

**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): June 7, 2016

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(IRS Employer
Identification No.)

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On June 7, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") will utilize a corporate presentation (the "Presentation") to present topline data from its Phase 2 dose-finding clinical study (the "AtEase Study") of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related post-traumatic stress disorder at the 2016 Biotechnology Innovation Organization (BIO) International Convention in San Francisco, California (the "BIO Convention"). The Company intends to place the Presentation on its website, which may contain non-public information. A copy of the Presentation is filed as Exhibit 99.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01, is furnished pursuant to, and shall not be deemed to be "filed" for the purposes of, Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in Item 7.01 of this Current Report shall not be incorporated by reference into any registration statement or any other document filed pursuant to the Securities Act of 1933, as amended, except as otherwise expressly stated in such filing. By filing this Current Report on Form 8-K and furnishing the information contained in this Item 7.01, including Exhibit 99.01, the Company makes no admission as to the materiality of any such information that it is furnishing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Presentation by the Company at the BIO Convention*

* 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: June 7, 2016

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



BIO International, San Francisco, June 7, 2016

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UPDATE

Topline Results With TNX-102 SL
In
Post-Traumatic Stress Disorder
June 7, 2016

Version 0019 6-7-16

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Cautionary Note on Forward-Looking Statements

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Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our 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 U.S Food and Drug Administration clearances or approvals and noncompliance with its regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by the Company 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, 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 the Company's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.



Investment Thesis for Tonix Pharmaceuticals

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UPDATE
Differentiated
Late-Stage
Program

- **TNX-102 SL (cyclobenzaprine sublingual tablets), 2.8 mg**
 - Differentiated with unique attributes that address unmet needs of target markets
- **Clinically validated in fibromyalgia (FM)**
 - Completed: Phase 2; demonstrated relief from chronic wide-spread pain
- **Enrollment in Phase 3 FM completed with topline results expected 3Q 2016**
- **Positive topline results in Phase 2 - post-traumatic stress disorder (PTSD)**

**Commercially
Attractive
Markets**

- **Target indications, FM and PTSD, are common chronic disorders**
 - Underserved markets with high levels of dissatisfaction
 - A differentiated product has potential to capture substantial share

TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg is an Investigational New Drug and is not approved for any indication.

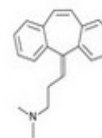
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Cyclobenzaprine: Potential To Improve Sleep Quality

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Cyclobenzaprine (CBP) is structurally a tricyclic molecule



Tricyclics and their metabolites differ significantly in their receptor binding profiles

CBP targets receptors with potential therapeutic effects for sleep disturbances

- Multimodal: high affinity, relative selectivity and functional antagonism
 - 5-HT_{2A}
 - α_1 -adrenergic
 - histamine H₁
- 6-7 fold lower affinity for SERT and NET (serotonin and norepinephrine transporters)
- Profile differs from active metabolite norcyclobenzaprine, amitriptyline and other tricyclics



TNX-102 SL: Innovative and Differentiated

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TNX-102 SL: A low-dose sublingual formulation of CBP

Designed to take advantage of targeted high affinity receptors of CBP

Differentiated from immediate release oral CBP:

- Formulated for transmucosal absorption to allow sublingual administration at bedtime
 - Rapid systemic exposure
 - Improved bioavailability
 - Avoids first-pass metabolism, reducing formation of norcyclobenzaprine (nCBP)
 - Half-life ($t_{1/2}$) of 72 hours
 - Distinct receptor binding profile less selective for target receptors
 - Potential undesirable off-target functional activities



TNX-102 SL

Fibromyalgia, PTSD

Portfolio of international patents filed under the Patent Cooperation Treaty (PCT)

Composition-of-matter (eutectic)

- Patents filed
- Protection expected to 2034

Pharmacokinetics (PK)

