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): September 16, 2019

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 1608, New York, New York 10022
(Address of principal executive offices) (Zip Code)

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

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TNXP	The NASDAQ Global Market

Item 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") announced the publication of a paper entitled "D-578, an orally active triple monoamine reuptake inhibitor, displays antidepressant and anti-PTSD effects in rats" (the "Publication") in the *European Journal of Pharmacology.* A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

The Company updated its corporate presentation, which it will present at the 2019 Annual National Association of Veterans' Research and Education Foundations (NAVREF) Conference on September 16, 2019, which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 and 99.02 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release, dated September 16, 2019, issued by the Company
99.02	Corporate Presentation by the Company

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: September 16, 2019

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Announces Publication of Paper on Triple Reuptake Inhibitor TNX-1600 (formerly D-578) in the European Journal of Pharmacology

NEW YORK, September 16, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the publication of a paper entitled "D-578, an orally active triple monoamine reuptake inhibitor, displays antidepressant and anti-PTSD effects in rats" in the *European Journal of Pharmacology.* The paper summarizes the behavioral pharmacological characterization of a novel triple reuptake inhibitor (TRI), TNX-1600, formerly known as D-578, which exhibits nanomolar potency at all three monoamine transporters (NET > SERT ≈ DAT) and exhibited little to no affinity for other off-target central nervous system (CNS) receptors. TNX-1600 was found to have greater efficacy in normalizing traumatic stress-induced extinction-retention learning in an animal model for posttraumatic stress disorder (PTSD) compared to paroxetine, a selective serotonin reuptake inhibitor (SSRI), which is approved by the U.S. Food and Drug Administration (FDA) to treat PTSD and other psychiatric conditions. These findings suggest TNX-1600 may reduce maladaptive retention of fearful memories via attenuation of the extinction learning and extinction retention deficits induced by traumatic stress, supporting further testing of this agent for the pharmacotherapy of PTSD. Additionally, TNX-1600 showed a robust effect in an animal model associated with antidepressant activity without affecting locomotor activity.

In August 2019, Tonix announced an exclusive license agreement with Wayne State University and an asset acquisition with TRImaran Pharma, Inc. (TRImaran) to in-license TNX-1600 to treat PTSD and potentially other CNS disorders. Under the terms of the agreement, Tonix was granted an exclusive license from Wayne State University for technology and patents related to TNX-1600 and other pyran-based compounds.

Tonix's President and Chief Executive Officer, Seth Lederman, M.D. said, "We are pleased to see the paper on TNX-1600 published in this peer-reviewed journal, and we believe that the findings support the development of this novel TRI as a potential treatment for PTSD."

Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions, to improve biodefense through potential medical counter-measures and to prevent and treat organ transplant rejection. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder, is being developed under separate Investigational New Drug applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development, the agitation in Alzheimer's program is Phase 2 ready and the alcohol use disorder program is in the pre-IND application stage. TNX-1300** (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. Tonix has two other programs in the pre-IND application stage of development for PTSD, but with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate) and TNX-1600***, a triple reuptake inhibitor. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted outside of the U.S. TNX-801 (live virus vaccine for percutaneous (scarification) administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. Finally, TNX-1500 is being developed to prevent and treat organ transplant rejection, as well as to treat autoimmune conditions, and is in the pre-IND application stage.

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

****TNX-1600* ((2*S*,4*R*,5*R*)-5-(((2-aminobenzo[*d*]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2*H*-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine), or a "triple reuptake" inhibitor.

This press release and further information about Tonix can be found atwww.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, risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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 substantial competition. 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Exhibit 99.02

Presentation to NAVREF

TONIX PHARMACEUTICALS

September 2019

Version P0196 9-16-19 (Doc 0535)

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 Tonix 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, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

Who we are:

- A clinical stage biopharmaceutical company dedicated to developing innovative treatments for patients and making meaningful contributions to society
- Focusing on small molecules and biologics to treat psychiatric, pain and addiction conditions, to improve biodefense through potential medical counter-measures and to prevent and treat organ transplant rejection

