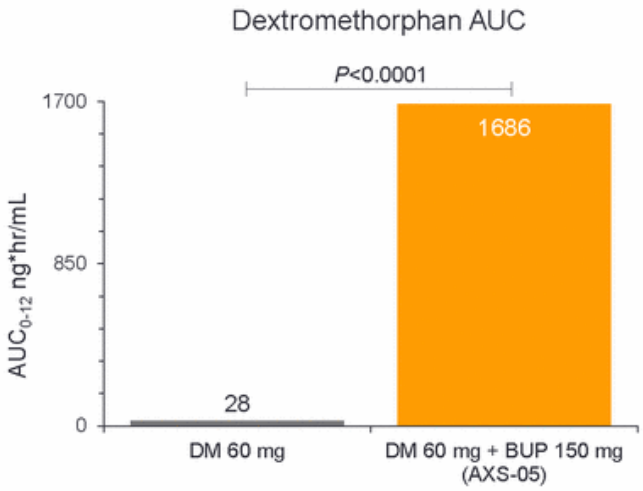
CNS Disorders:
PH 1 Results

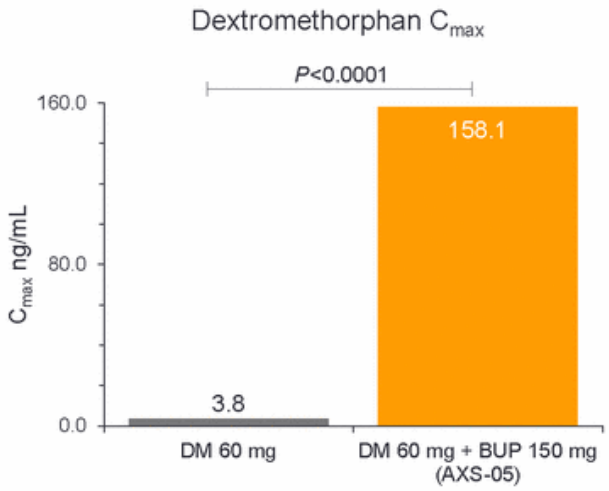




Axsome data on file.
†DM, Dextromethorphan; BUP, Bupropion.

CNS Disorders:
PH 1 Results





Dose†	AUC_{0-12} ng*hr/mL
DM 20 mg + Q 10 mg	525
DM 30 mg + Q 10 mg	883

Dose†	C_{max} ng/mL
DM 20 mg + Q 10 mg	53
DM 30 mg + Q 10 mg	85

Axsome data on file.
† Nuedexta® NDA 021879, FDA Clinical Pharmacology Review.
DM, Dextromethorphan; Q, Quinidine; BUP, Bupropion.

CNS Disorders:
TRD Overview

- Major Depressive Disorder (MDD) is a leading cause of disease burden in the US.[4]
- 63% and 44% of MDD patients have inadequate response to initial therapy and second line therapy, respectively.[2]
- Only 1 approved drug for TRD = unmet medical need.
- AXS-05 combines the MOA of 4 distinct anti-depressant drug classes into one novel oral therapeutic.
- DM antidepressant effects demonstrated preclinically and clinically.
- Phase 3 initiated.

3M patients in the U.S.[1-3]

PRODUCT CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
AXS-05	Treatment Resistant Depression			Initiated

