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): March 9, 2016

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

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

Copy of correspondence to:

Marc J. Ross, Esq.
James M. Turner, Esq.
Sichenzia Ross Friedman Ference LLP
61 Broadway
New York, New York 10006
Tel: (212) 930-9700 Fax: (212) 930-9725

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On March 9, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") will present data from its TNX-102 SL program for the management of fibromyalgia and treatment of post-traumatic stress disorder in a poster entitled "*Rapid Sublingual Absorption on Cyclobenzaprine (CBP) with Basifying Agents: Prospect for Bedtime Treatment of Fibromyalgia Syndrome (FM)*" (the "Poster"), at the American Society for Clinical Pharmacology and Therapeutics 2016 Annual Meeting in San Diego, California.

The foregoing description of the Poster is qualified in its entirety by reference to the Poster, a copy of which is filed as Exhibit 99.01 to, and is incorporated by reference in, this report.

On March 9, 2016, the Company issued a press release announcing the presentation of the Poster. A copy of the press release that discusses these matters is filed as Exhibit 99.02 to, and incorporated by reference in, this report.

The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01	*Rapid Sublingual Absorption on Cyclobenzaprine (CBP) with Basifying Agents: Prospect for Bedtime Treatment of Fibromyalgia Syndrome (FM)* Poster*
99.02	Press Release, dated March 9, 2016, issued by Tonix Pharmaceuticals Holding Corp.*

* Furnished herewith.

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: March 9, 2016

By: */s/ BRADLEY SAENGER*
Bradley Saenger
Chief Financial Officer

Rapid Sublingual Absorption of Cyclobenzaprine (CBP) with Basifying Agents: Prospect for Bedtime Treatment of Fibromyalgia Syndrome (FM)

Bruce Daugherty, Nunzia Ceppi Monti, Valentina Panzeri, Roberto Marelli, Enrico Magnocavallo, Giorgio Reiner and Seth Lederman
Tonix Pharmaceuticals, Inc., New York, NY and APR Applied Pharma Research s.a., Balerna, Switzerland

Funded by Tonix Pharmaceuticals, Inc.

Presentation Number LB-026

Background

Cyclobenzaprine (CBP) exposure during sleep improves daytime fibromyalgia (FM) symptoms and sleep quality[1]. CBP absorption into plasma is delayed after ingesting immediate release (IR) tablets. To speed absorption, TNX-102 SL*, a sublingual (SL) formulation of 2.8 mg CBP was developed for transmucosal absorption.

Methods

Plasma CBP was measured in healthy subjects (N=6/group) after a single tablet of TNX-102 SL 2.8 mg or CBP IR 5 mg, and PK parameters were calculated.

Results

TNX-102 SL is a eutectic CBP formulation which contains potassium phosphate dibasic as a basifying agent that disintegrates in saliva and rapidly dissolves. The addition of a basifying agent results in a higher pH, thereby rendering CBP in an un-ionized state at the mucosal membrane, thus rapidly driving CBP across the mucosa into the bloodstream. For TNX-102 SL 2.8 mg v. ingested CBP IR 5 mg, plasma CBP levels were: at 10 min 338 pg/ml v. below limit of detection (BLD); at 20 min 739 pg/mL v. BLD; at 30 min 988 pg/mL v. BLD; at 45 min 1209 v. 280 pg/mL (p=0.001); at 60 min 1545 v. 913 pg/mL (p=0.062); and at 120 min 2296 v. 1737 pg/mL (p=0.043). For TNX-102 SL 2.8 mg v. CBP IR 5 mg tablets, the mean exposure was 338% (p=0.009) higher at 1h, and 83% (p=0.034) higher at 2h. TNX-102 SL 2.8 mg had C_{max} = 3.4 ng/mL and AUC_{0-8} = 79 ng hr/mL while CBP IR 5 mg had C_{max} = 4.3 ng/mL and AUC_{0-8}= 92 ng hr/mL showing more efficient dose-adjusted absorption for TNX-102 SL. The plasma levels of norcyclobenzaprine (nCBP), the major metabolite of CBP, were lower with TNX-102 SL consistent with bypassing first pass hepatic metabolism. TNX-102 SL was well tolerated and side effects were similar to those of oral CBP although some subjects experienced numbness in the mouth that was transient and self-limited.

