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): December 19, 2016

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

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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 December 19, 2016, the Company issued a press release announcing that the U.S. Food and Drug Administration granted Breakthrough Therapy designation to the Company's TNX-102 SL for the treatment of posttraumatic stress disorder.

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 December 2016*
99.02	Press release, dated December 19, 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: December 19, 2016

By: */s/ SETH LEDERMAN*
Seth Lederman
Chief Executive Officer

Exhibit 99.01

Investor Presentation

TONIX PHARMACEUTICALS

December 2016

Version P0044 12-19-16

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 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.

Posttraumatic Stress Disorder (PTSD) program

On May 19, 2016, we reported encouraging topline data for TNX-102 SL* 5.6 mg in a military-related PTSD trial ("AtEase")

- PTSD was our "second" clinical program using our proprietary formulation TNX-102 SL
- Prior to the AtEase trial, no other investigational new drug or approved therapy had demonstrated efficacy in military PTSD in a large adequate well-controlled study

On August 29, 2016, we reported U.S. Food and Drug Administration (FDA) acceptance of the PTSD Phase 3 clinical program at the End-of-Phase 2 meeting

- However, advancing TNX-102 SL for PTSD was not in our budget

* TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an Investigational New Drug and has not been approved for any indication

Tonix (TNXP): Value proposition

On September 6, 2016 our lead Phase 3 program TNX-102 SL for fibromyalgia narrowly missed its primary endpoint in the first Phase 3 study ("AFFIRM")

- Received strong negative investor market response
- Reassuring safety profile and activity of TNX-102 SL at 2.8 mg for improvement in sleep quality in fibromyalgia sets stage for new clinical direction in PTSD

We simultaneously announced that we discontinued our fibromyalgia program and we are focusing our resources to PTSD

- High value Phase 3 clinical asset not well known to the market
- Encouraging evidence of safety and efficacy of TNX-102 SL was demonstrated in Phase 2 AtEase trial
- Regulatory clarity for PTSD based on FDA acceptance of PTSD Phase 3 clinical program at End-of-Phase 2 meeting

Pivot to PTSD: Rationale

- **Unmet medical need**
  - PTSD is a serious condition and the prevalence is increasing, especially combat-related
  - Military-related PTSD is not satisfactorily treated by existing FDA approved therapies
  - Two selective serotonin reuptake inhibitors (SSRIs) are approved for PTSD, but have not shown efficacy in military-related PTSD
- **Endpoint**
  - TNX-102 SL 5.6 mg had significant effects on the FDA-recognized primary endpoint, the Clinician Administered PTSD Scale, "CAPS-5"
- **Potential development and commercialization partners**
  - Several companies have U.S. psychiatry-focused specialty sales forces
  - Department of Defense (DoD) is interested in military-related PTSD and has the potential to support basic science and clinical development
- **Important target population**
  - U.S. veterans are in great need of a medicine that works for this serious condition

Breakthrough Therapy designation

- **FDA granted TNX-102 SL Breakthrough Therapy designation – reported December 19, 2016**
  - PTSD is a serious condition
  - TNX-102 SL has the potential to have advantages over existing therapies in military-related PTSD

- **Benefits of Breakthrough Therapy designation**
  - Priority review of the New Drug Application (NDA) within 6 months instead of 10 months
  - Rolling submission of portions of the NDA
  - An organizational commitment involving FDA's senior managers to accelerate the development and approval process contributing significant guidance

Tonix Pharmaceuticals PTSD Program

Phase 3 Ready Program

TNX-102 SL (cyclobenzaprine HCl sublingual tablets)

- A unique, innovative product designed for bedtime administration
- Targeting a chronic and serious psychiatric disorder: **PTSD**
  - ✓ **Therapeutic dose identified in Phase 2 study**
  - ✓ **Phase 3 clinical and product registration plan accepted by the FDA[1]**
  - ✓ **Targeting commencement of Phase 3 study in military-related PTSD in 1Q 2017**

Targeting An Attractive Market

PTSD

- High prevalence worldwide and receiving greater attention
- Not well served - high off-label usage[2] with unproven or contraindicated treatments[3]
- Potential opportunity to displace current standard-of-care and expand market

1. August 2016 FDA End-of-Phase 2 Meeting Minutes
2. Bernardy et al., J Clin Psychiatry, 2012; 73: 297
3. VA/DoD Clinical Practice Guideline for the Management of Post-Traumatic Stress, Version 2, 2010

What is PTSD?