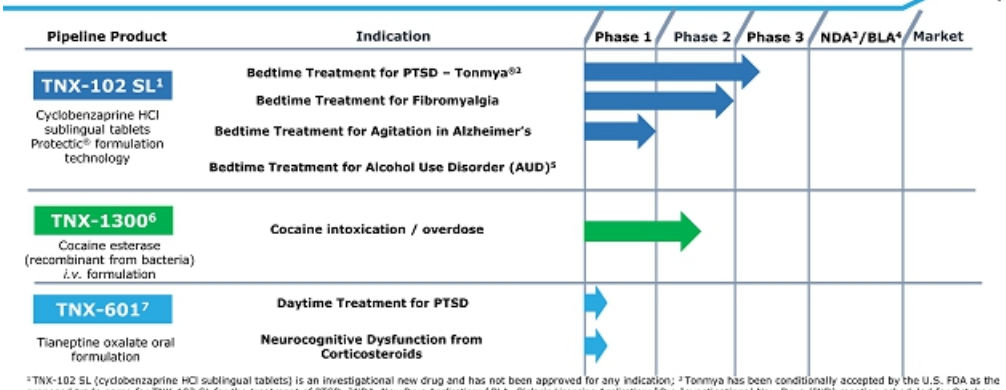
What we do:

- Target therapeutic areas with high need for improvement
  - Conditions with no, or inadequate, treatments
  - Significant patient populations not well served by existing therapies
- Develop innovative treatment options with possibility to be a "game changer"
  - Scientifically unique and innovative
  - Strong scientific rationale supported by preliminary clinical evidence and published literature
  - Proven regulatory pathways and established clinical endpoints
  - Built on a foundation of proprietary intellectual property

CNS Candidates in Clinical Development

Psychiatry, Pain and Addiction

TNX-102 SL and TNX-601 owned outright with no royalties due



¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication; ²Tonmya has been conditionally accepted by the U.S. FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD. ³NDA- New Drug Application; ⁴BLA -Biologic Licensing Application; ⁵Pre-Investigational New Drug (IND) meeting scheduled for October with FDA. Upon receiving FDA clearance of an IND application, TNX-102 SL for AUD will be Phase 2 ready as it is expected to qualify for the 505(b)(2) pathway for approval; ⁶TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication; ⁷TNX-601 is in the pre-IND stage in the U.S., but a Phase 1 study for formulation development is currently being conducted outside of the U.S.

Pipeline Summary – by Therapeutic Area

- **Psychiatry/PTSD:**
  - **TNX-102 SL – (sublingual cyclobenzaprine) for PTSD**
    - Phase 3
  - **TNX-601[1] – (tianeptine) for PTSD**
    - Phase 1 formulation development
  - **TNX-1600[2] – (triple reuptake inhibitor) for PTSD[3]**
    - Pre-clinical
- **Addiction Medicine:**
  - **TNX-1300[4] – (cocaine esterase) for cocaine intoxication**
    - Mid-Phase 2
  - **TNX-102 SL – (sublingual cyclobenzaprine) for alcohol use disorder[5] (AUD)**
    - Pre-clinical; FDA meeting in October to approve IND and Phase 2
- **Biodefense:**
  - **TNX-801 – (live horsepox vaccine) – for preventing smallpox**
    - Pre-clinical
  - **TNX-701 – (oral radioprotective agent) – for radioprotection**
    - Pre-clinical

[1]TNX-601 is in the pre-IND stage in the U.S., but a Phase 1 study for formulation development is currently being conducted outside of the U.S.; [2]TNX-1600, f.k.a. D-578 or (2S,4R,5R)-5-[[(2-aminobenzo[d]thiazol-6-yl)methyl]amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2H-pyran-4-ol is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine); [3]Dutta, AK, et al., Eur J. Pharmacol. 2019 862:172632; [4]TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication; [5]Pre-Investigational New Drug (IND) meeting scheduled for October with FDA. Upon receiving FDA clearance of an IND application, TNX-102 SL for AUD will be Phase 2 ready as it is expected to qualify for the 505(b)(2) pathway for approval.