Conclusions

TNX-102 SL delivers CBP rapidly across the sublingual mucosal membrane into plasma resulting in 12 times faster onset of absorption relative to oral CBP IR, and provides significantly increased plasma CBP levels during the first 2 hours. The relative bioavailability was 154% when compared to the CBP IR tablet. The SL formulation had no effect on T_{max}. Sublingual administration of CBP via TNX-102 SL bypasses "first-pass" metabolism reducing C_{max} and AUC to nCBP, the active metabolite. The pharmacokinetic properties of TNX-102 SL appear to be well suited for its development as a potential bedtime medication for FM in a long-term treatment regimen.

[1] Moldofsky H et al, (2011) J Rheum 38: 2653-2663

* TNX-102 SL is being investigated in the US for FM under a US IND and is not approved for any indication

Table 1. Demographic Data

Category	TNX-102 SL 2.8 mg N=6	CBP IR 5 mg N=6
Age (years)		
Mean (SD)	36.7 (15.0)	37.3 (15.4)
Gender, N (%)		
Female	4 (66.7%)	3 (50.0%)
Male	2 (33.3%)	3 (50.0%)
Ethnicity, N (%)		
Not Hispanic	5 (83.3%)	5 (83.3%)
Hispanic	1 (16.7%)	1 (16.7%)
BMI (kg/m²)		
Mean (SD)	26.160 (2.821)	25.873 (2.456)

Abbreviations: SL: sublingual; IR: immediate release; CBP: cyclobenzaprine; SD: standard deviation; BMI: body-mass index

Table 2. Treatment-Emergent Adverse Events

System Organ Class/ Preferred Term	TNX-102 SL 2.8 mg N (%)	CBP IR 5 mg N (%)
Gastrointestinal disorders	3 (50.0)	0
Hypoaesthesia oral	2 (33.3)	0
Oral mucosal erythema	1 (16.7)	0

Abbreviations: SL: sublingual; IR: immediate-release; CBP: cyclobenzaprine

Figure 1. TNX-102 SL 2.8 mg: Sublingual CBP Tablet

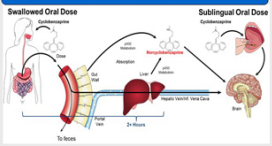

Figure 2. Proprietary CBP-HCl Eutectic Mixture Stabilizes Tablet Formulation

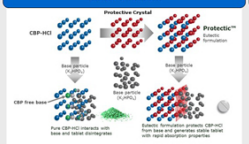

Figure 3. Formulation with Base Increases Systemic Absorption of Sublingual CBP

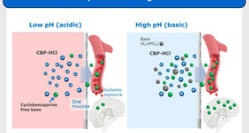

Figure 4. Pharmacokinetic Profile of TNX-102 SL 2.8 mg Tablet vs CBP IR 5 mg Tablet Plasma Levels of CBP

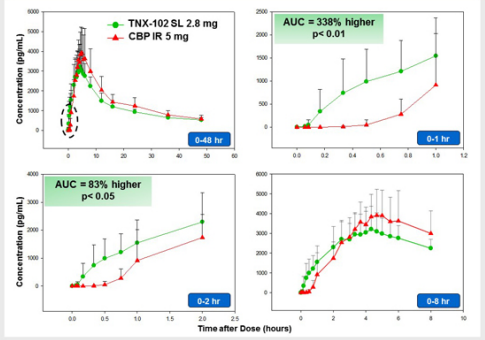

Figure 5. Pharmacokinetic Profile of TNX-102 SL 2.8 mg vs CBP IR 5 mg Plasma Levels of CBP and its Metabolite, nCBP

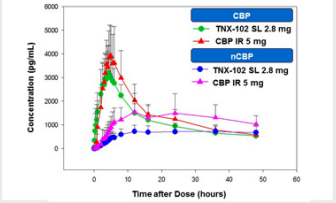

Table 3. Pharmacokinetic Parameters

Parameter	TNX-102 SL 2.8 mg N=6	CBP IR 5 mg N=6
	Cyclobenzaprine	
Absorption Lag Time (T_{lag})	0.050 hr (3 min)	0.622 hr (37 min)
Relative Bioavailability (F_{rel}), %	154	-
T_{max}*, hours	4.33 (1.99-6.00)	4.00 (3.33-5.99)
C_{max}, ng/mL	3.41 ± 0.99	4.26 ± 1.40
AUC_{0-48}, ng•hr/mL	57.4 ± 10.7	69.5 ± 18.8
$t_{1/2}$, hours	27.44 ± 3.32	25.06 ± 9.17
Parameter	**Norcyclobenzaprine**	
T_{max}*, hours	24.0 (8.00-48.00)	18.0 (8.01-36.00)
C_{max}, ng/mL	0.81 ± 0.25	1.71 ± 0.91
AUC_{0-48}, ng•hr/mL	30.5 ± 10.7	58.6 ± 25.7
$t_{1/2}$, hours	71.95 ± 30.97	60.70 ± 35.11