A chronic response to traumatic event(s)

- A majority of people will experience a traumatic event at some point in their lifetime[1]
  - 20% of women and 8% of men in the U.S. who experience significant trauma develop PTSD[1]
  - *Lifetime prevalence:* 6.8%[2] (~ 17 million adults in the U.S.)
    - Persistent - >1/3 fail to recover, even after several years following the trauma[2]
  - *Twelve month prevalence:* *U.S.* 3.5%[3] (~ 8.6 million adults)
    EU 2.3%[4] (~10 million adults)

Most common forms of trauma[1]

- Witnessing someone being badly injured or killed
- Natural disaster
- Life-threatening accident
- Sexual or physical assault

1. Kessler et al, Arch Gen Psychiatry 1995;52:1048.
2. Kessler et al., Arch Gen Psychiatry. 2005;. 62:593
3. Kessler et al., Arch Gen Psychiatry. 2005; 62: 617; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
4. The European Union Market Potential for a New PTSD Drug. Prepared for Tonix Pharmaceuticals by Procela Consultants Ltd September 2016.

What Are the Symptoms of PTSD?

Symptoms of PTSD fall into four clusters:

1. Intrusion (aversive memories, nightmares, flashbacks)
2. Avoidance (avoiding persons, places or situations)
3. Mood/cognitions (memory block, emotional numbing, detachment from others)
4. Hyperarousal (anxiety, agitation & **sleep disturbance**)

Symptoms assessed for diagnosis, severity and treatment effect

- **Clinician Administered PTSD Scale ("CAPS-5")**
  - Recognized as the standard for rating PTSD severity in clinical trials
  - Takes into account all four symptom clusters

What Are the Consequences of PTSD?

Consequences:

- Impaired daily function and substantial interference with work and social interactions
- Reckless or destructive behavior
- Increased health care utilization and greater medical morbidity

PTSD as a risk factor for:

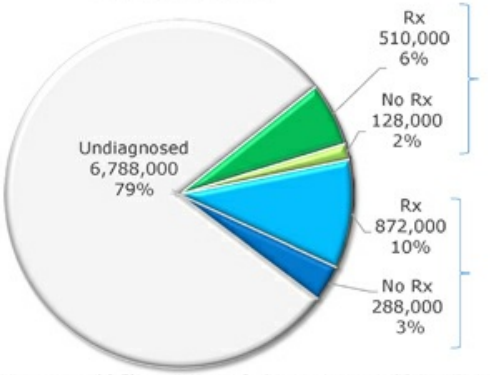
- Depression
- Alcohol or substance abuse
- Absenteeism/unemployment
- Homelessness
- Violent acts
- Suicidal thoughts and suicide

Unmet Needs:

- Effective therapy for populations not well served by current treatment (males, military trauma)
- Alternative therapy for the majority of patients unresponsive or intolerant to current treatments
- Drug therapy compatible and complementary with behavioral therapy

PTSD Prevalence and Market Characteristics

Prevalent Population (U.S.)
~8.6 million[1]



Veterans Treated in Veterans Administration (VA)[3,4]

Civilian Population[2]

Diagnosed population

- Large population (~1.8 million)
- Majority receive drug treatment
  - Civilians: ~75%[2]
  - Veterans: ~80%[4]

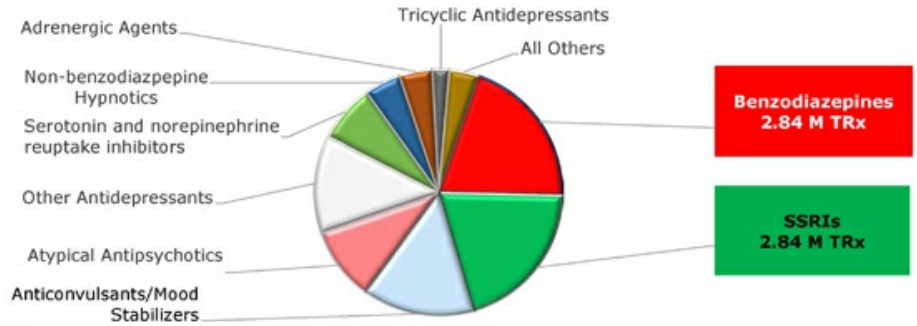
1. Kessler, et al., 2005; ; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
2. IMS Consulting, *Market Sizing & Treatment Dynamics: Post-Traumatic Stress Disorder (PTSD) Patients"*, 2016
3. Bowe and Rosenheck, 2015 ((638,451 veterans diagnosed with PTSD in the VA in fiscal year 2012 across all medical centers)
4. Bernardy et al., 2012 (80% of veterans diagnosed with PTSD had at least one medication from the Clinical Practice Guidelines)

What Drug Classes are Used to Treat PTSD?

