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): November 12, 2020

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.)**

26 Main Street, Suite 101, Chatham, New Jersey 07928
(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))

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

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.

Tonix Pharmaceuticals Holding Corp (the "Company") presented (the "Presentation") at the 3rd Annual Neuropsychiatric Drug Development Summit on November 12, 2020. The Presentation, which may contain nonpublic information, is filed as Exhibit 99.01 hereto and incorporated herein by reference. A copy of the press release that discusses this matter 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 Exhibits 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 they 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 8.01 Other Information.

On November 12, 2020, the Company outlined a new statistical method to analyze future Posttraumatic Stress Disorder ("PTSD") drug studies and presented a retrospective analysis using the new method of the Phase 3 HONOR study (P301) of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related PTSD. The proposed new statistical method, called Randomization Honoring Non-Parametric Combination of Tests, was applied to a retrospective analysis of the Phase 3 HONOR study and showed a nominal p-value of 0.03 compared to the p-value of the prospective primary analysis of 0.6 in TNX-102 SL's treatment benefit at Week 12 as measured by change from baseline in the using the Clinician Administered PTSD Scale for DSM-5.

The Company is planning a Phase 3 PTSD study of TNX-102 SL in Kenya, expected to initiate in the third quarter of 2021, and will focus on studying police.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Presentation by the Company
99.02	Press Release dated November 12, 2020, issued 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: November 12, 2020

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

Exhibit 99.01

TNX-102 SL Development for Posttraumatic Stress Disorder (PTSD)

TONIX PHARMACEUTICALS

November 12, 2020
3rd Annual Neuropsychiatric Drug Development Summit
Seth Lederman, MD - CEO

Version P0255 11-12-20 (Doc 0731)

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, risks related to failure to obtain U.S. Food and Drug Administration clearances or approvals and noncompliance with its regulations; our need for additional financing; delays and uncertainties caused by the global COVID-19 pandemic; substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties. 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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.

Team and Collaborators

Tonix

- Seth Lederman, MD
- Greg Sullivan, MD
- Herb Harris, MD, PhD
- Perry Peters
- Ashild Peters, RN
- Mandy Ng, PhD
- Candace Flint

Philip Stark, PhD

- Univ. of Calif, Berkeley

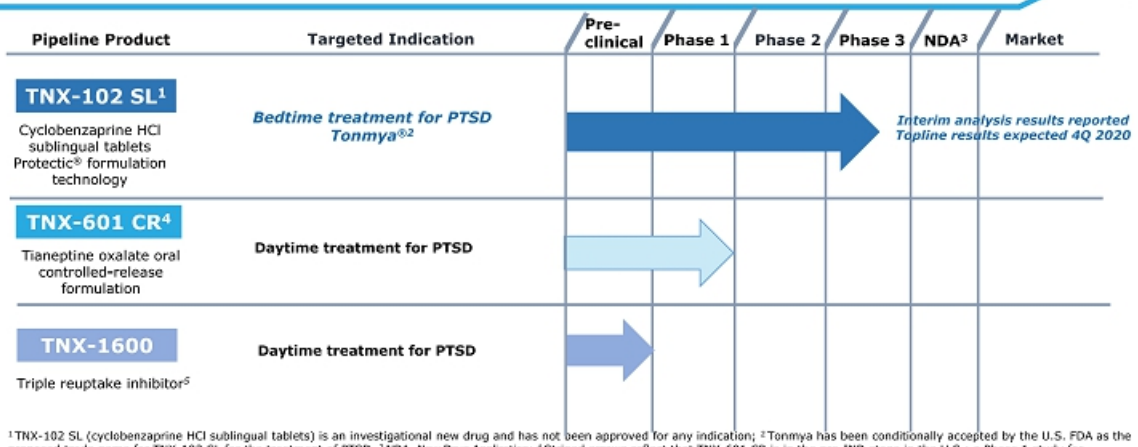
Ben Vaughn

- Rho

Disclosures:

- Tonix employees hold shares and/or options in Tonix
- Philip Stark is a consultant to Tonix
- Ben Vaughn is an employee of Rho, which is a contractor to Tonix

