

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): May 30, 2018

TONIX PHARMACEUTICALS HOLDING CORP.
(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(IRS Employer
Identification No.)

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

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

Copy of correspondence to:

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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))

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.

Item 7.01 Regulation FD Disclosure.

On May 30, 2018, Tonix Pharmaceuticals Holding Corp. (the “Company”) presented at the 2018 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting a presentation (the “Presentation”) entitled *Including Suicidal Individuals in Treatment Trials: Treatment of Military-Related PTSD with TNX-102 SL, a Novel Formulation of Cyclobenzaprine Hypothesized to Address PTSD through Improvement in Sleep Quality*, which the Company intends to place on its website, and which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.01 hereto and incorporated herein by reference.

Item 8.01 Other Events.

On May 31, 2018, the Company issued a press release regarding the Presentation. A copy of the press release is filed as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Current Report, including all exhibits, 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, and is not deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

[99.01 Presentation by the Company *](#)

[99.02 Press release, dated May 31, 2018, 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: May 31, 2018

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

**Including Suicidal Individuals in Treatment Trials:
Treatment of Military-Related PTSD with TNX-102 SL,
a Novel Sublingual Formulation of Cyclobenzaprine Hypothesized
to Address PTSD through Improvement in Sleep Quality**

Gregory Sullivan MD
Chief Medical Officer
Tonix Pharmaceuticals

***An AFSP/ASCP Workshop:
Inclusion of Suicidal Individuals in Treatment Trials: Now is the Time***
*Wed May 30th 2:45-4:45PM
Poinciana 1-2*

Disclosures

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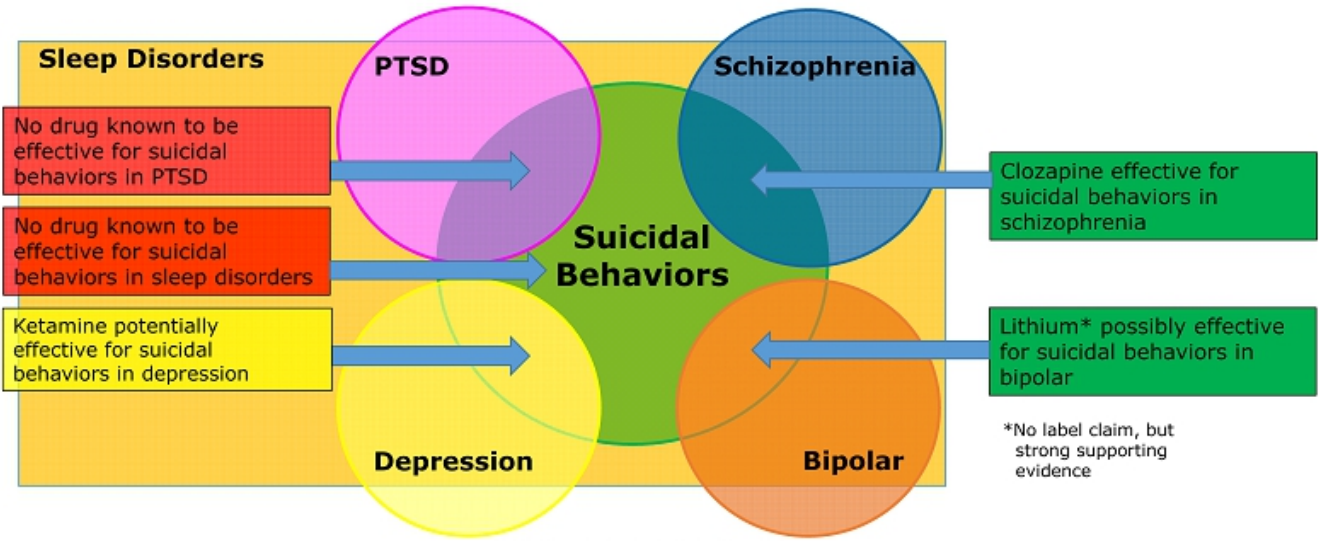
- Gregory Sullivan MD is an employee of Tonix Pharmaceuticals and owns stock and stock options in the company
- TNX-102 SL is an investigational new drug and has not been approved for any indication
- Presentation contains mention of two off-label uses of medications (lithium for reducing suicidal behaviors in bipolar disorder and ketamine for reducing suicidal behaviors in major depressive disorder)

