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 4, 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:

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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))

Item 2.02 Results of Operations and Financial Condition.

On March 4, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the fiscal year ended December 31, 2015. A copy of the press release that discusses this matter is filed as Exhibit 99.01 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 7.01 Regulation FD Disclosure.

The Company intends to utilize an updated investor presentation to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain non-public information. A copy of the presentation is filed as Exhibit 99.02.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.02, 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 99.02, 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	Press Release, dated March 4, 2016, issued by Tonix Pharmaceuticals Holding Corp.*
99.02	Corporate Presentation by the Company for March 2016*

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* 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 4, 2016

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2015 Financial Results and Provides Programs Update

New York, NY – March 4, 2016 – Tonix Pharmaceuticals Holding Corp. (NASDAQ: TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced financial results for the fourth quarter and full year ended December 31, 2015.

"Tonix made tremendous progress over the course of 2015 on the clinical, regulatory and operational fronts. We remain very focused on progressing our flagship clinical development program, a Phase 3 trial in fibromyalgia of Tonmya® (TNX-102 SL, cyclobenzaprine HCl sublingual tablets, 2.8 mg) and our registration-quality Phase 2 study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in PTSD," said Seth Lederman, M.D., president and chief executive officer of Tonix. "We look forward to the year ahead as we will announce top-line data from our Phase 2 AtEase clinical trial of TNX-102 SL in PTSD in the second quarter, followed by top-line data from our Phase 3 AFFIRM study in fibromyalgia in the third quarter of this year."

At December 31, 2015, Tonix held cash, cash equivalents, and marketable securities totaling approximately $43.0 million.

Recent Clinical Highlights and Upcoming Milestones

Tonmya – Fibromyalgia Program

- Tonix is developing TNX-102 SL for daily use at bedtime for the management of fibromyalgia, a chronic condition.
- In May 2015, Tonix commenced the randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial of Tonmya in fibromyalgia.
- Tonix expects to report top-line data from the AFFIRM trial in the third quarter of 2016.
- The primary efficacy endpoint in AFFIRM is a 30% pain responder analysis at week 12.
- Tonix expects to commence a second, 12-week Phase 3 trial of Tonmya in fibromyalgia in the second quarter of 2016.
- Results from the completed Phase 2b BESTFIT clinical trial of Tonmya in fibromyalgia was the subject of three posters presented at the American College of Rheumatology Annual Meeting on November 10, 2015.

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, non-restorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life and frequently are disabled. To learn more, please visit www.affirmstudy.com.

TNX-102 SL – PTSD Program

- Tonix is also developing TNX-102 SL, the same proprietary product candidate as Tonmya, for daily use at bedtime for the management of PTSD, a chronic condition.
- In December 2015, Tonix exceeded full enrollment of approximately 240 patients with military-related PTSD in the randomized, double-blind, placebo-controlled, 12-week Phase 2 AtEase clinical trial of TNX-102 SL.
- Tonix expects to report top-line data from the AtEase study in the second quarter of 2016.
- The primary efficacy endpoint of AtEase will evaluate the performance of TNX-102 SL 2.8 mg as measured by the mean change from baseline on the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5).
- In December 2015, Tonix signed a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Materiel Development Activity (USAMMDA) to explore expansion and potential development of TNX-102 SL for the treatment of military-related PTSD.

PTSD affects approximately 8.4 million Americans and is a chronic and severely debilitating condition, in which patients experience nightmares and disturbed sleep, and which is associated with depression and suicide. Individuals who suffer from PTSD experience impaired social functioning, occupational disability, intense anxiety and avoidance, emotional numbness, intense guilt or worry, agitation and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable or violent behaviors, additional reasons that make it a critical public health concern. PTSD can develop from witnessing or experiencing a traumatic event or ordeal in which there was the threat or actual occurrence of grave physical harm.

TNX-201 – Episodic Tension Headache Program

In June 2015, Tonix initiated a single-dose Phase 2 proof-of-concept clinical trial to evaluate the ability of TNX-201 (dexisometheptene mucate capsules 140 mg) to treat episodic tension-type headache. Tonix completed the randomized, double-blind, placebo controlled study in the first quarter of 2016. In February 2016, Tonix reported that the drug failed to show efficacy and development was terminated.

Fourth Quarter and Full Year Financial Results

Tonix reported a net loss of $13.4 million, or $0.71 per share, for the fourth quarter of 2015, compared to a net loss of $9.0 million, or $0.83 per share, for the fourth quarter of 2014. For the year ended December 31, 2015, Tonix reported a net loss of $48.1 million, or $2.86 per share, compared to a net loss of $27.6 million, or $2.77 per share, for the comparable period in 2014. At December 31, 2015, Tonix's cash, cash equivalents and marketable securities totaled $43.0 million compared to $38.2 million at December 31, 2014.