PTSD Candidates in Development



[1] TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication; [2] Tonmya has been conditionally accepted by the U.S. FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD. [3] NDA- New Drug Application; [4] Striped arrows reflect that TNX-601 CR is in the pre-IND stage in the U.S.; a Phase 1 study for formulation development was completed outside of the U.S.; [5] (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 monoamines

TNX-102 SL: Hypothesized Novel Mechanism Targets Sleep Quality for Recovery from PTSD

PTSD is a disorder of recovery

- Most people exposed to extreme trauma recover over a few weeks
- In PTSD, recovery process impeded due to insufficient sleep-dependent memory processing[1,2]

Memory processing is essential to recovery

- Ongoing vulnerability to memory intrusions and trauma triggers if there is deficient consolidation of new learning (extinction)

TNX-102 SL targets sleep quality[3]

- The active ingredient in TNX-102 SL, cyclobenzaprine, interacts with receptors that regulate sleep quality: strongly binds and potently blocks 5-HT_{2A}, α_1-adrenergic, histamine H_1, and muscarinic M_1 receptors, permissive to sleep-dependent recovery processes

[1]Straus LD, Acheson DT, Risbrough VB, Drummond SPA. Sleep Deprivation Disrupts Recall of Conditioned Fear Extinction. Biol Psychiatry Cogn Neurosci Neuroimaging. 2017; 2(2):123-129. [2]Murkar ALA, De Koninck J. Consolidative mechanisms of emotional processing in REM sleep and PTSD. Sleep Med Rev. 2018; 41:173-184.
[3]Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015, Toronto Ontario, Canada

TNX-102 SL: Sublingual Formulation is Designed for Bedtime Administration

TNX-102 SL: Proprietary sublingual formulation of cyclobenzaprine (CBP) with transmucosal absorption

- Innovation by design with patent protected CBP/mannitol eutectic
- Rapid systemic exposure
- Increases bioavailability during sleep hours
- Avoids first-pass metabolism
  - Lowers exposure to long-lived active major metabolite, norcyclobenzaprine (norCBP)

CBP undergoes extensive first-pass hepatic metabolism when orally ingested

- Active major metabolite, norCBP[1]
  - Long half-life (~72 hours)
  - Less selective for target receptors (5-$HT_{2A,}$ α_1-adrenergic, histamine H_1)
  - More selective for norepinephrine transporter

TNX-102 SL 505(b)(2) NDA approval can rely on the safety of the reference listed drug (AMRIX®)[2]

[1] Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015, Toronto Ontario, Canada
[2] FDA Minutes (November 26, 2018)

No Recognized Abuse Potential in Clinical Studies

Active ingredient is cyclobenzaprine, which is structurally related to tricyclic antidepressants

- Cyclobenzaprine interacts with receptors that regulate sleep quality: 5-$HT_{2A,}$ α_1-adrenergic, histaminergic H_1, and muscarinic M_1 receptors
- Cyclobenzaprine does *not* interact with the same receptors as traditional hypnotic sleep drugs, benzodiazepines or non-benzodiazepines that are associated with retrograde amnesia
- Cyclobenzaprine-containing product was approved 40 years ago and current labeling (May 2016) indicates no abuse or dependence concern

TNX-102 SL NDA can be filed without drug abuse and dependency assessment studies*

*April 2017 meeting minutes from the March 2017 FDA meeting

Three Recent PTSD Trials Testing TNX-102 SL (cyclobenzaprine sublingual tablets)

Phase 2 P201 "AtEase" – Military-related PTSD[1]

- **Reported May 2016 (mITT, N=231)**
- 3 groups: Placebo (n= 92), TNX 2.8 mg (n= 90) and TNX 5.6 mg (n=49)
- Primary endpoint (2.8 mg dose): CAPS-5 CFB, Week 12: MMRM, *P*=0.26 (two-sided)
- Secondary endpoints (5.6 mg dose): CAPS-5 (*P* =0.053), **PGIC (*P*=0.035)** and CGI-I (*P*=0.041)

Phase 3 P301 "HONOR" – Military-related PTSD[2]

- **Discontinued August 2018 (randomized, N=358) due to "futility" at interim analysis (IA)**
- 2 groups at IA: Placebo (n= 125) and TNX 5.6 mg (n= 127)
- Primary endpoint (5.6 mg dose): CAPS-5 CFB, Week 12: MMRM with MI, *P*=0.60 (two-sided)
- Secondary endpoints (5.6 mg dose): **PGIC (*P*=0.020)** and CGI-I (*P* =0.34)