Unmet Need for Effective and Safe Therapies for Treatment of PTSD

No FDA-approved products for PTSD since Pfizer's Zoloft® (sertraline) and GSK's Paxil® (paroxetine) circa 2000

- Neither has shown efficacy in military-related PTSD
- Male PTSD patients often unresponsive or intolerant of current treatments
- Side effects relating to sexual dysfunction, sleep disruption and weight gain are commonly reported

PTSD is signature wound of last 25 years of war

- Affects servicemember health and performance, force readiness, retention
- Believed to be the underlying cause of suicide in many cases

TNX-102 SL: a Potential Bedtime Treatment for PTSD

First investigational new drug to show treatment effect in military-related PTSD in two potential pivotal efficacy studies

- Phase 2 study (P201/AtEase) showed TNX-102 SL 5.6 mg had a strong signal of treatment effect at Week 12 as measured by CAPS-5[1]
- Phase 3 study (P301/HONOR) provided evidence of effectiveness as early as 4 weeks after treatment but diminished over time due to high placebo response
  - Retrospective analysis showed persistent effectiveness at Week 12 in subgroup with Time Since Trauma ≤9 years from screening
- Both studies can be used as supportive evidence of efficacy and safety for TNX-102 SL NDA submission
- No serious or unexpected adverse events related to TNX-102 SL were reported

Phase 3 study (P302/RECOVERY) initiated in March 2019 and currently enrolling

[1] CAPS-5 = Clinician-Administered PTSD Scale for DSM-5

Potential Therapeutic Advantages of TNX-102 SL

TNX-102 SL is believed to treat PTSD by improving sleep *quality*

- The brain naturally processes memories during sleep
- In PTSD emotionally charged memories disturb sleep and disrupt memory processing
- TNX-102 SL is believed to normalize memory processing and facilitate extinction consolidation (breaking the link between "triggers" and PTSD symptoms)

TNX-102 SL active ingredient is *NEITHER* a benzodiazepine nor a narcotic

- Does **NOT** interact with the same receptors as traditional hypnotic sleep drugs associated with retrograde amnesia and is **NOT** an opiate

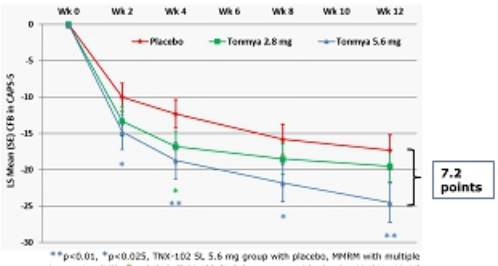
TNX-102 SL is non-addictive

- Cyclobenzaprine is the active ingredient of an orally ingested immediate release tablet (Flexeril®), approved 40 years ago
  - Flexeril's current labeling indicates no abuse and dependence concern at higher doses (15-30 mg/day) than TNX-102 SL (5.6 mg/day)
- TNX-102 SL NDA can be filed without drug abuse and dependency assessment studies

Once-daily sublingual dose taken at bedtime enhances patient adherence

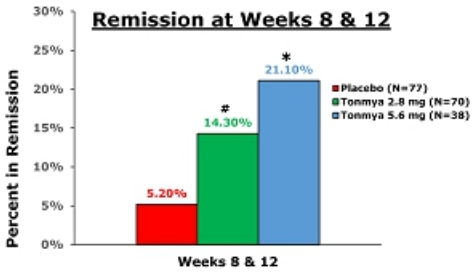
TNX-102 SL Phase 2 Dose-Effect in Military-Related PTSD[1]

PTSD Symptoms (CAPS-5[2] Score)



**p<0.01, *p<0.025, TNX-102 SL 5.6 mg group with placebo, MMRM with multiple imputation (MI); #p=0.018, TNX-102 SL 2.8 mg group with placebo, MMRM with MI

Remission at Weeks 8 & 12



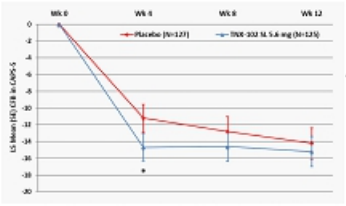
Remission = Loss of Diagnosis and CAPS-5 < 11
Asterisk and hashmark represent pairwise comparisons between TNX-102 SL and Placebo; #p=0.08, Odds Ratio 3.01 (0.89, 10.18)
*p=0.02, Odds Ratio 4.60 (1.27, 16.66); logistic regression