T_{lag} is defined at the first nominal sampling time after administration from which onward the CBP concentrations consistently exceed the limit of quantitation; Relative Bioavailability (F_{rel}) was calculated using the formula, F_{rel} = 100 x [Dose (IR) x AUC (SL)/Dose (SL) x AUC (IR)]; Mean ± SD; *Median (Min-Max)

Exhibit 99.02

Tonix Pharmaceuticals Presents Pharmacokinetic Data on TNX-102 SL as a Potential Treatment for the Management of Fibromyalgia and Treatment of Post-Traumatic Stress Disorder at the ASCPT 2016 Annual Meeting

- TNX-102 SL is a sublingual formulation of cyclobenzaprine designed for bedtime administration currently under development for the long-term management of fibromyalgia and treatment of post-traumatic stress disorder-

- TNX-102 SL pharmacokinetic data demonstrated increased plasma levels of 338% during the first hour and 83% during the first two hours after administration compared with immediate-release cyclobenzaprine oral tablet-

New York, NY – March 9, 2016 – Tonix Pharmaceuticals Holding Corp. (NASDAQ: TNXP) (Tonix), today announced that it is presenting data from its TNX-102 SL (cyclobenzaprine HCI sublingual tablets, 2.8 mg) program for the management of fibromyalgia and treatment of post-traumatic stress disorder (PTSD) in a poster presentation at the American Society for Clinical Pharmacology and Therapeutics 2016 Annual Meeting in San Diego, CA.

Tonix is currently evaluating TNX-102 SL in a randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial in fibromyalgia and a randomized, double-blind, placebo-controlled, registration-quality Phase 2 AtEase clinical trial in military-related PTSD. Tonix expects to report top-line AFFIRM data in the third quarter of 2016 and top-line AtEase data in the second quarter of 2016. TNX-102 SL is designed for bedtime administration and the long term management of fibromyalgia and treatment of PTSD.

The poster entitled, "*Rapid Sublingual Absorption on Cyclobenzaprine (CBP) with Basifying Agents: Prospect for Bedtime Treatment of Fibromyalgia Syndrome (FM),*" is being presented by Bruce Daugherty, PhD, Chief Scientific Officer of Tonix.

Tonix's recent research confirms that their proprietary cyclobenzaprine (CBP) sublingual formulation has a differentiated pharmacokinetic profile from the oral immediate release (IR) CBP tablet. The results are encouraging because by design TNX-102 SL has the desirable pharmacokinetic properties as a potential bedtime medication for fibromyalgia or PTSD. The pharmacokinetic data demonstrated the following:

- TNX-102 SL shows evidence of rapid delivery of CBP across the sublingual mucosal membrane into plasma resulting in 12 times faster onset of absorption relative to the oral CBP IR tablet;
- TNX-102 SL increased plasma levels of 338% during the first hour and 83% during the first two hours after administration compared with oral CBP IR tablet;
- The relative bioavailability of cyclobenzaprine is 154% with TNX-102 SL compared to the oral CBP IR tablet;
- The active metabolite, norcyclobenzaprine, is reduced by 48% with TNX-102 SL; and
- The most frequent adverse event reported in this single-dose comparative bioavailability/pharmacokinetic study was transient numbness in the oral cavity, which was experienced in 50% of the TNX-102 SL subjects and resolved within 30-45 minutes.

The poster LB-026 highlighting the pharmacokinetic properties of TNX-102 SL as a potential bedtime medication for fibromyalgia and PTSD is available on Tonix's website at www.tonixpharma.com.

The United States Food and Drug Administration (FDA) has conditionally accepted "Tonmya" as the proposed trade name of TNX-102 SL for fibromyalgia. TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

Safe Harbor / Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

Contact:

Bradley J. Saenger
Chief Financial Officer
(212) 980-9155 x107
bradley.saenger@tonixpharma.com

Jenene Thomas Communications (investors)
Jenene Thomas
(908) 938-1475
jenene@jenenethomascommunications.com

Dian Griesel Int'l. (media)
Susan Forman / Laura Radocaj
(212) 825-3210
sforman@dgicomm.com
lradocaj@dgicomm.com

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