# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# 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): July 26, 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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James M. Turner, Esq.
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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, and which the Company intends to place on its website, 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 8.01 Other Events.**

On July 26, 2016, the Company issued a press release announcing that the Company has initiated enrollment in its REAFFIRM trial, a second Phase 3 clinical study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia.

A copy of the press release that discusses this matter is filed as Exhibit 99.02 to, and incorporated by reference in, this report. The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| | |
|---|---|
| 99.01 | Corporate Presentation by the Company for July 2016* |
| 99.02 | Press release, dated July 26, 2016, issued by Tonix Pharmaceuticals Holding Corp.* |

* Furnished herewith.

**SIGNATURE**

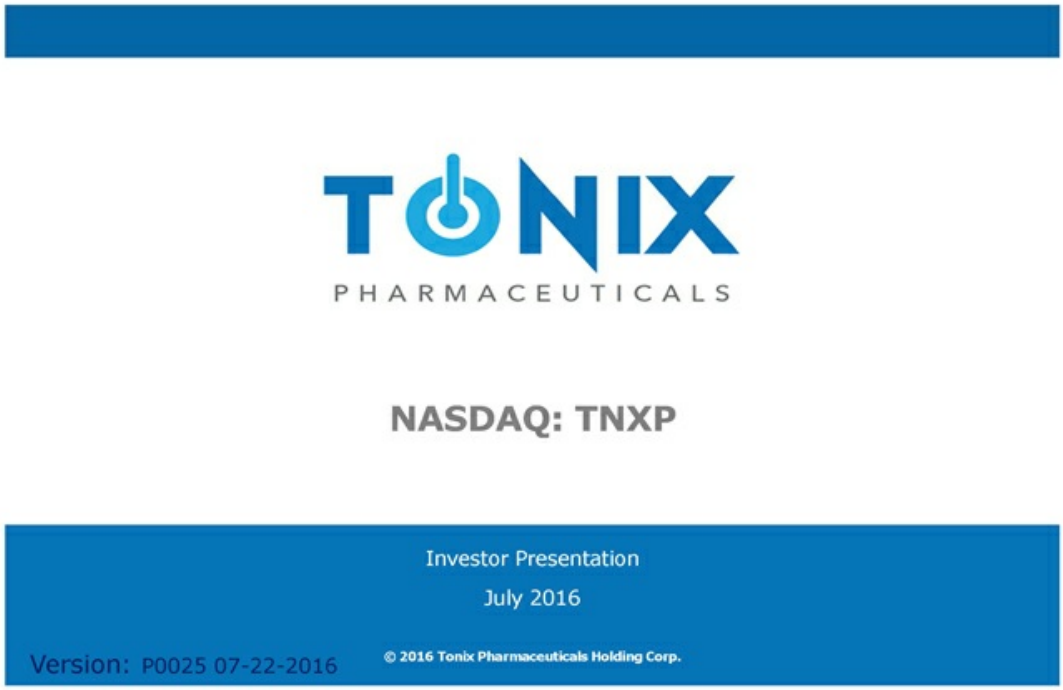
Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**TONIX PHARMACEUTICALS HOLDING CORP.**

Date: July 26, 2016

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

**Exhibit 99.01**



# 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.

TONIX PHARMACEUTICALS

# Developing innovative medicines for large and growing markets



- **Targeting two common central nervous system disorders**
  - One clinical-stage proprietary candidate targeting two indications
  - Differentiated product with potential for sustainable competitive advantages
- **Fibromyalgia – Phase 3 trial to report in 3Q 2016**
  - TNX-102 SL 2.8 mg was active in a Phase 2b study of fibromyalgia
  - Central pain disorder
  - Phase 3 study (AFFIRM) clinical phase completed
- **Post-traumatic stress disorder (PTSD) – Phase 2 trial reported May 2016**
  - TNX-102 SL 5.6 mg was active in treating military-related PTSD
  - Serious mental health problem[1]
  - Planning Phase 3 program in military-related PTSD
- **All intellectual property owned by Tonix**

[1]*Schnurr, PP et al., Contemporary Clinical Trials 2015;41:75.*

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



TONIX PHARMACEUTICALS

# Pipeline led by TNX-102 SL for fibromyalgia



| Candidate | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 | NDA | Market | Near-term Catalyst |
|---|---|---|---|---|---|---|---|---|
| TNX-102 SL 2.8 mg (*Tonmya®**) | Fibromyalgia | | | | | | | Topline data 3Q 2016 |
| TNX-102 SL 5.6 mg | Post-Traumatic Stress Disorder | | | | | | | Phase 3 starting 1Q 2017 |

