

**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 28, 2016

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(IRS Employer
Identification No.)

509 Madison Avenue, Suite 306, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

Copy of correspondence to:

Marc J. Ross, Esq.
James M. Turner, Esq.
Sichenzia Ross Friedman Ference LLP
61 Broadway
New York, New York 10006
Tel: (212) 930-9700 Fax: (212) 930-9725

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 (see General Instruction A.2. below):

- 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.

Tonix Pharmaceuticals Holding Corp. (the "Company") intends to utilize an updated investor presentation to conduct meetings with investors, stockholders and analysts and at investor conferences, which may contain non-public information. A copy of the presentation is filed as Exhibit 99.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01, is furnished pursuant to, and shall not be deemed to be "filed" for the purposes of, Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in Item 7.01 of this Current Report shall not be incorporated by reference into any registration statement or any other document filed pursuant to the Securities Act of 1933, as amended, except as otherwise expressly stated in such filing. By filing this Current Report on Form 8-K and furnishing the information contained in this Item 7.01, including Exhibit 99.01, the Company makes no admission as to the materiality of any such information that it is furnishing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Corporate Presentation by the Company for June 2016*

* Furnished herewith.

SIGNATURE

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

TONIX PHARMACEUTICALS HOLDING CORP.

Date: June 28, 2016

By: /s/ BRADLEY SAENGER

Bradley Saenger

Chief Financial Officer



Investor Presentation - June 2016

1



UPDATE

Topline Results With TNX-102 SL
In
Post-Traumatic Stress Disorder
June 2016

Version 0021 6-21-16

© 2016 Tonix Pharmaceuticals Holding Corp



Cautionary Note on Forward-Looking Statements

2

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain U.S Food and Drug Administration clearances or approvals and noncompliance with its regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by the Company on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. All of the Company's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.



Investment Thesis for Tonix Pharmaceuticals

3

UPDATE
Differentiated
Late-Stage
Program

- **TNX-102 SL (cyclobenzaprine sublingual tablets), 2.8 mg**
 - Differentiated with unique attributes that address unmet needs of target markets
- **Clinically validated in fibromyalgia (FM)**
 - Completed: Phase 2; demonstrated relief from chronic wide-spread pain
- **Enrollment in Phase 3 FM completed with topline results expected 3Q 2016**
- **Positive topline results in Phase 2 - post-traumatic stress disorder (PTSD)**

Commercially
Attractive
Markets

- **Target indications, FM and PTSD, are common chronic disorders**
 - Underserved markets with high levels of dissatisfaction
 - A differentiated product has potential to capture substantial share

TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg is an Investigational New Drug and is not approved for any indication.

© 2016 Tonix Pharmaceuticals Holding Corp



Therapeutic Approach Used to Develop TNX-102 SL

4



Pursuing what is most important to patients and their physicians...

Reduce burden of disease (therapeutic benefit)

... With a Unique Approach

Achieve therapeutic benefit by improving sleep quality

Sleep quality:

- How refreshing or satisfying was his or her sleep?
- Emotional, mental, and physical rejuvenation to feel well and focused
- Not always correlated with sleep quantity (~insomnia/sedative hypnotics)



Relevance of Sleep Disturbances for FM and PTSD

5

Sleep disturbances:

- ✓ Core symptoms of FM and PTSD
 - Disturbances may be qualitatively different
- ✓ Believed to have a role in the pathophysiology of both disorders

	Sleep As a Core Symptom	Pathophysiology	Therapeutic Benefit 1° Clinical Endpoint	Pharmacological Action 2° Clinical Endpoint
FM	✓ Unrefreshing sleep	CNS processing of sensory input <ul style="list-style-type: none">• 'Central-sensitization' or amplification of pain signals associated with disturbed sleep	Relief of chronic widespread pain	Relief from sleep disturbances
PTSD	✓ Nightmares ✓ Hyperarousal	Stress ≈ Hyperarousal ≈ Sleep Disturbances <ul style="list-style-type: none">• Hyperarousal and hypervigilance interfere with sleep	Reduce PTSD symptoms	Relief from sleep disturbances Reduce hyperarousal