Including Suicidal Individuals in Clinical Trials

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- Multiple psychiatric disorders are associated with increased risk of suicide
 - Examples: Major Depression, Bipolar Disorder, Schizophrenia, PTSD
- Making an impact on these suicide rates requires inclusion of this subpopulation in clinical trials
- Focusing on patient safety, outpatient trials require some degree of exclusion of those at most imminent risk who likely need more comprehensive and possibly inpatient care
- We have struck this balance in our Phase 2 trial of TNX-102 SL for military-related PTSD and this is what we have learned

Pharmacological Treatment of Underlying Disorders May Decrease Suicidal Behaviors



Studying Predictors of Suicide

- Limited body of work on death from suicide, in part explained by:
 - Suicides being relatively rare events at the population level
 - Difficulty in predicting who will die by suicide even in high risk samples
 - Necessity for data collected prior to death
- Research on predictors of suicide such as suicidal ideation and suicide attempts helps fill this critical gap, although caution is warranted:
 - Major limitation: only ~15% of those surviving a suicide attempt eventually die by suicide
 - These predictors do not necessarily provide information about a direct relationship between a psychiatric disorder such as PTSD (or a symptom such as sleep disturbance) and death by suicide
- Interventional clinical trials in psychiatric disorders offer an important opportunity to learn more about predictors of suicide
- And without biomarkers specific for predicting suicide, suicidal ideation and behaviors are the most definitive endpoints to assess an intervention aimed at preventing suicide

Suicide-PTSD Link Established but Controversy Remains

Abundance of evidence suggests PTSD increases risk of death by suicide

- Consistent evidence of a strong association while accounting for pre-existing psychiatric comorbidity¹
 - Danish registry (n=208,918) study found 5.3 greater rate of death from suicide for persons with PTSD than without (adjusted for gender, age, marital status, income, pre-existing depression diagnosis)
 - Denmark study (n=22,716) found 13 times the rate with PTSD
 - US Army service members 2001-2009 who died by suicide almost 13 times more likely have received PTSD diagnosis compared to all Army service members for same time period
- Picture somewhat clouded by several studies suggesting a protective effect of PTSD from death by suicide¹
 - Some of these findings may be explained by methodological biases
 - In samples with high levels of "comorbid PTSD and depression", statistical adjustment for depression may adjust out elements of PTSD, i.e. DSM-5 PTSD cluster D symptoms, that are most related to suicide risk
 - If depression is on a causal pathway between PTSD and suicide (PTSD->depression->suicide), adjustment for depression would obscure the relationship
 - In studies with high levels of psychopathology, such as patients discharged from inpatient psychiatric units, risk of suicide from PTSD in comparison to reference groups with very elevated risk (e.g. MDD, bipolar disorder or schizophrenia) may look relatively protective

¹ Gradus, PTSD Research Quarterly 2017 28:1-8.

Suicides in the US Military

- Suicide rate among active duty US Army personnel was increasing since 2004¹
 - 2001: 9 per 100,000
 - 2009: 22 per 100,000
 - Surpassed comparable civilian rates in 2008
 - Suicides in US military currently account for nearly 20% of all military deaths
- Increase (2003-2008) paralleled by increase in prevalence of mental disorders across the Army
- Rate of suicide for Active Component,* all Services:² 19.9 per 100,000
- Most common methods:²
 - Firearms 68.3%
 - Hanging 24.9%
- High risk and self-destructive behaviors also increased during the Iraq and Afghanistan wars, with substantial rise in motorcycle³ and other motor vehicle deaths upon return to US

¹ Black et al. Military Psychology 2011;23:433-451

² Department of Defense Suicide Event Report (DoDSER), Cal Yr 2014 Ann Report

³ MSMR 2011;3:2-5. *Non-Reserve

Rising Suicide Risk and Rates in US Veterans since 2001

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- Retrospective multivariate analysis of 3.8 million US military personnel between 2001-2011¹, with outcome of death by suicide in Cox proportional hazard models showed:
 - Hazard rate increased with first year of separation (HR 2.49)
 - Hazard rate remained elevated for those separated ≥ 6 years earlier (HR 1.63)
- In 2014², 18% of all suicides among US adults identified as veterans of the US military service
- Since 2001², the age-adjusted rate of suicide has increased among:
 - US veteran males by 30.5%
 - US veteran females by 85.2%

¹ Shen et al, Lancet Psychiatry 2016;3:10-39-48.