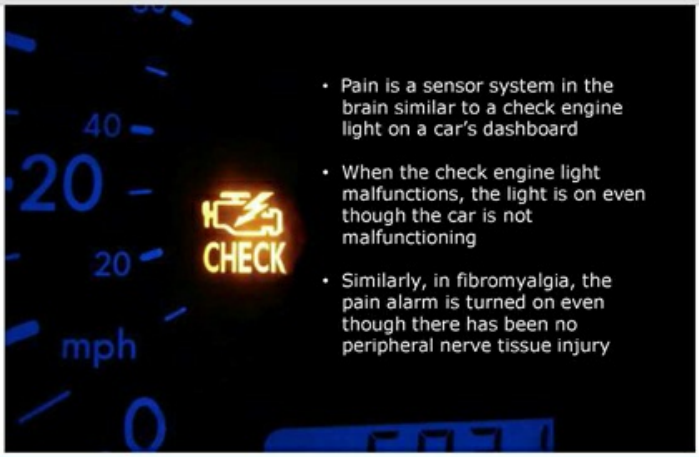
* Tonmya® has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

*NDA = New Drug Application; FDA = U.S. Food and Drug Administration.*

TONIX PHARMACEUTICALS

## Concept: Fibromyalgia is inappropriate central pain signaling in the absence of peripheral injury






- Pain is a sensor system in the brain similar to a check engine light on a car's dashboard
- When the check engine light malfunctions, the light is on even though the car is not malfunctioning
- Similarly, in fibromyalgia, the pain alarm is turned on even though there has been no peripheral nerve tissue injury

*Volkswagen Check Engine [Photograph]. (2011, October 14). Wikipedia*



TONIX PHARMACEUTICALS

# Fibromyalgia is a chronic, debilitating disorder that imposes a significant societal and economic burden



- **Fibromyalgia is considered neurobiological disorder characterized by[1]:**
  - Chronic widespread pain
  - Nonrestorative sleep
  - Fatigue
  - Diminished cognition
- **Believed to result from amplified sensory and pain signaling in central nervous system[1]**
- **Causes significant impairment in all areas of life[2]**
  - Lower levels of health-related quality of life – reduced daily functioning
  - Interference with work (loss of productivity, disability)
- **Inflicts substantial strain on the healthcare system**
  - Average patient has 20 physician office visits per year[3]
  - Annual direct medical costs are twice those for non-fibromyalgia individuals[4]

[1]*Phillips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.*
[2]*Schaefer et al., Pain Pract, 2015.*
[3]*Robinson et al, Pain Medicine 2013;14:1400.*
[4]*White et al, J Occupational Environ Med 2008;50:13.*



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# Fibromyalgia is a prevalent disorder but remains underdiagnosed




Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year[2,3]

- **1.1% diagnosis rate = 2.7 million U.S. adults[1]**
  - Suggests under-diagnosis
- **Approximately 2.3 million U.S. adults receive treatment[2]**
- **Approved drugs achieved 2014 U.S. sales of $1.2 billion[3]**
  - Represent about 5.6 million prescriptions[4]

[1]*Lawrence et al, Arthritis Rheum 2008;58:26; Vincent et al, Arthritis Care Res 2013;65:786; Jones et al, Arthritis Rheum 2015;67:568; U.S. Census Bureau, 2013 Projection.*
[2]*Robinson RL et al, Pain Med 2012;13:1366.*
[3]*Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.*
[4]*Independent study conducted by IMS Consulting Group, April 2015 using IMS MIDAS (ex-manufacturing price), factored for fibromyalgia based on IMS National Disease and Therapeutic Index (NDTI).*



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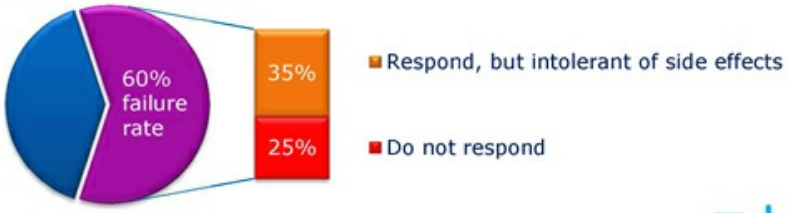
## Fewer than half of those treated for fibromyalgia receive sustained benefit from the three currently marketed drugs



- **The treatment objective is to restore functionality and quality of life by broadly improving symptoms while avoiding significant side effects**
- The majority fail therapy due to **lack of a response** or **poor tolerability**[1]