- Patents filed
- Protection expected to 2033

Method-of-use

- Fibromyalgia: patents issued, 2020 expiry
- PTSD: patents filed



BestFit Study - TNX-102 SL Phase 2 in Fibromyalgia

TNX-102 SL once-daily at bedtime
2.8 mg N = 103

Placebo once-daily at bedtime
N = 102

- Randomized, double-blind, placebo-controlled study in **fibromyalgia**
- **N=205** randomized from 17 U.S. sites
- Efficacy endpoint:
 - Pre-specified primary endpoint: change in week 12 **mean pain score** (p=0.17)
 - Difference in 30% pain **responder analysis** at week 12 between TNX-102 SL and placebo
- Other efficacy endpoints:
 - Fibromyalgia Impact Questionnaire-Revised (**FIQ-R**)
 - Patient Global Impression of Change
 - PROMIS Sleep Disturbance



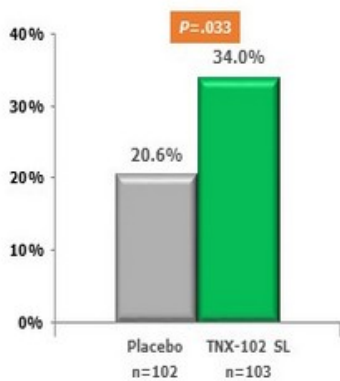
1. FDA-accepted primary endpoint in current Phase 3 AFFIRM study



Response at Week 12

Pain Relief

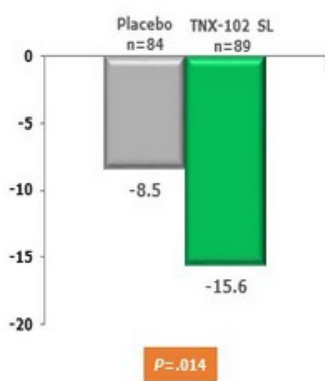
30% Responder Rate Based on Pain NRS



Logistic regression
NRS=Numeric Rating Scale

Reduction in Disease Burden

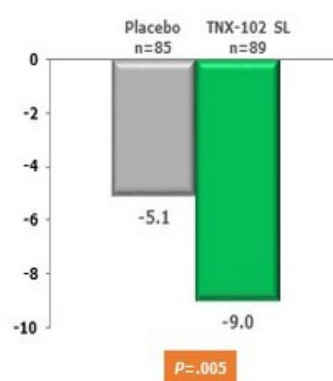
FIQ-R Total Score (MMRM)



MMRM=Mixed model for repeated measures
FIQ-R=Fibromyalgia Impact Questionnaire-Revised

Reduction in Sleep Disturbances

PROMIS Sleep T-Score (MMRM)



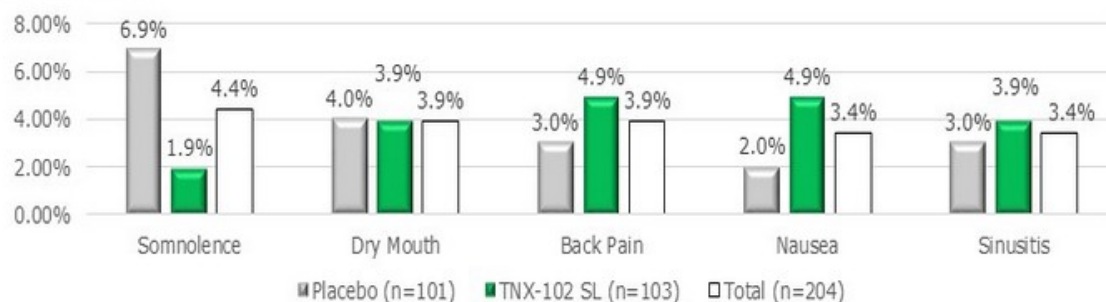
MMRM=Mixed model for repeated measures



BestFit Safety and Tolerability Profile

No serious adverse events (SAE) reported with TNX-102 SL

Systemic adverse events reported by at least 3.0% of the total BESTFIT study population:



Most frequent local adverse events were administration site reactions

- Transient tongue numbness (44% TNX-102 SL vs. 2% placebo)
- Abnormal taste (8% TNX-102 SL vs. 0% placebo)



AFFIRM Study - TNX-102 SL Phase 3 in Fibromyalgia

FULLY ENROLLED - Topline Expected 3Q 2016

TNX-102 SL once-daily at bedtime
2.8 mg *N* ≈ 259

Placebo once-daily at bedtime
N ≈ 259

- Randomized, double-blind, placebo-controlled study in **fibromyalgia**
- **N=519**; 35 U.S. clinical sites
- Primary efficacy endpoint:
 - Difference in 30% pain **responder analysis** at Week 12 between TNX-102 SL and placebo