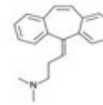
CNS = central nervous system



Cyclobenzaprine: Potential to Improve Sleep Quality

6

Cyclobenzaprine (CBP) is structurally a tricyclic molecule



Tricyclics and their metabolites differ significantly in their receptor binding profiles

CBP targets receptors with potential therapeutic effects for sleep disturbances

- Multimodal: high affinity, relative selectivity and functional antagonism
 - 5-HT_{2A}
 - α_1 -adrenergic
 - histamine H₁
- 6-7 fold lower affinity for SERT and NET (serotonin and norepinephrine transporters)
- Profile differs from active metabolite norcyclobenzaprine, amitriptyline and other tricyclics



TNX-102 SL: Innovative and Differentiated

7

TNX-102 SL: A low-dose sublingual formulation of CBP

Designed to take advantage of targeted high affinity receptors of CBP

Differentiated from immediate release oral CBP:

- Formulated for transmucosal absorption to allow sublingual administration at bedtime
 - Rapid systemic exposure
 - Improved bioavailability
 - Avoids first-pass metabolism, reducing formation of norcyclobenzaprine (nCBP)
 - Half-life ($t_{1/2}$) of 72 hours
 - Distinct receptor binding profile less selective for target receptors
 - Potential undesirable off-target functional activities



TNX-102 SL: Novel, Proprietary Formulation

8

Key Product Features:

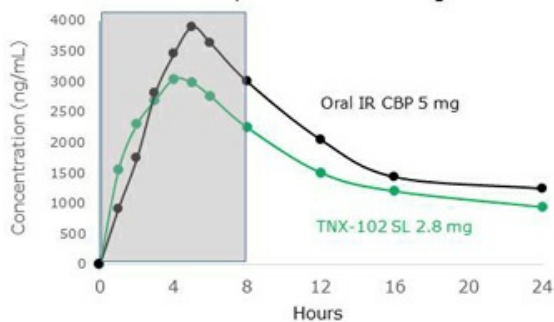
API	Cyclobenzaprine HCl
Route of Administration	Sublingual - rapid absorption - avoids first-pass metabolism
Formulation	Protectic™ - protective eutectic formulation - intellectual property rights - stability for transmucosal formulation
Dose	2.8 mg tablet - very low dose
Dosing	At bedtime - once daily



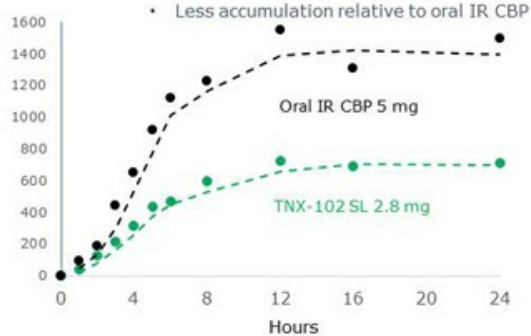
TNX-102 SL: Results from Single-Dose PK Study

TNX-102 SL 2.8 mg PK Profile relative to 5 mg oral IR CBP:

- CBP:**
- ✓ Rapid absorption for bedtime dosing
 - ✓ Peak concentration (C_{max}) reduced by 20%
 - ✓ Maintains desired nighttime characteristics
 - Peak concentration (t_{max}) occurs at ~4 hours
 - ~50% of exposure occurs during the first 8 hours



- nCBP:**
- ✓ More prominent from hours 8-24 ('daytime')
 - ✓ Reduced exposure to nCBP by 48%
 - Anticipate at steady-state:
 - Equally present day and night
 - Less accumulation relative to oral IR CBP





TNX-102 SL

Fibromyalgia, PTSD

Portfolio of international patents filed under the Patent Cooperation Treaty (PCT)

Composition-of-matter (eutectic)

- Patents filed
- Protection expected to 2034

Pharmacokinetics (PK)