² VA Suicide Prevention Program, Facts about Veteran Suicide, July 2016

Disturbed Sleep and Suicide Risk

Abundance of evidence showing link between poor sleep and increased risk of suicidal ideation and behaviors

- Large epidemiological studies showing sleep disturbance as risk for suicide death^{1,2}
- Specific sleep disturbance symptoms (i.e. insomnia and nightmares) have unique relationships with suicidal ideation, attempts, and suicide³
- Suicidal ideation or attempts in individuals with PTSD criterion A-qualifying traumas higher among those with *trauma-related nightmares* (62%) than without (20%)⁴ in prior month
- Studies of veterans demonstrating link between insomnia and suicidal ideation^{5,6,7}
- Treatment study in veterans showed reduced suicidal ideation among those receiving Cognitive Behavior Therapy for insomnia (N=405)⁸

¹ Bjorngaard et al. *Sleep* 2011 34:1155-9; ² Fugino et al. *Suicide Life Threat Behav* 2005 35:227-37; ³ Pigeon et al. *Sleep Med Clin* 2015 10:41-8; ⁴ Littlewood et al. *Journal of Clinical Sleep Medicine* 2016 12:393-399; ⁵ Chkravorty et al. *Addict Behav* 2014 39:399-405; ⁶ Davidson et al. *Suicide Life Threat Behav* 2013 43:279-89; ⁷ Ribeiro et al. *J Affect Disord* 2012 136:743-50; ⁸ Trockel et al, *Sleep* 2015 38:259-65.

Rationale for Including Suicidal Individuals in the Clinical Trial of TNX-102 SL in PTSD

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- More representative sample of the condition for evaluating the efficacy TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 2.8 mg and 5.6 mg, as a potential treatment for military-related PTSD
- TNX-102 SL taken nightly at bedtime and absorbed sublingually (transmucosal), is hypothesized to reduce PTSD symptoms through improvement in sleep quality, potentially also addressing suicidal behaviors via upstream effects on sleep improvement
- Retrospective analyses of safety data in the Phase 2 AtEase study combined with other datasets acquired by similar methodology may provide important new information and insights leading to better prediction of, and interventions to prevent, suicides

Phase 2 AtEase Study in Military-Related PTSD

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Placebo at bedtime once-daily
N = 92

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

TNX-102 SL at bedtime once-daily
5.6 mg (2 x 2.8 mg)
N = 49

12 weeks

- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- Enrolled 245 participants at 24 US clinical sites
- Enrolled patients with baseline CAPS-5 score ≥ 29
- **Primary Efficacy Analysis:**
 - Difference in CAPS-5 score change from baseline between TNX-102 SL 2.8 mg and placebo at week 12
- Key Secondary Measures:
 - PROMIS Sleep Disturbance, CGI-I, SDS

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CAPS-5, Clinician-Administered PTSD Scale for DSM-5;
CGI-I, Clinical Global Impression - Improvement scale;
SDS, Sheehan Disability Scale

Design of Phase 2 AtEase Study: Inclusions and Exclusions Based on SI/SB

- **Exclusions based on Columbia-Suicide Severity Rating Scale (C-SSRS)**
 - **Five types of Suicidal Ideation (SI)** rated as present or absent during lookback period
 - Type 1 - Wish to be Dead
 - Type 2 - Non-Specific Active Suicidal Thoughts
 - Type 3 - Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act
 - Type 4 - Active Suicidal Ideation with Some Intent to Act, without Specific Plan
 - Type 5 - Active Suicidal Ideation with Specific Plan and Intent

} Excluded if < 6 months prior to Screening
 - **Four types of Suicidal Behaviors (SB)** rated as having occurred or not during lookback period
 - Actual Attempt
 - Interrupted Attempt
 - Aborted Attempt
 - Preparatory Acts or Behavior

