# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 8-K/A

**(Amendment No. 1)**

**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**

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# TONIX PHARMACEUTICALS HOLDING CORP.

**(Exact name of registrant as specified in its charter)**

| **Nevada** | **001-36019** | **26-1434750** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(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:**

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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))

**Explanatory Note**

Tonix Pharmaceuticals Holding Corp. (the "Company") is filing this Amendment No. 1 on Form 8–K/A to the Company's Current Report on Form 8–K dated June 28, 2016, which was filed on June 28, 2016, in order to refile Exhibit 99.01 (the "Exhibit"). Two of the slides in the Exhibit were not final versions and only contained field codes for data and not the actual data itself.

**Item 7.01 Regulation FD Disclosure.**

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 29, 2016

By: */s/ BRADLEY SAENGER*
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

# Investor Presentation - June 2016



TONIX PHARMACEUTICALS

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

Version 0021 6-21-16

# Cautionary Note on Forward-Looking Statements



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



**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.*

# Therapeutic Approach Used to Develop TNX-102 SL



**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



**Sleep disturbances:**

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

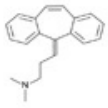
| | Sleep As a Core Symptom | Pathophysiology | Therapeutic Benefit 1° Clinical Endpoint | Pharmacological Action 2° Clinical Endpoint |
|---|---|---|---|---|
| **FM** | ✓ **Unrefreshing sleep** | **CNS processing of sensory input**<br>• 'Central-sensitization' or amplification of pain signals associated with disturbed sleep | **Relief of chronic widespread pain** | **Relief from sleep disturbances** |
| **PTSD** | ✓ **Nightmares**<br>✓ **Hyperarousal** | **Stress ≈ Hyperarousal ≈ Sleep Disturbances**<br>• Hyperarousal and hypervigilance interfere with sleep | **Reduce PTSD symptoms** | **Relief from sleep disturbances**<br>**Reduce hyperarousal** |

CNS = central nervous system

# Cyclobenzaprine: Potential to Improve Sleep Quality



**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-$HT_{2A}$
  - $\alpha_1$-adrenergic
  - histamine $H_1$
- 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



**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



**Key Product Features**:

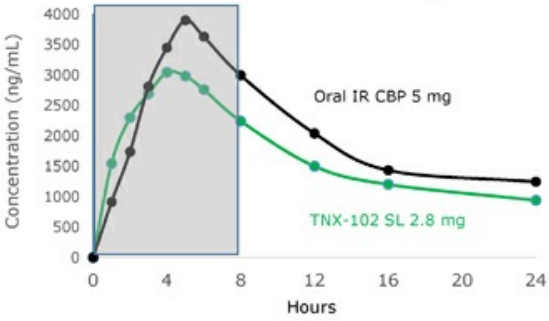
| | |
|---|---|
| API | Cyclobenzaprine HCl |
| Route of Administration | Sublingual - rapid absorption<br>- avoids first-pass metabolism |
| Formulation | Protectic™ - protective eutectic formulation<br>- intellectual property rights<br>- stability for transmucosal formulation |
| Dose | 2.8 mg tablet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