Phase 3 P302 "RECOVERY" – Civilian PTSD[3]

- **Stopped enrollment in Feb 2020 (randomized, N=192) when interim analysis recommended stop for "futility"**
- 2 groups: Placebo (n ~ 96) and TNX 5.6 mg (n ~ 96)
- **Remains blinded**

[1]ClinicalTrials.gov Identifier: NCT02277704
[2]ClinicalTrials.gov Identifier: NCT03062540
[3]ClinicalTrials.gov Identifier: NCT03841773

Abbreviations: CAPS-5 = Clinician-Administered PTSD Scale for DSM-5; CFB = change from baseline; CGI = Clinician Global Impression - Improvement; PGIC = Patient Global Impression of Change; mITT = modified Intent-to-Treat; MMRM = mixed model repeated measures; MI = multiple imputation

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 and 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

Highlights of Three Recent PTSD Trials Testing TNX-102 SL

Focus on rater training, patient retention and data quality
- First studies to use CAPS-5
- Rater training, certification, and reliability overseen by Frank Weathers PhD and associates
- Periodic re-assessment of raters by recorded interviews
- Development of systematic method to compute "Severity" from "Intensity" and "Frequency", which since has been adopted for current CAPS-5 by National Center for PTSD

Recruitment of participants by social media
- Successfully engaged and recruited military PTSD participants, both current military and veterans

Enrollment of only well-vetted screenings by sponsor medical monitors
- Comprehensive pre-randomization process established
- Thorough scrutiny of index traumas to ensure all meet DSM-5 PTSD Criterion A
- Attention to correct scoring of CAPS-5 and enrollment severity thresholds met as well as PTSD diagnosis

Inclusion of participants with suicidality
- Inclusion of Columbia Suicide Severity Rating Scale (C-SSRS) of up to Type 3 Suicidal Ideation
- Sites trained on Safety Planning Intervention for subjects experiencing increased suicidality during trial

Handling of missing data by multiple imputation
- Prior approvals in PTSD were prior to the National Academy of Sciences report on missing data

Modern randomization protocols
- Randomization stratified by site, sex and other factors, e.g. smoking status (current/not current), current MDE (yes/no)

Abbreviations: MDE = major depressive episode

Common Themes from Three Recent PTSD Trials Testing TNX-102 SL

- **Consistent nominal improvement on sleep item on CAPS-5**
  - E6 sleep disturbance item
  - Supported by nominal benefits in PROMIS Sleep Disturbance
  - Evidence of "target engagement", appropriate dosing and pharmacokinetics
- **High placebo response measured by CAPS-5 change from baseline**
  - Studies appear to have provided "enhanced" standard of care
- **Drug separation from placebo at Week 4 was not sustained at Week 12[1]**
  - Continued trend of improvement in placebo groups throughout courses of studies
- **Patient Global Impression of Change (PGIC) consistently improved at Week 12**
  - Patient self-assessment is not tied to disease constructs of CAPS-5/DSM-5
  - Clinician Global Impression of Improvement (CGI-I) also tended to improvement, although was more correlated with CAPS-5 change relative to that seen with PGIC

[1]In P201, 2.8 mg dose was nominally positive at week 4; in P301, 5.6 mg dose nominally positive at week 4

Heterogeneity of Study Participants

- **PTSD diagnosis may include a heterogeneous group of different stress disorders**
  - Psychiatric nosology and diagnosis remain clinical and pre-molecular
  - No validated biomarkers for diagnosis or response
- **PTSD may be a single entity, but might be a common manifestation of a heterogeneous group of different stress disorders**
  - Military and civilian PTSD are typically triggered by very different stressors
  - Males and females may manifest symptoms differently
  - Time since trauma ≤9 years or >9 years appears to stratify for drug response
- **Response to TNX-102 SL may be heterogeneous**
  - Drug metabolizing enzymes?
  - Neurotransmitter receptor and transporter gene alleles?
  - Comorbid undiagnosed sleep disorders that may be unresponsive to this treatment?