} Excluded if < 12 months prior to Screening
- **Exclusions based on Screening MINI Module B**
 - Suicidality score of High (≥ 17) based on past month SI and lifetime suicide attempt
 - YES answer to item:
 - B10 - Intent to act on thoughts of killing self
 - B11 - Intent to die as a result of a suicidal act
 - Meets criteria for CURRENT Suicidal Behavior Disorder (Attempt <12 months prior to Screening) - same exclusion as for C-SSRS

Protocol Recommended Interventions for C-SSRS Types of Suicidal Ideation During Trial

- Type 1: Standard clinical care
- Types 2 and/or 3: Medical monitor recommended implementation of a Safety Planning Intervention (SPI) for any visit with these types of SI present
 - SPI developed by Barbara Stanley (Columbia U.) and Greg Brown (U of Penn) and adopted by US Veteran’s Administration (VA)
 - SPI is a brief clinical intervention aimed at mitigating suicide risk
 - Consists of clinician- and patient-developed list of six coping strategies and sources of support that participants can refer to and utilize to alleviate a suicidal crisis
 - Training in SPI provided at IM and in form of slide deck tutorial and VA SPI manual
 - Sites could alternatively utilize an internally-developed intervention for safety if similar in scope and purpose to the VA SPI
- Types 4 and/or 5: Protocol required participant be withdrawn from the study and referred for appropriate emergency care

SAFETY PLAN: VA VERSION	
Step 1: Warning signs:	
1.	_____
2.	_____
3.	_____
Step 2: Internal coping strategies - things I can do to take my mind off my problems without contacting another person:	
1.	_____
2.	_____
3.	_____
Step 3: People and social settings that provide distraction:	
1.	Name _____ Phone _____
2.	Name _____ Phone _____
3.	Place _____ 4. Place _____
Step 4: People whom I can ask for help:	
1.	Name _____ Phone _____
2.	Name _____ Phone _____
3.	Name _____ Phone _____
Step 5: Professionals or agencies I can contact during a crisis:	
1.	Clinician Name _____ Phone _____ Clinician Pager or Emergency Contact # _____
2.	Clinician Name _____ Phone _____ Clinician Pager or Emergency Contact # _____
3.	Local Urgent Care Services _____ Urgent Care Services Address _____ Urgent Care Services Phone _____
4.	VA Suicide Prevention Resource Coordinator Name _____ VA Suicide Prevention Resource Coordinator Contact # _____
5.	VA Suicide Prevention Hotline (toll-free: 1-800-273-TALK (8255), push 1 to reach a VA mental health specialist, _____ Text option (838256), Online chat at www.veteranscrisisline.net/chat
Step 6: Making the environment safe:	
1.	_____
2.	_____

AtEase Study Demographics and Characteristics

Sex distribution - 93% male / 7% female

Index traumas

98% had trauma during military service
85% combat traumas
Mean (SD) time since index trauma was 7 (3.4) yrs

Deployed an average of 2.3 times

Racial distribution

66% Caucasian
24% African American
2% American Indian or Alaskan Native
2% Asian

Ethnic distribution

81% Not Hispanic or Latino
19% Hispanic or Latino

Baseline CAPS-5¹ and MADRS² scores

Mean (SD) Baseline CAPS-5 Score 39.5 (7.85)
Mean (SD) Baseline MADRS Score 17.1 (5.83)

Family Status

29% single
46% married or living with partner
24% separated or divorced

Employment Status

62% employed
11% not able to work due to symptoms of PTSD

Education

14% High school graduate or GED
57% Some college
21% College graduate
6% Graduate degree

Substance Use

72% current alcohol users
38% current tobacco users
19% current THC/cannabinoid users

¹ CAPS-5, Clinician-Administered PTSD Scale for DSM-5
² MADRS, Montgomery-Åsberg Depression Rating Scale