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

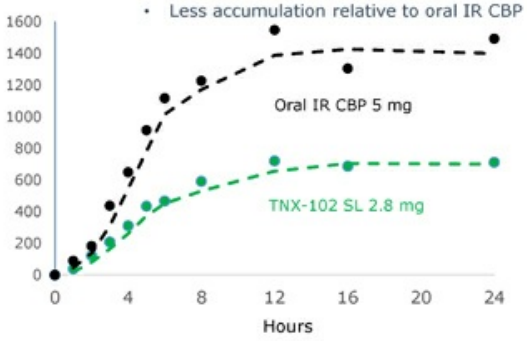


**TNX-102 SL 2.8 mg PK Profile relative to 5 mg oral IR CBP:**

**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




Tonix Study F104

# Intellectual Property



**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



**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

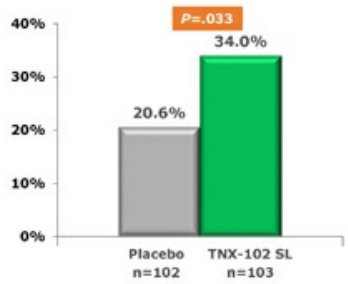
# BestFit Key Clinical Results



## Response at Week 12

***Pain Relief***

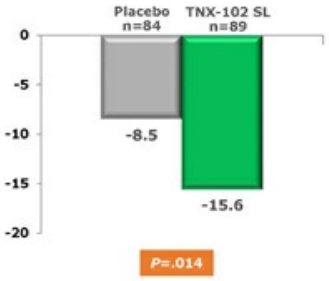
30% Responder Rate Based on Pain NRS




Logistic regression
NRS=Numeric Rating Scale

***Reduction in Disease Burden***

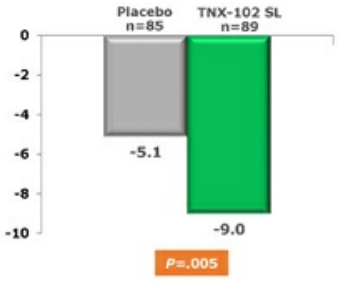
FIQ-R Total Score (MMRM)




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

# BestFit Safety and Tolerability Profile



**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:**

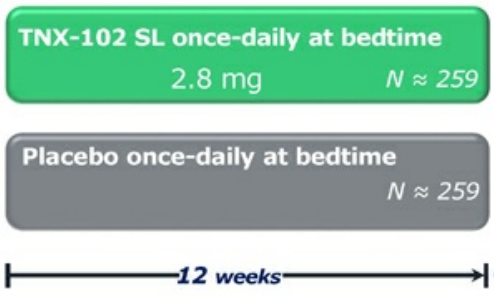

**Most frequent local adverse events were administration site reactions**

- 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**




- 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

# Targeting Military-related PTSD



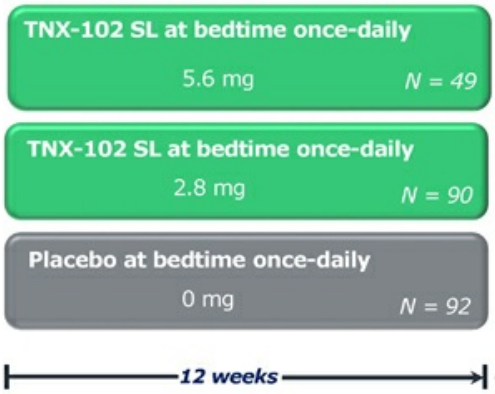
**Military-related PTSD not well-served by existing FDA-approved therapies**

- **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 subgroup[2]
  Paroxetine: no sex-related difference in treatment outcomes[3]
- **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






- 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

# AtEase Study



**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

# AtEase Study - Index Trauma

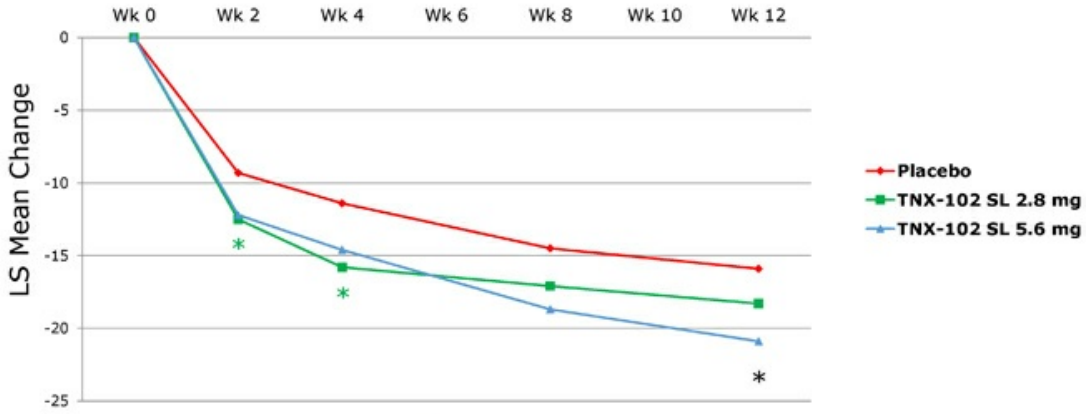


| Index Traumas During Military Service Related to Dx of PTSD | Patient Count |
|---|---|
| Being involved in an IED explosion or suicide bombing | 35 |
| Being attacked or ambushed | 33 |
| Witnessing death or injury of fellow soldiers | 30 |
| Witnessing IED explosion | 29 |
| Receiving incoming artillery, 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 |