**Treated Population**




[1]*Market research by Frost & Sullivan, commissioned by Tonix (2011).*



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## Large need for new fibromyalgia therapies that provide broad symptom improvement with better tolerability



- **Currently-approved medications may have side effects that limit long-term use[1]**
  - Many patients skip doses or discontinue altogether within months of treatment initiation
- **Medication-related side effects may be similar to fibromyalgia symptoms**
- **High rates of discontinuation, switching and augmentation**
  - Attempt to treat multiple symptoms and/or avoid intolerable side effects
  - Average of 2-3 medications used simultaneously[2]
  - The typical patient has tried six different medications[3]
- **Substantial off-label use of narcotic painkillers and prescription sleep aids[3]**

[1]*Nuesch et al, Ann Rheum Dis 2013;72:955-62.*
[2]*Robinson RL et al, Pain Medicine 2012;13:1366.*
[3]*"Patient Trends: Fibromyalgia", Decision Resources, 2011.*



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# Tonix is developing TNX-102 SL for fibromyalgia



- **Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP)**
  - Designed for daily bedtime administration with no titration
  - Efficient transmucosal absorption
  - Avoidance of first-pass metabolism reduces formation of long-lived metabolite
- **TNX-102 SL's pharmacologic action is believed to improve sleep quality**
  - Non-restorative sleep is a common clinical and diagnostic feature of fibromyalgia[1]
  - Evolving understanding of the role of sleep in pain control and fibromyalgia development[2]
  - TNX-102 SL targets receptors believed to play key roles in sleep physiology
- **Phase 2b "BESTFIT" study was successfully completed in 3Q14**
- **Topline data from ongoing Phase 3 "AFFIRM" study expected to report in 3Q16**

[1]*Swick TJ, Ther Adv Musculoskel Dis 2011;3:167-178.*
[2]*Choy EH, Nat Rev Rheumatol; 2015: 11:513-520.*



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## Phase 2b "BESTFIT" study of TNX-102 SL in fibromyalgia



- **BESTFIT = BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy**
  - Randomized, double-blind, placebo-controlled trial
  - 2010 American College of Rheumatology diagnostic criteria for fibromyalgia
  - 205 participants randomized 1:1 at 17 U.S. sites
  - Sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime for 12 weeks
  - Evaluated measures of pain, sleep quality, and other assessments of fibromyalgia



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# BESTFIT results on key clinical endpoints



| Category | Endpoint – week 12[1] | *p* value |
|---|---|---|
| Pain Relief | 30% responder analysis[2] | **0.033** |
| Sleep Quality | PROMIS Sleep Disturbance | 0.005 |
| Overall response to therapy | PGIC | 0.025 |
| Assessment of disease impact | FIQ-R Total score | 0.014 |

*$p < 0.05$ → statistically significant*

BESTFIT pre-specified primary endpoint: change in week 12 mean pain score (p=0.172)

- PROMIS = Patient-Reported Outcomes Measurement Information System
- PGIC = Patient Global Impression of Change
- FIQ-R = Fibromyalgia Impact Questionnaire - Revised

*[1]Intent-to-treat analysis, N=205 (TNX-102 SL N=103, placebo N=102).*
*[2]FDA-accepted primary endpoint in current Phase 3 AFFIRM study.*
*Source: Phase 2b BESTFIT study data.*



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# TNX-102 SL safety and tolerability profile in the BESTFIT study



- **No serious adverse events (SAE) reported with TNX-102 SL**
- **Systemic adverse events reported by at least 3% of the total BESTFIT population**

| | TNX-102 SL (N=103) | Placebo (N=101) | Total (N=204) |
|---|---|---|---|
| **Somnolence** | 1.9 | 6.9 | 4.4 |
| **Dry Mouth** | 3.9 | 4.0 | 3.9 |
| **Back Pain** | 4.9 | 3.0 | 3.9 |
| **Nausea** | 4.9 | 2.0 | 3.4 |
| **Sinusitis** | 3.9 | 3.0 | 3.4 |

- **Most frequent local adverse events were administration site reactions**
  - Previously reported in Phase 1 studies; no detectable bias on efficacy results
  - Transient tongue numbness (44% TNX-102 SL vs. 2% placebo)
  - Abnormal taste (8% TNX-102 SL vs. 0% placebo)
- **Trial completion rates of 86% with TNX-102 SL vs. 83% with placebo**

