**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): February 5, 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))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock | TNXP | The NASDAQ Global Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

Tonix Pharmaceuticals Holding Corp. (the "Company") updated its investor presentation, which is used 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 nonpublic information. A copy of the presentations is filed as Exhibit 99.01 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 8.01. Other Event.**

On February 5, 2020, the Company announced the outcome of the interim analysis for the Phase 3 study for its lead product candidate for the treatment of posttraumatic stress disorder. A copy of the press release discussing this matter is filed as Exhibit 99.02, and incorporated by reference in, this report.

*Forward- Looking Statements*

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

**Item 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit No. | Description. |
|---|---|
| 99.01 | Corporate Presentation by the Company for February 2020 |
| 99.02 | Press release of the Company, dated February 5, 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: February 5, 2020

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

**Exhibit 99.01**

# Investor Presentation



TONIX PHARMACEUTICALS

February 2020

**Version P0220 2-5-20 (Doc 0593)**

# Cautionary Note on Forward-Looking Statements



Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to failure to obtain U.S. Food and Drug Administration clearances or approvals and noncompliance with its regulations; our need for additional financing; substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

# Tonix Pharmaceuticals: Lead Program



**In Phase 3 clinical development of TNX-102 SL[1] for Fibromyalgia**

- Chronic pain condition

**Fibromyalgia milestones (Phase 3 RELIEF study):**

- 2nd Half 2020 - Interim analysis results expected
- 1st Half 2021 - Topline data expected

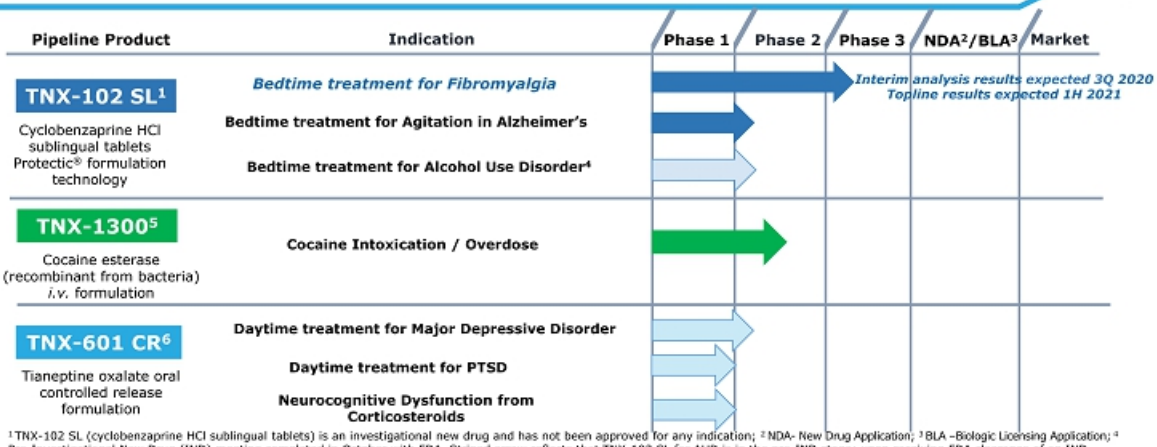
[1] TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication

# CNS Candidates in Clinical Development

## Pain, Psychiatry and Addiction

***TNX-102 SL and TNX-601 owned outright with no royalties due***






¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication; ²NDA- New Drug Application; ³BLA –Biologic Licensing Application; ⁴Pre-Investigational New Drug (IND) meeting completed in October with FDA. Striped arrow reflects that TNX-102 SL for AUD is in the pre-IND stage; upon receiving FDA clearance of an IND application, it will be Phase 2 POC ready as it is expected to qualify for the 505(b)(2) pathway for approval; ⁵TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication; ⁶Striped arrows reflect that TNX-601 CR is in the pre-IND stage in the U.S.; a Phase 1 study for formulation development was recently completed outside of the U.S.

# Preclinical Pipeline[1]



| Pipeline Product | Indication(s) | Category |
|---|---|---|
| **TNX-1600**<br>Triple reuptake inhibitor[2] | Daytime treatment for PTSD | Psychiatry |
| **TNX-1500[3]**<br>Anti-CD154 monoclonal antibody | Prevention and treatment of organ transplant rejection<br>Treatment of autoimmune conditions | Transplant<br>Autoimmunity |
| **TNX-1700**<br>rTFF2[4] | Treatment for gastric and pancreatic cancers | Oncology |
| **TNX-801[3]**<br>Live horsepox virus (HPXV) vaccine from cell culture | Smallpox and monkeypox preventing vaccine | Biodefense |
| **TNX-1200[3]**<br>Live vaccinia virus (VACV) vaccine from cell culture | Smallpox and monkeypox preventing vaccine | Biodefense |
| **TNX-701[3]**<br>Radioprotection drug oral capsules | Protection from radiation injury | Biodefense |