- Patents filed
- Protection expected to 2033

Method-of-use

- Fibromyalgia: patents issued, 2020 expiry
- PTSD: patents filed



BestFit Study - TNX-102 SL Phase 2 in Fibromyalgia

11

TNX-102 SL once-daily at bedtime
2.8 mg *N* = 103

Placebo once-daily at bedtime
N = 102

- Randomized, double-blind, placebo-controlled study in **fibromyalgia**
- **N=205** randomized from 17 U.S. sites
- Efficacy endpoint:
 - Pre-specified primary endpoint: change in week 12 **mean pain** score (p=0.17)
 - Difference in 30% pain **responder analysis** at week 12 between TNX-102 SL and placebo
- Other efficacy endpoints:
 - Fibromyalgia Impact Questionnaire-Revised (**FIQ-R**)
 - Patient Global Impression of Change
 - PROMIS Sleep Disturbance



1. FDA-accepted primary endpoint in current Phase 3 AFFIRM study

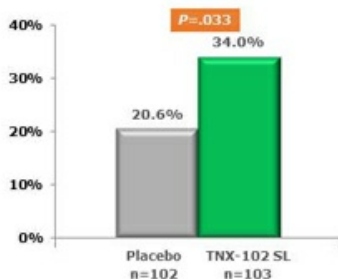
© 2016 Tonix Pharmaceuticals Holding Corp



Response at Week 12

Pain Relief

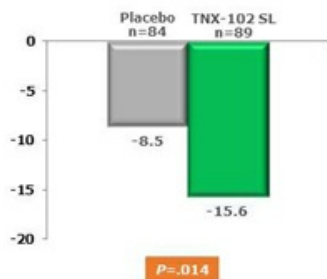
30% Responder Rate Based on Pain NRS



Logistic regression
NRS=Numeric Rating Scale

Reduction in Disease Burden

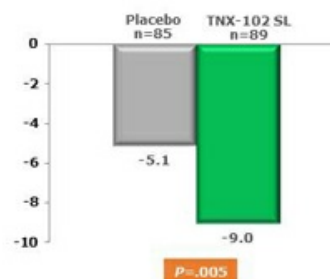
FIQ-R Total Score (MMRM)



MMRM=Mixed model for repeated measures
FIQ-R=Fibromyalgia Impact Questionnaire-Revised

Reduction in Sleep Disturbances

PROMIS Sleep T-Score (MMRM)



MMRM=Mixed model for repeated measures



No serious adverse events (SAE) reported with TNX-102 SL

Systemic adverse events reported by at least 3.0% of the total BESTFIT study population:



Most frequent local adverse events were administration site reactions

- Transient tongue numbness (44% TNX-102 SL vs. 2% placebo)
- Abnormal taste (8% TNX-102 SL vs. 0% placebo)



AFFIRM Study - TNX-102 SL Phase 3 in Fibromyalgia

FULLY ENROLLED - Topline Expected 3Q 2016

TNX-102 SL once-daily at bedtime
2.8 mg $N \approx 259$

Placebo once-daily at bedtime
 $N \approx 259$

- Randomized, double-blind, placebo-controlled study in **fibromyalgia**
- **N=519**; 35 U.S. clinical sites
- Primary efficacy endpoint:
 - Difference in 30% pain **responder analysis** at Week 12 between TNX-102 SL and placebo



- Second Phase 3 Study ("REAFFIRM") expected to begin in July 2016
 - Expected to be similar to AFFIRM in design and sample size



Military-related PTSD not well-served by existing FDA-approved therapies

- **No treatment response observed in U.S. military population**
Sertraline: negative in large multicenter trial in U.S. military (placebo numerically better)¹
Paroxetine: not studied in military population
- **Inconsistent treatment response observed in males**
Sertraline: FDA conducted post-hoc analysis concluded no effect for male civilian subgroup²
Paroxetine: no sex-related difference in treatment outcomes³
- **Important tolerability issues with SSRIs in this population**
Sexual dysfunction
Insomnia

1. Friedman et al., 2007, 2. Zoloft Package Insert, August, 2014, 3. Paxil Package Insert, June, 2014



AtEase Study - TNX-102 SL Phase 2 in PTSD

TNX-102 SL at bedtime once-daily
5.6 mg N = 49

TNX-102 SL at bedtime once-daily
2.8 mg N = 90

Placebo at bedtime once-daily
0 mg N = 92

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

- **N=231**; 24 U.S. clinical sites

- Primary efficacy endpoint:

Difference in Clinician-Administered PTSD Scale (**CAPS-5**) score between TNX-102 SL 2.8 mg and placebo at week 12