Market highly fragmented, with benzodiazepines being widely prescribed (but not indicated[1])

- Multiple medications per patient (or "Polypharmacy") is the norm
  - Approximately 55% of patients receive a benzodiazepine, and 53% receive an selective serotonin reuptake inhibitor (SSRI)
- SSRIs are the only FDA approved drug class

Estimated PTSD Market Volume (Civilian Population Only) ~14.1 million TRx*[2]



* TRx = Total prescriptions

1. VA/DoD Clinical Practice Guideline for the Management of Post-Traumatic Stress, Version 2, 2010
2. IMS Consulting, *Market Sizing & Treatment Dynamics: Post-Traumatic Stress Disorder (PTSD) Patients*", 2016

Relevance of Sleep Disturbances for PTSD

Sleep disturbances:

- Core symptom of PTSD (component of intrusion and hyperarousal symptom clusters)
- Believed to play roles in the pathophysiology of PTSD

	Sleep As a Core Symptom	Pathophysiology	Pharmacological Action 2° Clinical Endpoint	Therapeutic Benefit 1° Clinical Endpoint
PTSD	• **Nightmares** • **Hyperarousal**	**Stress ≈ Hyperarousal ≈ Sleep Disturbances** Hyperarousal and hypervigilance interfere with sleep and emotional memory processing during sleep	**Reduced hyperarousal**	**Reduced PTSD symptoms and disability**

TNX-102 SL: Innovative and Unique By Design

Active Pharmaceutical Ingredient (API) is cyclobenzaprine (CBP), is structurally related to tricyclic antidepressants (TCAs)

- TCAs and their metabolites differ widely in their receptor binding and pharmacokinetic profiles[1]

Different from other tricyclics

- **CBP is more selective for high affinity sites believed to have a role in sleep quality[2]**
  - 5-HT_{2A}
  - α_1-adrenergic
  - histamine H_1
- **CBP undergoes extensive first-pass hepatic metabolism when administered orally**
  - Major metabolite, norcyclobenzaprine (nCBP)
    - Long half-life (~72 hours)
    - Less selective for target receptors (5-HT_{2A}, α_1-adrenergic, histamine H_1)
    - More selective for norepinephrine transporter

Different from oral CBP formulation

TNX-102 SL: Innovative sublingual formulation of CBP

- Rapid systemic exposure
- Increased bioavailability
- Avoids first-pass metabolism
- Lowers exposure to long-lived active major metabolite, nCBP

1. Rudorfer and Potter, *Cellular and Molecular Neurobiology, 1999 19:373*
2. Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015,Toronto, Ontario, Canada

Why Initially Target Military-Related PTSD?

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

- ***No clear treatment response observed in U.S. military population***

  Sertraline: failed to show efficacy in a large multicenter trial in U.S. military (placebo numerically better)[1]
  Paroxetine: no large trials conducted with predominantly military trauma

- **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]

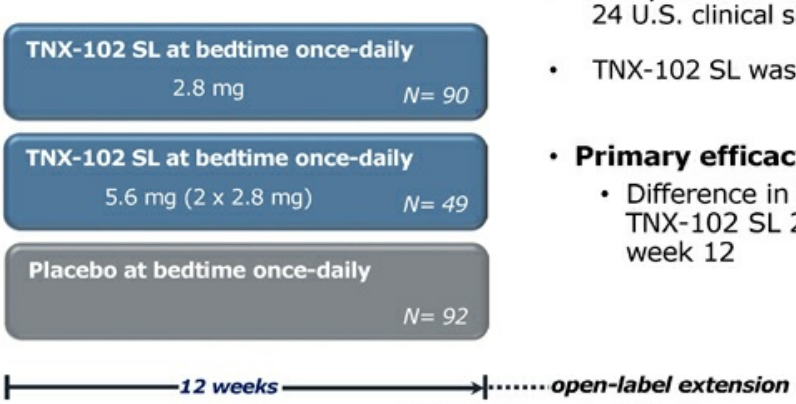
- **Important tolerability issues with SSRIs in this population**

  Sexual dysfunction[2,3]
  Insomnia[2,3]
  SSRI withdrawal syndrome[4]

1. Friedman et al., J Clin Psychiatry 2007; 68:711, 2. Zoloft Package Insert, August, 2014, 3. Paxil Package Insert, June, 2014,
4. Fava et al., Psychother Psychosom 84:72-81, 2015

Phase 2 AtEase Study in Military PTSD

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



- Enrolled patients with baseline CAPS-5 ≥ 29
- Analysis from 231 patients; 24 U.S. clinical sites
- TNX-102 SL was active at 5.6 mg dose
- **Primary efficacy analysis:**
  - Difference in CAPS-5 score between TNX-102 SL 2.8 mg and placebo at week 12