[1] Experimental new medicines and biologics, not approved for any indication
[2] (2S,4R,5R)-5-(((2-aminobenzo[d]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2H-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine)
[3] Programs owned outright with no royalties due
[4] Recombinant Trefoil Family Factor 2

# TNX-102 SL



**TNX-102 SL**

- Novel sublingual formulation of cyclobenzaprine HCl[1] designed for long-term daily use at bedtime
- Rapid absorption
- Transmucosal absorption bypasses first pass liver metabolism
- Dynamic pharmacokinetic profile with increase in cyclobenzaprine concentration during sleep induction and decrease leading up to awakening
- Cyclobenzaprine is the active ingredient of oral (swallowed) muscle relaxants, Flexeril® and Amrix ®

**TNX-102 SL is believed to treat fibromyalgia by improving sleep *quality,* in contrast to sleep *quantity***

- **Quality** involves restorative properties of sleep
- **Quantity** is time spent asleep
- TNX-102 SL targets clinical conditions for which improved sleep quality may have a therapeutic benefit
- Reduction in disease-specific symptoms with sleep improvement as a secondary endpoint

[1] Cyclobenzaprine is the active ingredient of oral (swallowed) muscle relaxants, Flexeril® and Amrix®

# TNX-102 SL Intellectual Property – Patent Protection expected until 2035



## Composition of matter (eutectic): protection expected to 2034/2035

10 patents issued worldwide; 35 patent applications pending

## Composition of matter (sublingual): protection expected to 2033

6 patents issued worldwide; 21 patent applications pending

# Fibromyalgia



**Fibromyalgia is considered a neurobiological disorder characterized by[1]: chronic widespread pain, non-restorative sleep, fatigue, diminished cognition**

**Believed to result from inappropriate pain signaling in central nervous system in the absence of peripheral injury[1]**

**An estimated 6-12 million adults in the U.S. have fibromyalgia[2]**

**Causes significant impairment in all areas of life[3]**

- Lower levels of health-related quality of life – reduced daily functioning
- Interference with work (loss of productivity, disability)

**Fewer than half of those treated for fibromyalgia receive complete relief from the three FDA-approved drugs[4]**

**Inflicts substantial strain on the healthcare system**

- Average patient has 20 physician office visits per year[5]
- Annual direct medical costs are twice those of non-fibromyalgia individuals[6]

[1] Phillips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.
[2] American Chronic Pain Association (www.theacpa.org, 2018)
[3] Schaefer et al., Pain Pract, 2015.



[4] The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica); Duloxetine (Cymbalta); Milnacipran (Savella)
[5] Robinson et al, Pain Medicine 2013;14:1400.
[6] White et al, J Occupational Environ Med 2008;50:13.

# 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]**

**High rates of discontinuation, switching and augmentation**

- Attempts to treat multiple symptoms and/or avoid intolerable side effects
- Average of 2-3 medications used simultaneously[2]
- Typical patient has tried six different medications[3]
- Medication-related side effects may be similar to fibromyalgia symptoms

**Substantial off-label use of narcotic painkillers and prescription sleep aids[3]**

- Among those diagnosed, more than one-third have used prescription opioids as a means of treatment[4]

**TNX-102 SL is a non-opioid, centrally-acting analgesic that could provide a new therapeutic option for fibromyalgia patients**

[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.
[4] Berger A, Dukes E, Martin S, Edelsberg J, Oster G, Int J Clin Pract, 2007; 61(9):1498–1508.

# Potential Role of Sleep Quality in Fibromyalgia




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

**Believed to result from inappropriate pain signaling in central nervous system**

- Absence of peripheral injury[1]

**Pain is a sensor system in the brain**

- When the system malfunctions, the pain alarm is turned on even through there has been no peripheral nerve tissue injury

**Improving sleep quality is believed to reduce pain and fatigue in FM**

- Suggesting sleep dysfunction is pathogenic in FM

**TNX-102 SL acts as a non-opioid, centrally-acting analgesic to aid in the management of fibromyalgia**

[1] Philips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.