Key Demographics / Characteristics of AtEase

- 93% of the sample was male
- 98% had trauma during military service and were deployed on average 2.3 times
- Mean time since index trauma was 7 years
- Race and ethnicity generally consistent with U.S. military distribution
- Similar baseline CAPS-5 scores and MADRS scores across treatment arms
 - Average CAPS-5 scores were greater than 39 for all groups ('severe' PTSD*)

*personal communication – Frank Weathers PhD, National Center for PTSD



Index Traumas During Military Service Related to Dx of PTSD	Patient Count
Being involved in an IED explosion or suicide bombing	35
Being attacked or ambushed	33
Witnessing death or injury of fellow soldiers	30
Witnessing IED explosion	29
Receiving incoming artillery, rocket, or mortar fire	10
Being wounded or injured	9
Being responsible for the death of a noncombatant	9
Witness suicide-related deaths or injury	9
Seeing ill or injured women or children you were unable to help	8
Witnessing death or injury of civilians	7
Handling or uncovering human remains	6
Sexual assault	6
Involved in serious vehicular accident (Humvee, helicopter, plane)	6
Shooting or directing fire at the enemy	5
Knowing someone seriously injured or killed	4
All others	19

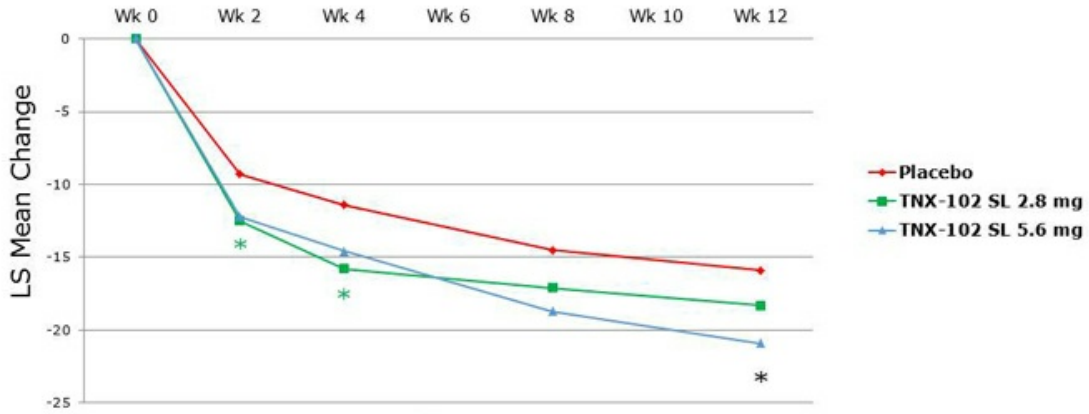
Proprietary and Confidential

© 2016 Tonix Pharmaceuticals Holding Corp



AtEase Study Results

CAPS-5 LS Total Score Mean Change from Baseline

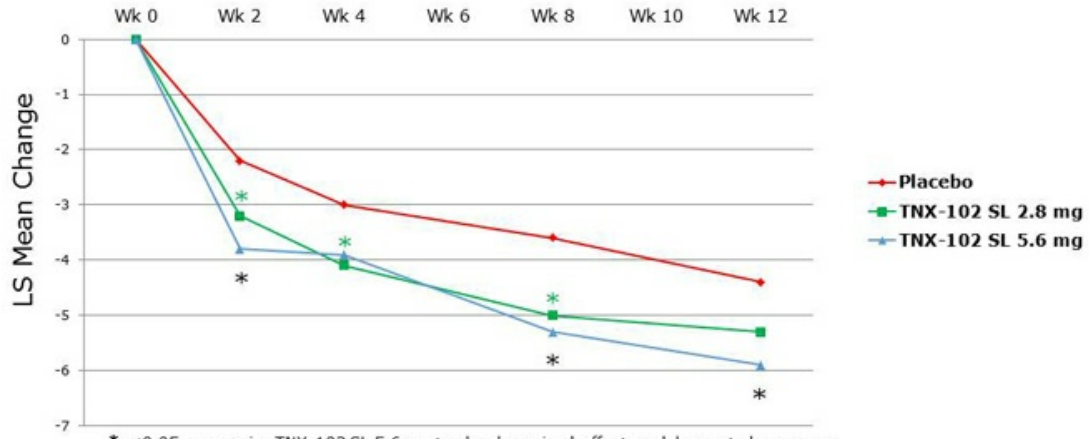


*p=0.031, comparing placebo and TNX-102 SL 5.6 mg, *p<0.05, comparing placebo and TNX-102 SL 2.8 mg, by MMRM with MI, mixed-effect model repeated measures with multiple imputation; CAPS-5, Clinician Administered PTSD Scale for DSM-5; LS Mean, least squares mean



