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 21, 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.)

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 8.01. Other Events.

On May 21, 2020, Tonix Pharmaceuticals Holding Corp., a Nevada corporation, posted two posters (together, the "Posters") for the American Society of Clinical Psychopharmacology (ASCP) 2020 Annual Meeting to be held May 29-30, 2020. Copies of the Posters and the press release which discusses this matter are attached hereto as Exhibits 99.01, 99.02 and 99.03, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)	**Exhibit No.**	**Description**.
	99.01	Poster Presentation
	99.02	Poster Presentation
	99.03	Press Release of the Company, dated May 21, 2020

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 21, 2020

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

EXHIBIT 99.01

Phase 1 Pharmacokinetic Study of a Once-Daily Formulation of TNX-601 CR* (Tianeptine Oxalate Controlled-Release) Tablets

Gregory M Sullivan[a1], Siobhan Fogarty[1], Regina Kiu[1], Bernd Meibohm[2], Seth Lederman[1]

[1]Tonix Pharmaceuticals Inc, [2]University of Tennessee Health Sciences Center

*TNX-601 CR is an investigational drug and has not been approved for any indication

[a] Presenter

INTRODUCTION

Tianeptine is an atypical antidepressant with a novel mechanism of action that has been marketed since the late 1980's for the treatment of major depressive disorder (MDD) in Europe, Asia and Latin America, yet has not been available in the United Kingdom or North America. Most clinical studies of tianeptine in depression have compared its efficacy with other classes of antidepressants, in particular the selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs), and tianeptine has been shown to have comparable efficacy to these classes and better tolerability. Moreover, tianeptine has been shown to exhibit prominent anxiolytic effects in depression studies, and there is preliminary evidence suggesting therapeutic effects in posttraumatic stress disorder (PTSD), including combat PTSD, which is considered less treatment responsive.

Tianeptine's precise mechanism of antidepressant effect has been elusive, as it does not have affinity for traditional central nervous system receptors or transporters associated with antidepressant efficacy. Yet an abundance of pre-clinical evidence points to indirect inhibitory modulation of glutamatergic receptor activity, via AMPA and NMDA receptors, and release of BDNF, which results in adaptive neural plasticity.[1] Tianeptine demonstrates unique neuroprotective properties in the rodent model, inhibiting pathological stress-induced changes in glutamatergic transmission in hippocampus and amygdala, opposing the effects of chronic stress on brain structures and neuroplasticity. Relatively recent work also demonstrated tianeptine weakly binds to the human µ-opioid receptor (hMOR) with $K_{i\ Human}$ of 383 ± 183 nM, with agonist activity at MOR shown for both G protein and cAMP inhibition.[2] It was reported that the acute and chronic antidepressant-like effects of tianeptine in mice require MOR.[3] In the murine model at relatively high dose (30 mg/kg), it also produced opiate-like behavioral effects such as analgesia and reward, yet demonstrated no evidence of tolerance or withdrawal. Its primary metabolite MC5, which is active and has a longer elimination half-life, produced behavioral effects comparable with tianeptine in the murine model. It is not clear whether tianeptine's relatively weak MOR agonism is relevant to its antidepressant mechanism at the typical dosage of 37.5 mg/d for tianeptine sodium. Yet, the MOR activity is likely relevant to tianeptine's abuse potential at supratherapeutic oral dosages between one to two orders of magnitude higher, consistent with case reports of abuse at very high doses.

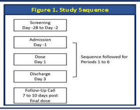
The marketed form of tianeptine is amorphous tianeptine sodium 12.5 mg (Stablon®), which is taken three-times daily in depression. We have identified a new oxalate crystalline salt of tianeptine with improved pharmaceutical properties for development in the US. In the present Phase 1 study of tianeptine oxalate, we compared the pharmacokinetics (PK) and safety of immediate-release (IR) tianeptine oxalate 13.1 mg (TNX-601) to tianeptine sodium 12.5 mg (which both contain 11.9 mg of tianeptine), and to several novel controlled-release (CR) formulations of the oxalate salt. Of these CR formulations, here we highlight the PK in fasted and fed states of TNX-601 CR 39.4 mg, the formulation selected for development as a once-daily treatment for the indications of MDD, PTSD, and neurocognitive dysfunction secondary to corticosteroids.