*Source: Lederman et al., poster at American College of Rheumatology, 2015.*



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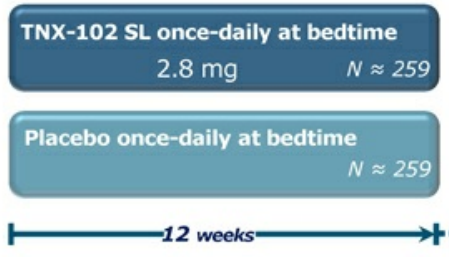
# Clinical phase completed in Phase 3 trial of TNX-102 SL for fibromyalgia



- Phase 3 AFFIRM study is fully enrolled




- 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

**Topline data expected 3Q 2016**

- Second Phase 3 Study ("RE-AFFIRM") enrollment initiated in July 2016
  - Expected to be similar to AFFIRM in design and sample size



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# TNX-102 SL in Phase 2 development for PTSD



| Candidate | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 | NDA | Market | Near-term Catalyst |
|---|---|---|---|---|---|---|---|---|
| TNX-102 SL (*Tonmya*®*) 2.8 mg | Fibromyalgia | | | | | | | Topline data 3Q 2016 |
| **TNX-102 SL 5.6 mg** | **Post-Traumatic Stress Disorder** | | | | | | | **Phase 3 Starting 1Q 2017** |

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

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# PTSD is a chronic stress disorder triggered by a traumatic event



- **PTSD is characterized by:**
  - re-experiencing the triggering event
  - negative alterations in mood/cognition
  - situation/stimulus avoidance
  - hyperarousal (anxiety, agitation & sleep disturbance)
- **Considered a stress response, but prolonged and does not resolve with time**
  - 20% of women and 8% of men who experience significant trauma develop PTSD[1]
- **Associated with significant life disruption**
  - Social isolation, inability to maintain employment, loss of independent living
  - Unpredictable acts of violence, suicidal thoughts

[1] *Kessler et al, Arch Gen Psychiatry 1995;52:1048.*



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# PTSD is a prevalent problem for both civilians and the military




- **~70% are considered to have moderate to severe symptoms**
- **Of those diagnosed, ~50% utilize professional healthcare (psychotherapy/pharmacotherapy)[2]**

- **Higher prevalence in military population**
  - 20% of veterans from recent conflicts will have potential/provisional PTSD[3]
  - ~638,000 veterans with PTSD in the VA health system (2012)[4]
  - Majority are male
  - Alcohol and substance abuse are common

*[1]Kessler RC at al, Arch Gen Psychiatry 2013;62:617; U.S. Census Bureau, 2013 Projection.*
*[2]Wang et al, Arch Gen Psychiatry 2005;62:629.*
*[3]Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD.*
*[4]Bowe et al, J Dual Diagnosis 2015;11:22.*



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# Limitations of current FDA-approved pharmacotherapies for military-related PTSD



- **No treatment response observed in U.S. military population**
  - Sertraline: negative large multicenter trial in U.S. military veterans[1]
    - Placebo numerically superior on CAPS-2
  - 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 gender-related difference in treatment outcome[3]
- **Important tolerability issues with SSRIs in this population**
  - Sexual dysfunction
  - Insomnia

*SSRI: Selective Serotonin Reuptake Inhibitor.*
*[1]Friedman MJ et al. J Clin Psychiatry 2007;68:711-20.*
*[2]Zoloft® Package Insert, Pfizer, August 2014.*
*[3] Paxil® Package Insert, Glaxo, June 2014.*



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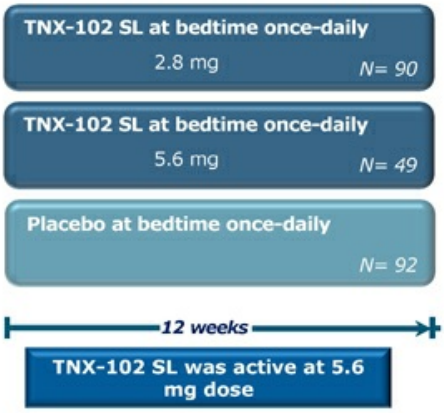
# Phase 2 AtEase trial of TNX-102 SL in PTSD






- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- Analysis from 231 patients; 24 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 week 12



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# Phase 2 AtEase study of TNX-102 SL in PTSD



## AtEase Study

- Randomized, double-blind, placebo-controlled trial
- DSM-5 diagnostic criteria for PTSD
- 231 participants studied 2:1:2 at 24 U.S. sites
  - 1 x TNX-102 SL 2.8 mg: 2 x TNX-102 SL 2.8 mg: placebo
- Evaluated CAPS-5 as primary endpoint
  - Pre-specified primary analysis was 2.8 mg dose