Placebo Response – "Hard to Beat"

- **Improvement of placebo group makes it difficult for any drug to separate**
  - Dramatic placebo responses suggest measurement issue with primary endpoint
  - Such dramatic recoveries are not consistent with known natural history of established PTSD
- **Placebo response is growing across psychiatry and particularly in the US**
  - Schizophrenia studies indicate US placebo response is higher than in other countries[1,2]
  - Unclear etiology
  - PTSD is a global problem, so ex-US studies can evaluate if this trend is a problem
- **Repeated CAPS-5 administrations may confound data collection and/or lead to "enhanced" standard of care**
  - One week "lookback" CAPS, which has been the standard for pharmacotherapy trials, considered by many to be too short a period to adequately describe recent symptom status due to the high variability in PTSD symptom week to week
  - In psychotherapy trials of PTSD, typically only include a baseline and endpoint CAPS, and utilize 1-month lookback

[1]Gopalakrishnan, M *et al. J Clin Psychiatry*. 2020; 81(2):19r12960
[2]Laughren, TP *J Clin Psychiatry*. 2020; 81(2):19com13110
[3]Hodgins, GE et al. 2018; *J Clin Psychopharm* 38,3 (2018): 200-206.

Placebo Responses in PTSD Trials

	PTSD Population Type	Outcome Measure	Percent Change from Baseline in CAPS Observed Means		
			PBO	TNX-2.8mg	TNX-5.6mg
Tonix P201/AtEase 2016 - TNX-102 SL	Military-related	CAPS-5	-46%	-51%	-58%
			PBO		TNX-5.6mg
Tonix P301/HONOR 2018 - TNX-102 SL	Military-related	CAPS-5	-43%		-50%
			PBO	Parox. 20mg	Parox. 40mg
Marshall et al 2001[1] - paroxetine	Predom. Civilian	CAPS-2	-34%	-53%	-51%
			PBO		Parox. 20-50mg
Tucker et al 2001[2] - paroxetine	Predom. Civilian	CAPS-2	-34%		-48%
			PBO		Sert. 50-200mg
Davidson et al 2001[3] - sertraline	Predom. Civilian	CAPS-2	-36%		-45%
			PBO		Sert. 50-200mg
Brady et al 2000[4] - sertraline	Predom. Civilian	CAPS-2	-31%		-43%
			PBO*		Sert. 50-200mg*
Friedman et al 2007[5] - sertraline	Military-related	CAPS-2	-21%		-18%

			Sert+EMM#	PE+PBO#	PE+Sert#
Rauch et al 2019[6] - PE, Sert, Combo	Military-related	CAPS-IV	-37%	-35%	-38%

[1]Marshall et al. *Am J Psychiatry* 2001;158:1982-1988.
[2]Tucker et al. *J Clin Psychiatry* 2001;62:860-868.
[3]Davidson et al. *Arch Gen Psychiatry* 2001;58:485-492.
[4]Brady et al. *JAMA* 2000;283:1837-1844.
[5]Friedman et al. *J Clin Psychiatry* 2007;68:711-720.
[6]Rauch et al. *JAMA Psychiatry*. 2019;76:117-126.

**adjusted* mean CFB used as observed not available in report

#Week 12 CAPS-IV CFB used in this 24 week trial for comparison purposes; listed pharmacotherapy trials all were 12 weeks

Abbreviations: CAPS = Clinician-Administered PTSD Scale; EMM = enhanced medication management; Parox = paroxetine; PBO = placebo; PE = prolonged exposure; Sert = sertraline;

Randomization is Often Overlooked as an Element in Randomized Clinical Trials (RCTs)[1]

In our trials a population of patients defined by inclusion and exclusion criteria are randomized into treatment groups in complex processes

- Attempts to balance drug and placebo groups at individual sites and to balance other potential confounders such as sex

The statistical *P*-values are directly connected to the experiment

- The *P*-values flow from the randomization
- Rigorous analysis should proceed via Jerzy Neyman's "Ticket Model,"[2] later generalized by Donald Rubin to "Potential Outcomes"[3]

The parametric *P*-values are *pro forma*

- The null hypothesis behind the parametric *P*-values involves counterfactual assumptions about how the subjects were selected and how the data were collected

For some designs, the parametric *P*-value is an asymptotic approximation to the statistical *P*-value

- The two can be numerically close, but they can also differ substantially

[1]Rosenberger WF, "Randomization", Statistics in Medicine 2019 98:1-12
[2]Neyman 1930 Neyman, Jerzy. Sur les applications de la theorie des probabilites aux experiences agricoles: Essai des principes. Master's Thesis (1923). English Translation: https://projecteuclid.org/euclid.ss/1177012031
[3]Rubin, Donald (2005). "Causal Inference Using Potential Outcomes". J. Amer. Statist. Assoc. 100 (469): 322–331. doi:10.1198/016214504000001880.