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.

The United States Food and Drug Administration (FDA) has conditionally accepted "Tonmya" as the proposed trade name of TNX-102 SL for fibromyalgia. Tonmya, TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved by the FDA for any indication.

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.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts) (1)
(unaudited)

	Three Months ended December 31,		Twelve Months ended December 31,	
	2015	2014	2015	2014
Costs and expenses				
Research and development	$ 9,490	5,775	$ 35,504	18,617
General and administrative	3,912	3,229	12,658	9,039
Total costs and expenses	13,402	9,004	48,162	27,656
Operating loss	(13,402)	(9,004)	(48,162)	(27,656)
Interest income, net	42	15	108	40
Net loss	$ (13,360)	(8,989)	$ (48,054)	(27,616)
Net loss per common share, basic and diluted	$ (0.71)	(0.83)	$ (2.86)	(2.77)
Weighted average common shares outstanding, basic and diluted	18,832	10,776	16,791	9,986

(1) The condensed consolidated statements of operations for the years ended December 31, 2015 and 2014 have been derived from the audited financial statements, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	December 31, 2015	December 31, 2014 (1)
Assets		
Cash, cash equivalents and marketable securities	$ 43,016	$ 38,184
Prepaid expenses and other current assets	3,343	852
Total current assets	46,359	39,036
Non-current assets	659	506
Total assets	$ 47,018	$ 39,542
Liabilities and stockholders' equity		
Total liabilities	$ 6,756	$ 3,450
Stockholders' equity	40,262	36,092
Total liabilities and stockholders' equity	$ 47,018	$ 39,542

(1) The condensed consolidated balance sheets for the years ended December 31, 2015 and 2014 have been derived from the audited financial statements, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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Source: Tonix Pharmaceuticals Holding Corp.

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Exhibit 99.02

NASDAQ: TNXP

Investor Presentation

March 2016

Version: P0010-03-3-16

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, 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.

TONIX PHARMACEUTICALS

Developing innovative medicines for large and growing markets

- **Targeting two common central nervous system disorders**
  - One clinical-stage proprietary candidate targeting two indications
  - Differentiated product with potential for sustainable competitive advantages
- **2016 to reveal results from two clinical trials**
  - Fibromyalgia – Phase 3 to report in 3Q
  - Post-traumatic stress disorder – Phase 2 to report in 2Q
- **All intellectual property owned by Tonix**

TONIX PHARMACEUTICALS

Pipeline led by TNX-102 SL for fibromyalgia

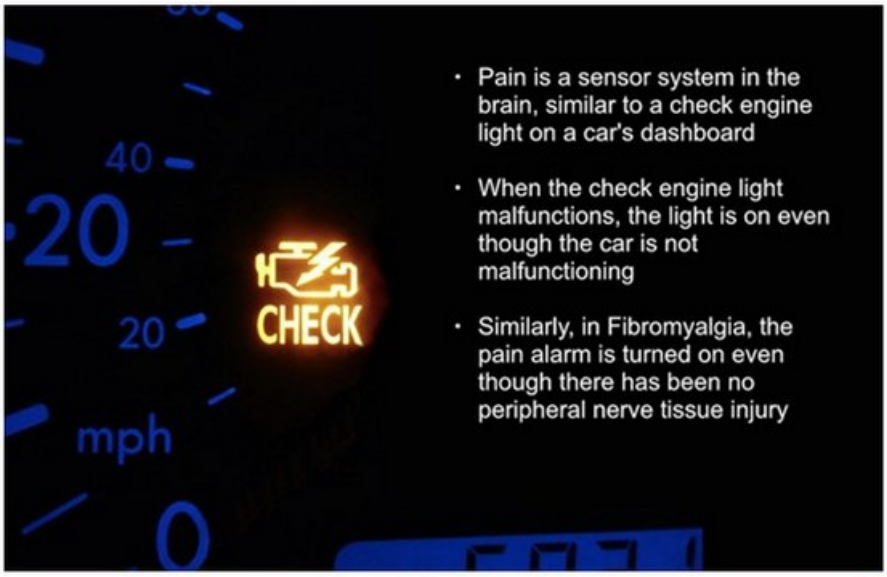
Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
TNX-102 SL (*Tonmya™**)	Fibromyalgia							Top line data 3Q 2016
TNX-102 SL	Post-Traumatic Stress Disorder							Top line data 2Q 2016

* Tonmya™ has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Concept: Fibromyalgia is inappropriate central pain signaling in the absence of peripheral injury



Volkswagen Check Engine [Photograph]. (2011, October 14). Wikipedia

Fibromyalgia is a chronic, debilitating disorder that imposes a significant societal and economic burden