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# 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*



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# AtEase results on key clinical endpoints

**TNX-102 SL 5.6 mg subgroup compared to placebo**



| Category | Endpoint – week 12[1] | *p* value |
|---|---|---|
| PTSD Symptoms | CAPS-5 (MMRM with MI) | **0.031** |
| Global improvement | CGI-I | 0.041 |
| Arousal and reactivity | CAPS-5 cluster | 0.048 |
| Sleep Quality | CAPS-5 sleep | 0.010 |

**AtEase pre-specified primary analysis**: change from baseline at week 12 mean CAPS-5 score on 2.8 mg (p=0.211)

*$p < 0.05$ → statistically significant*

- MMRM with MI: Mixed-effect Model Repeated Measures with Multiple Imputation
- CAPS-5: Clinician Administered PTSD Scale-5
- CGI-I: Clinician Global Impression- Improvement

[1]*Intent-to-treat analysis, N=231 (TNX-102 SL 2.8 mg N=90, TNX-102 SL 5.6 mg N= 49, placebo N=92).*

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# AtEase Study Results

## Total CAPS-5 – Primary endpoint of Phase 3 program




*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; LS Mean, least squares mean

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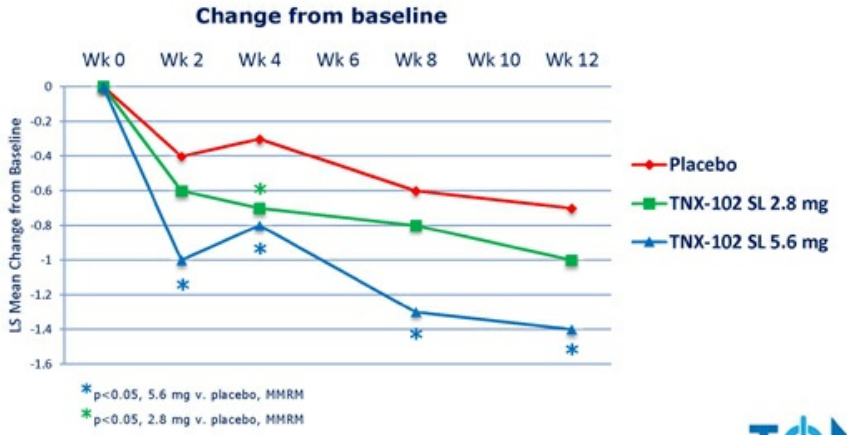
# AtEase Study Results

## CAPS-5: Sleep disturbance

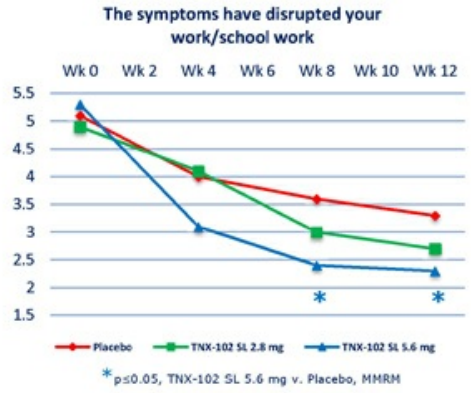




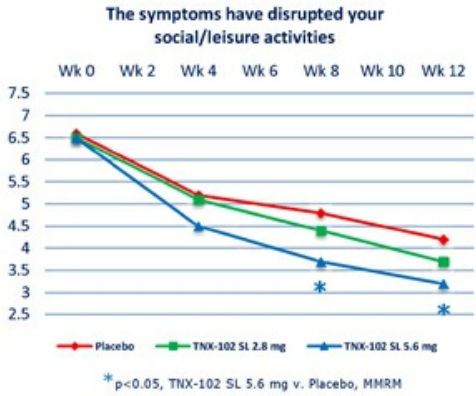
# AtEase Study Results

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






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




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

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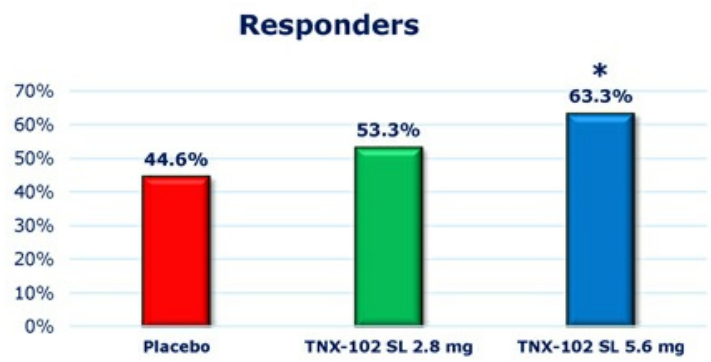
# AtEase Study Results