Proposed Solution: Randomization Honoring (RH) Method[1]

Respects the method in which study subjects are randomized into drug and placebo groups

- Technically, randomization ***IS*** "The Experiment"

Accounts for the *dependence* of the drug and placebo groups properly

- If an individual is in one group, that individual is not in the other group
- Groups are not *independent*

Consistent with the randomization procedure performed in the study, with no additional assumptions (aside from "non-interference")

- A study subject's response depends only on whether that subject is assigned to drug or placebo, and not on the group assignment of other subjects in the study

All the probability assertions flow from the actual randomization of the study

Uses simulation to estimate the probabilities

[1] https://www.stat.berkeley.edu/~stark/Seminars/npc-tonix-20.slides.pdf

How Does CAPS-5 Dimensionality Affect Its Use as a Measure of Change in Symptoms or Syndrome

CAPS-5 consists of 20 items that can be considered dimensions

- CAPS-5 was developed as a diagnostic tool based on DSM-5 PTSD criteria
- Paxil® (paroxetine) and Zoloft® (sertraline) were approved for PTSD based on earlier versions of the CAPS with 3 less items, a different scoring system (severity = intensity + frequency), and avoidance symptoms were not requisite for diagnosis

"Total CAPS-5" score collapses 20 dimensions into one dimension

- Simple addition of the item scores loses data
- Items that are rarely endorsed dilute the effects of items that are frequently endorsed and change in the direction of improvement by Principal Component Analysis[1]

Future trial statistical analysis:

- **Fewer dimensions?**
  - Trimming the CAPS-5 to fewer items increases "power", specifically, removing items that are rarely endorsed: flashbacks, amnesia and reckless/self-destructive behavior
  - Tension of "pseudo-specificity" (although FDA approved pimivanserin for delusions and hallucinations in Parkinson's)
  - Dr. John Krystal/Yale VA study of trazodone for insomnia in PTSD with primary endpoint of sleep improvement[2]
  - Trimming is in the direction of the NIMH Research Domain Criteria ("RDoC") approach
- **All dimensions?**
  - Methodologies that use all dimensions have the potential to detect drug/placebo separation in trials with smaller N's

[1]Data on file
[2]ClinicalTrials.gov Identifier: NCT03668041

Multi-dimensional Analyses

"21st Century Cures Act" addressed use of novel trial designs, simulations and analyses

- Requiring guidance and encouraging increased reliance on novel and adaptive clinical trial designs, including use of modeling and simulation (sec 3021(b)(2))
- Then-Commissioner Gottlieb expressed strong interest in the use of these innovative tools to expedite product development

Practical and ethical considerations motivate efficient extraction of data from trials with the lowest N's

- Excessively large studies, needlessly:
  - Increase the cost of developing drugs and discourage innovation
  - Delay the approval, marketing and availability of effective drugs
  - Prolong the exposure of participants to ineffective drugs
  - Sometimes show statistically significant effects that are not *clinically* meaningful

- "Adequate and well controlled" implies that drug approvals should be based on reasonably sized RCTs that show a statistically significant ($p < 0.05$) probability that drug benefit did NOT occur by chance

Proposed Solution: Randomization Honoring (RH) Non-Parametric (NP) Combination of Tests (COT)

Each of the 20 individual items is treated as a separate measurement that contributes evidence about the null hypothesis

- Randomization Honoring (RH) can incorporate non-parametric (NP) combination of tests (COT), collectively the method is RHNPCOT[1,2]

Framework of non-parametric combination of tests (RHNPCOT) consists of two stages (both stages utilize randomization tests with multiple replications):

(1) Computing randomization *p*-values for the 20 individual items
(2) Combining the 20 *p*-values to produce a single overall *p*-value

Respects the method in which study subjects are randomized into drug and placebo groups *AND* preserves information from 20 dimensions

[1]Pesarin F, Salmaso L. Permutation tests for complex data. theory, applications and software. Chichester: John Wiley & Sons, Ltd. ISBN: 978-0-470-51641-6; 2010: Chapter 4, "The Nonparametric Combination Methodology" p 117-175.
[2]Arboretti, R et al. Test statistics in medical research: traditional methods vs multivariate NPC permutation tests. *Urology* 2015; 85 (2): 130-136.