AtEase Study Demographics and Characteristics

- 93% of the randomized patients were male
- 98% had trauma during military service
- Deployed an average of 2.3 times
- Mean time since index trauma was 7 years
- Race and ethnicity generally consistent with U.S. military distribution
- Current Major Depressive Disorder 14% by MINI 7.0
- Similar baseline CAPS-5 scores and MADRS scores across treatment arms

Variable	Placebo N=92	TNX-102 SL 2.8 mg N=90	TNX-102 SL 5.6 mg N=49	Overall N=231
Baseline CAPS-5 Scores (SD)	39.5 (7.7)	39.5 (8.0)	39.3 (8.1)	39.5 (7.85)
Baseline MADRS Scores (SD)	17.3 (6.5)	17.6 (5.2)	16.1 (5.5)	17.1 (5.83)

CAPS-5, Clinician Administered PTSD Scale for DSM-5
MADRS, Montgomery-Åsberg Depression Rating Scale
MINI 7.0, Mini-International Neuropsychiatric Interview, version 7
SD, standard deviation

AtEase Study: Traumas Associated with PTSD

Index Trauma During Military Service	Patient Count*
Being involved in an IED explosion or suicide bombing	35
Witness death or injury of fellow soldiers	33
Witnessing IED explosion	30
Receiving incoming artillery, rocket, or mortar fire	29
Being wounded or injured	10
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	9
Witnessing death or injury of civilians	8
Handling or uncovering human remains	7
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
Being responsible for the death of an enemy combatant	4
Seeing dead bodies or human remains	4
Other	11

*Some patients experienced more than one trauma

AtEase Study – Summary of Primary and Secondary Analyses (week 12)

Assessment	Domain	Analysis	p-Values	
			2.8 mg (N=90)	5.6 mg (N=49)
CAPS-5	Total	MMRM	0.259^	0.053
	Total	MMRM with Multiple Imputation	0.211	0.031*
	Total	MMRM w/ Hybrid LOCF/BOCF	0.172	0.037*
	Total	ANCOVA	0.090	0.038*
CAPS-5 clusters/items	Arousal & Reactivity cluster (E)	MMRM	0.141	0.048*
	Sleep item (E6)	MMRM	0.185	0.010*
	Exaggerated Startle item (E4)	MMRM	0.336	0.015*
CGI-I	Responders	Logistic Regression	0.240	0.041*
PGIC	Mean score	MMRM	0.075	0.035*
Sheehan Disability Scale	Work/school item	MMRM	0.123	0.050*
	Social/leisure item	MMRM	0.198	0.031*

BOCF, baseline observation carried forward; CGI-I, Clinical Global Impression - Improvement scale; LOCF, last observation carried forward; MMRM, mixed model repeated measures; PGIC, Patient Global Impression of Change

^Primary analysis p-value not significant comparing TNX-102 SL 2.8 mg versus placebo

*p<0.05

AtEase Study: Safety and Tolerability Profile

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

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

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

*at rates of >5% in either drug-treated arm, Safety population N=237

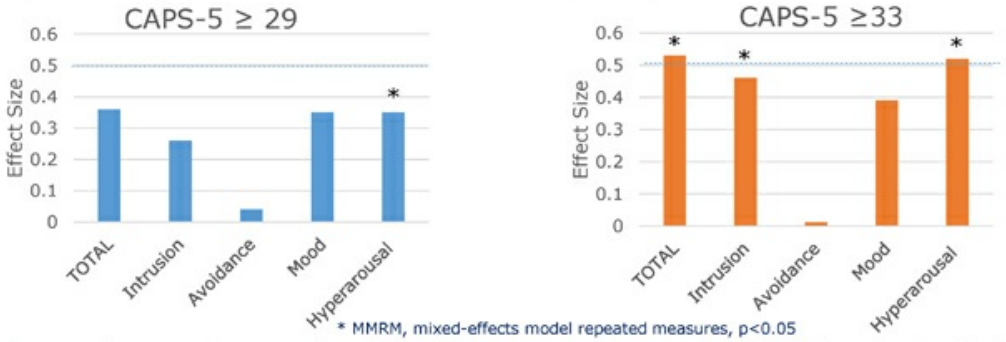
AtEase: Retrospective Analysis for TNX-102 SL 5.6 mg

Prior pharmacotherapy trials in PTSD used *earlier versions* of CAPS (e.g. CAPS-2)

- Different scoring range from CAPS-5
- Most frequently used a score of ≥ 50 for entry (similar to CAPS-5 ≥ 33[1])
- FDA has accepted this higher entry criteria (CAPS-5 ≥ 33) for Phase 3 program