METHODS

Study TNX-TI-P101 was a single center, open-label, non-randomized, 6 sequential period study designed to investigate the PK and relative bioavailability of TNX-601 IR and prototype modified release (MR) tablets in healthy male and female subjects. The study enrolled 12 healthy adult subjects to receive single oral doses of investigational product (IP) sequentially in 6 treatment periods. Subjects screened for inclusion up to 28 days before Day 1 of Period 1. Each period followed the same study design (**Figure 1**).

Subjects were confined to a clinical unit the evening prior to dosing (Day -1) and remained on site until 48 hours post-dose.

Figure 1. Study Sequence



In each period, subjects received a single dose of one of the following treatment regimens, with a minimum washout period of 7 days between each period:

Table 1. Investigational Product Administration

Period	Regimen	N	Investigational Product, Dose and Fasted/Fed State
1	A	12	1 × Stablon 12.5 mg coated tablet (reference) in the fasted state (11.9 mg tianeptine)
2	B	12	1 × TNX-601 IR Tablet 13.1 mg in the fasted state (11.9 mg tianeptine)
3	C	12	1 × TNX-601 P1 MR Tablet 39.4 mg in the fasted state (35.7 mg tianeptine)
4	D	12	1 x TNX-601 P2 MR Tablet 39.4 mg in the fasted state (35.7 mg tianeptine)
5	E	12	1 x TNX-601 P1 MR Tablet 39.4 mg in the fed state (high fat; 35.7 mg tianeptine)
6	F*	6	1 x TNX-601 P3 MR Tablet 50 mg in the fed state (high fat; 45.4 mg tianeptine)
6	F*	6	1 x TNX-601 P3 MR Tablet 50 mg in the fasted state (45.4 mg tianeptine)

* Regimen F was a split cohort with 6 subjects dosed in the fed state (after a high-fat/high calorie breakfast) and 6 subjects dosed in the fasted state.

This study was designed to assess the PK performance of matrix MR tablet formulation prototypes. The matrix prototypes had a 2-dimensional design space with flexibility to CR rate via changing a polymer content/composition and dose, in response to emerging clinical PK data, to allow optimization of the MR formulation. The relative bioavailability of an IR TNX-601 formulation was also assessed and compared to Stablon. The effect of food on the PK of plasma tianeptine and the MC5 metabolite following selected TNX-601 CR prototype was explored by comparing Regimens C and E (data from an alternate MR formulation evaluated for food effect in Regimen F is not shown).

Quotient Sciences, Nottingham, UK was responsible for the manufacture of the IR and prototype MR formulations according to Good Manufacturing Practice (GMP) in Quotient Sciences' MHRA-licensed facility. Reference product Stablon was acquisitioned by Quotient. Plasma concentrations of tianeptine and MC5 were determined using validated analytical methods at LGC Ltd, Fordham, Cambridgeshire, UK. Lower limit of quantification was 2 ng/mL for tianeptine and 1 ng/mL for MC5.

MHRA approval was granted for the Clinical Trial Authorisation (CTA) application for this study.

The following PK parameters are displayed for tianeptine and active metabolite MC5:

AUC_{0-24}: Area under the curve from time 0 to 24 h post-dose; concentration
AUC_{0-inf}: Area under the curve from time 0 extrapolated to infinity
C_{max}: Maximum observed concentration
AUC_{extrap}: Percentage of AUC(0-inf) extrapolated beyond the last measurable concentration
T_{max}: Time of maximum observed concentration
$T_{1/2}$: Apparent elimination half-life
CL/F: Apparent total body clearance calculated after a single extravascular administration where F (fraction of dose bioavailable) is unknown (plasma tianeptine only)
Vz/F: Apparent volume of distribution based on the terminal phase calculated after a single extravascular administration where F (fraction of dose absorbed) is unknown (plasma tianeptine only)
F_{rel}: Relative bioavailability of TNX-601 IR tablet compared to Stablon and of TNX-601 CR tablet in fasted compared to fed state based on C_{max}, AUC_{0-last} and AUC_{0-inf}

Formal statistical analysis was performed on the PK parameters Cmax, AUC(0-last) and AUC(0-inf) for tianeptine and MC5 and were analyzed using mixed modelling techniques. The adjusted means including differences from the pairwise comparisons and their associated 90% confidence intervals (CIs) were obtained from the model. The adjusted geometric mean ratios and associated 90% CIs are presented together with the p-value from the pairwise comparisons. For all PK parameters presented in the tables, the arithmetic means are displayed.