[1] Completed Phase 2 P201/AtEase study: Retrospective analysis of TNX-102 SL 5.6 mg on CAPS-5 ≥33 (high-moderate) subgroup. Primary analysis of P201/AtEase, based on TNX-102 SL 2.8 mg in participants with entry CAPS-5 ≥29 (moderate PTSD severity), was not statistically significant.
[2] CAPS-5 = Clinician administered PTSD Scale for DSM-5

Primary Outcome (CAPS-5) in Phase 3 Study: mITT and ≤9 Years Time Since Trauma Subgroup

Phase 3 P301/HONOR Study[1]

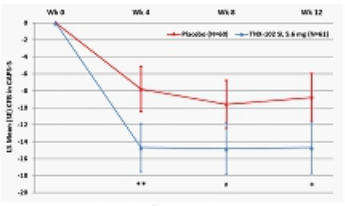
Modified intent to treat (mITT) population



*p=0.019, TNX-102 SL 5.6 mg group v. placebo, using mixed model repeated measures (MMRM) with multiple imputation (MI)

~50% mITT Population

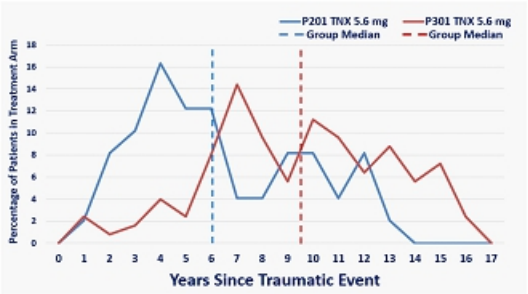
Time Since Trauma (TST) ≤9 yrs



**p=0.004, *p=0.039, #p=0.069, TNX-102 SL 5.6 mg group v. placebo, using MMRM with MI

[1] Phase 3 P301/HONOR study: stopped in July 2018. Separation on primary endpoint did not cross pre-specified study continuation threshold at Week 12 in the interim analysis at ~50% randomization; no safety or tolerability issues discovered.

Retrospective Comparison of Time Since Trauma in P201/AtEase versus P301/HONOR (TNX-102 SL 5.6 mg Groups)



P301 study was initiated approximately two years later than Phase 2 P201

- The median time since trauma in P301 was 9.5 years compared to the median time since trauma in P201 of 6.0 years for TNX-102 SL 5.6 mg treated groups

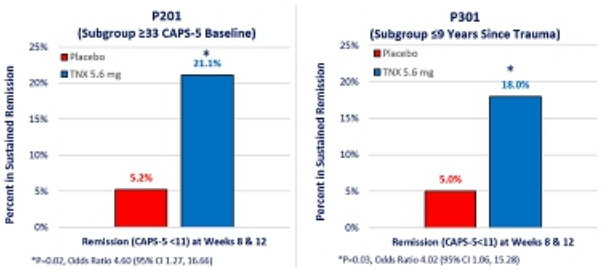
Sustained Remission in Phase 2 and Phase 3 Studies:
Retrospective Analyses of P201 Entry CAPS-5 ≥33 and P301 ≤9 Years Since Trauma Subgroups

Remission is a clinical state that is essentially asymptomatic

In order to confirm remission:

- Determined rates of participants who met remission status at *both* Week 8 and Week 12

Rate of remission in ≤9 years since trauma group in P301 is similar to baseline CAPS-5 ≥ 33 group in P201[1]



[1] Majority of P201 participants were ≤ 9 years since trauma and ~80% of P201 participants and all of P301 participants were ≥ 33 CAPS-5 at baseline

Adverse Events (AEs) in P201/AtEase and P301/HONOR Studies

	P201			P301	
Category of Adverse Reaction Preferred Term	Placebo (N=94)	TNX 2.8 mg (N=93)	TNX 5.6 mg (N=50)	Placebo (N=134)	TNX 5.6 mg (N=134)
Systemic Adverse Events*#					
Somnolence	6.4%	11.8%	16.0%	9.0%	15.7%
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%		
Local Administration Site Reactions*#					
Hypoaesthesia oral	2.1%	38.7%	36.0%	1.5%	37.3%
Paraesthesia oral	3.2%	16.1%	4.0%	0.7%	9.7%
Glossodynia	1.1%	3.2%	6.0%		
Product Taste Abnormal				3.0%	11.9%