First Stage of RHNPCOT Randomization

Treatment codes are randomly allotted to the observed data 10,000 times by generating sets of randomization lists that simulate (and are valid under) the original randomization system used

- The test statistic is calculated for each of the 20 items and 10,000 samples, and for the original observed data with actual treatment codes
- The randomization lists are simulations of the randomization scheme
- The percentile rank of the observed data's test statistic relative those with randomly assigned treatments yields a 1-sided *p*-value for a randomized test of the null hypothesis that treatment does not matter
- If treatment assignment has no impact, the observed data would be unlikely to be in the tail of the distribution of values of the test statistic for the random assignments

1-percentile is the *p*-value under the null hypothesis

- This results in a vector of 20 *p*-values for the 20 CAPS-5 items

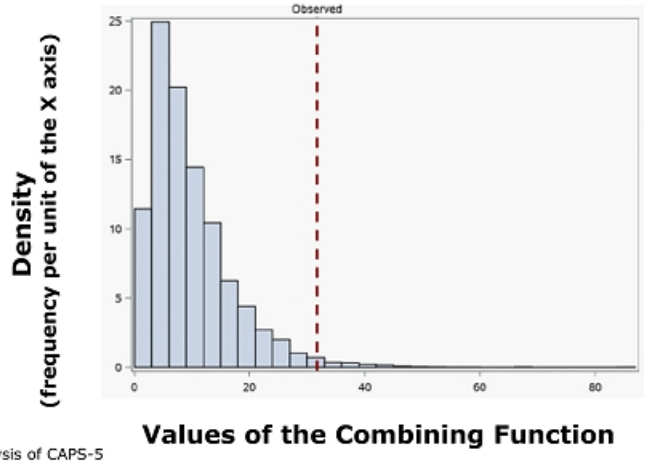
Second Stage of RHNPCOT Randomization

The 20 *p*-values {p_i} are combined into a single summary statistic using Fisher's combining function

- $-2\sum_{i=1}^{20}\ln(p_i)$.
- If the 20 *p*-values were continuous and independent, this statistic would have a X^2 distribution with 20 degrees of freedom
- The independence assumption is clearly violated and the distribution is discrete, so the randomization approach is utilized again to calibrate Fisher's combination to produce an overall p-value
- The above statistic is calculated for each of the 10,000 random treatment assignments and the percentile rank of the combination for the observed data among those 10,000 values is obtained

As in Stage 1, this percentile is a one-sided *p*-value for a randomized test of the null hypothesis that treatment has no effect

Phase 3 P301 Data: Histogram Values of the Combining Function (for Random Reallocations)[1]



[1]Retrospective analysis of CAPS-5 Week 12 change from baseline

Phase 3 P301 Study: Comparison of Primary Analysis with Retrospective Analysis of CAPS-5 Week 12 Change from Baseline by RHNPCOT

Primary analysis

- MMRM[1] with MI[2], *P*=0.6 (two-sided)

Retrospective RHNPCOT analysis

- RHNPCOT using Medians with MI, *P*=0.03 (two-sided)

[1]MMRM = Mixed model repeated measures
[2]MI = Multiple imputation

RHNPCOT[1]

Honors the actual randomization method of the study
- Uses modern analyses and simulations which are advocated by 21st Century Cures Act

Preserves information from 20 dimensional CAPS-5
- Unlike "total CAPS-5" which collapses data into one dimension

Measure of benefit from all of the CAPS-5 items
- Not a "trimmed" CAPS-5 with fewer items
- No *a posteriori* selection, elimination or weighting of measurements

Assesses PTSD improvement at the Syndromal Level – not Symptom Level
- Not pseudo-specific

Efficient use of data with smaller numbers of study participants
- Ethical (not exposing volunteers unnecessarily) and practical (allows for reasonably sized studies)
- Provides benefit of statistical methods that weren't practical before computers