The safety analysis population included all subjects who received at least 1 dose of IP. Safety was assessed by adverse events (AEs), Columbia Suicide Severity Rating Scale (C-SSRS), physical exams, vital signs, electrocardiograms (ECG) and laboratory parameters.

RESULTS

Pharmacokinetic Results: PK results for plasma tianeptine and metabolite MC5 are presented for TNX-601 IR 13.1 mg in comparison with reference product Stablon 12.5 mg in **Table 2** and **Figure 2**, both dosed in a fasted state. For AUC_{0-last} and AUC_{0-inf}, TNX-601 13.1 mg had significantly greater relative bioavailability than Stablon, and it also had a 16% longer half-life. The inter-subject variability associated with tianeptine and MC5 exposure was not changed between the salt forms.

Table 2. PK Parameters of Plasma Tianeptine & MC5 with Stablon and TNX-601

	Regimen A Stablon 12.5 mg N=11	Regimen B TNX-601 13.1 mg N=12	Regimen A Stablon 12.5 mg N=11	Regimen B TNX-601 13.1 mg N=12
Parameter (Mean)	Tianeptine		Metabolite MC5	
AUC_{0-24} (h*ng/mL)	921	976	524	595
AUC_{0-last} (h*ng/mL)	910	967	624	718
F_{rel} AUC_{0-last} (%)	105.18 [101.47, 109.02], p=0.029		112.08 [106.98, 117.43], p=0.001	
AUC_{0-inf} (h*ng/mL)	928	987	648	751
F_{rel} AUC_{0-inf} (%)	105.36 [101.46, 109.42], p=0.031		112.98 [107.87, 118.34], p<0.001	
C_{max} (ng/mL)	241	248	53.6	58.4
F_{rel} C_{max} (%)	102.07 [95.05, 109.61], p=0.61		104.67 [97.16, 112.77], p=0.29	
AUC_{extrap} (%)	2.03	2.16	3.89	4.43
T_{max} (h)	1.59	1.18	3.18	3.08
$T_{1/2}$ (h)	3.26	3.77	9.54	10.12
CL/F (mL/min)	233	216	*ND	*ND
Vz/F (L)	63.3	74.8	*ND	*ND

*ND = not done

PK results for plasma tianeptine and metabolite MC5 are presented for TNX-601 CR 39.4 mg, comparing fasted and fed states, in **Table 3** and **Figure 3**. The C_{max} was significantly greater in the fed state for both tianeptine and MC5, by 41% and 32%, respectively. And the relative bioavailability was reduced by 11% in the fed state. The $T_{1/2}$ for TNX-601 CR 39.4 mg was reduced by about 27%.

Figure 2. Mean (±SD) Tianeptine and MC5 Concentrations for Stablon and TNX-601

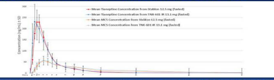


Figure 3. Mean (±SD) Tianeptine and MC5 Concentrations for TNX-601 CR in Fasted and Fed States

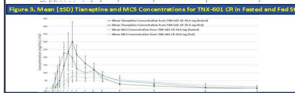


Table 3. PK Parameters of Plasma Tianeptine & MC5 with TNX-601 CR in Fasted and Fed States

	Regimen C TNX-601 CR 39.4 mg (fasted) N=12	Regimen E TNX-601 CR 39.4 mg (fed) N=12	Regimen C TNX-601 CR 39.4 mg (fasted) N=12	Regimen E TNX-601 CR 39.4 mg (fed) N=12
Parameter (Mean)	Tianeptine		Metabolite MC5	
AUC_{0-24} (h*ng/mL)	2130	2030	1310	1350
AUC_{0-last} (h*ng/mL)	2380	2110	1860	1820
F_{rel} AUC_{0-last} (%)	89.22 [81.59, 97.56], p=0.043		97.02 [90.55, 103.96], p=0.45	
AUC_{0-inf} (h*ng/mL)	2430	2290	2130	1980
F_{rel} AUC_{0-inf} (%)	92.81 [84.63, 101.77], p=0.17		93.57 [86.25, 101.51], p=0.17	
C_{max} (ng/mL)	243	342	81.2	107
F_{rel} C_{max} (%)	139.70 [114.19, 170.91], p=0.013		134.19 [117.30, 153.51], p=0.002	
AUC_{extrap} (%)	2.35	1.79	8.66	7.04
T_{max} (h)	3.59	5.25	9.13	8.09
$T_{1/2}$ (h)	7.12	5.23	11.86	11.45
CL/F (mL/min)	262	273	*ND	*ND
Vz/F (L)	174	123	*ND	*ND