- Second Phase 3 Study ("REAFFIRM") expected to begin in July 2016
 - Expected to be similar to AFFIRM in design and sample size



Military-related PTSD not well-served by existing FDA-approved therapies

- **No treatment response observed in U.S. military population**
Sertraline: negative in large multicenter trial in U.S. military (placebo numerically better)¹
Paroxetine: not studied in military population
- **Inconsistent treatment response observed in males**
Sertraline: FDA conducted post-hoc analysis concluded no effect for male civilian subgroup²
Paroxetine: no sex-related difference in treatment outcomes³
- **Important tolerability issues with SSRIs in this population**
Sexual dysfunction
Insomnia

1. Friedman et al., 2007, 2. Zoloft Package Insert, August, 2014, 3. Paxil Package Insert, June, 2014



The AtEase Study - TNX-102 SL Phase 2 in PTSD

TNX-102 SL at bedtime once-daily
5.6 mg N = 49

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

Placebo at bedtime once-daily
0 mg N = 92

- Randomized, double-blind, placebo-controlled trial in **military-related PTSD**

- **N=231**; 24 U.S. clinical sites

- Primary efficacy endpoint:

Difference in Clinician-Administered PTSD Scale (**CAPS-5**) score between TNX-102 SL 2.8 mg and placebo at week 12





Key Demographics / Characteristics of AtEase

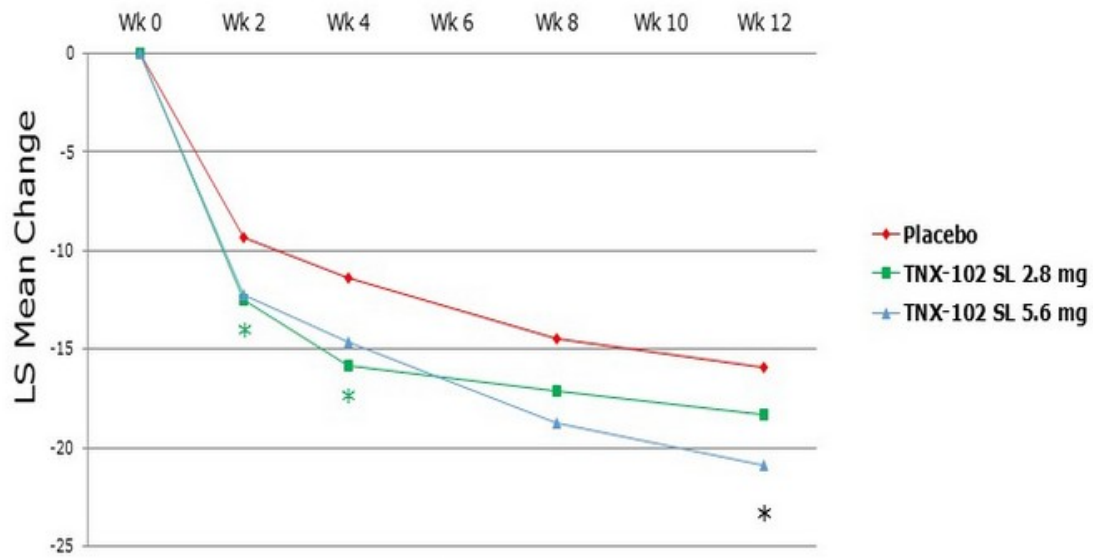
- 93% of the sample was male
- 98% had trauma during military service and were deployed on average 2.3 times
- Mean time since index trauma was 7 years
- Race and ethnicity generally consistent with U.S. military distribution
- Similar baseline CAPS-5 scores and MADRS scores across treatment arms
 - Average CAPS-5 scores were greater than 39 for all groups ('severe' PTSD*)