# AtEase Study Results



## CAPS-5 LS Total Score Mean Change from Baseline

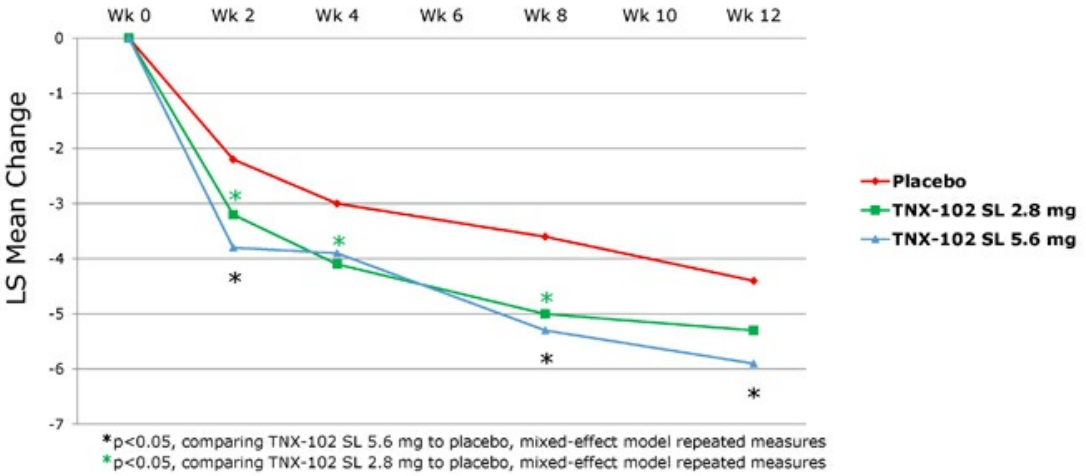



*p=0.031, comparing placebo and TNX-102 SL 5.6 mg, *p<0.05, comparing placebo and TNX-102 SL 2.8 mg, by MMRM with MI, mixed-effect model repeated measures with multiple imputation; CAPS-5, Clinician Administered PTSD Scale for DSM-5; LS Mean, least squares mean

# AtEase Study Results



## CAPS-5 Arousal and Reactivity Cluster Score Mean Change

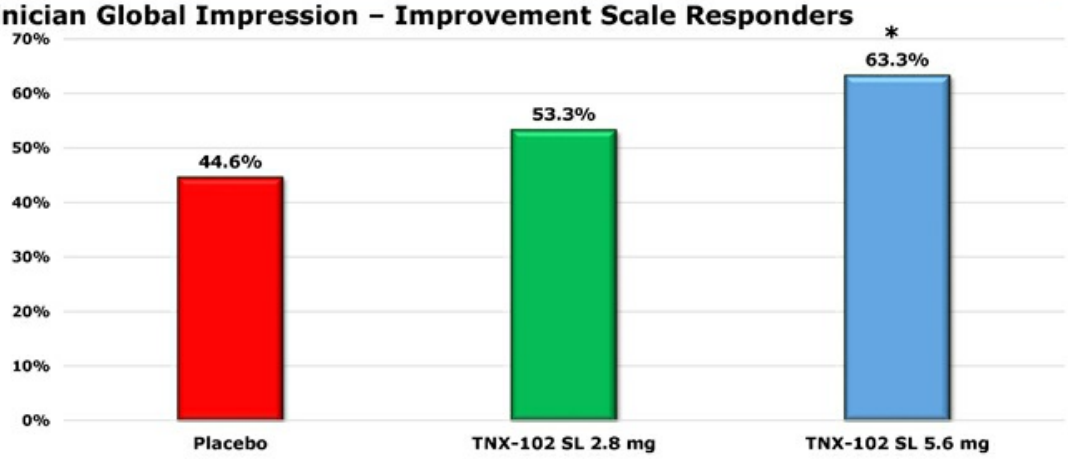



*p<0.05, comparing TNX-102 SL 5.6 mg to placebo, mixed-effect model repeated measures
*p<0.05, comparing TNX-102 SL 2.8 mg to placebo, mixed-effect model repeated measures