*ND = not done

Safety Results: Single doses of Stablon 12.5 mg fasted (reference), 13.1 mg TNX-601 IR fasted, 39.4 mg TNX-601 MR prototype 1 fasted, 39.4 mg TNX-601 MR prototype 2 fasted, 39.4 mg TNX-601 MR prototype 1 fed, 50 mg TNX-601 MR prototype 3 fed and 50 mg TNX-601 MR prototype 3 fasted were well tolerated in 12 healthy male (7) and female (5) subjects. Two subjects reported TEAEs assessed as possibly related to IP, namely headache and somnolence, while all other TEAEs were assessed as not related to IP. All TEAEs were mild in severity and all resolved by the end of the study. There were no significant laboratory, vital signs, ECG, C-SSRS or physical examination findings.

CONCLUSIONS

- Following single oral administration of TNX-601 13.1 mg IR tablet, although there was greater relative bioavailability of tianeptine and MC5 compared to single dose of Stablon 12.5 mg tablet, there was no clinically relevant difference in tianeptine relative bioavailability (C_{max}, AUC_{0-last} and AUC_{0-inf}), no change in MC5 C_{max} and <20% increase in MC5 AUC_{0-last} and AUC_{0-inf} compared to single dose Stablon 12.5 mg. Inter-subject variability associated with tianeptine and MC5 exposure was also unchanged after TNX-601 13.1 mg IR compared to Stablon.
- A single dose of TNX-601 CR 39.4 mg resulted in a similar tianeptine C_{max} and an AUC_{0-24} which was approximately 80% of that predicted following a single day of TID dosing of the Stablon 12.5 mg reference; while exposure to MC5 (C_{max} and AUC_{0-24}) was similar to that predicted following a single day of TID dosing of the Stablon 12.5 mg reference.
- Administration of TNX-601 CR 39.4 mg tablet with a high fat breakfast demonstrated a delay in absorption and an increase in tianeptine and MC5 C_{max} of approximately 34 to 39% compared to the same dose in the fasted state. There was no clinically relevant increase in overall exposure (AUC_{0-last} and AUC_{0-inf}) to tianeptine or MC5.
- A controlled-release formulation of tianeptine oxalate, TNX-601 CR 39.4 mg, was manufactured and tested, and demonstrated PK characteristics suitable for once-daily dosing which will be advanced to clinical testing in MDD, PTSD, and corticosteroid-induced cognitive dysfunction.

CITATIONS

1. McEwen BS, Chattarji S, Diamond DM, Jay TM, Reagan LP, Svenningsson P, Fuchs E. The neurobiological properties of tianeptine (Stablon): from monoamine hypothesis to glutamatergic modulation. Mol Psychiatry. 2010 Mar;15(3):237-49.

2. Gassaway MM, Rives ML, Kruegel AC, Javitch JA, Sames D. The atypical antidepressant and neurorestorative agent tianeptine is a µ-opioid receptor agonist. Transl Psychiatry. 2014 Jul 15;4(7):e411.

3. Samuels BA, Nautiyal KM, Kruegel AC, Levinstein MR, Magalong VM, Gassaway MM, Grinnell SG, Han J, Ansonoff MA, Pintar JE, Javitch JA, Sames D, Hen R. The Behavioral Effects of the Antidepressant Tianeptine Require the Mu-Opioid Receptor. Neuropsychopharmacology. 2017 Sep;42(10):2052-2063.

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Presented at the American Society of Clinical Psychopharmacology (ASCP) 2020 Annual Meeting Virtual Conference, May 29-30, 2020; Virtual Poster Session Friday, May 29th, 12:30 PM-2:00 PM EDT

EXHIBIT 99.02

Pharmacokinetic Results of a Dose Proportionality and Food Effect Study of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL)

Gregory Sullivan[1], Regina Kiu[1], Bernd Meibohm[2], and Seth Lederman[1]
[1]Tonix Pharmaceuticals Inc, [2]University of Tennessee Health Sciences Center