Concordant with Patient Global Impression of Change (PGIC)
- Patient reported yardstick of benefit – not connected to theoretical constructs of nosology
- PGIC is clinically meaningful

[1]https://www.stat.berkeley.edu/~stark/Seminars/npc-tonix-20.slides.pdf

Future Plans

Pharmacogenomics on study participants

- P302 has high rate of consent for DNA collection
- P301 has a subset of participant DNA available
- Exome sequencing to focus on:
  - Drug metabolizing enzymes
  - Neurotransmitter receptors and transporters
  - Genes related to sleep quality
  - Genes related to fear extinction memory processing

Plan to propose new analysis for primary endpoint in next PTSD studies

- Statistical analysis plan to use RHNPCOT for primary analysis

P3 Study in US

- Protocol in development

P3 Study on Kenyan Police

- Protocol in development with Moi University – expected start date Q32021

Crisis in Psychiatry Randomized Controlled Trials (RCTs)

Paradox: while clinical methods (particularly randomization) and data quality are improving, success in subsequent studies has become harder to predict

- Randomization sequence typically attempts to stratify by site, sex and other criteria (either via "adaptive randomization" or stratification)

Probability of success of subsequent psychiatry RCTs based on "power" are unreliable

- Many "positive" psychiatry trial results cannot be replicated
- Often takes multiple trials to get 2 "positive" trials[1]
  - FDA does not limit the number of studies that can be performed (i.e., no "called strikes")
- Without confidence about replicating "positive" studies, pharma companies are abandoning psychiatry

Pharma has searched for reasons

- Heterogeneity of patients – implicates imprecise psychiatric diagnosis and measurement
  - NIMH Research Domain Criteria ("RDoC")
  - Pseudo-specificity redux (e.g., pimivanserin for hallucinations & delusions in Parkinson's Disease)
- Recent requirement to adjust for "missing data" has "moved the goal line" for approval
  - Several drugs approved without "missing data" considerations would not be approved today
- Placebo effect is "growing", particularly in the US[2,3,4]
  - US sites have bigger placebo effects than foreign sites?

[1]Khin, NA et al. *J Clin Psychiatry*. 2011; 72(4):464-472
[2]Gopalakrishnan, M *et al. J Clin Psychiatry*. 2020; 81(2):19r12960
[3]Laughren, TP *J Clin Psychiatry*. 2020; 81(2):19com13110
[4]Hodgins, GE et al. 2018; J *Clin Psychopharm* 38,3 (2018): 200-206.

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!

Exhibit 99.02

Tonix Pharmaceuticals Outlines New Statistical Method to Analyze Future PTSD Studies at the 3rd Annual Neuropsychiatric Drug Development Summit

Increasing Placebo Responses in PTSD Drug Trials Raise Questions About Current Methods of Measuring or Analyzing PTSD Symptom Change Over Time

The U.S. 21st Century Cures Act Provides Direction on New Statistical Analyses Using Simulations

Tonix Plans to Study TNX-102 SL in a New Phase 3 PTSD Trial in Kenya

CHATHAM, N.J., November 12, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today that Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals, outlined a new statistical method to analyze future Posttraumatic Stress Disorder (PTSD) drug studies and presented a retrospective analysis using the new method of the Phase 3 HONOR study (P301) of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), for the treatment of military-related PTSD at the 3rd Annual Neuropsychiatric Drug Development Summit today.

“The paradox that confounds modern PTSD studies is that the placebo response has increased over time, even as we and others have striven to improve study methods and data quality” said Dr. Lederman. “In many studies, the placebo response has increased to the point where it has become very difficult for the treatment arm to be successful in a randomized placebo-controlled PTSD clinical trial. The measurements of PTSD placebo improvement in randomized clinical trials using the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) are inconsistent with what is known about the natural history of PTSD. In real world settings, PTSD patients do not dramatically improve without treatment like they appear to do in randomized clinical trials. Therefore, an opportunity and need exist to improve upon the measurement of PTSD symptoms in trials or the analysis of the data from trials. The 2017 21st Century Cures Act provides direction to the U.S. Food and Drug Administration (FDA) and to sponsors that new data analyses and particularly simulations should be used to improve clinical trial design and data analysis.”