AtEase Study Results

CAPS-5 Arousal and Reactivity Cluster Score Mean Change



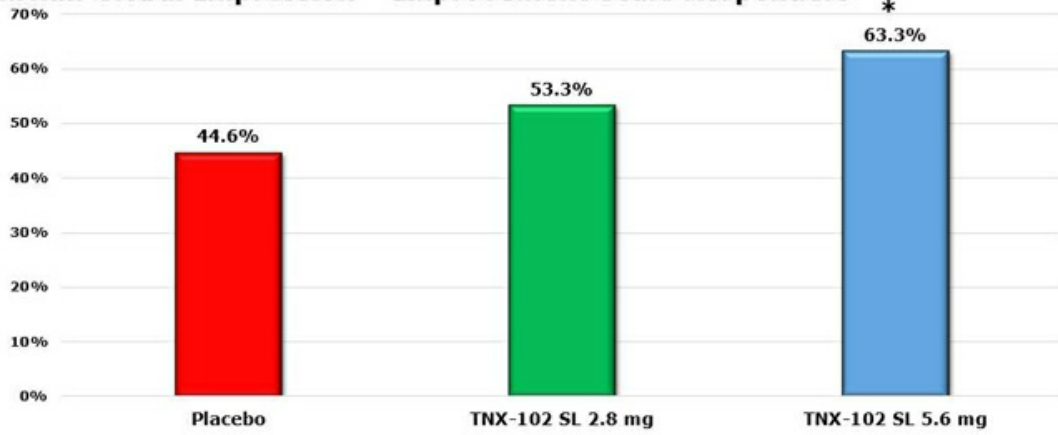
*p<0.05, comparing TNX-102 SL 5.6 mg to placebo, mixed-effect model repeated measures

*p<0.05, comparing TNX-102 SL 2.8 mg to placebo, mixed-effect model repeated measures



AtEase Study Results

Clinician Global Impression – Improvement Scale Responders



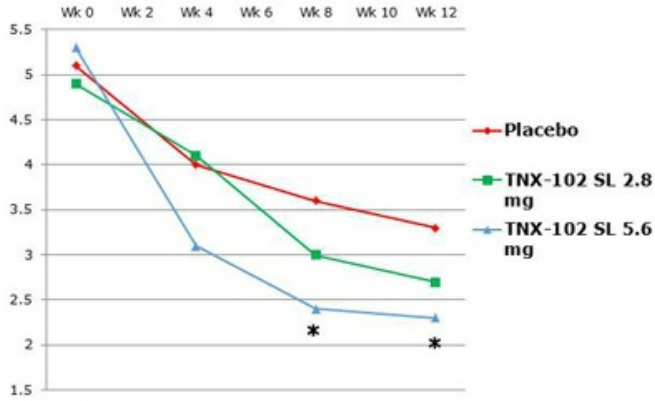
*p=0.041, Logistic regression comparing placebo and TNX-102 SL 5.6 mg
Responders are those rated as "much improved" or "very much improved"



AtEase Study Results

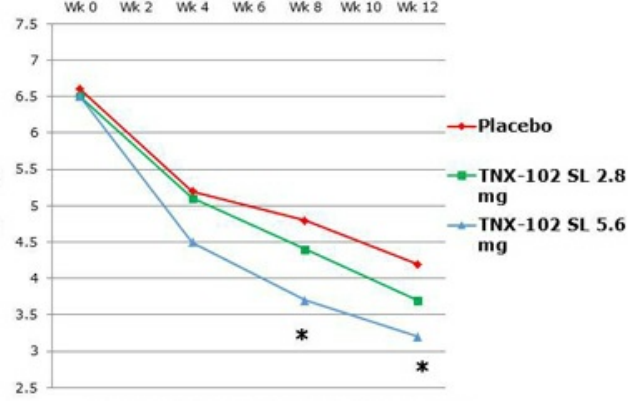
Sheehan Disability Scale – Work/School & Social/Leisure Domains