Suicidal Ideation and Attempt History in AtEase Study: Screening C-SSRS Results

Suicidal Ideation (SI) and Behavior (B) at Screening (N=237)			
	Lifetime	Past 6 Months	US Army#
Any Type of Suicidal Ideation	32.1%	10.5%	13.9%
C-SSRS Type 1 SI	30.4%	10.5%	
C-SSRS Type 2 SI	20.7%	5.1%	
C-SSRS Type 3 SI	12.7%	5.1%	
C-SSRS Type 4 SI	8.4%	0.0% (exclusionary)	
C-SSRS Type 5 SI	8.0%	0.0% (exclusionary)	5.3%
Intensity of Ideation Score* - mean (standard deviation)	11.7 (4.86)	9.6 (3.49)	
	Lifetime	Past 12 Months	
Suicidal Behavior			
Preparatory Acts or Behaviors	2.5%	0% (exclusionary)	
Aborted Attempt	3.0%	0% (exclusionary)	
Interrupted Attempt	1.3%	0% (exclusionary)	
Actual Attempt	5.5%	0% (exclusionary)	2.4%
Non-Suicidal Self Injurious Behavior	1.3%	0%	

* Intensity of Ideation among those with any suicidal ideation in lookback period

Rates in non-deployed US Army soldiers in Army STARRS All-Army Study (AAS). Nock et al, JAMA Psychiatry 2014;71:514-522.

Suicidal Ideation and Attempt History in AtEase Study: Screening MINI Suicidality Module B Results

MINI Module B Suicidality Rating at Screening	
Low Suicidality (score of 1-8)	15.6%
Moderate Suicidality (score of 9-16)	2.1%
High Suicidality (score of ≥ 17) (exclusionary)	0%
Lifetime Attempt on MINI Module B	8.4%

AtEase Study Screen Fails versus Inclusion in Individuals with SI/SB

- 455 individuals were screened for the AtEase study
- 210 of these were screen failed
 - 11 were screen failed due to SI/SB exclusions
 - 5 due to MINI Suicidality module score ≥ 17
 - 4 due to suicidal behavior in 12 months prior to screening
 - 2 due to increased suicide risk based on PI judgement
- 237 of 245 randomized in AtEase were in the safety population
 - 76 had experienced lifetime SI
 - 25 had experienced SI in past 6 months
 - 29 had lifetime suicidal behaviors
 - 13 of these individuals had made an actual suicide attempt
 - Firearm use in 12 of the 29 lifetime suicidal behaviors
 - 3 preparatory actions – purchasing or loading a gun with intention to kill self
 - 3 aborted attempts with firearm to head
 - 2 were interrupted when about to use firearm
 - 4 attempted suicide with firearm that failed to fire

AtEase Study Results: Safety and Tolerability

Systemic adverse events (AEs) and local administration site reactions occurring at ≥5% rate in either TNX-102 SL group:

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%
Local 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%

[†]Oral hypoaesthesia (tongue/mouth numbness) was most common AE, generally transient (<60 minutes), non-dose related and rated mild in 89% and moderate in 11% on TNX-102 SL; *Safety Population (Total N=237)

Trial Completion Rates[^]: 73% Placebo; 79% TNX-102 SL 2.8 mg; 84% TNX-102 SL 5.6 mg

[^] modified Intention-to-Treat Population

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Approach Taken to SI/SB Adverse Event Reporting

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- Any post screening increase in C-SSRS SI over Type 1 considered an adverse event
- Any emergence of Type 4 and/or Type 5 SI post screening considered a serious adverse event (SAE)
- Any emergence of C-SSRS-defined SB considered an SAE

What was found during the AtEase study:

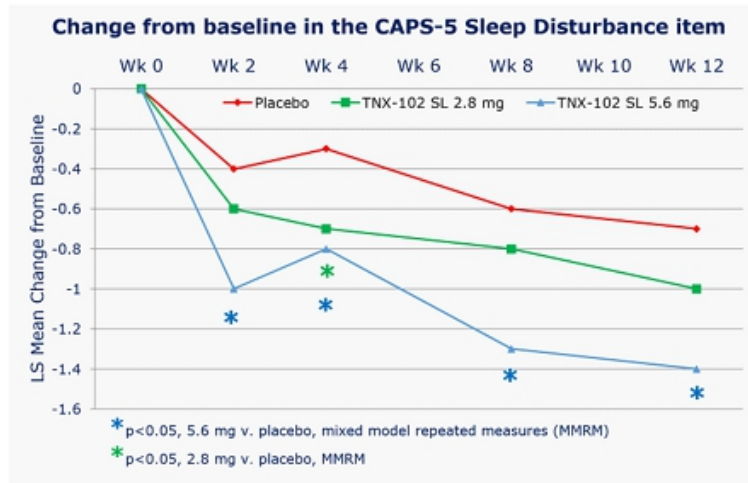
- 4 AEs of increased SI in 3 patients
 - Placebo (2); TNX-102 SL 2.8 mg (1)
- 1 SAE involving C-SSRS Type 5 SI and interrupted suicide attempt
 - Placebo patient

Suicidal Ideation in the AtEase Study at Baseline and Week 12

Suicidal Ideation (SI) and Behavior (B) at Baseline and Week 12 using Since Last Visit C-SSRS						
	Baseline			Week 12		
	Placebo	TNX-2.8mg	TNX-5.6mg	Placebo	TNX-2.8mg	TNX-5.6mg
	N=94	N=93	N=50	N=68	N=72	N=41
Any Type of Suicidal Ideation, N	2	5	2	1	2	0
C-SSRS Type 1 SI, N	2	5	1	1	2	0
C-SSRS Type 2 SI, N	0	0	1	1	0	0
C-SSRS Type 3 SI, N	0	0	1	1	0	0
C-SSRS Type 4 SI, N	0	0	0	1	0	0
C-SSRS Type 5 SI, N	0	0	0	1	0	0
Intensity of Ideation Score, Mean	14.0	13.2	6.0	15.0	10.0	NA
Suicidal Behavior						
Preparatory Acts or Behaviors, N	0	0	0	0	0	0
Aborted Attempt, N	0	0	0	0	0	0
Interrupted Attempt, N	0	0	0	1	0	0
Actual Attempt, N	0	0	0	0	0	0
Non-Suicidal Self Injurious Behavior (NSSIB), N	1	0	1	0	0	0
Cumulative NSSIB, N				1	1	1

TNX-102 SL 5.6 mg Provided Significant Improvement in Sleep Disturbance in the AtEase Study

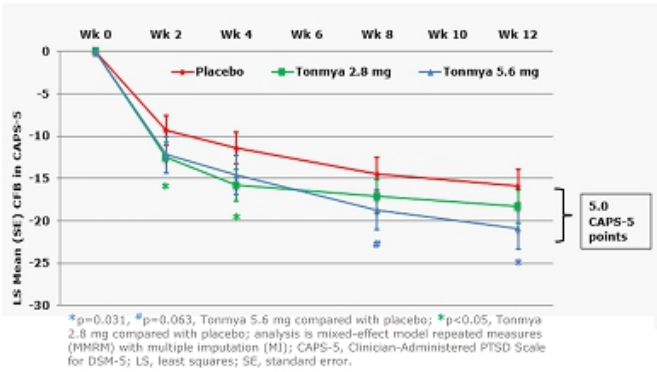
- Mechanism of action of TNX-102 SL is hypothesized to be through improvement in sleep quality
- Sleep responded early in treatment with TNX-102 SL, by Week 2 on CAPS-5 sleep disturbance item



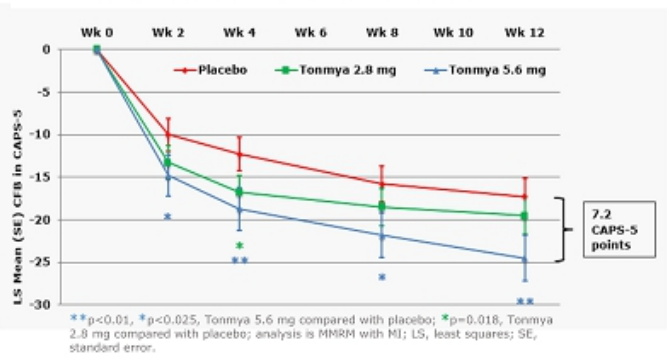
CAPS-5 Treatment Response in Modified Intention-to-Treat Population and in Retrospective Analysis for Subgroup with Entry CAPS-5 ≥ 33