# Phase 3 F301/AFFIRM[1] Study Results of TNX-102 SL 2.8 mg in Fibromyalgia



## General study characteristics:

Randomized, double-blind, placebo-controlled trial in fibromyalgia at 35 U.S. sites (N=519)

## Primary endpoint: Mean Pain

Mean change from baseline at Week 12 (TNX-102 SL 2.8 mg vs. placebo)

**TNX-102 SL at bedtime once-daily**
2.8 mg — *N= 262*

**Placebo at bedtime once-daily**
*N= 257*

*12 weeks* → ····· ***12-week open-label extension***

## Efficacy analyses:

- Primary endpoint (30% responder analysis), p=0.095
- Key Secondary Endpoint: mean pain improvement after 12 weeks of treatment) (MMRM statistical method), p< 0.001
- Significant improvements in other secondary endpoints measuring sleep quality and sleep disturbances, fatigue, patient global impression of change, global physical health, and fibromyalgia symptom and function domains
- Good tolerability with most common adverse events generally mild and transient events related to the sublingual administration of the drug

[1]ClinicalTrials.gov Identifier NCT02436096

# Phase 3 AFFIRM (F301) Study Results:
## Mean Pain Analyzed by Mixed Model Repeated Measures (MMRM), with and without Multiple Imputation (MI)



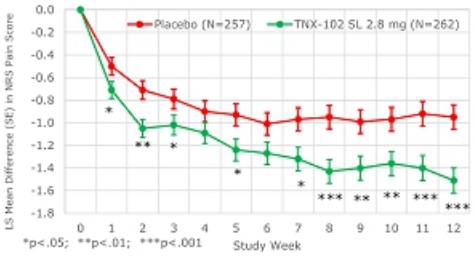
**Pre-specified secondary analysis of AFFIRM:**

- Mean Pain Analysis, MMRM
- TNX-102 SL N=262; Placebo N=257
- Difference in Least Square Mean (SE): -0.6 (0.15); 95% CI (-0.8, -0.3); p<0.001

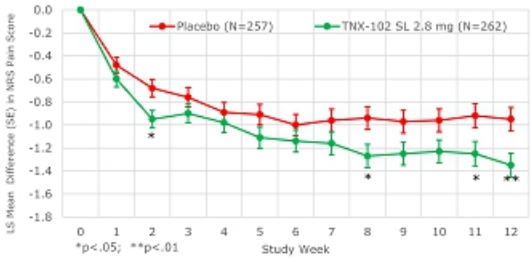
**Retrospective analysis of AFFIRM:**

- Mean Pain Analysis, MMRM with MI[#]
- TNX-102 SL N=262; Placebo N=257
- Difference in Least Square Mean (SE): -0.4 (0.14); 95% CI (-0.7, -0.1); p=0.005
- Tonix intends to use MMRM with MI for analyzing the primary endpoint for the new RELIEF (F304) study, in line with current FDA statistical guidance on handling of missing data

**Change in Pain Scores Over 12 Weeks: MMRM**




**Change in Pain Scores Over 12 Weeks: MMRM with MI**




[#]As will be the case for the RELIEF F304 primary analysis, all discontinuations due to Adverse Event and Lack of Efficacy are imputed using MI based on baseline values; all other discontinuations assumed to be Missing at Random and are imputed with MI using weekly data of subjects.

# TNX-102 SL for Fibromyalgia
## New Phase 3 Study: Higher (2x) Dose, New Primary Endpoint



**Clear guidance from FDA to advance fibromyalgia program using higher dose (5.6 mg)**

**Long-term safety of 5.6 mg dose collected in PTSD studies expected to support fibromyalgia NDA**

**Retrospective analysis of mean pain improvement after 12 weeks of treatment showed statistically significant improvement using both statistical methods: MMRM ($p < 0.001$) and MMRM with MI ($p < 0.01$)**

- MMRM with MI to be used going forward

**First patient enrolled in the new Phase 3 RELIEF study in December 2019**

# TNX-102 SL 5.6 mg for Fibromyalgia:
## New Phase 3 F304/RELIEF[1] Study Enrolling



### General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia in approximately 40 U.S. sites (N=470)
- Adaptive Design: one planned unblinded interim analysis based on 50% of randomized participants


### Primary endpoint (Week 14):

- Daily diary pain severity score change (TNX-102 SL 5.6 mg vs. placebo) from baseline in the weekly average as measured by the numerical rating scale (NRS), using mixed model repeated measures analysis with multiple imputation (MMRM with MI)

### Key Secondary endpoints (Week 14) include:

- Patient Global Impression of Change (PGIC): Proportion of patients with a rating of "very much improved" or "much improved"
- Fibromyalgia Impact Questionnaire – Revised (FIQR): Symptoms Domain

**Interim analysis results expected 2H 2020**

**Topline results expected 1H 2021 based on currently-planned sample size**

**Potential pivotal efficacy study to support NDA approval**

[1]CinicalTrials.gov Identifier: NCT04172831
[2]Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