The symptoms have disrupted your work/school work



* $p < 0.05$, TNX-102 SL 5.6 mg v. Placebo, MMRM, MMRM, mixed-effects model repeated measure

The symptoms have disrupted your social/leisure activities



* $p < 0.05$, TNX-102 SL 5.6 mg v. Placebo, MMRM



AtEase Study Results Adverse Events ($\geq 5\%$ rate in any group)

Preferred Term	Placebo N=94*	TNX-102 SL 2.8 mg N=93*	TNX-102 SL 5.6 mg N=50*	Overall N=237*
Local Administration Site Conditions				
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)	54 (37.8%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)	17 (11.9%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)	6 (4.2%)
Systemic Adverse Events				
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)	19 (13.3%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)	12 (8.4%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)	11 (7.7%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)	10 (7.0%)
Sedation	1 (1.1%)	2 (2.2%)	6 (12.0%)	8 (5.6%)
Upper respiratory tract infection	5 (5.3%)	3 (3.2%)	2 (4.0%)	5 (3.5%)
Abnormal dreams	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)
Weight increased	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)

Completer Rate:
Placebo 73%
TNX-102 SL 2.8 mg 79%
TNX-102 SL 5.6 mg 84%



AtEase Study Summary of Results

24

Presented at American Society of Clinical Psychopharmacology, May 31, 2016

- **Recruited a population with severe military-related PTSD, almost exclusively combat traumas incurred during OIF/OEF/OND deployments:**
 - Predominantly male
- **TNX-102 SL at 5.6 mg daily at bedtime for 12 weeks:**
 - Reduced severity of PTSD (CAPS-5, $p=0.031$, Effect Size=0.39)
 - Reduced key symptoms (hyperarousal, insomnia, startle)
 - Improved global symptoms (CGI-I) and function (SDS work/school and social/leisure)
 - Tolerability evidenced by retention rate (84%) and low systemic side effects with only one discontinuation for AE (increased nightmares)
- **TNX-102 SL at 2.8 mg daily at bedtime for 12 weeks:**
 - Reduced PTSD symptoms (CAPS-5) at weeks 2 and 4
 - Reduced hyperarousal at weeks 2, 4 and 8
 - Non-significant intermediate effects at week 12 on PTSD symptoms, global and functional improvement (CAPS-5 total, sleep and startle items, CGI-I, SDS)

OIF/OEF/OND, Operation Iraqi Freedom/Operation Enduring Freedom/Operation New Dawn
CGI-I, Clinician Global Impression - Improvement scale; CAPS-5, Clinician Administered PTSD Scale for DSM-5;
SDS, Sheehan Disability Scale

© 2016 Tonix Pharmaceuticals Holding Corp



AtEase Study Conclusions

25

- **This is the first multicenter randomized clinical trial of any medication that has demonstrated efficacy in a population with military-related PTSD**
- **Early effects on sleep and hyperarousal are consistent with the mechanistic hypothesis for TNX-102 SL**
 - Primary actions on sleep disturbance and autonomic balance.
- **Next steps**
 - Phase 3 trial in military-related PTSD
 - Phase 3 trial in civilian PTSD



Differentiated

- Innovative sublingual tablet
- Rapid bedtime absorption
- Peak concentration during sleep period (first 8 hours)
- Reduced exposure to long-lived active metabolite

Efficacy Results

- FM (Phase 2b); pain relief and improvement in functional and global outcomes
- PTSD (Phase 2); reduction in overall disease impact (CAP-5) in difficult to treat population