- **Fibromyalgia is considered neurobiological disorder characterized by[1]:**
  - Chronic widespread pain
  - Nonrestorative sleep
  - Fatigue
  - Diminished cognition
- **Believed to result from amplified sensory and pain signaling in central nervous system[1]**
- **Causes significant impairment in all areas of life[2]**
  - Lower levels of health-related quality of life – reduced daily functioning
  - Interference with work (loss of productivity, disability)
- **Inflicts substantial strain on the healthcare system**
  - Average patient has 20 physician office visits per year[3]
  - Annual direct medical costs are twice those for non-fibromyalgia individuals[4]

[1] *Phillips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.*
[2] *Schaefer et al., Pain Pract, 2015.*
[3] *Robinson et al, Pain Medicine 2013;14:1400.*
[4] *White et al, J Occupational Environ Med 2008;50:13.*

TONIX PHARMACEUTICALS

Fibromyalgia is a prevalent disorder but remains underdiagnosed

Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year[2,4]

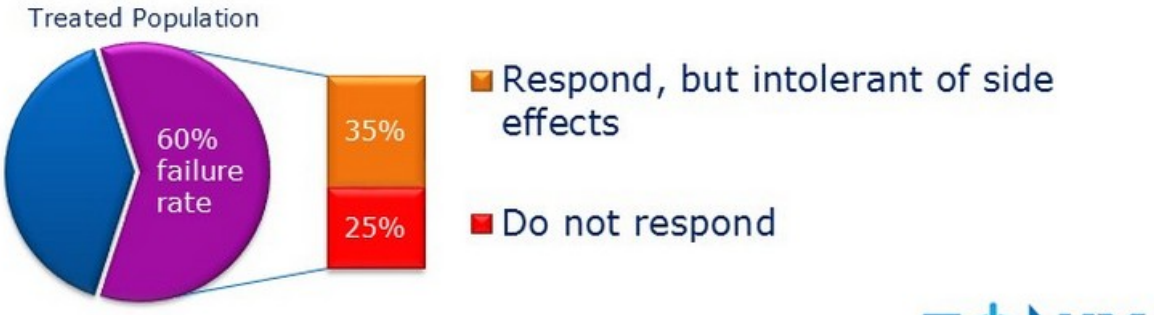
- **1.1% diagnosis rate = 2.7 million U.S. adults[1]**
  - Suggests under-diagnosis
- **Approximately 2.3 million U.S. adults receive treatment[2]**
- **<u>Approved</u> drugs achieved 2014 U.S. sales of $1.2 billion[3]**
  - Represent about 5.6 million prescriptions[4]

[1] *Lawrence et al, Arthritis Rheum 2008;58:26; Vincent et al, Arthritis Care Res 2013;65:786; Jones et al, Arthritis Rheum 2015;67:568; U.S. Census Bureau, 2013 Projection.*
[2] *Robinson RL et al, Pain Med 2012;13:1366.*
[3] *Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.*
[4] *Independent study conducted by IMS Consulting Group, April 2015 using IMS MIDAS (ex-manufacturing price), factored for fibromyalgia based on IMS National Disease and Therapeutic Index (NDTI).*

TONIX PHARMACEUTICALS

Fewer than half of those treated for fibromyalgia receive sustained benefit from the three FDA-approved drugs

- **The treatment objective is to restore functionality and quality of life by broadly improving symptoms while avoiding significant side effects**
- The majority fail therapy due to **lack of a response** or **poor tolerability**[1]



[1]*Market research by Frost & Sullivan, commissioned by Tonix (2011).*

Large need for new fibromyalgia therapies that provide broad symptom improvement with better tolerability

- **Currently-approved medications may have side effects that limit long-term use[1]**
  - Many patients skip doses or discontinue altogether within months of treatment initiation
- **Medication-related side effects may be similar to fibromyalgia symptoms**
- **High rates of discontinuation, switching and augmentation**
  - Attempt to treat multiple symptoms and/or avoid intolerable side effects
  - Average of 2-3 medications used simultaneously[2]
  - The typical patient has tried six different medications[3]
- **Substantial off-label use of narcotic painkillers and prescription sleep aids[3]**

[1]Nuesch et al, Ann Rheum Dis 2013;72:955-62.
[2]Robinson RL et al, Pain Medicine 2012;13:1366.
[3]"Patient Trends: Fibromyalgia", Decision Resources, 2011.