# Common Adverse Events (AEs) Related to TNX-102 SL in prior Posttraumatic Stress Disorder (PTSD) Studies



| | P201 | | | P301 | |
|---|---|---|---|---|---|
| Category of Adverse Reaction<br>Preferred Term | Placebo (N=94) | TNX 2.8 mg (N=93) | TNX 5.6 mg (N=50) | Placebo (N=134) | TNX 5.6 mg (N=134) |
| Systemic Adverse Events*# | | | | | |
| Somnolence | 6.4% | 11.8% | 16.0% | 9.0% | 15.7% |
| Dry mouth | 10.6% | 4.3% | 16.0% | | |
| Headache | 4.3% | 5.4% | 12.0% | | |
| Insomnia | 8.5% | 7.5% | 6.0% | | |
| Sedation | 1.1% | 2.2% | 12.0% | | |
| Local Administration Site Reactions*# | | | | | |
| Hypoaesthesia oral | 2.1% | 38.7% | 36.0% | 1.5% | 37.3% |
| Paraesthesia oral | 3.2% | 16.1% | 4.0% | 0.7% | 9.7% |
| Glossodynia | 1.1% | 3.2% | 6.0% | | |
| Product Taste Abnormal | | | | 3.0% | 11.9% |

*only adverse events (AEs) are listed that are at a rate of ≥ 5% in any TNX-treated group
#no values in a row for either study means the AE in the active group(s) in that study was at a rate of <5%

**No serious and unexpected AEs related to TNX-102 SL**

- Systemic AEs comparable between studies and also consistent with those described in approved oral cyclobenzaprine product labeling
- Severity and incidence of oral hypoesthesia (oral numbness) are not dose related and similar in both studies

# Opportunities to Expand to Other Indications



**Role of sleep disturbance more established in common psychiatric and neurological/pain disorders**

- Recognized as a core symptom of many of these disorders
- Traditional sleep medications, which increase sleep quantity, may not provide benefit (benzodiazepines in major depression) or are contraindicated

**Psychiatric Disorders**

- Stress Disorders (PTSD)
- Mood Disorders (Depression)
- Anxiety Disorders
- Addiction (Alcohol Use Disorder)

**Psychiatric Symptoms of Neurological Disorders**

- Agitation in Alzheimer's
- Psychosis in Parkinson's, Alzheimer's and other dementias

**Chronic Pain States**

- Chronic wide-spread pain (fibromyalgia)
- Osteoarthritis

**Growing recognition that there are many disorders where sleep disturbances may have a role in the pathophysiology (cardiovascular, metabolic, neurologic)**

- Sleep quality plays a homeostatic role *in several disorders*

# TNX-102 SL: Potential Treatment for Agitation in Alzheimer's Disease (AAD)



**Agitation is one of the most distressing and debilitating of the behavioral complications of Alzheimer's disease**

- Includes emotional lability, restlessness, irritability and aggression[1]

**Link between disturbed sleep and agitation in Alzheimer's[1-3]**

- Agitation is commonly diurnal (e.g., "sundowning")

**Prevalence**

- Agitation is likely to affect more than half of the 5.3 million Americans who currently suffer from moderate to severe Alzheimer's disease; expected to nearly triple by 2050[4]

**Significant unmet need** with no FDA approved drugs for the treatment of AAD

**Proposed Phase 2 study can potentially serve as a pivotal efficacy study to support NDA approval[5]**

[1]Rose, K.et al. (2015). *American Journal of Alzheimer's Disease & Other Dementias*, *30*:78
[2]Shih, Y. H., et al. (2017). *Journal of the American Medical Directors Association*, *18*, 396.
[3]Canevelli, M., et al. (2016). *Frontiers in medicine*, *3*.
[4]The Alzheimer's Association, 2017 Alzheimer's Disease Facts and Figures: https://www.alz.org/facts/
[5]FDA comments on final protocol received October 2018

# TNX-102 SL: Potential Treatment for Alcohol Use Disorder (AUD)



**AUD is a chronic relapsing brain disease**

- Characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using

**Sleep disturbance is extremely common in alcohol recovery**[1]

- Significantly impacts daytime cognition, mood, and ability to participate in alcohol treatment, and is associated with increased risk of relapse

**Prevalence**

- An estimated 36 million adults in the U.S. have AUD[2]

**Three FDA-approved medications**

- Remains an unmet need due to compliance and safety issues

**Pre-IND meeting with the FDA completed in October 2019**

- Discussed 505(b)(2) development plan for TNX-102 SL as a treatment for AUD
- FDA official meeting minutes confirmed plan to submit IND application in 1Q 2020 for a Phase 2 Proof of Concept Study

[1]Arnedt et al, J Addict Dis. 2007 ; 26(4): 41–54
[2]Grant et al, JAMA Psychiatry 2015; 72(8): 757-766; www.census.gov

# TNX-1300* for the Treatment of Cocaine Intoxication



**Recombinant protein that degrades cocaine in the bloodstream[1]**

- Double-mutant cocaine esterase (CocE)
- CocE was identified in bacteria (Rhodococcus) that use cocaine as its sole source of carbon and nitrogen and that grow in soil surrounding coca plants[2]
- CocE catalyzes the breakdown of cocaine into metabolites ecgonine methyl ester and benzoic acid