CAPS-5 LS Total Score Mean Change from Baseline (CFB)

Modified Intention-to-Treat Population



Subgroup with entry CAPS-5 ≥ 33



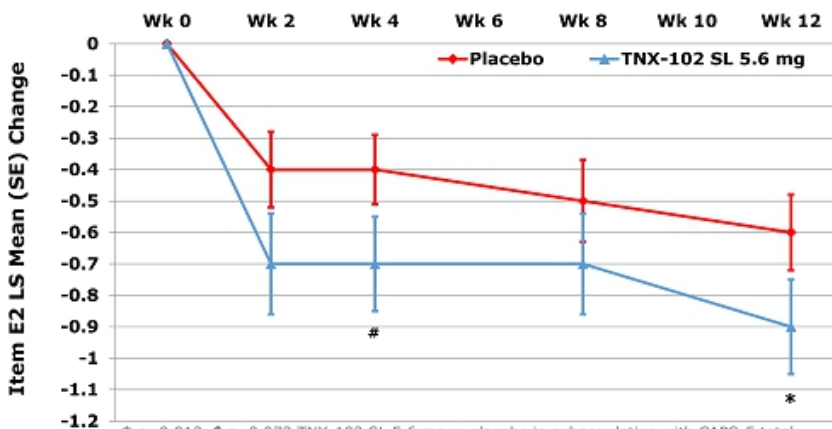
A baseline CAPS-5 score ≥ 33 was set as entry criterion in ongoing Phase 3 HONOR study

CAPS-5 Item 16 (E2) – New to DSM-5/CAPS-5

- Reckless or self-destructive behavior
 - Risk
 - “In the past month/week, have there been times when you were taking more risks or doing things that might have caused you harm?”
 - Can you give me some examples?
 - How much risk do you take? (How dangerous are these behaviors? Were you injured or harmed in some way?)”
 - Frequency
 - How often have you taken these kinds of risks in the past month/week? (# of times)
 - Trauma-relatedness
 - Did this behavior start or get worse after (index trauma)?
- As per DSM-5, intended for behaviors such as dangerous driving, excessive alcohol or drug use, and self-injurious or suicidal behavior
- Due to exclusion of SB in past year and very low rates of any non-suicidal self injurious behavior or SB *during* trial, item appeared to be *primarily indexing dangerous, high risk activities in prior week that had developed or got worse after index trauma(s)*

Reduction in Reckless or Self-Destructive Behavior Item Compared with Placebo Over 12 Weeks in Subjects with More Severe PTSD (Baseline CAPS-5 total ≥ 33)

CAPS-5 Item E2: Reckless or self-destructive behavior



- Placebo N=77
 - For subgroup with baseline E2>0:
 - N = 25 of 77
 - Change from Baseline in subjects with E2>0, mean (SD): -1.8 (1.34)
- TNX-102 SL 5.6 mg N=38
 - For subgroup with baseline E2>0:
 - N = 9 of 38
 - Change from baseline in subjects with E2>0, mean (SD): -2.9 (0.64)

* p=0.012, # p=0.073, TNX-102 SL 5.6 mg v. placebo in subpopulation with CAPS-5 total baseline score of ≥ 33 ; LS, least squares; MMRM, mixed-effects model repeated measures; SE, standard error

Conclusions about Including Suicidal Individuals in Phase 2 Trial of Military-Related PTSD

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- AtEase military-related PTSD sample had higher lifetime rates of SI/B compared with non-deployed Army sample
- Rates of since-last-visit SI and SB during study were extremely low, such that meaningful statistical inferences are not possible
- Employing Safety Planning Intervention (SPI) for C-SSRS Types 2 and/or 3 helpful for ensuring intensive clinical management for safety
- High risk behaviors were reduced with treatment in more severe subpopulation
- Non-exclusion of PTSD participants with history of SI/B greatly strengthens generalizability of any treatment findings for this population
 - Future outpatient studies could reduce SI/SB exclusions further, such as no C-SSRS Types 4 or 5 in past month and no SB in past 3 months
- Inclusion of individuals with SI/B in pharmacotherapy trials such as AtEase provides critical data for meta-analyses aimed at better understanding of the predictors of suicide, reducing the risk, and facilitating the development of drug candidates for the prevention of death by suicide

Thank you...!