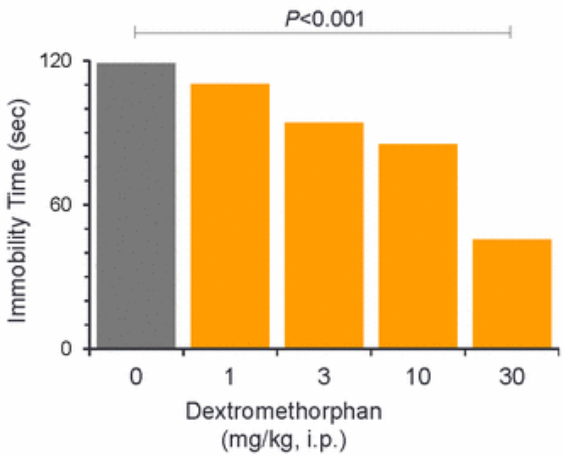
1. Marcus SC, Olfson M. *Arch Gen Psychiatry* 2010;67:1265-1273. 2. Rush AJ, et al. *Am J Psychiatry* 2006;163:1905-1917. 3. U.S. Census Bureau, Population April 1, 2010 to July 1, 2013.
4. Mathers CD, *PLoS Med* 2006; 3(11): e442

CNS Disorders:
TRD Preclinical and Clinical Rationale

Preclinical:

- DM significantly decreased immobility time in a dose-dependent fashion.[1]

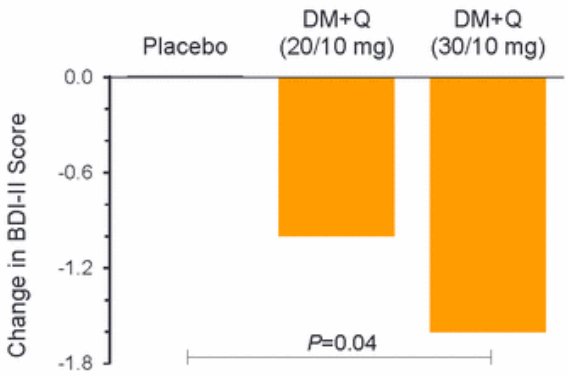
Antidepressant-like Effects of DM in Forced Swim Test in Mice



Clinical:

- DM significantly reduces depressive symptoms in a dose-dependent fashion.[2]

Depressive Symptom Reduction in PBA Patients Treated with DM and Metabolic Inhibitor

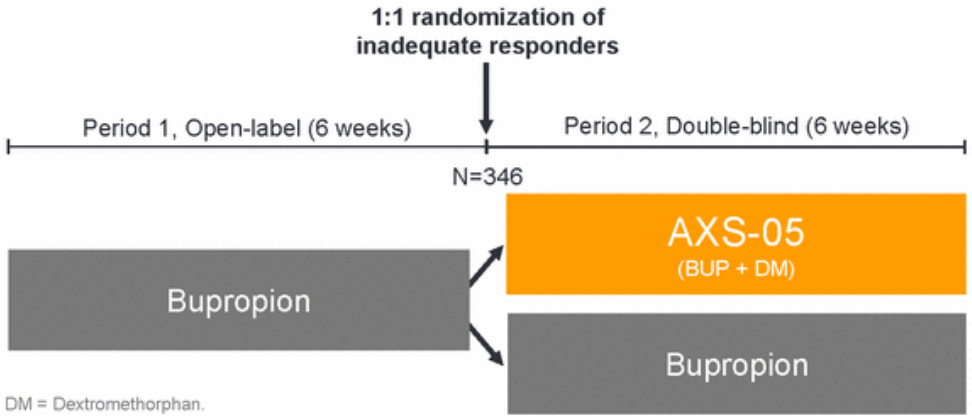


1. Nguyen L, et al. *PLoS One*. 2014;Feb 28;9(2):e89985. 2. Pioro EP, et al. *Ann Neurol*. 2010;68:693-702.

CNS Disorders:
TRD Phase 3 Design

Stride1Study AXS-05

A Phase 3 trial to assess the efficacy and safety of AXS-05 in the treatment of TRD.



BUP = Bupropion; DM = Dextromethorphan.

- **Primary Endpoint:** Change in depression score from randomization to end of study, measured using the Montgomery-Asberg Depression Rating Scale (MADRS).
- **Key Inclusion Criteria:**
  - Male or female 18-65 years old
  - History of inadequate response to 1 or 2 adequate antidepressant treatments
- **Dosage:** Daily for six weeks.