Compared CAPS-5 Severity Entry Criteria ≥ 29 versus ≥ 33 on Effect Size for AtEase

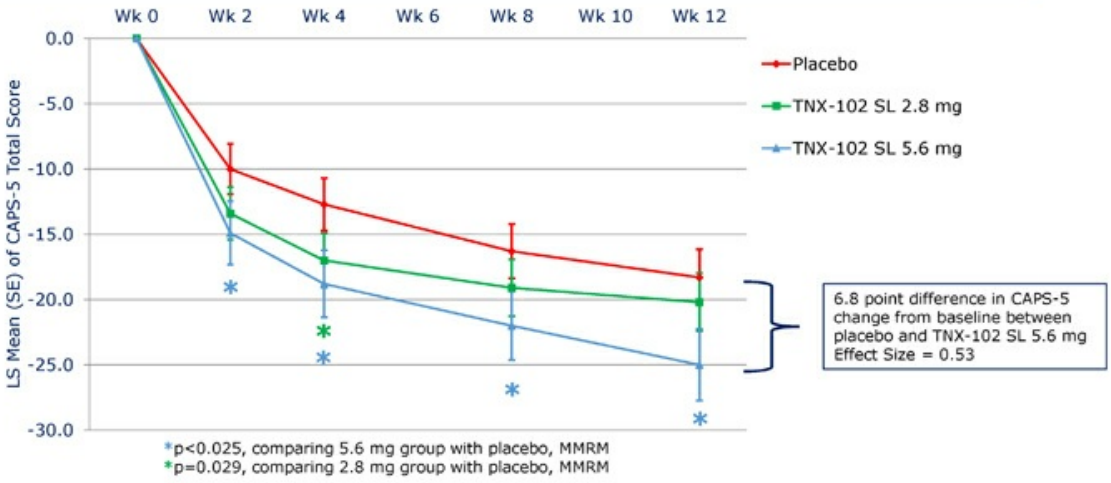
- Retrospective analysis showed more robust effect with high entry criteria



* MMRM, mixed-effects model repeated measures, p<0.05

[1]*Sullivan, Gregory, et al. Poster session presented at: Military Health System Research Symposium (MHSRS) 2016 Annual Meeting; 2016 Aug 15-18; Kissimmee, FL. URL: http://bit.ly/2bFo4mx*

Retrospective Analysis of CAPS-5 in patients with entry CAPS-5 ≥ 33[1]



[1]Primary analysis was TNX-102 SL 2.8 mg with entry CAPS-5 ≥ 29

Week 12 outcome measures for TNX-102 SL 5.6 mg vs. placebo in military-related PTSD for CAPS-5 ≥ 29 and CAPS-5 ≥ 33 at baseline

	PBO N=92, 5.6mg N=49; CAPS-5 ≥ 29		PBO N=77, 5.6mg N=38; CAPS-5 ≥ 33	
Outcome Measure	**ES[1]**	**p-value[2]**	**ES[1]**	**p-value[2]**
CAPS-5				
Total score	0.36	0.053	0.53	*0.013
Cluster B (intrusion)	0.26	0.161	0.46	*0.026
Cluster C (avoidance)	0.04	0.963	0.12	0.522
Cluster D (mood/cognition)	0.35	0.062	0.39	0.065
Cluster E (arousal and reactivity)	0.35	*0.048	0.52	*0.012
E6 (Sleep item)	0.51	*0.010	0.51	*0.013
E2 (Reckless/Self Destruct)	0.15	0.140	0.30	*0.012
CGI–I (responders)	2.11	*0.041	2.29	*0.042
SDS				
Total Score	0.33	0.079	0.35	0.093
Work/School item	0.34	0.050	0.41	*0.040
Social/Leisure item	0.38	*0.031	0.35	0.116
Family Life/Home Responsibilities item	0.12	0.524	0.15	0.455

1Cohen's d for CAPS-5 and Sheehan Disability Scale outcome measures; odds ratio from logistic regression for CGI-I.
2CAPS-5 and Sheehan Disability Scale outcome measures: p-values from mixed-effects model repeated measures statistical test on the mean change from baseline difference between TNX-102 SL 5.6 mg and placebo; CGI-I: p-values from a repeated measure logistic regression (Responder defined as a patient who was rated as "1" very much improved, or "2" much improved at week 12). *denotes statistical significance difference with p<0.05, not adjusted for multiple comparisons; Abbreviations: 5.6 mg=TNX-102 SL 5.6 mg; CAPS-5=Clinician-Administered PTSD Scale for DSM-5; ES=Effect Size; N=number of patients; PBO=Placebo; SDS=Sheehan Disability Scale.