TONIX PHARMACEUTICALS

Tonix is developing TNX-102 SL for fibromyalgia

- **Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP)**
  - Designed for daily bedtime administration with no titration
  - Efficient transmucosal absorption
  - Avoidance of first-pass metabolism reduces formation of long-lived metabolite
- **TNX-102 SL's pharmacologic action is believed to improve sleep quality**
  - Non-restorative sleep is a common clinical and diagnostic feature of fibromyalgia[1]
  - Evolving understanding of the role of sleep in pain control and fibromyalgia development[2]
  - TNX-102 SL targets receptors believed to play key roles in sleep physiology
- **Phase 2b "BESTFIT" study was successfully completed in 3Q14**
- **Top line data from ongoing Phase 3 "AFFIRM" study expected to report in 3Q16**

[1]Swick TJ, Ther Adv Musculoskel Dis 2011;3:167-178.
[2]Choy EH, Nat Rev Rheumatol; 2015: 11:513-520.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Phase 2b "BESTFIT" study of TNX-102 SL in fibromyalgia

- **BESTFIT = BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy**
  - Randomized, double-blind, placebo-controlled trial
  - 2010 American College of Rheumatology diagnostic criteria for fibromyalgia
  - 205 participants randomized 1:1 at 17 U.S. sites
  - Sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime for 12 weeks
  - Evaluated measures of pain, sleep quality, and other assessments of fibromyalgia

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

TONIX PHARMACEUTICALS

BESTFIT results on key clinical endpoints

Category	Endpoint – week 12[1]	*p* value
Pain Relief	30% responder analysis[2]	**0.033**
Sleep Quality	PROMIS Sleep Disturbance	0.005
Overall response to therapy	PGIC	0.025
Assessment of disease impact	FIQ-R Total score	0.014

$p < 0.05$ → statistically significant

BESTFIT pre-specified primary endpoint: change in week 12 mean pain score (p=0.172)

- PROMIS = Patient-Reported Outcomes Measurement Information System
- PGIC = Patient Global Impression of Change
- FIQ-R = Fibromyalgia Impact Questionnaire - Revised

[1]Intent-to-treat analysis, N=205 (TNX-102 SL N=103, placebo N=102).
[2]FDA-accepted primary endpoint in current Phase 3 AFFIRM study.
Source: Phase 2b BESTFIT study data.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL safety and tolerability profile in the BESTFIT study

- **No serious adverse events (SAE) reported with TNX-102 SL**
- **Systemic adverse events reported by at least 3% of the total BESTFIT population**

	TNX-102 SL *(N=103)*	Placebo *(N=101)*	Total *(N=204)*
Somnolence	1.9	6.9	4.4
Dry Mouth	3.9	4.0	3.9
Back Pain	4.9	3.0	3.9
Nausea	4.9	2.0	3.4
Sinusitis	3.9	3.0	3.4

- **Most frequent local adverse events were administration site reactions**
  - Previously reported in Phase 1 studies; no detectable bias on efficacy results
  - Transient tongue numbness (44% TNX-102 SL vs. 2% placebo)
  - Abnormal taste (8% TNX-102 SL vs. 0% placebo)
- **Trial completion rates of 86% with TNX-102 SL vs. 83% with placebo**

Source: Phase 2b BESTFIT study data – Preliminary Study Report.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL in Phase 3 clinical development for fibromyalgia

- Phase 3 AFFIRM Study is underway

TNX-102 SL once-daily at bedtime
2.8 mg *N = 250*

Placebo once-daily at bedtime
N = 250

12 weeks → *open-label extension*

- Randomized, double-blind, placebo-controlled study in fibromyalgia
- N=500; approximately 35 U.S. clinical sites
- **Primary efficacy endpoint:**
  - Difference in 30% pain responder analysis at Week 12 between TNX-102 SL and placebo

Top line data expected 3Q 2016

- Second Phase 3 Study ("REAFFIRM") expected to begin in 2Q 2016
  - Expected to be similar to AFFIRM in design and size

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

TONIX PHARMACEUTICALS

TNX-102 SL in Phase 2 development for post-traumatic stress disorder (PTSD)

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
TNX-102 SL (*Tonmya™**)	Fibromyalgia							Top line data 3Q 2016
TNX-102 SL	**Post-Traumatic Stress Disorder**							**Top line data 2Q 2016**

** Tonmya™ has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.*

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

PTSD is a chronic stress disorder triggered by a traumatic event

- **PTSD is characterized by:**
  - re-experiencing the triggering event
  - negative alterations in mood/cognition
  - situation/stimulus avoidance
  - hypervigilance (anxiety, difficulty sleeping)
- **Considered a stress response, but prolonged and does not resolve with time**
  - 20% of women and 8% of men who experience significant trauma develop PTSD[1]
- **Associated with significant life disruption**
  - Social isolation, inability to maintain employment, loss of independent living
  - Unpredictable acts of violence, suicidal thoughts

[1] *Kessler et al, Arch Gen Psychiatry 1995;52:1048.*

TONIX PHARMACEUTICALS

PTSD is a prevalent problem for both civilians and the military

- **~70% are considered to have moderate to severe symptoms**
- **Of those diagnosed, ~50% utilize professional healthcare (psycho/pharmacotherapy)[2]**