The proposed new statistical method, called Randomization Honoring Non-Parametric Combination of Tests (RHNPCOT), was applied to a retrospective analysis of the Phase 3 HONOR study and showed a nominal p-value of 0.03 compared to the p-value of the prospective primary analysis of 0.6 in TNX-102 SL’s treatment benefit at Week 12 as measured by change from baseline in the CAPS-5.

Dr. Lederman added, “The RHNPCOT statistical method addresses key goals of the 21st Century Cures Act as a potential path forward in PTSD drug development and testing. It respects the actual randomization method of the study, preserves information from the 20 distinct items of the CAPS-5, efficiently uses data, and brings the analysis of CAPS-5 more into line with the patient self-reported outcome measure, Patient Global Impression of Change (PGIC). The PGIC has particular importance because it measures how study participants themselves rate how they feel and because it is not tied to any theoretical disease construct. We have requested that FDA consider RHNPCOT as an exploratory outcome in our completed, but still blinded Phase 3 RECOVERY (P302) PTSD study. We expect to unblind the RECOVERY study before year end. Exploratory analysis of RECOVERY by RHNPCOT will provide additional information about the utility of the method. We plan to propose RHNPCOT as a primary analysis for future PTSD studies.”

In other psychiatric conditions, the placebo response is growing faster in the U.S. than in other countries[1,2]. Tonix is planning a Phase 3 PTSD study of TNX-102 SL in Kenya, expected to initiate in the third quarter of 2021, and will focus on studying police. The primary site for this multi-center study is Moi University School of Medicine in Eldoret, Kenya. The study was planned and the agreements negotiated when Dr. Lukoye Atwoli was Professor and Dean at Moi University School of Medicine. Dr. Atwoli was the principal investigator of the planned study before being recently recruited to be Dean of Aga Khan University Medical College East Africa based in Nairobi, the Capital of Kenya.

Dr. Atwoli, now Professor of Psychiatry and Dean at Aga Khan University Medical College stated, "We in Kenya are very excited to be setting up the plans for a clinical trial to evaluate a treatment for PTSD in our region. This kind of research is not common in our part of the world. We believe there are opportunities to improve care in our population, but also to bolster the ability of our young researchers to carry out that kind of work. We are grateful to Tonix for supporting us and look forward to a long-term collaboration."

Dr. Lederman stated, "PTSD knows no borders. We are impressed with the clinical trial capabilities at Moi University and several other sites in Kenya. We look forward to working with Dr. Atwoli and other experts to perform a study of TNX-102 SL on PTSD in Kenyan police."

An archived replay of Dr. Lederman's presentation will be available on the IR Events tab of the Investors section of the Tonix website at www.tonixpharma.com.

About the 3rd Neuropsychiatric Drug Development Summit

The 3rd Annual Neuropsychiatric Drug Development Summit focuses on unravelling the complexities of developing clinically transformative neuropsychiatric drugs. With an emphasis on depressive disorders, schizophrenia, addiction and PTSD, this meeting provides a platform for thought leaders to have open reflections and share competitive knowledge. The meeting will put the spotlight on innovations in clinical trial design, defining better clinical endpoints and the emergence of the next generation of anti-psychotics.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year and the first quarter of 2021. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox. Tonix is also developing TNX-2300* and TNX-2600*, live replicating vaccine candidates for the prevention of COVID-19, but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects topline data in the Phase 3 RELIEF study in the fourth quarter of 2020. Tonix is also currently enrolling participants in the Phase 3 RALLY study for the management of fibromyalgia using TNX-102 SL, and the results are expected in second half of 2021. TNX-102 SL is also in development forPTSD, agitation in Alzheimer's disease (AAD) and alcohol use disorder (AUD). The PTSD program is in Phase 3 development while AAD and AUD are Phase 2 ready. The AAD program has FDA Fast Track designation. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD; TNX-1500* (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions; and TNX-1700* (rTFF2), a biologic being developed to treat gastric and pancreatic cancers.

[1]Gopalakrishnan, M *et al. J Clin Psychiatry.* 2020; 81(2):19r12960

[2]Laughren, TP *J Clin Psychiatry*. 2020; 81(2):19com13110

*TNX-1800, TNX-801, TNX-2300, TNX-2600, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have not been approved for any indication.

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; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; 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, 2019, as filed with the Securities and Exchange Commission (the “SEC”) on March 24, 2020, 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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