**Phase 2 study completed by Rickett Benckiser (TNX-1300 was formerly RBP-8000)[3]**

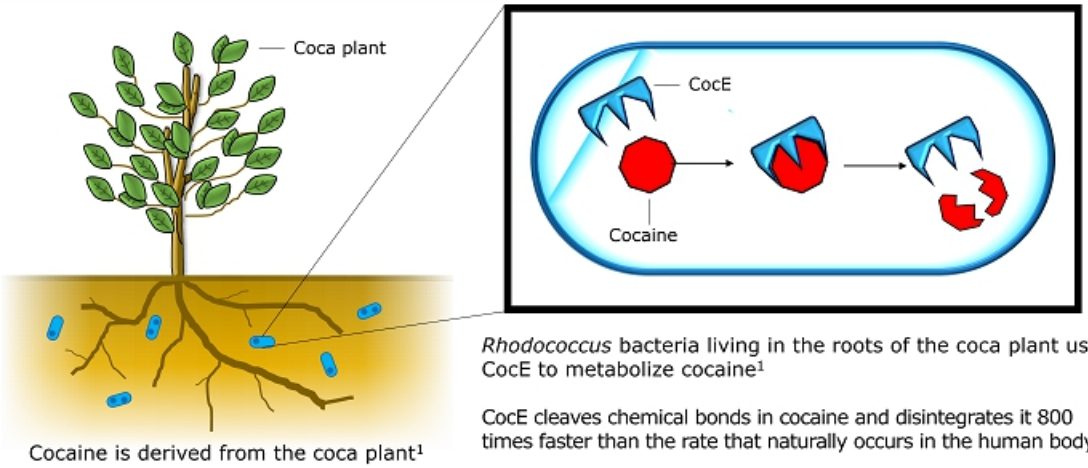
- Volunteer cocaine abusers received cocaine 50 mg *i.v.* infusion over 10 minutes
- TNX-1300 given one minute after completion of cocaine infusion
  - Rapidly reversed the physiologic effects of cocaine; cocaine plasma exposures dropped by 90% within two minutes
  - Well tolerated with the most frequently reported adverse events being gastrointestinal disorders (including dry mouth, nausea); nervous systems disorders (including headache, dizziness) and skin and subcutaneous tissue disorders (including hyperhidrosis, dermatitis)

**TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

[1] Gao D et al, Mol Pharmacol. 2009. 75(2):318-23.
[2] Bresler MM et al, Appl Environ Microbiol. 2000. 66(3):904-8.
[3] Nasser AF et al, J Addict Dis. 2014;33(4):289-302.

# TNX-1300 (Cocaine Esterase or CocE) Is a Fast-acting Cocaine Antidote






Cocaine is derived from the coca plant[1]

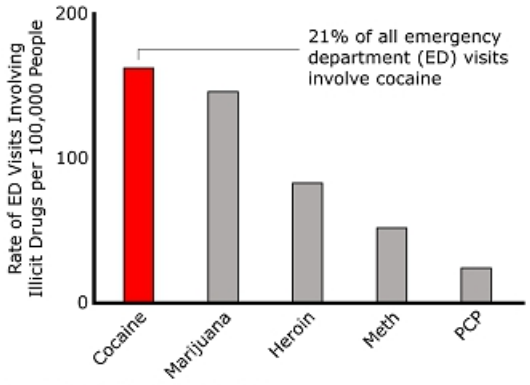
*Rhodococcus* bacteria living in the roots of the coca plant use CocE to metabolize cocaine[1]

CocE cleaves chemical bonds in cocaine and disintegrates it 800 times faster than the rate that naturally occurs in the human body[1]

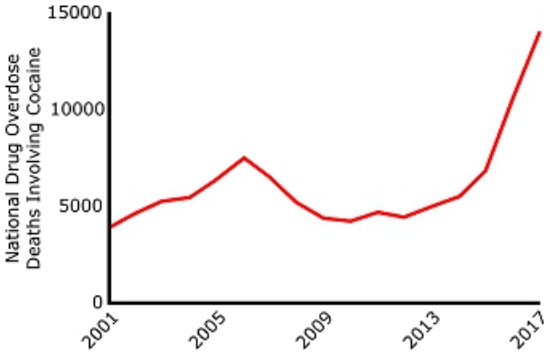
1. Narasimhan D et al. *Future Med Chem*. 2012.