## Clinician Global Impression – Improvement Scale






*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"



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# TNX-102 SL safety and tolerability profile in the AtEase study

**No serious adverse events reported with TNX-102 SL deemed related to treatment** 27

| Administration Site Reactions | Placebo (N=94) | TNX-102 SL 2.8 mg (N=93) | TNX-102 SL 5.6 mg (N=50) | Total TNX-102 SL (N=143) |
|---|---|---|---|---|
| Hypoaesthesia oral | 2.1% | 38.7% | 36.0% | 37.8% |
| Paraesthesia | 3.2% | 16.1% | 4.0% | 11.9% |
| Glossodynia | 1.1% | 3.2% | 6.0% | 4.2% |
| **Systemic Adverse Events** | | | | |
| Somnolence | 6.4% | 11.8% | 16.0% | 13.3% |
| Dry Mouth | 10.6% | 4.3% | 16.0% | 8.4% |
| Headache | 4.3% | 5.4% | 12.0% | 7.7% |
| Insomnia | 8.5% | 7.5% | 6.5% | 7.0% |
| Sedation | 1.1% | 2.2% | 12.0% | 5.6% |

**Trial completion rates: 73% placebo; 79% TNX-102 SL 2.8 mg; 84% TNX-102 SL 5.6 mg**

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## AtEase Study Conclusions



- **This is the first large, multicenter trial that demonstrated efficacy in a population with military-related PTSD**
  - Male predominant (93%)
  - Low incidence of co-morbid FM (7%)
  - Low incidence of current major depression (14%)
- **Early effects on sleep and hyperarousal are consistent with the mechanistic hypothesis of TNX-102 SL primary actions on sleep disturbance and autonomic balance**



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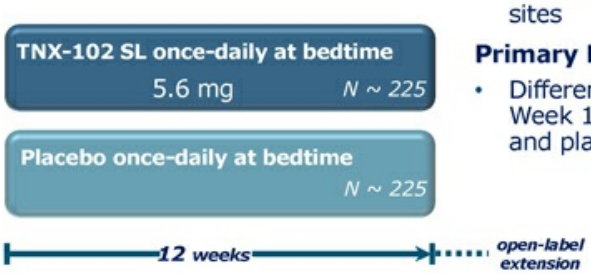
# Phase 3 program in PTSD being planned



**Planning to repeat AtEase in military-related PSTD:**

- **Larger study**
- **Targeting start in 1Q 2017**




**General Study Characteristics**:

- Randomized, double-blind, placebo-controlled study in PTSD
- N~450; approximately 35 U.S. clinical sites

**Primary Efficacy Endpoint:**

- Difference in total CAPS-5 analysis at Week 12 between TNX-102 SL 5.6 mg and placebo

**Topline data for Phase 3 in military-related PSTD study anticipated 1H 2018**

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# Intellectual property



**Wholly-owned by Tonix with no obligations to others**

**TNX-102 SL**
Fibromyalgia, PTSD

- **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



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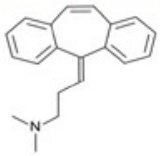
## TNX-102 SL: active pharmaceutical ingredient



- **Cyclobenzaprine is a tricyclic molecule that binds to a number of central nervous system (CNS) receptor types**



- **Highest affinity for three receptors believed to have a role in treating sleep disturbances**
  - 5-$HT_{2A}$ receptor
  - $\alpha_1$ adrenergic receptor
  - $H_1$ receptor



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# TNX-102 SL: Pharmacokinetic profile after sublingual route of administration



- **Very rapid absorption after dosing (measurable in plasma within 3 minutes of administration)**
  - Maintains $T_{max}$ at ~4 hours after administration
  - Approximately 50% of exposure to cyclobenzaprine occurs during first 8 hours
- **Avoids first-pass hepatic metabolism to persistent metabolite, norcyclobenzaprine**
  - Large reduction in exposure to norcyclobenzaprine (-48% $AUC_{0-48}$)
  - Should equally reduce both daytime and nighttime exposure to norcyclobenzaprine at steady-state
  - Decreased potential for adverse events