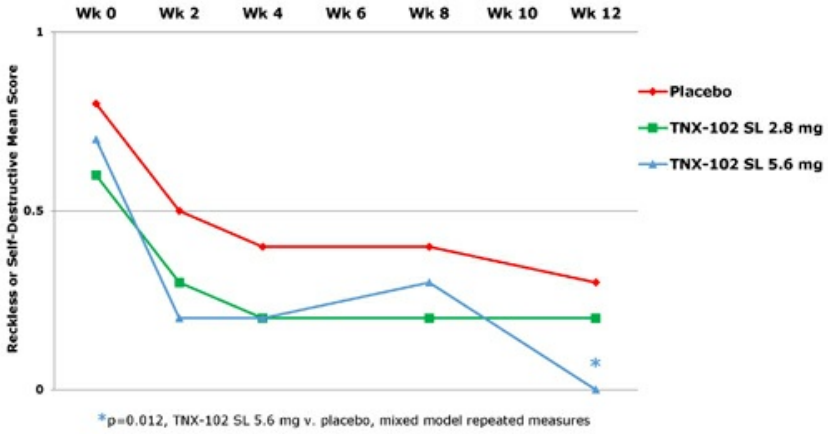
Week 12 outcome measures for TNX-102 SL 5.6 mg vs. placebo in combat PTSD subset for CAPS-5 ≥ 29 and CAPS-5 ≥ 33 at baseline

	PBO N=74, 5.6mg N=46; CAPS-5 ≥ 29		PBO N= 64, 5.6mg N=35; CAPS-5 ≥ 33	
Outcome Measure	**ES[1]**	**p-value[2]**	**ES[1]**	**p-value[2]**
CAPS-5				
Total score	0.42	*0.037	0.57	*0.013
Cluster B (intrusion)	0.26	0.183	0.50	*0.031
Cluster C (avoidance)	0.04	0.824	0.11	0.570
Cluster D (mood/cognition)	0.41	*0.035	0.42	0.061
Cluster E (arousal and reactivity)	0.40	*0.036	0.57	*0.012
E6 (Sleep item)	0.58	*0.003	0.58	*0.010
E2 (Reckless/Self Destruct)	0.15	0.178	0.30	*0.019
CGI–I (responders)	2.15	*0.049	2.12	0.082
SDS				
Total Score	0.41	*0.039	0.47	*0.032
Work/School item	0.40	*0.026	0.40	*0.015
Social/Leisure item	0.50	*0.013	0.51	*0.028
Family Life/Home Responsibilities item	0.19	0.328	0.22	0.274

1Cohen's d for CAPS-5 and Sheehan Disability Scale outcome measures; odds ratio from logistic regression for CGI-I.
2CAPS-5 and Sheehan Disability Scale outcome measures: p-values from mixed-effects model repeated measures statistical test on the mean change from baseline difference between TNX-102 SL 5.6 mg and placebo; CGI-I: p-values from a repeated measure logistic regression (Responder defined as a patient who was rated as "1" very much improved, or "2" much improved at week 12). *denotes statistical significance difference with $p<0.05$, not adjusted for multiple comparisons; Abbreviations: 5.6 mg=TNX-102 SL 5.6 mg; CAPS-5=Clinician-Administered PTSD Scale for DSM-5; ES=Effect Size; N=number of patients; PBO=Placebo; SDS=Sheehan Disability Scale.

Analysis Using CAPS-5 ≥ 33 As Entry Criteria

Reckless or Self-Destructive Behavior Item on CAPS-5



*p=0.012, TNX-102 SL 5.6 mg v. placebo, mixed model repeated measures

Reckless or self-destructive behavior can include dangerous driving, high-risk thrill-seeking, excessive alcohol or drug use, injurious behaviors to self or others, or suicidal behaviors.

Phase 2 AtEase Study Conclusions

First large multi-center trial demonstrating efficacy of an Investigational New Drug (IND) in military-related PTSD

- ✓ TNX-102 SL therapeutic dose (5.6 mg) identified
- ✓ Symptom reduction (CAPS-5)
- ✓ Functional improvement (Sheehan Disability Scale domains)
- ✓ Clinical global impression of improvement (CGI-I)
- ✓ Evidence of meaningful clinical improvement supports the Breakthrough Therapy designation