# Cocaine Intoxication Is a Growing Problem in the U.S.

**Cocaine is involved in more emergency department (ED) visits than any other illicit substance[1]**




**Drug overdose deaths involving cocaine have increased dramatically in recent years[2]**




1. CBHSQ. DAWN 2011. Rockville, MD: SAMHSA; 2013
2. NIDA. Overdose death rates. https://www/drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

Note: Figures are for illustrative purposes

# TNX-601 CR* (Tianeptine Oxalate Controlled Release) Tablets



**Proprietary new controlled release formulation for once-daily dosing**

- Suitability for once-daily dosing established in Phase 1 pharmacokinetic study, completed outside of the U.S.
  - Well tolerated in study and side effects were consistent with the known safety profile of tianeptine sodium
- Tianeptine sodium immediate release is approved and marketed outside of the U.S. for three times a day dosing for the treatment of depression
  - Once-daily dosing for TNX-601 CR believed to have an adherence advantage over three times a day dosing with tianeptine sodium
- Plan to request pre-IND meeting with FDA in first half 2020
- Plan for Phase 2 study in depression, ex-U.S., in second half 2020

**Proprietary new oxalate salt with improved pharmaceutical properties**

- Tianeptine oxalate is crystalline, while tianeptine sodium is amorphous

**Issued patents directed to tianeptine and tianeptine oxalate**

- **Composition of Matter:** Issued US patent directed to oxalate salt, U.S. Patent No. 10,449,203
- **Method of Use:** Issued U.S. and European patents directed to methods of treating cognitive impairment associated with corticosteroid treatment (U.S. Patent No. 9,314,469; European Patent No. 3246031)

**TNX-601 (tianeptine oxalate CR tablets) is in the pre-IND stage in the U.S. and has not been approved for any indication.*

# TNX-601 CR: A Potential Daytime Treatment for Depression and PTSD



**Depression: majority suffering from depression do not have an adequate response to initial antidepressant therapy**

- Tianeptine sodium immediate release (IR) tablets for three times a day dosing is approved as an antidepressant in the EU, Russia, Asia and Latin America; first marketed for depression in France in 1989
- Tianeptine sodium is reported to have prominent anti-anxiety effects in depression with a low incidence of sexual side effects
- TNX-601 CR leverages the established efficacy and safety of tianeptine sodium IR as a treatment for depression outside of the U.S.
- Despite multiple approved products for depression in the U.S., there remains significant interest and need for new treatments, particularly for medicines that modulate the glutamatergic system

**PTSD: heterogeneous condition, so not all patients are expected to respond to a single medicine**

- TNX-601 CR modulates the glutamatergic system
- Published studies show tianeptine is active in the treatment of PTSD[1-4]
- Leverages Tonix expertise in PTSD (clinical and regulatory, market analysis, etc.)

[1] Frančišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
[2] Rumyantseva GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
[3] Aleksandrovskiĭ IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
[4] Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747

# TNX-801 (Synthesized Live Horsepox Virus): A Potential Smallpox and Monkeypox Preventing Vaccine



**Pre-IND Stage**

**Potential improvement over current biodefense tools against smallpox**

- ✓ Demonstrated protective vaccine activity in mice and macaques
- ✓ Collaboration with Professor David Evans and Dr. Ryan Noyce at University of Alberta

**Currently approved smallpox and monkeypox vaccines**

- ✓ Two vaccines are FDA approved for smallpox: ACAM2000® (vaccinia) and Jynneos® (MVA-BN) and only Jynneos is approved for monkeypox[1]

**Regulatory strategy**

- We intend to meet with FDA to discuss the most efficient and appropriate investigational plan to support the licensure
  - ✓ Planning non-inferiority, active comparator study using an FDA approved product

**Targeting a Potential Public Health Issue**

**Material threat medical countermeasure under 21st Century Cures Act**

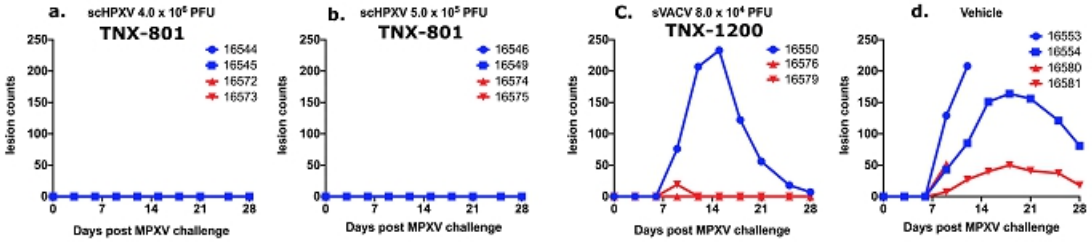
- Qualifies for **Priority Review Voucher (PRV)** upon licensure[2]
  - ✓ **PRVs have no expiration date, are transferrable and have sold for ~$125 M**

[1]ACAM2000 is a registered trademark of Emergent BioSolutions and Jynneos is a registered trademark of Bavarian Nordic
[2]BLA/NDA priority 6-month review is expected.