OBJECTIVE

TNX-102 SL is a sublingual (SL) formulation of cyclobenzaprine (CBP), administered as 2 x 2.8 mg tablets, designed for bedtime dosing that is being developed by Tonix Pharmaceuticals for fibromyalgia (FM), posttraumatic stress disorder (PTSD), agitation in Alzheimer's Disease (AAD), and alcohol use disorder (AUD). Previous Phase 1 pharmacokinetic (PK) studies comparing TNX-102 SL with immediate release (IR) and extended release (ER) formulations of oral CBP (AMRIX® 30 mg ER capsules) show that TNX-102 SL provides transmucosal absorption, rapid systemic exposure, avoidance of first-pass metabolism, and lower exposure to long-lived major metabolite, norcyclobenzaprine (norCBP) (unpublished). Approved oral CBP products have significant increases in absorption with food, a source of greater variability in plasma drug levels. Food effects therefore may add unpredictability for patients in terms of therapeutic benefits or side effects experienced by patients. This Phase 1 PK study evaluated the dose-proportionality of TNX-102 SL 2.8 mg to 5.6 mg, and the potential for food effect with TNX-102 SL 5.6 mg.

DESIGN

Study TNX-CY-F110 (F110) was a single center, single-dose, randomized, open-label, 3-period, crossover, dose-proportionality and food effect study to support the registration of TNX-102 SL 5.6 mg. This study was designed to:

1. Evaluate the dose-proportionality of TNX-102 SL 2.8 mg vs. TNX-102 SL 5.6 mg (administered as 2 x 2.8 mg tablets) under fasting conditions
2. Evaluate the effect of food on TNX-102 SL 5.6 mg under fasting and fed conditions
3. Assess the safety and tolerability of TNX-102 SL in healthy subjects.

The study enrolled 16 healthy adult subjects and consisted of 3 randomized treatment periods. Subjects were confined on site from at least 10 hours before dosing until 24-hour post-dose. In each period, subjects received a single dose of one of the following treatments, with a washout period of at least 28 days between each period:

Treatment A:	1 x TNX-102 SL 2.8 mg under fasting conditions
Treatment B:	2 x TNX-102 SL 2.8 mg under fasting conditions
Treatment C:	2 x TNX-102 SL 2.8 mg under fed conditions

Thirty-four (34) serial plasma samples were taken from pre-dose, up to 360 hours post-dose in each period to compare pharmacokinetic (PK) parameters of CBP and norCBP between treatments.

Safety was assessed by adverse events (AEs), Columbia Suicidality Severity Rating Scale (C-SSRS), physical exam, vital signs, electrocardiograms (ECG), and laboratory parameters.

METHODS

The following PK parameters were calculated by standard non-compartmental methods for CBP and norCBP:

AUC_{0-t}, AUC_{0-Inf}, C_{max}, Residual area, T_{max}, $T_{½ el}$

Dose-proportionality and no food effect will be concluded if the 90% confidence intervals for the ratio of geometric means based on least-squares means from the ANOVA of the LN-transformed dose-normalized AUC_{0-t}, AUC_{0-Inf}, and C_{max} are within 80.0% to 125.0%.

RESULTS

Pharmacokinetic Results:
PK results for CBP are presented in **Figure 1** and **Table 1**. Following a single dose of TNX-102 SL 2.8 mg under fasting conditions (Treatment A), the mean AUC_{0-t} and C_{max} was 64.4 h*ng/mL and 2.5 ng/mL . Following a single dose of TNX-102 SL 5.6 mg under fasting conditions (Treatment B), the mean AUC_{0-t} and C_{max} was 128.1 h*ng/mL and 5.1 ng/mL . Following a single dose of TNX-102 SL 5.6 mg under fed conditions (Treatment C), the mean AUC_{0-t} and C_{max} was 133.1 h*ng/mL and 4.5 ng/mL. The mean T_{max} for TNX-102 SL 2.8 mg fasted, 5.6 mg fasted and 5.6 mg fed were 4.4 h, 4.2 h and 5.1 h.