To our research participants for their collaboration in the AtEase study!

To our site PIs and Staff!

To Tonix personnel responsible for AtEase:

➤ Seth Lederman, Judy Gendreau, Ashild Peters, Perry Peters, Gregory Sullivan

And to key consultants:

➤ Pauliana Hall, R. Michael Gendreau, Amy Schaberg, Frank Weathers, Jonathan Davidson

Tonix Pharmaceuticals Presented New Data Related to Suicidal Ideation and Behaviors in Military-Related PTSD from the Phase 2 AtEase Study at the American Society of Clinical Psychopharmacology

Clinical Benefit of Tonmya, an FDA-Designated Breakthrough Therapy for PTSD, was Evidenced in AtEase

NEW YORK, May 31, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix), presented data from the Phase 2 AtEase study of Tonmya®* (cyclobenzaprine HCl sublingual tablets) for the treatment posttraumatic stress disorder (PTSD). The presentation focused on the rationale for including suicidal individuals in the clinical trial of a treatment for PTSD.

“There are several examples in major psychiatric disorders in which pharmacological treatment of the underlying disorder may decrease suicidal behaviors,” said Gregory Sullivan, M.D., Chief Medical Officer of Tonix. “Individuals with military-related PTSD have an elevated risk for suicidal behaviors, and it was hypothesized that addressing underlying PTSD with Tonmya might have an impact on reducing suicidal behaviors. Suicidal individuals were included in the AtEase study as it provided for a more representative sample of the condition for evaluating the efficacy Tonmya 2.8 mg and 5.6 mg as a potential treatment for military-related PTSD.”

“Taken nightly at bedtime and absorbed by a sublingual (transmucosal) route, Tonmya is believed to reduce PTSD symptoms through improvement in sleep quality, potentially also addressing suicidal behaviors via upstream effects on sleep improvement,” Dr. Sullivan continued “While rates of suicidal ideation and behaviors were not high enough to allow meaningful statistical analyses in AtEase, these data, combined with other datasets acquired by similar methodology, may provide important new information and insights leading to better prediction of, and interventions to prevent, suicides in PTSD.”

As has been previously disclosed, a retrospective analysis of Tonmya 5.6 mg in the more severe PTSD subpopulation (Clinician-Administered PTSD Scale score of ≥ 33 at baseline) resulted in significantly reduced reckless or self-destructive behaviors at Week 12, potentially fulfilling a critical need in the military and veteran populations with PTSD who have elevated rates of suicidal and high-risk life-threatening behaviors. Local administration site reactions, i.e., transient mild tongue/mouth numbness, were reported more frequently in Tonmya patients in the AtEase study.

These results were presented on May 30, 2018 at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting being held in Miami Beach, Fl. The presentation entitled, *Including Suicidal Individuals in Treatment Trials: Treatment of Military-Related PTSD with TNX-102 SL, a Novel Sublingual Formulation of Cyclobenzaprine Hypothesized to Address PTSD through Improvement in Sleep Quality*, will be made available on the Company’s website (www.tonixpharma.com/research-development/scientific-presentations).

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD which has been designated as a Breakthrough Therapy in December 2016. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

About Tonmya and the Phase 3 HONOR Study

Tonmya is a sublingual transmucosal tablet formulation of cyclobenzaprine that is in Phase 3 development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets) was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the U.S., the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants in approximately 40 U.S. sites. Results from an interim analysis, based on approximately the first 50% of randomized participants, are anticipated in the third quarter of 2018. In a Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that (i) a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive, and (ii) an additional abuse assessment study is not required for the NDA filing. Additional details of the HONOR study are available at www.thehonorstudy.com or <https://clinicaltrials.gov/ct2/show/NCT03062540>.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under an effective IND. TNX-102 SL is cleared to enter a Phase 2, potential pivotal efficacy study in agitation in Alzheimer's disease. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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, 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, and periodic 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. The information set forth herein speaks only as of the date thereof.

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