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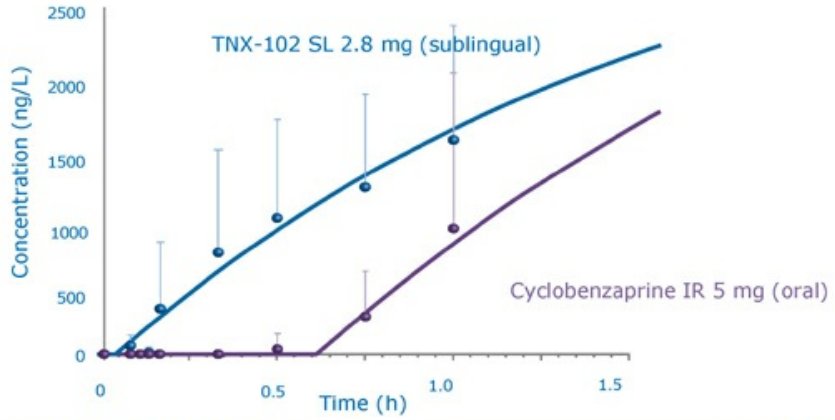
# Cyclobenzaprine is detected in plasma within minutes following sublingual TNX-102 SL

**Plasma Concentration Versus Time of TNX-102 SL Compared to oral Cyclobenzaprine IR** 33




*Source: U.S. Patent applications 13/918,692 – Transmucosal absorption.*



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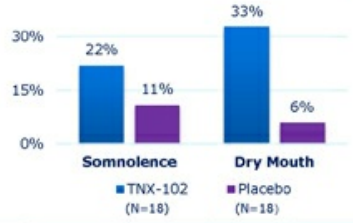
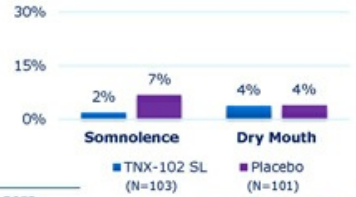
# Somnolence and dry mouth with oral and sublingual cyclobenzaprine in fibromyalgia patients



- **ORAL – Phase 2a[1]:**
  - Dose TNX-102 (CBP capsules, 1 mg)
  - Dosing regimen
    - titrated from 1 mg to a range of 2 to 4 mg
    - average of 3.1 mg per day
    - Administered once daily for 8 weeks
    - Administered between dinner and bedtime




- **SUBLINGUAL – Phase 2b (BESTFIT)[2]:**
  - Dose TNX-102 SL (CBP sublingual tablets, 2.8 mg)
  - Dosing regimen
    - 2.8 mg per day
    - Administered once daily for 12 weeks
    - Administered at bedtime




[1]Moldofsky H, et al "Effects of bedtime very low dose cyclobenzaprine..." J. Rheumatol 2011 38:2653.
[2]Lederman, S et al., Arthritis Rheumatol. 2015; 67 (suppl 10).

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# Financial overview



| NASDAQ: TNXP | |
|---|---|
| Cash, cash equivalents, and marketable securities reported at March 31, 2016 | $ 27.5 million |
| Net proceeds from underwritten offering in 2Q16 | $9.1 million |
| Net proceeds from overallotment in 3Q16 | $1.4 million |
| Shares outstanding (July 25, 2016) | 25.8 million |



TONIX PHARMACEUTICALS

# Management team



| | |
|---|---|
| **Seth Lederman, MD**<br>President & CEO | TARGENT X · Fusilev (levoleucovorin) for injection · vela |
| **Bruce Daugherty, PhD, MBA**<br>Chief Scientific Officer | MERCK · Roche |
| **Gregory Sullivan, MD**<br>Chief Medical Officer | Columbia University Department of Psychiatry · New York State Psychiatric Institute |
| **Bradley Saenger, CPA**<br>Chief Financial Officer | Shire · VERTEX · Steward · pwc |
| **Jessica Edgar Morris**<br>EVP, Administration | Deutsche Bank · svb Silicon Valley Bank · American Capital |
| **Ronald Notvest, PhD**<br>EVP, Commercial Planning & Development | Wyeth · Rapamune sirolimus · Evidec |

# Board of directors



| | |
|---|---|
| **Seth Lederman, MD**<br>Chairman | **Ernest Mario, PhD**<br>ALZA, Glaxo, Reliant Pharma |
| **Stuart Davidson**<br>Labrador Ventures, Alkermes, Combion | **Charles Mather**<br>BTIG, Janney, Jefferies, Cowen, Smith Barney |
| **Patrick Grace**<br>Apollo Philanthropy, WR Grace, Chemed | **John Rhodes**<br>NYSERDA, NRDC, Booz Allen Hamilton |
| **Donald Landry, MD, PhD**<br>Chair of Medicine, Columbia University | **Samuel Saks, MD**<br>Jazz Pharma, ALZA, Johnson & Johnson |