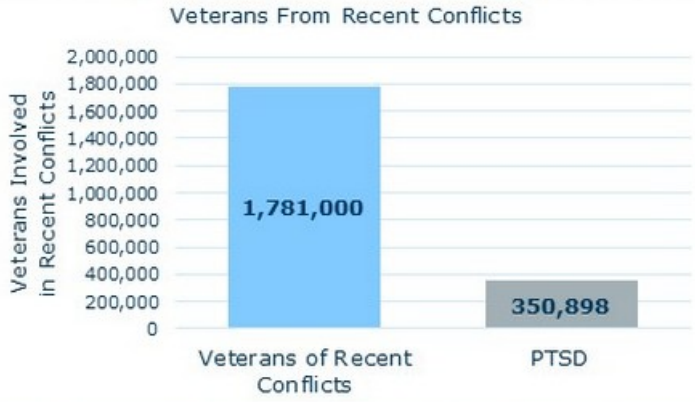
- **Higher prevalence in military population**
  - 20% of veterans from recent conflicts will have potential/provisional PTSD[3]
  - ~638,000 veterans with PTSD in the VA health system (2012)[4]
  - Majority are male
  - Alcohol and substance abuse are common

[1]Kessler RC at al, Arch Gen Psychiatry 2013;62:617; U.S. Census Bureau, 2013 Projection.
[2]Wang et al, Arch Gen Psychiatry 2005;62:629.
[3]Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD.
[4]Bowe et al, J Dual Diagnosis 2015;11:22.

TONIX PHARMACEUTICALS

PTSD veteran population: recent conflicts only

Veteran Administration (VA) records indicate that 20% of veterans from recent conflicts will have potential or provisional PTSD

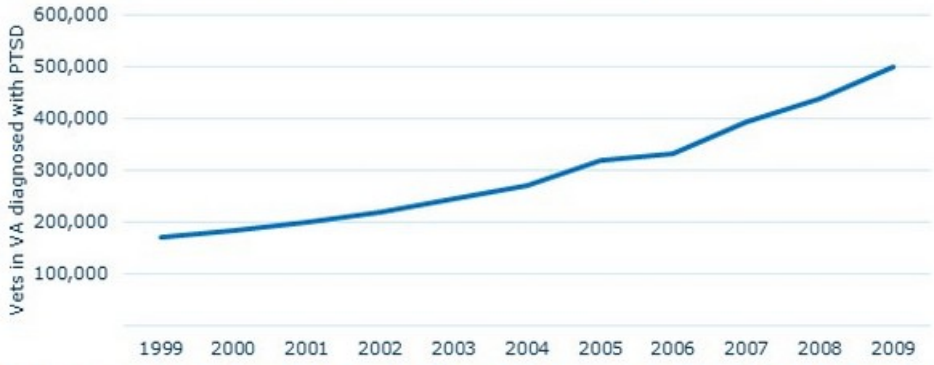


Source: Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD. Cumulative from 1st Qtr FY 2002 through Qtr FY 2014 (October 1, 2001 – March 31, 2014)

PTSD veteran population: all conflicts

The number of veterans in the VA system and diagnosed with PTSD has been rising[1]

- Does not include veterans with PTSD not treated or diagnosed in the VA system



As of 2012, the number of veterans within VA diagnosed with PTSD reach 638,451[2]

[1]*Bernardy et al., J Clin Psychiatry, 2012, 73:297-303*
[2]*Bowe et al, J Dual Diagnosis, 2014, 11:22-32*

TONIX PHARMACEUTICALS

Significant gap in current therapeutic landscape for PTSD

- **Medicines approved for PTSD often provide inadequate and/or inconsistent benefit**
  - Limited to two SSRI antidepressants, both of which carry suicidality warnings
  - U.S. Institute of Medicine (IOM) concluded that evidence of treatment effect is low[1]
  - Lack of efficacy evidence in those with a history of combat-related trauma[2]
- **Sleep dysfunction in PTSD is resistant to currently-approved options**
  - 95%+ report insomnia, 83% report recurrent dreams of the trauma[3]
  - Correlated with disease severity, depression, substance abuse and suicide[4]
  - Drugs approved for insomnia have been shown to not improve PTSD sleep dysfunction
- **Off-label use of anxiolytics, sedative-hypnotics, and antipsychotics is common[5]**
  - Limited evidence of effectiveness; may be harmful
  - May interfere with other treatments such as cognitive behavioral therapy (CBT)

SSRI = selective serotonin reuptake inhibitor.

[1] Marshall et al, Am J Psychiatry 2001;158:1982.

[2] Jonathan Davidson, personal communications, 2014.

[3] Green B. Post-traumatic stress disorder: Symptom profiles in men and women. Curr Med Res Opin 2003;19:200–4.

[4] Germain et al, J Anxiety Disord 2005;19:233; Krakow et al, J Nerv Ment Dis 2002;190:442.