# No Overt Clinical Signs Observed in TNX-801 Vaccinated Macaques After MPXV Challenge[1]



## No monkeypox lesions observed after monkeypox (MPXV) challenge in any of the eight animals vaccinated with TNX-801




Legend: Cynomolgus macaques (4 per group), were vaccinated *via* scarification using a bifurcated needle. Two different doses of TNX-801 (scHPXV) vaccine were tested (panel a and b); one dose of TNX-1200 (sVACV)(panel c); or vehicle (panel d). After monkeypox (MPXV) challenge, no lesions were seen in any of the 8 animals vaccinated with TNX-801 (panel a and b). One animal in the TNX-1200 arm died from unrelated causes, and two of three remaining animals showed lesions by Day 69 (panel c). All four vehicle vaccinated animals developed lesions (panel d.) Clinical signs of systemic monkeypox infections were seen in all 4 vehicle-vaccinated animals (panel d) by Day 69, but TNX-801 and TNX-1200 vaccinated animals were protected. In Panels a-d, blue symbols are male animals and red are female.
Methods: 4 of 4 animals in the $4x10^6$ PFU dose, and 3 of 4 animals in the $5x10^5$ PFU dose groups exhibited a "take" at Day 7 after a single vaccination. A take is a biomarker of protective immunity. In the TNX-1200 (sVACV) arm only 1 of 4 animals exhibited a take after a single vaccination. The animals that did not present a take were revaccinated on Day 14: the one TNX-801 animal was revaccinated with $5x10^5$ PFU TNX-801 and the 3 TNX-1200 animals were revaccinated with $2.4x10^5$ PFU TNX-1200. All but one of the TNX-1200 animals subsequently produced a take. Tolerability was comparable for TNX-801 and TNX-1200.

[1]Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf )

# Pipeline Summary – by Select Therapeutic Areas



## Pain

- **TNX-102 SL – (sublingual cyclobenzaprine) for fibromyalgia**
  Phase 3/RELIEF

## Psychiatry

- **TNX-102 SL – (sublingual cyclobenzaprine) for agitation in Alzheimer's**
  Phase 2-ready
  *FDA Fast Track designation*
- **TNX-601 – (tianeptine oxalate) for depression and PTSD**
  Phase 2-ready, ex-U.S.
- **TNX-1600 – (triple reuptake inhibitor) for PTSD**
  Pre-clinical

## Addiction Medicine

- **TNX-1300 – (cocaine esterase) for cocaine intoxication**
  Phase 2
  *FDA Breakthrough Therapy designation*
- **TNX-102 SL – (sublingual cyclobenzaprine) for alcohol use disorder**
  FDA official meeting minutes confirmed plan to submit IND application for a Phase 2 PoC study

## Biodefense

- **TNX-801 – (live horsepox vaccine) – for preventing smallpox**
  Pre-clinical
- **TNX-1200 – (live vaccinia vaccine) – for preventing smallpox**
  Pre-clinical
- **TNX-701 – (oral radioprotective agent) – for radioprotection**
  Pre-clinical

# Milestones – Recently Completed and Upcoming



| | |
|---|---|
| ☑ May 2019 | In-licensed TNX-1300, in Phase 2 development for cocaine intoxication |
| ☑ October 2019 | Completed long-term exposure studies in PTSD to evaluate tolerability of TNX-102 SL 5.6 mg |
| ☑ October 2019 | Met with FDA to discuss Phase 2 study for TNX-102 SL to treat AUD |
| ☑ 4th Quarter 2019 | Confirmed once-daily dosing for TNX-601 CR in PK study |
| ☑ 4th Quarter 2019 | Enrolled first patient in Phase 3 F304/RELIEF study for management of fibromyalgia |
| ☑ February, 2020 | Interim analysis results reported from Phase 3 P302/RECOVERY study in PTSD |
| ❑ **1st Quarter 2020** | **Expect to submit IND application to support Phase 2 POC study in AUD** |
| ❑ **3rd Quarter 2020** | **Interim analysis results from Phase 3 F304/RELIEF study in fibromyalgia expected** |
| ❑ **2nd Half 2020** | **Expect to initiate Phase 2 study of TNX-601 CR in depression, ex-U.S.** |
| ❑ **1st Half 2021** | **Topline data from Phase 3 F304/RELIEF study in fibromyalgia expected** |

# Management Team



**Seth Lederman, MD**
President & CEO

TARGENT X | Fusilev (levoleucovorin) for injection | vela

**Gregory Sullivan, MD**
Chief Medical Officer

Columbia University Department of Psychiatry | New York State Psychiatric Institute

**Bradley Saenger, CPA**
Chief Financial Officer

Shire | VERTEX | Steward | pwc

**Jessica Morris**
Chief Operating Officer

Deutsche Bank | svb SiliconValleyBank | American Capital

# Financial Overview



| NASDAQ: TNXP | |
|---|---|
| Cash and cash equivalents, September 30, 2019 | $10.0 million |
| Net proceeds from equity offering in 4Q2019 | $8.1 million |
| Common stock outstanding as of January 13, 2020 | 8.5 million shares |

TONIX PHARMACEUTICALS
NASDAQ: TNXP

*Thank you*!