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# Milestones – recent and upcoming



## TNX-102 SL – Fibromyalgia

| | | |
|---|---|---|
| ☑ | May 2015 | Began Phase 3 AFFIRM study |
| ☑ | November 2015 | Presented additional data from Phase 2b BESTFIT study at ACR Meeting |
| ☑ | May 2016 | Reported completion of enrollment in Phase 3 AFFIRM study |
| ☑ | July 2016 | Commence enrollment of 2nd Phase 3 RE-AFFIRM study |
| ☐ | Q3 2016 | Report results from Phase 3 AFFIRM study |

## TNX-102 SL – Post-Traumatic Stress Disorder

| | | |
|---|---|---|
| ☑ | December 2015 | Entered into Collaborative Research and Development Agreement (CRADA) with the United States Army Medical Materiel Development Activity (USAMMDA) |
| ☑ | December 2015 | Reported completion of enrollment in Phase 2 AtEase study |
| ☑ | May 2016 | Report results from AtEase study |
| ☐ | Q1 2017 | Target commencement of Phase 3 study in PTSD |



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**NASDAQ: TNXP**

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**Exhibit 99.02**

**Tonix Pharmaceuticals Initiates Second Pivotal Phase 3 Clinical Study of TNX-102 SL in Fibromyalgia**

*First Pivotal Phase 3 Study of TNX-102 SL to Report Topline This Quarter*

NEW YORK, July 26, 2016 – Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced today that the first patient has been randomized in RE-AFFIRM, the second Phase 3 clinical study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, in fibromyalgia.

Seth Lederman, M.D., president and chief executive officer of Tonix, said, "We have taken an important step forward in advancing the clinical development of a much-needed new therapy for the 5 to 15 million people in the U.S. suffering with fibromyalgia by initiating our second pivotal Phase 3 study of TNX-102 SL in fibromyalgia. This is a once-daily bedtime sublingual formulation designed to treat fibromyalgia by improving sleep quality, and given the results of our Phase 2b BESTFIT study, we believe TNX-201 SL could offer therapeutic benefits to patients with fibromyalgia across a broad spectrum of symptoms**.** It has the potential to capture an important share of the $1.2 billion market for approved fibromyalgia drugs. The clinical phase of AFFIRM, our first Phase 3 study of TNX-102 SL in fibromyalgia, is now complete and we anticipate announcing its topline data later this quarter."

RE-AFFIRM is a randomized, double-blind, placebo-controlled study similar in design to the ongoing AFFIRM Phase 3 clinical trial of TNX-102 SL in fibromyalgia. The U.S. Food and Drug Administration (FDA) requires two well-documented registration-quality clinical studies to support marketing approval of a new drug. Like AFFIRM, RE-AFFIRM is expected to enroll approximately 500 fibromyalgia patients at approximately 35 clinical centers in the U.S. For information about RE-AFFIRM, please visit www.clinicaltrials.gov.

RE-AFFIRM will evaluate the efficacy of TNX-102 SL, taken daily at bedtime, in improving pain, sleep quality, and other clinical measures, as well as safety. As accepted by the FDA, the primary outcome assessment of the study will be a pain responder analysis, defined as the proportion of patients who report at least a 30 percent reduction in pain from baseline at the end of the 12-week treatment period. In Tonix's Phase 2b BESTFIT trial of TNX-102 SL in fibromyalgia patients, the 30 percent responder analysis was a pre-specified secondary outcome measure and achieved a statistically significant p-value of 0.033.

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

**About Fibromyalgia**

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

**About TNX-102 SL**

TNX-102 SL is designed to deliver cyclobenzaprine to the bloodstream rapidly via sublingual (under the tongue) absorption and to bypass first-pass hepatic metabolism. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is under clinical development for the treatment of fibromyalgia and PTSD and is intended to provide broad spectrum improvement by targeting sleep and the stress response. Tonix is developing TNX-102 SL 2.8 mg for daily bedtime administration for the treatment of fibromyalgia and TNX-102 SL 5.6 mg for daily bedtime administration for the treatment of PTSD. The FDA has provisionally accepted the trademark Tonmya® for TNX-102 SL for fibromyalgia.

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

**Forward Looking Statements**

*Certain statements in this press release are forward-looking within the meaning of 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," "expect," 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 FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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 Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.*

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