CNS Disorders:
Agitation in AD Overview

- Agitation and aggression seen in approximately 45% of AD patients during 5-year period.[3]
- Characterized by emotional distress, aggressive behaviors, disruptive irritability, disinhibition, and caregiver burden.[4]
- Associated with[4,5]:
  - Accelerated cognitive decline
  - Earlier nursing home placement
  - Increased mortality
- No approved medication = unmet medical need.
- Proof of concept: DM plus metabolic inhibitor reduced agitation in AD patients.
- Successful FDA written guidance received—Phase 2/3 planned.
- IND filing anticipated by end of 2016.

2M patients in the U.S.[1,2]

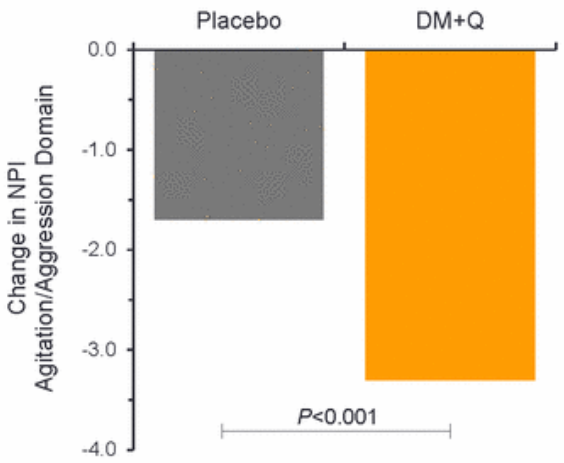
PRODUCT CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
AXS-05	Agitation in Alzheimer's Disease			

1. Ryu, SH, et al. *Am J Geriatr Psychiatry*. 2005;13:976-983. 2. Hebert, LE, et al. *Neurology*. 2013;80:1778-1783. 3. Steinberg M, et al. *Int J Geriatr Psychiatry*. 2008;2:170-177. 4. Antonsdottir IM, et al. *Expert Opin Pharmacother*. 2015;11:1649-1656. 5. Rabins PV et al. Alzheimers Dement. 2013; 9:204-207

CNS Disorders:
Agitation in AD Clinical Rationale

- Randomized, double-blind, placebo-controlled, two-stage trial.
  - Placebo (n=93), 30 mg DM + 10 mg quinidine (Q) (n=125), for stage 1.
- DM+Q treatment reduced agitation/ aggression in AD by 46% vs. 24% for placebo (P<0.001)—primary endpoint.
- Statistically significant improvement in multiple secondary endpoints.
- DM plasma levels achieved with AXS-05 in target therapeutic range.
- Potential for additional contribution from bupropion component of AXS-05.

Change in Agitation/Aggression Scores in AD with DM and Metabolic Inhibitor Quinidine (Q)



Cummings J, et al. *JAMA*. 2015;314:1242-1254.

Our Team

Management

Herriot Tabuteau, MD
Founder & CEO
- Antecip Capital
- HealthCor

Randall Kaye, MD
CMO
- Former CMO of Avanir
- 10 years in medical affairs and marketing at Pfizer

Robert Niecestro, PhD
Head of Regulatory
- 11 approved NDAs
- 45 approved INDs

Board of Directors

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

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

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

Herriot Tabuteau, MD
Chairman

Summary

- Two differentiated Phase 3-stage assets: AXS-02, AXS-05.
- Three Phase 3 trials in three indications initiated and ongoing.
- Additional late-stage trials planned in other indications.
- Targeting unmet medical needs.
- Potential to change current medical practice.
- Mitigated development risk—known chemical entities, established proof of concept.
- Significant and growing markets for each product.
- Patent protection to 2034.
- $44.1 million of cash as of March 31, 2016.
- Proven management team.

AXSOME
THERAPEUTICS

Thank you.

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