*personal communication – Frank Weathers PhD, National Center for PTSD



AtEase Study Results

CAPS-5 LS Total Score Mean Change from Baseline

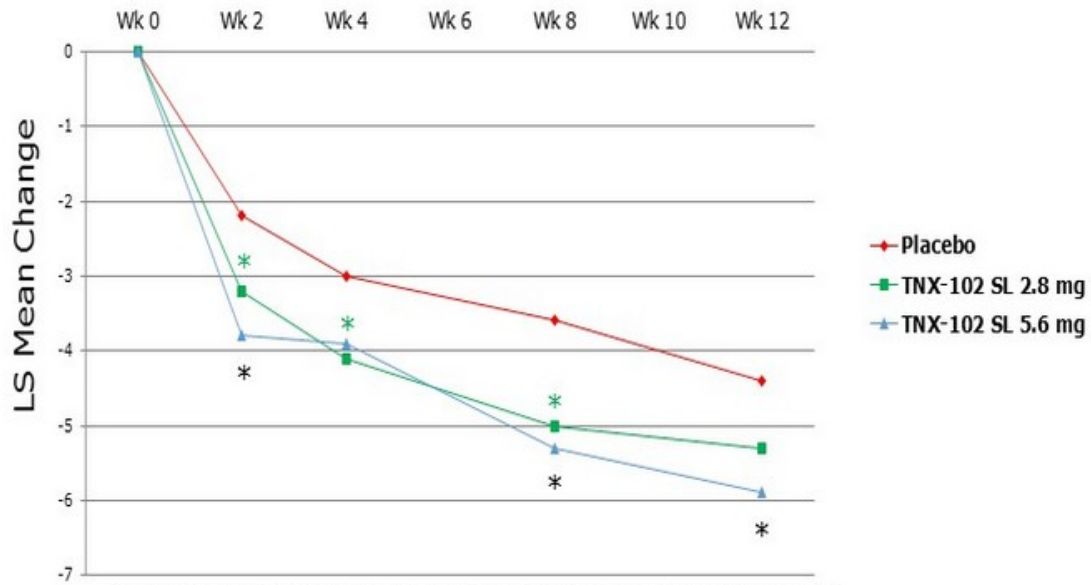


*p=0.031, comparing placebo and TNX-102 SL 5.6 mg, *p<0.05, comparing placebo and TNX-102 SL 2.8 mg, by MMRM with MI, mixed-effect model repeated measures with multiple imputation; CAPS-5, Clinician Administered PTSD Scale for DSM-5; LS Mean, least squares mean



AtEase Study Results

CAPS-5 Arousal and Reactivity Cluster Score Mean Change



*p<0.05, comparing TNX-102 SL 5.6 mg to placebo, mixed-effect model repeated measures

*p<0.05, comparing TNX-102 SL 2.8 mg to placebo, mixed-effect model repeated measures



AtEase Study Results

Adverse Events ($\geq 5\%$ rate in any group)

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Preferred Term	Placebo N=94*	TNX-102 SL 2.8 mg N=93*	TNX-102 SL 5.6 mg N=50*	Overall N=237*
Local Administration Site Conditions				
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)	54 (37.8%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)	17 (11.9%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)	6 (4.2%)
Systemic Adverse Events				
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)	19 (13.3%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)	12 (8.4%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)	11 (7.7%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)	10 (7.0%)
Sedation	1 (1.1%)	2 (2.2%)	6 (12.0%)	8 (5.6%)
Upper respiratory tract infection	5 (5.3%)	3 (3.2%)	2 (4.0%)	5 (3.5%)
Abnormal dreams	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)
Weight increased	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)

* safety population

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AtEase Study - Index Trauma

Index Traumas During Military Service Related to Dx of PTSD	Patient Count
Being involved in an IED explosion or suicide bombing	35
Being attacked or ambushed	33
Witnessing death or injury of fellow soldiers	30
Witnessing IED explosion	29
Receiving incoming artillery, rocket, or mortar fire	10
Being wounded or injured	9
Being responsible for the death of a noncombatant	9
Witness suicide-related deaths or injury	9
Seeing ill or injured women or children you were unable to help	8
Witnessing death or injury of civilians	7
Handling or uncovering human remains	6
Sexual assault	6
Involved in serious vehicular accident (Humvee, helicopter, plane)	6
Shooting or directing fire at the enemy	5
Knowing someone seriously injured or killed	4
All others	19



Summary: Tonix Pharmaceuticals

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Thank You!