Figure 1. Mean (±SD) Cyclobenzaprine Plasma Concentrations

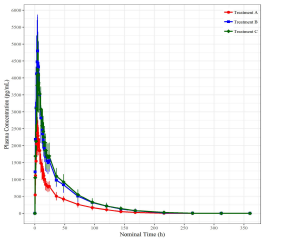

Table 1. Summary of Pharmacokinetic Parameters by Treatment Group for Cyclobenzaprine

Parameter (Mean)	Treatment A TNX 2.8 mg (fasted) N=15	Treatment B TNX 5.6 mg (fasted) N=16	Treatment C TNX 5.6 mg (fed) N=16
AUC_{0-t} (h*ng/mL)	64.4	128.1	133.1
Ratio (90% CI) (%)	100.2 (94.5, 106.2)	104.1 (99.0, 109.3)	
AUC_{0-Inf} (h*ng/mL)	67.7	132.3	136.9
Ratio (90% CI) (%)	102.3 (96.8, 108.0)	103.7 (98.6, 109.0)	
C_{max} (ng/mL)	2.5	5.1	4.5
Ratio (90% CI) (%)	97.9 (92.1, 104.1)	89.0 (82.1, 96.6)	
Residual Area (%)	5.2	3.2	2.8
T_{max} (h)	4.4	4.2	5.1
$T_{1/2el}$ (h)	35.4	36.4	37.9

PK results for norCBP are presented in **Figure 2** and **Table 2**. Following a single dose of TNX-102 SL 2.8 mg under fasting conditions (Treatment A), the mean AUC_{0-t} and C_{max} was 79.5 h*ng/mL and 0.6 ng/mL . Following a single dose of TNX-102 SL 5.6 mg under fasting conditions (Treatment B), the mean AUC_{0-t} and C_{max} was 158.1 h*ng/mL and 1.2 ng/mL . Following a single dose of TNX-102 SL 5.6 mg under fed conditions (Treatment C), the mean AUC_{0-t} and C_{max} was 156.2 h*ng/mL and 1.1 ng/mL . The mean T_{max} for TNX-102 SL 2.8 mg fasted, 5.6 mg fasted and 5.6 mg fed were 24.2 h, 31.8 h and 32.9 h.

Figure 2. Mean (±SD) Norcyclobenzaprine Plasma Concentrations

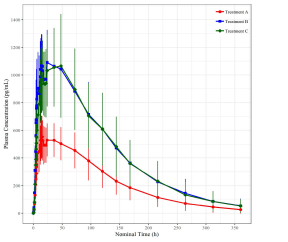

Table 2. Summary of Pharmacokinetic Parameters by Treatment Group for Norcyclobenzaprine

Parameter	Treatment A TNX 2.8 mg (fasted) N=15	Treatment B TNX 5.6 mg (fasted) N=16	Treatment C TNX 5.6 mg (fed) N=16
AUC_{0-t} (h*ng/mL)	79.5	158.1	156.2
Ratio (90% CI) (%)	99.1 (92.2, 106.6)	96.1 (89.5, 103.2)	
AUC_{0-Inf} (h*ng/mL)	82.4	164.1	161.8
Ratio (90% CI) (%)	99.0 (91.8, 106.8)	95.9 (89.2, 103.2)	
C_{max} (ng/mL)	0.6	1.2	1.1
Ratio (90% CI) (%)	97.5 (91.3, 104.0)	94.9 (87.7, 102.7)	
Residual Area (%)	2.9	3.0	2.9
T_{max} (h)	24.2	31.8	32.9
$T_{1/2el}$ (h)	61.3	63.0	62.0

Safety Results:
In F110, 16 subjects were randomized and 1 subject was withdrawn from the study due to an adverse event unrelated to the study drug. There were no unexpected treatment-emergent adverse events (TEAEs) observed. The most commonly reported TEAEs by subjects were related to local administration site reactions following a single dose of TNX-102 SL 2.8 mg fasted, TNX-102 SL 5.6 mg fasted and TNX-102 SL 5.6 mg fed were hypoaesthesia oral (37.5%) and product taste abnormal (31.3%). The most commonly reported systemic TEAEs were somnolence (43.8%) and headache (18.8%). The TEAEs reported by ≥ 3 subjects are presented in **Table 3**. No deaths or serious adverse events were reported. All TEAEs were mild or moderate in severity and are consistent with prior clinical studies of TNX-102 SL at the 2.8 mg and 5.6 mg doses.