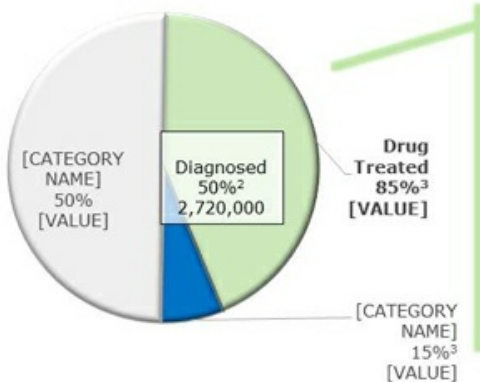
Addresses significant unmet needs of target markets

- Effective therapies that are well tolerated



Fibromyalgia: Market Characteristics

Prevalence Population ~5.4 million¹



Market Characteristics

Prevalence

One of the more common chronic pain disorders

Diagnosed population

Large population (~2.7 million)
Majority receive drug treatment

Treatment Pattern:

Polypharmacy the norm - average 2.6 drugs/patient³
Rotation through therapy common: average ~5 drugs/year³

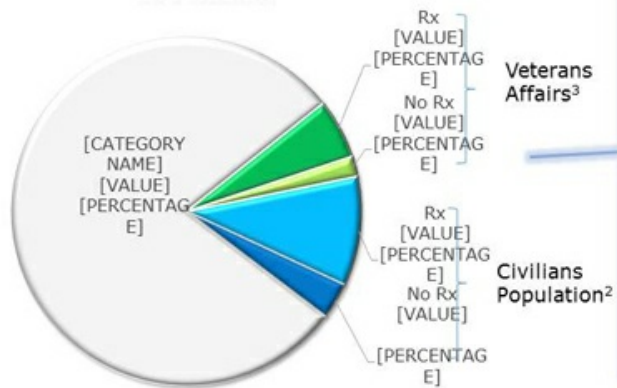
Unmet Need:

Majority of patients do not respond or cannot tolerate therapy⁴

1. Queiroz, 2013 prevalence rate of 2.2% of adult population - adjusted for estimated U.S. adult population in 2016
 2. Vincent et al., 2013; diagnosed prevalence rate was 1.1% of adult population or 50% of the prevalent population
 3. Robinson, et al., 2012
 4. Market research by Frost & Sullivan, commissioned by Tonix, 2011



Prevalence Population ~8.4 million¹



Market Characteristics

Prevalence:
One of the more common psychiatric disorders
Large undiagnosed population (79%)

Diagnosed population
Large population (~1.8 million)
Majority receive drug treatment
Civilians: ~75%²
Veterans: ~84%⁴

Treatment Pattern:
Benzodiazepines & SSRIs most common drug therapy^{2,4}
Concomitant medication rate high²

Unmet Need:
Non-responders to treatment - few alternatives
Subpopulations not well served by current treatments
Tolerability issues in sensitive population

1. Kessler, et al., 2005; Prevalence rate of 3.5% applied to estimate of U.S. population in 2016
 2. IMS Consulting, *Market Sizing & Treatment Dynamics: Post-Traumatic Stress Disorder (PTSD) Patients*, 2016
 3. Bowe, et al., 2014
 4. Bernardy et al., 2012



Financial overview

29

NASDAQ: TNPX

Cash, cash equivalents, and marketable securities reported at March 31, 2016 \$ 27.5 million

Net proceeds from underwritten stock offering in 2Q16 \$9.1 million

Shares outstanding (June 21, 2016) 25.1 million



Management team

Seth Lederman, MD President & CEO	  
Bruce Daugherty, PhD, MBA Chief Scientific Officer	 
Gregory Sullivan, MD Chief Medical Officer	 
Bradley Saenger, CPA Chief Financial Officer	   
Jessica Edgar Morris EVP, Administration	  
Ronald Notvest, PhD EVP, Commercial Planning & Development	  



Board of directors

31

Seth Lederman, MD

Chairman

Ernest Mario, PhD

ALZA, Glaxo, Reliant Pharma

Stuart Davidson

Labrador Ventures, Alkermes, Combion

Charles Mather

BTIG, Janney, Jefferies, Cowen, Smith Barney

Patrick Grace

Apollo Philanthropy, WR Grace, Chemed

John Rhodes

NYSERDA, NRDC, Booz Allen Hamilton

Donald Landry, MD, PhD

Chair of Medicine, Columbia University

Samuel Saks, MD

Jazz Pharma, ALZA, Johnson & Johnson



Thank You!