Effects on sleep and hyperarousal

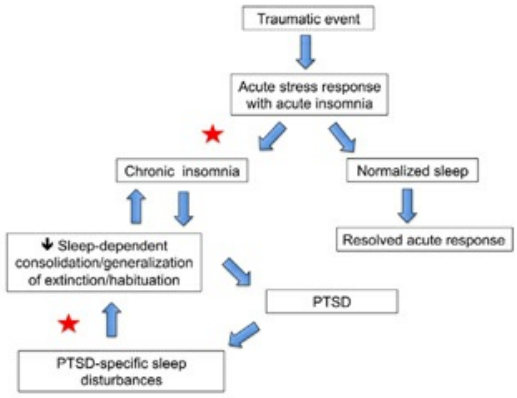
- ✓ Consistent with mechanistic hypothesis

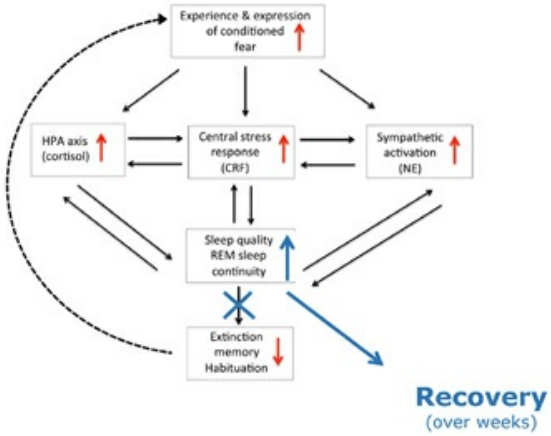
Well-tolerated; side effects include:

- ✓ Systemic: somnolence, dry mouth, headache and sedation
- ✓ Local administration site reactions: transient tongue numbness

Comprehensive AtEase study results from scientific presentations available at:
http://www.tonixpharma.com/research-development/scientific-presentations

Hypothesized mechanism of action in PTSD
Attenuation of Sleep Disruption by TNX-102 SL Leads to Recovery





Diagrams adapted from Pace-Schott et al. Biol Mood Anxiety Disord 2015;5:3

Planned Phase 3 Program in PTSD

To confirm AtEase findings in military-related PTSD:

- Larger adaptive design study
- Targeting start in 1Q 2017

TNX-102 SL once-daily at bedtime
5.6 mg *N ~ 275 (90*)*

Placebo once-daily at bedtime
N ~ 275 (90)*

12 weeks

** First interim analysis*

General Study Characteristics:

- Randomized, double-blind, placebo-controlled, entrance CAPS-5 ≥ 33
- One to two planned unblinded interim analyses (IAs)
- First IA (N ~180) for efficacy stop or sample size adjustment
- Potential to enroll 550 patients
- Approximately 30 U.S. clinical sites

Primary Efficacy Endpoint:

- Mean change from baseline in total CAPS-5 at Week 12 compared between TNX-102 SL 5.6 mg and placebo

First IA topline data anticipated 2H 2017

Commercialization Options

Tonix is exploring a variety of options to commercialize TNX-102 SL, including commercializing on our own or partnering all or some indications in specific regions of the world.

Commercial Considerations:

- Primary physician audience is well defined: psychiatrists (~30,000 in U.S.)
  - Small specialty sales force sufficient for coverage
- Primary market research with psychiatrists indicate strong interest in new therapeutic options

Intellectual Property

TNX-102 SL

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
- PTSD: patents filed

Financial overview

NASDAQ: TNXP	
Cash, cash equivalents, and marketable securities reported at September 30, 2016	$26.7 million
Net proceeds from underwritten offering in 4Q16	$4.6 million
Shares outstanding (December 19, 2016)	39.2 million

Management Team

Seth Lederman, MD President & CEO	TARGENT Fusilev (levoleucovorin) for injection vela
Gregory Sullivan, MD Chief Medical Officer	Columbia University Department of Psychiatry · New York State Psychiatric Institute
Bradley Saenger, CPA Chief Financial Officer	Shire · VERTEX · Steward · pwc
Jessica Morris EVP, Operations	Deutsche Bank · svb Silicon Valley Bank · American Capital

Board of Directors

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

Milestones – recent and upcoming

TNX-102 SL – Posttraumatic Stress Disorder

☑	December 2015	Entered into Collaborative Research and Development Agreement (CRADA) with the United States Army Medical Materiel Development Activity (USAMMDA)
☑	May 2016	Report results from AtEase study
☑	August 2016	End-of-Phase 2 meeting with FDA - Proposed Phase 3 clinical and NDA plan accepted - Breakthrough Therapy Designation Request can be submitted for review
☑	December 2016	Breakthrough Therapy designation granted by FDA
☐	1Q 2017	Target commencement of Phase 3 study in military-related PTSD
☐	2H 2017	Anticipated topline data from interim analysis of Phase 3 study in ~180 military-related PTSD patients

Summary

Strong position for value growth with Phase 3 trial in a major medical indication: PTSD including military-related PTSD

- Phase 3 asset not previously well-known to the investor marketplace

TNX-102 SL for PTSD is designed as a Breakthrough Therapy

- Accelerated development and approval process is expected

Funded through 1st interim analysis (180 patients) of Phase 3 PTSD trial expected to initiate in 1Q 2017

- Topline data from 1st interim analysis expected to be available 2H 2017

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!