# AtEase Study Results



## Clinician Global Impression – Improvement Scale Responders

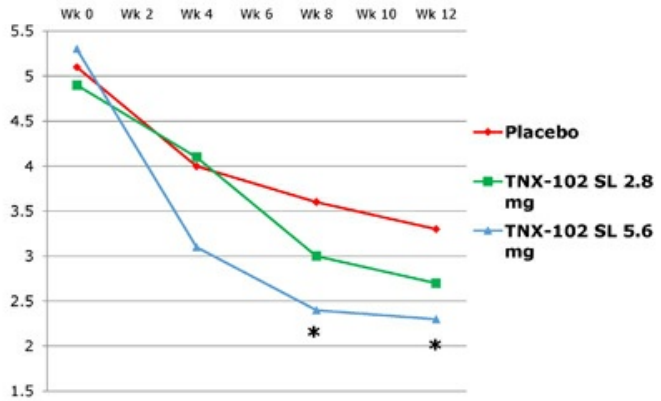



*p=0.041, Logistic regression comparing placebo and TNX-102 SL 5.6 mg
Responders are those rated as "much improved" or "very much improved"

# AtEase Study Results
## Sheehan Disability Scale – Work/School & Social/Leisure Domains

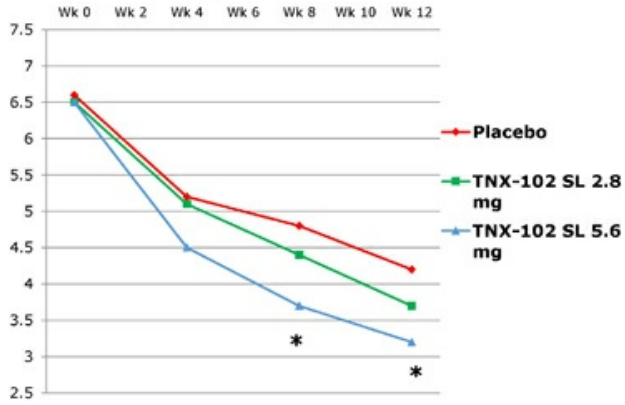


**The symptoms have disrupted your work/school work**




*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 (≥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



## 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

# AtEase Study Conclusions



- **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

# TNX-102 SL Value Proposition



***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

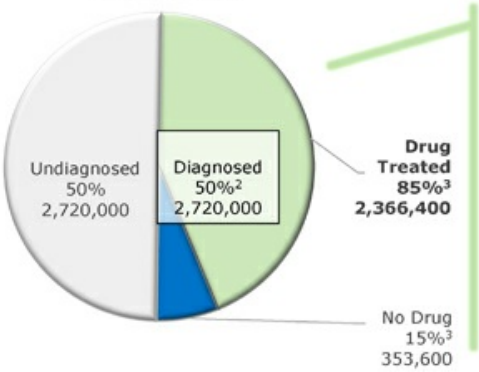
***Addresses significant unmet needs of target markets***

- Effective therapies that are well tolerated

# Fibromyalgia: Market Characteristics



**Prevalence Population ~5.4 million[1]**




**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/patient[3]
Rotation through therapy common: average ~5 drugs/year[3]

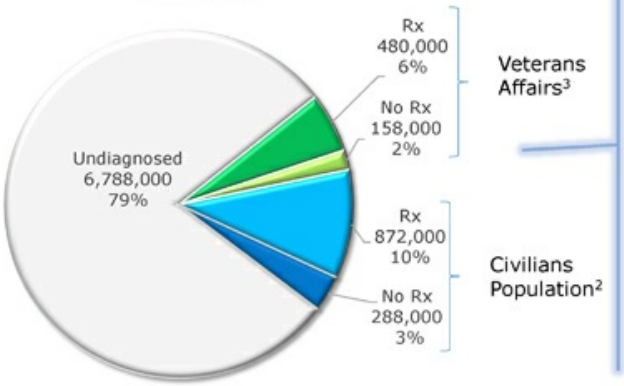
**Unmet Need:**
Majority of patients do not respond or cannot tolerate therapy[4]

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

# PTSD - Market Summary



## Prevalence Population ~8.4 million[1]




## 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 high[2]

**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



| NASDAQ: TNXP | |
|---|---|
| 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**<br>President & CEO | TARGENT Fusilev (levoleucovorin) for injection vela |
| **Bruce Daugherty, PhD, MBA**<br>Chief Scientific Officer | MERCK Roche |
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# *Thank You!*