[5] Bernardy et al., J Clin Psychiatry, 2012, 73:297-303.

TONIX PHARMACEUTICALS

Targeting sleep quality is a novel mechanism of action in PTSD therapy

- **PTSD patients complain of sleep disturbance as a core symptom[1]**
  - Distressing dreams (nightmares) are part of "re-experiencing"
  - Avoidance can be of bed/sleep due to fear of nightmares
  - Restless sleep is part of the "hyper-arousal" cluster of PTSD diagnostic criteria
- **Sleep disturbance after trauma is linked to onset of PTSD[2]**
- **Sleep disturbance also correlates with depression, substance abuse and suicidal behaviors in PTSD[3]**
- **TNX-102 SL is a tricyclic molecule that potently targets three molecular mechanisms[4], each of which is associated with treating aspects of disturbed sleep, enhancing sleep quality**
  - Blocks the 5-HT_{2A} receptor (like trazodone)
  - Blocks the α_1 adrenergic receptor (like prazosin)
  - Blocks the H_1 receptor (like low-dose doxepin)

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[1] American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, 2013.
[2] Koren et al, AJP 159:855-857, 2002; Mellman et al, AJP 159:1969-1701, 2002.
[3] Germain, AJP 170:372-382, 2013; McHugh et al, J Traumatic Stress 27:82-89, 2014 Betts et al, Journal of Anxiety Disorders 27:735-41, 2013.
[4] Daugherty et al, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015 Toronto, Ontario, Canada.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Tonix's AtEase study in military-related PTSD: primary endpoint and power considerations

- **Primary endpoint is the change from baseline of the Clinician Administered PTSD Scale for DSM-5 (CAPS-5)**
  - Raters are trained, certified, and monitored for reliability throughout the study
- **Powered at ≥80% to detect an effect size of 0.5 (Cohen's *d*)**
  - Translates to detection of difference of approximately 10 points (8.5-11.5) at group level between TNX-102 SL 2.8 mg and placebo for the reduction in total CAPS-5 score
    - Approximately 66 completers needed in each of the TNX-102 SL and placebo groups
  - A 10-point difference on CAPS-5 between treatment groups is approximately equivalent to a 17-point difference on CAPS-4 for DSM-IV

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

TONIX PHARMACEUTICALS

Limitations of current FDA-approved pharmacotherapies for PTSD

- **Britain's National Institute for Clinical Excellence (NICE) National Clinical Practice Guideline for management of PTSD reported an effect size in paroxetine trials of 0.42 and for sertraline trials, the effect size was 0.26[1]**
  - A *priori,* NICE had set a threshold of 0.5 as an effect size that would indicate a clinically meaningful effect on PTSD
  - NICE stated that neither of these two FDA-approved therapies had conclusive evidence to determine if there was a clinically important difference from placebo

- **Limited treatment response to SSRIs in Males and US Military**
  - In a review of sertraline registration trials, no effect on PTSD demonstrated for male subgroups in an FDA-conducted post-hoc analysis
  - None of the four double-blind placebo-controlled trials of SSRIs in US military veterans demonstrated any evidence that SSRIs were superior to placebo[2]

[1] *National Clinical Practice Guideline No. 26, National Institute for Clinical Excellence, 2005.*
[2] *Davidson J, Journal of Psychopharmacology, 2015.*

TONIX PHARMACEUTICALS

TNX-102 SL's potential as a treatment for PTSD is supported by clinical evidence and pharmacology

- **TNX-102 SL is active on receptor sites believed to have treatment potential for sleep problems in PTSD**
  - Targeted receptors include 5-HT2a, alpha-1 adrenergic, and histamine-1 receptors
- **Efficacy of "tricyclic" drug class in PTSD is supported by clinical data[1]**
  - Oral tricyclics have side effects that limited their use
- **Improvements observed in BESTFIT study relate to PTSD core symptoms[2]**

Outcome Measure at Week 12 in BESTFIT	*p* value
PROMIS Sleep Disturbance	0.005
FIQ-R Anxiety Item	0.012
FIQ-R Sensitivity Item	0.020

$p < 0.05$ → statistically significant

1 Davidson J, J Psychopharm 2015;29;264.
2 Phase 2b BESTFIT study data.
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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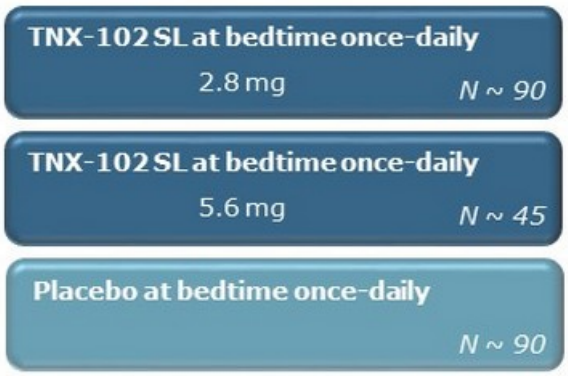
Phase 2 "AtEase" trial of TNX-102 SL in PTSD is fully enrolled



- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- Randomized>240; approximately 25 U.S. clinical sites
- **Primary efficacy endpoint:**
  - Difference in Clinician-Administered PTSD Scale (CAPS) score between TNX-102 SL 2.8 mg and placebo at 12 weeks

Top line data expected 2Q 2016

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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Intellectual property

Wholly-owned by Tonix with no obligations to others

TNX-102 SL
Fibromyalgia, PTSD

- **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

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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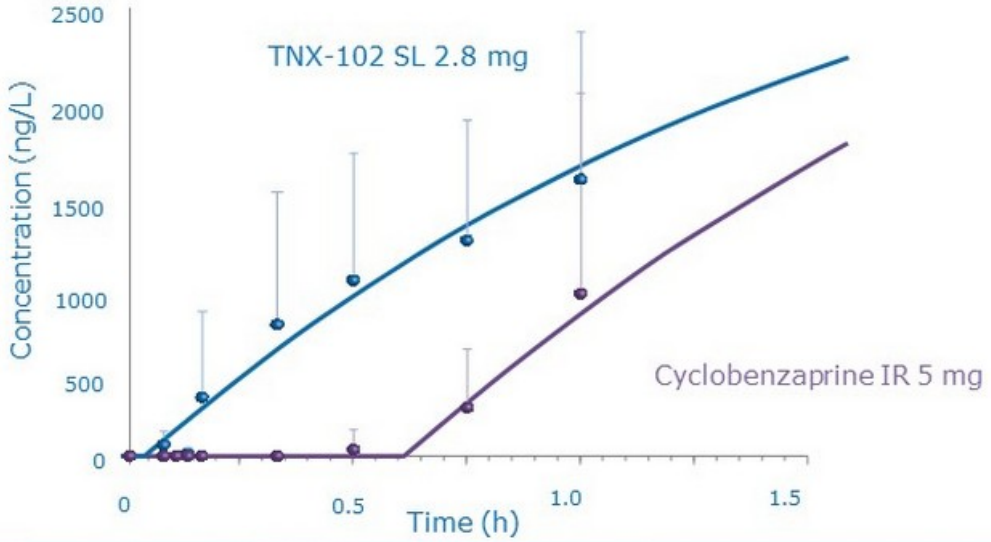
Cyclobenzaprine is detected in plasma within minutes following sublingual TNX-102 SL

Plasma Concentration Versus Time of TNX-102 SL Compared to Cyclobenzaprine IR



Source: US Patent applications 13/918,692 – Transmucosal absorption

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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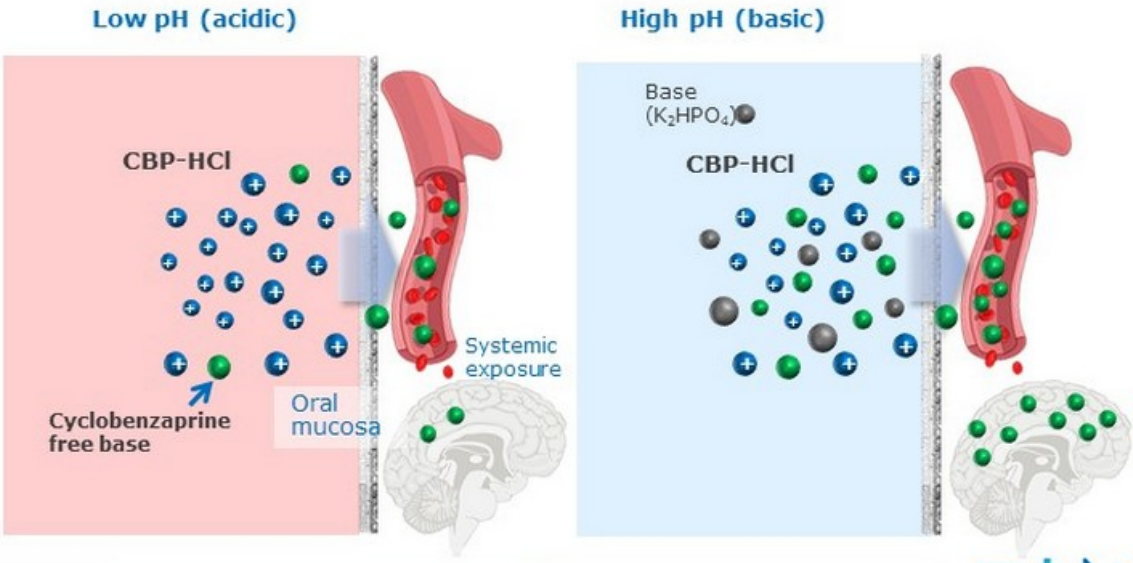
Formulation with base increases systemic absorption of sublingual cyclobenzaprine[1]