**Exhibit 99.02**

**Tonix Pharmaceuticals Announces Outcome of Interim Analysis for Phase 3 RECOVERY Study of Tonmya® (TNX-102 SL) in PTSD**

*RECOVERY Study has Stopped Enrollment Due to Inadequate Separation from Placebo at Week-12 Based on Interim Analysis Results of the First 50% of Enrolled Participants*

*Company Plans to Unblind and Report Top Line Results in the Second Quarter After Currently Enrolled Study Participants Have Completed*

*Company is Currently Enrolling a Phase 3 Study of TNX-102 SL in Fibromyalgia Syndrome and Expects Interim Results in the Third Quarter*

NEW YORK, February 6, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today that the Company has decided to stop enrollment in the Phase 3 RECOVERY study of Tonmya[#] or TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the treatment of posttraumatic stress disorder (PTSD) following an unblinded, pre-specified interim analysis by the Independent Data Monitoring Committee (IDMC). Based on interim analysis results of the first 50% of enrolled participants, the IDMC recommended stopping the trial for futility as Tonmya is unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms, as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with Tonmya and those receiving placebo. Preliminary blinded safety data from these participants did not reveal any serious and/or unexpected adverse events and the decision to discontinue enrolling in the study is not related to safety. The Company intends to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data to determine the next steps in this program, with the topline results expected to be reported in the second quarter of 2020. The Company is reallocating resources from the PTSD program to the Phase 3 fibromyalgia study of TNX-102 SL 5.6 mg that is currently enrolling and from which interim results are expected in the third quarter.

“We are disappointed for patients suffering from PTSD that the interim analysis did not detect a signal that would warrant continued enrollment in this Phase 3 study.” commented Seth Lederman, M.D., President and Chief Executive Officer. “These results underscore the difficulty in treating PTSD.”

** TNX-102 SL is an investigational new drug and has not been approved for any indication.*

*[#] Tonmya is the FDA conditionally accepted proprietary name for TNX-102 SL for the treatment of PTSD*

**About the Phase 3 RECOVERY Study**

The RECOVERY study is a double-blind, randomized, placebo-controlled, adaptive design study evaluating the efficacy and safety of Tonmya 5.6 mg over 12 weeks of treatment for civilian and military-related PTSD. The study is designed to enroll approximately 250 participants across approximately 30 clinical sites in the U.S. An interim analysis was conducted by an unblinded IDMC for potential sample size re-estimation after half the target population was enrolled and evaluable. Enrollment is restricted to individuals with PTSD who experienced an index trauma within nine years of screening. The primary efficacy endpoint will be the mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with Tonmya and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. Earlier versions of the CAPS were used to support the approval of the two currently marketed PTSD treatments.

**About Posttraumatic Stress Disorder (PTSD)**

PTSD can develop from witnessing or experiencing a traumatic event in which there was the severe threat of, or actual occurrence of, grave physical harm or death. PTSD affects approximately 12 million Americans and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of intrusive memories, flashbacks, and nightmares. PTSD typically is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and sometimes is associated with clinical depression and suicidal thinking. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable violent or suicidal behaviors.

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat pain, addiction and psychiatric conditions. Tonix's lead product candidate, TNX-102 SL*, is in Phase 3 development as a bedtime treatment for fibromyalgia. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya**) in PTSD will stop enrolling and topline data are expected in the second quarter of 2020. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. The Company has started enrollment in the Phase 3 RELIEF trial in fibromyalgia and expects data from an interim analysis in the second half 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 for AUD is in the pre-Investigational New Drug (IND) application stage. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for PTSD, as well as for depression. The first efficacy study will be performed outside the U.S. TNX-1600 (a triple reuptake inhibitor) is a third product candidate being developed for PTSD, as a daytime treatment. Tonix's programs for treating addiction conditions also include TNX-1300*** (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. 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-801 (live horsepox virus vaccine for percutaneous administration) and TNX-1200 (live vaccinia virus vaccine for percutaneous administration) are vaccines 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-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.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.

This press release and further information about Tonix can be found at www.tonixpharma.com.

**Forward-Looking Statements**

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**Contacts**

Bradley Saenger (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505