Table 3. Treatment-Emergent Adverse Events Reported by ≥ 3 Subjects

Preferred Terms, n (%)	TNX-102 SL N=16
Somnolence	7 (43.8%)
Hypoaesthesia Oral	6 (37.5%)
Product Taste Abnormal	5 (31.3%)
Nasopharyngits	5 (31.3%)
Headache	3 (18.8%)

CONCLUSION

TNX-102 SL 2.8 mg and 5.6 mg were well tolerated in healthy subjects. Based on the PK results, the rate and extent of absorption of CBP and norCBP increased in a dose-proportional manner from 2.8 mg to 5.6 mg of TNX-102 SL. No food effect was observed for CBP or norCBP for TNX-102 SL 5.6 mg. The absence of a food effect is consistent with transmucosal absorption after sublingual administration, and this is expected to provide more predictable plasma levels compared to oral formulations of CBP.

Presented at the Virtual American Society of Clinical Psychopharmacology (ASCP), May 29-30, 2020; Poster Session II: May 30, 12:45 AM – 2:15 PM

EXHIBIT 99.03

Tonix Pharmaceuticals Posted Results from Pharmacokinetic Analyses of TNX-102 SL and TNX-601 CR in Advance of Virtual Poster Presentations at the American Society of Clinical Psychopharmacology

NEW YORK, May 21, 2020 - Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, posted two posters for the American Society of Clinical Psychopharmacology (ASCP) 2020 Annual Meeting to be held online virtually on May 29-30, 2020. The posters can be found on the Scientific Presentations page of Tonix's website.

A poster, titled "Pharmacokinetic Results of Dose Proportionality and Food Effect Study of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL)" includes pharmacokinetic (PK) analyses of TNX-102 SL that is being developed as a bedtime treatment for fibromyalgia, posttraumatic stress disorder (PTSD), agitation in Alzheimer's disease (ADD) and alcohol use disorder (AUD). Sixteen healthy subjects, ages 18-65, were randomized in a 3-way crossover to receive a single dose of TNX-102 SL 2.8 mg fasted, TNX-102 SL 5.6 mg fasted, and TNX-102 SL 5.6 mg fed using a standardized high-fat meal.

A poster, titled "Phase 1 Pharmacokinetic Study of a Once-Daily Formulation of TNX-601 CR (Tianeptine Oxalate Controlled-Release) Tablets," includes PK analyses of TNX-601 CR which is being developed as a once-daily treatment of major depressive disorder (MDD), PTSD and corticosteroid-induced cognitive dysfunction. In this single-center, open-label, multiple sequential period study, a single cohort of 12 male and female healthy volunteers were administered in successive periods: tianeptine sodium 12.5 mg (Stablon®[1]), tianeptine oxalate 13.1 mg (TNX-601), tianeptine oxalate CR (TNX-601 CR) 39.4 mg in a fasted state; and TNX-601 CR in a fed state using a standardized high-fat meal.

Dr. Gregory Sullivan, Chief Medical Officer of Tonix said, "Based on the PK results of the study with TNX-102 SL, the rate and extent of absorption of CBP increased in a dose-proportional manner from 2.8 mg to 5.6 mg of CBP. No food effect was observed for CBP for TNX-102 SL 5.6 mg. The absence of a food effect is consistent with transmucosal absorption after sublingual administration, and this is expected to provide more predictable plasma levels compared to oral swallowed forms of CBP."

Dr. Sullivan continued, "Based on the PK results of the TNX-601 CR study, TNX-601 CR 39.4 mg demonstrated PK appropriate for once-daily dosing with minimal food effect. TNX-601 CR was well-tolerated, without unexpected side effects, and with profiles consistent with the ex-U.S.-marketed sodium salt form of tianeptine dosed three times a day. We believe these findings support further development of TNX-601 CR, the once-daily formulation of tianeptine, in MDD, PTSD and corticosteroid-induced cognitive dysfunction."

[1] Stablon is a registered trademark of Les Laboratoires SERVIER (France).

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. Tonix is developing four potential vaccines, based on the horsepox viral vector platform to protect against the novel coronavirus disease emerging in 2019, or COVID-19: TNX-1800, TNX-1810, TNX-1820 and TNX-1830*. TNX-1800 is designed to express the Spike protein of the SARS-CoV-2 and to a predominant T cell response. TNX-1810, TNX-1820 and TNX-1830 are designed to express different proteins from SARS-CoV-2 and to elicit almost pure T cell responses. TNX-801* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL**, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in September of 2020 and topline data in the first quarter of 2021. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya***) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) application stage. 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 cocaine intoxication and has FDA Breakthrough Therapy Designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. Tonix's preclinical pipeline includes 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. TNX-1200* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-1800, TNX-1810, TNX-1820, TNX-1830, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

***Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

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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