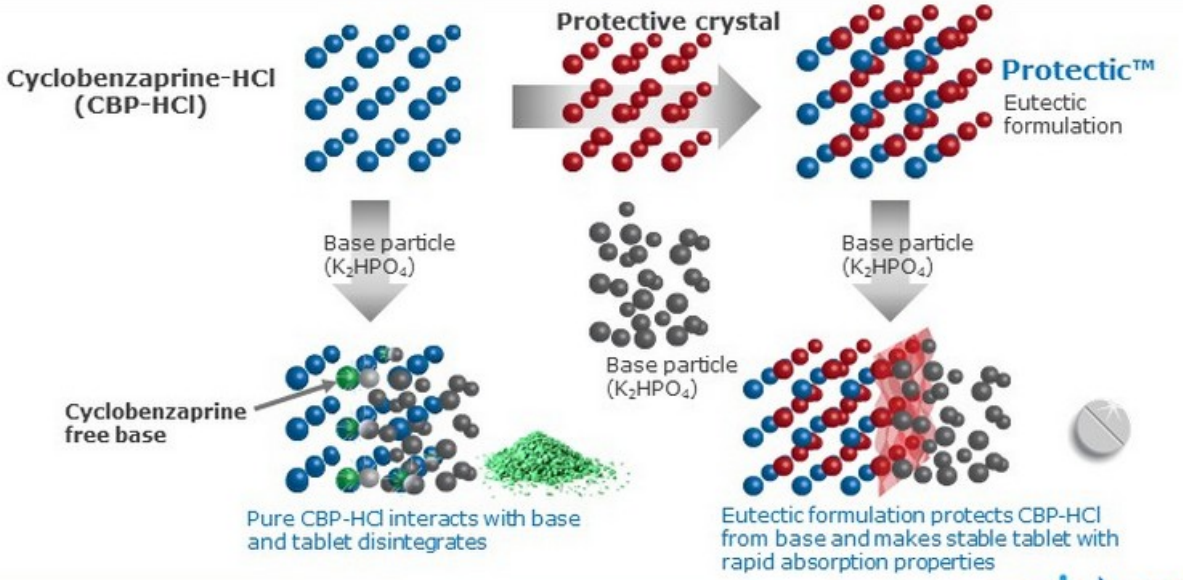
Concentration gradient increases diffusion of free base across oral mucosa (Le Chatelier's Principle) 28



[1]US Patent applications 13/918,692. 14/214,433 and 14/776,624 - Eutectic Formulations

TONIX PHARMACEUTICALS

Proprietary cyclobenzaprine hydrochloride eutectic mixture stabilizes tablet formulation[1]



[1]US Patent applications 14/214,433 and 14/776,624 - Eutectic Formulations

Financial overview

NASDAQ: TNXP	
Cash, cash equivalents, and marketable securities reported at December 31, 2015	$ 43.0 million
Cash used in operations in 2015	$ 42.5 million
Shares outstanding (March 3, 2016)	18.9 million

TONIX PHARMACEUTICALS

Management team

Seth Lederman, MD
President & CEO

Bruce Daugherty, PhD, MBA
Chief Scientific Officer

Gregory Sullivan, MD
Chief Medical Officer

Bradley Saenger, CPA
Chief Financial Officer

Jessica Edgar Morris
EVP, Administration

Ronald Notvest, PhD
EVP, Commercial Planning & Development

Board of directors

Seth Lederman, MD Chairman	**Ernest Mario, PhD** ALZA, Glaxo, Reliant Pharma
Stuart Davidson Labrador Ventures, Alkermes, Combion	**Charles Mather** BTIG, Janney, Jefferies, Cowen, Smith Barney
Patrick Grace Apollo Philanthropy, WR Grace, Chemed	**John Rhodes** NYSERDA, NRDC, Booz Allen Hamilton
Donald Landry, MD, PhD Chair of Medicine, Columbia University	**Samuel Saks, MD** Jazz Pharma, ALZA, Johnson & Johnson

Milestones – recent and upcoming

TNX-102 SL – Fibromyalgia

☑	May 2015	Began Phase 3 AFFIRM study
☑	November 2015	Presented additional data from Phase 2b BESTFIT study at ACR Meeting
☐	3Q 2016	Report top-line results from AFFIRM study

TNX-102 SL – Post-Traumatic Stress Disorder

☑	December 2015	Entered into CRADA with USAMMDA
☑	December 2015	Reported completion of enrollment in Phase 2 AtEase study
☐	2Q 2016	Report top-line results from AtEase study

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