



NASDAQ: TNXP

Investor Presentation

January 2016

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Developing innovative medicines for large and growing markets

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- ⦿ **Targeting common pain conditions and a serious psychiatric disorder**
 - Two clinical-stage proprietary candidates targeting three indications
 - Differentiated products with potential for sustainable competitive advantages
- ⦿ **2016 to reveal results from three clinical trials**
 - Fibromyalgia – Phase 3 to report in 3Q
 - Post-traumatic stress disorder – Phase 2 to report in 2Q
 - Episodic tension-type headache – proof-of-concept Phase 2 to report in 1Q
- ⦿ **All intellectual property owned by Tonix – from internal R&D**

Pipeline led by TNX-102 SL for fibromyalgia

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Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
TNX-102 SL (Tonmya*)	Fibromyalgia							Top line data 3Q 2016
TNX-102 SL	Post-Traumatic Stress Disorder							Top line data 2Q 2016
TNX-201	Episodic Tension-Type Headache							Top line data 1Q 2016

* Tonmya has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
 TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) and TNX-201 (dexisometheptene mucate) are Investigational New Drugs and are not approved for any indication.

TNX-102 SL in Phase 3 clinical development for fibromyalgia

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Phase 3 AFFIRM Study is underway

TNX-102 SL once-daily at bedtime

2.8 mg

N = 250

Placebo once-daily at bedtime

N = 250

Randomized, double-blind, placebo-controlled study in fibromyalgia

N = 500; approximately 35 U.S. clinical sites

Primary efficacy endpoint:

- Difference in 30% pain responder analysis at Week 12 between TNX-102 SL and placebo

Top line data expected 3Q 2016

12 weeks → **open-label extension**

Second Phase 3 Study ("REAFFIRM") expected to begin in 2Q 2016

- Expected to be similar to AFFIRM in design and size

Source: Phase 2b BESTFIT study data.

TNX-102 SL is an Investigational New Drug and is not approved for any indication.

Phase 2 “AtEase” trial of TNX-102 SL in PTSD is fully enrolled

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TNX-102 SL at bedtime once-daily

2.8 mg

N = 88

TNX-102 SL at bedtime once-daily

5.6 mg

N = 44

Placebo at bedtime once-daily

N = 88

⚡ Randomized, double-blind, placebo-controlled trial in military-related PTSD

⚡ *N*=240+; approximately 25 U.S. clinical sites

⚡ Primary efficacy endpoint:

- Difference in Clinician-Administered PTSD Scale (CAPS) score between TNX-102 SL 2.8 mg and placebo at 12 weeks



Top line data expected 2Q 2016

TNX-102 SL is an Investigational New Drug and is not approved for any indication.

Phase 2 proof-of-concept trial of TNX-201 in ETTH is fully enrolled

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TNX-201

140 mg

$N = 100$

Placebo

$N = 100$

- ⚡ Randomized, double-blind, placebo-controlled trial in episodic tension-type headache
- ⚡ Goal is to assess treatment of approx. 150 headaches
- ⚡ ~10 U.S. clinical sites

Top line data expected 1Q 2016

- ⚡ **A proof-of-concept study to evaluate:**
 - Proportion of subjects who report "pain free" at several intervals post-dose
 - Proportion of subjects who use rescue medication during the 24 hour post-dose period
 - Change from baseline in pain severity score at several intervals post-dose
- ⚡ **Results will be used to support discussion with FDA on Phase 3 study design**

Milestones – recent and upcoming

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TNX-102 SL – Fibromyalgia

- ☒ May 2015 Began Phase 3 AFFIRM study
- ☒ November 2015 Presented additional data from Phase 2b BESTFIT study at ACR Annual Meeting
- ☐ 3Q 2016 Report top-line results from AFFIRM study

TNX-102 SL – Post-Traumatic Stress Disorder

- ☒ December 2015 Entered into CRADA with USAMMDA
- ☒ December 2015 Reported completion of enrollment in Phase 2 AtEase study
- ☐ 2Q 2016 Report top-line results from AtEase study

TNX-201 – Episodic Tension-Type Headache

- ☒ June 2015 Presented non-clinical data at AHS Annual Meeting (receptor, animal models)
- ☒ December 2015 Reported completion of enrollment in proof-of-concept Phase 2 study
- ☐ 1Q 2016 Report top-line results from Phase 2 study