*only adverse events (AEs) are listed that are at a rate of ≥ 5% in any TNX-treated group
#no values in a row for either study means the AE in the active group(s) in that study was at a rate of <5%

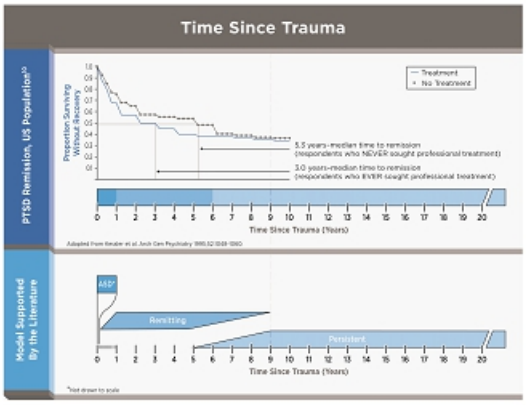
No serious or unexpected AEs in P201 or P301 related to TNX-102 SL

- Systemic AEs comparable between studies and also consistent with those described in approved oral cyclobenzaprine product labeling
- Severity and incidence of oral hypoesthesia (oral numbness) are not dose related and similar in both studies

Time Since Trauma – Remitting and Persistent Phases of PTSD

Kessler et al[1] studied remission in PTSD with and without therapy

- Identified remitting and persistent phase of PTSD – with transition at approximately 6 years post trauma
- Supported by other studies[2-6]



[1]Kessler et al. *Arch Gen Psychiatry* 1995;52:1048-1060.
[2]Ammenta et al. *BMC Psychiatry* 2018;18:48.
[3]Galatzer-Levy et al. *PLOS ONE* 2013;8:e70084.
[4]Perkonigg et al. *Am J Psychiatry* 2005;162:1320-1327.
[5]Santiago et al. *PLOS ONE* 2013;8:e59236.
[6]Davidson & Connor. *Eur Neuropsychopharmacol* 2001;11(Supp3):S148-S149.

TNX-102 SL for PTSD: New Phase 3 P302/RECOVERY Study – Initiated 1Q 2019

General study characteristics:

- Randomized, double-blind, placebo-controlled study with baseline CAPS-5[1] ≥ 33 in approximately 30 U.S. sites
- Enrollment restricted to study participants with PTSD who experienced an index trauma ≤ 9 years from the date of screening
- Both civilian and military-related PTSD to be included

Primary endpoint:

- CAPS-5[1] mean change from baseline at Week 4 (TNX-102 SL 5.6 mg vs. placebo)

Key Secondary endpoints include:

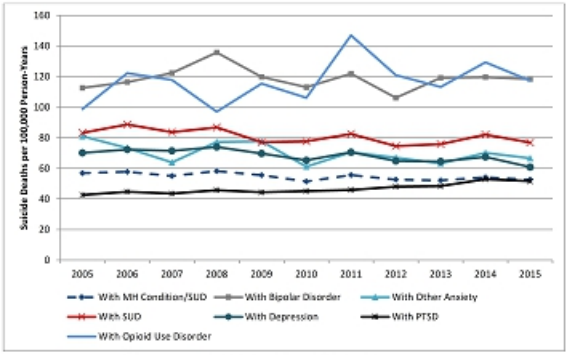
- CAPS-5 mean change from baseline at Week 12 (TNX-102 SL 5.6 mg vs. placebo)
- Change from baseline Clinical Global Impression – Severity scale
- Change from baseline Sheehan Disability Scale total score