Exhibit 99.02

Tonix Pharmaceuticals' PTSD Phase 3-Ready Drug Candidate, TNX-102 SL, Granted Breakthrough Therapy Designation by the FDA

Responding to AtEase study results in military-related PTSD population, FDA agrees to work closely with Tonix to develop and review TNX-102 SL for PTSD as efficiently as possible

NEW YORK, Dec. 19, 2016 – Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for PTSD, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to TNX-102 SL* for the treatment of posttraumatic stress disorder (PTSD).

The benefits of Breakthrough Therapy designation include the eligibility for priority review of the New Drug Application (NDA) within 6 months instead of 10 months and rolling submission of portions of the NDA, in addition to an organizational commitment involving FDA's senior managers contributing significant guidance. The FDA is committing to provide Tonix timely advice and interactive communications related to the design and efficient execution of a drug development program.

"We are very pleased that the FDA has granted Breakthrough Therapy designation to TNX-102 SL for PTSD," stated Seth Lederman, M.D., president & chief executive officer of Tonix. "This decision reflects the FDA's recognition that PTSD is a serious disease, and that preliminary clinical evidence from our Phase 2 AtEase study in military-related PTSD supports TNX-102 SL's potential advantage over currently-available PTSD therapies. In addition to being Phase 3-ready, the timeline for the manufacturing of commercial product to support a Breakthrough Therapy application aligns with our TNX-102 SL registration plan. As we prepare to initiate our Phase 3 HONOR study in the first quarter of 2017, we look forward to benefiting from the FDA's commitment to expedite the development and review of TNX-102 SL for PTSD by intensively involving senior staff in a proactive and collaborative effort. We believe our joint commitment to accelerate the development and registration of TNX-102 SL can potentially provide patients with PTSD, including those with military-related PTSD, an improved treatment option in the most expeditious manner possible."

Tonix held a successful End-of-Phase 2/Pre-Phase 3 meeting with the FDA in the third quarter of this year, based on positive data from its 12-week randomized, double-blind, placebo-controlled Phase 2 AtEase study. Tonix plans to begin enrolling patients into its first Phase 3 study, the HONOR study, in the first quarter of 2017 after receiving FDA agreement on the study design and interim analysis plan.

“Since TNX-102 SL is designated as a Breakthrough Therapy, we anticipate receiving FDA comments on the HONOR study protocol and proposed interim analysis plan imminently. We proposed two interim analyses for the HONOR study as part of an adaptive design, an approach recommended by the FDA to accelerate the establishment of clinical evidence of efficacy to support a Breakthrough Therapy approval,” stated Gregory Sullivan, M.D., chief medical officer of Tonix.

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

About FDA Breakthrough Therapy Designation

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a drug candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include priority review of the NDA in 6 months instead of 10 months under standard review, rolling submission of portions of the application ahead of completion of the full NDA dossier, and an organizational commitment involving FDA's senior managers with more intensive guidance from the FDA. In some cases, the development program for the Breakthrough Therapy could be shorter than for other drugs intended to treat the disease being studied. However, FDA notes that a compressed drug development program still must generate adequate data to demonstrate that the drug is safe, effective and meets the statutory standard for approval. Breakthrough Therapy designation does not change the standards for approval. If a clinical development program granted Breakthrough Therapy designation does not continue to meet the criteria, FDA may rescind the designation.

According to an FDA presentation on December 14, 2016, there have been a total of 404 Breakthrough Therapy designation requests since inception in July 9, 2012 through November 30, 2016. Of those, psychiatry projects constitute approximately 5% of the requests. Out of all 404 Breakthrough Therapy designation requests, 141 (35%) have been granted so far. Of those granted, nine (6%) were for psychiatric products.

The commitment of the FDA Psychiatry Division to expediting approval of medicines with Breakthrough Therapy designation for serious psychiatric condition is exemplified in the first approval of a Breakthrough Therapy psychiatry product, NUPLAZID® (pimavanserin) for hallucinations associated with Parkinson's disease. NUPLAZID was designated as a Breakthrough Therapy in September 2014, the NDA was submitted in September 2015 and NDA approval was received in April 2016.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, with its lead program focusing on posttraumatic stress disorder. This disorder is a serious condition 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 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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