Potential pivotal efficacy study to support NDA approval

[1]CAPS-5 = Clinician-Administered PTSD Scale for DSM-5

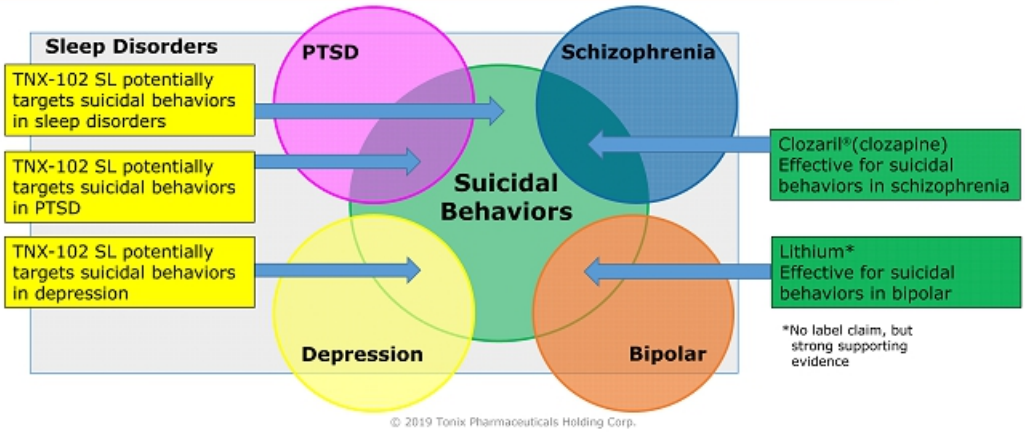
Clear Suicide-PTSD Link Among Veterans Using the Veterans Health Administration (VHA)[1]

Figure 32. Suicide Rate per 100,000 Person-Years, Among Veteran VHA Users With Mental Health (MH) Conditions or Substance Use Disorders (SUD), by Condition and Year



[1]*VA National Suicide Data Report* 2005–2015 Office of Mental Health and Suicide Prevention June 2018

Potential for TNX-102 SL to Decrease Suicidal Behaviors in PTSD, Sleep Disorders and Depression



Crisis in the Pharmacotherapy of PTSD Endures

"The urgent need to find effective pharmacologic treatments for PTSD should be considered a national mental health priority."

- From the Consensus Statement of the PTSD Psychopharmacology Working Group[1]

- **Despite the consensus about a crisis, industry's investment in new PTSD drug treatments continues to lag**
  - Dramatic decline in Big Pharma development of psychiatric drugs since 1990s
  - Small molecule drugs that enter the brain have shorter periods of market exclusivity than biologics[2]
  - Patent protection exclusivity has shortened because of patent law changes[3]
  - Psychiatry drug development is risky--unsuccessful trials are typically seen in the clinical development programs for psychiatric drugs that ultimately receive FDA approval[4]
  - Psychiatry drugs do not command the prices of oncology drugs or orphan disease drugs

[1]Krystal, JH., et al "It Is Time to Address the Crisis in the Pharmacotherapy of Posttraumatic Stress Disorder: A Consensus Statement of the PTSD Psychopharmacology Working Group. Biol. Psychiatry. 2017 Oct 1;82(7):e51-e59. doi: 10.1016
[2]The Patient Protection and Affordable Care Act. 2010 - provides 12 years of exclusivity to biologics
[3]Uruguay Round Agreement Act. 1994
[4]Turner, EH, NEJM 2008 358: 253

President's Roadmap to Empower Veterans and End a National Tragedy of Suicide – "PREVENTS"[1]

- **Executive Order on a National Roadmap to Empower Veterans and End Suicide – March 19 2019**
  - Task force empaneled; VA Secretary Wilkie is Co-Chair
  - Dr. Barbara Van Dahlen has been appointed Executive Director
- **"(iii) develop strategies to better ensure the latest research discoveries are translated into practical applications and implemented quickly.**
- **(vii) develop a public-private partnership model to foster collaborative, innovative, and effective research that accelerates these efforts."[2]**

[1] https://www.whitehouse.gov/presidential-actions/executive-order-national-roadmap-empower-veterans-end-suicide/
[2] Executive Order Mandate: Sec. 7(b)(iii) and (vii)

PTSD – New Learnings and Recommendations

- **PTSD within 9 years of trauma has a higher rate of drug responsiveness to TNX-102 SL**
  - Decrease in spontaneous remission after ~6 years in the National Comorbidity study supports loss of plasticity over time[1]
- **PTSD changes over time**
  - Early diagnosis and treatment are likely important
- **Task Force is empaneled to develop public-private partnerships**
  - PREVENTS Task Force should consider a partnerships with industry to develop PTSD therapeutics

[1]Kessler et al. *Arch Gen Psychiatry* 1995;52:1048-1060

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!