



July 2019



## 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 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 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, as well as the Registration Statement on Form S-1, as filed with the SEC on July 1, 2019. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.



## Free Writing Prospectus Statement

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This presentation highlights basic information about us and the offering to which this communication relates. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities.

We have filed a registration statement (including a prospectus, which currently is in preliminary form) with the U.S. Securities and Exchange Commission ("SEC") for the offering to which this presentation relates. The registration has not yet become effective. Before you invest, you should read the preliminary registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and this offering. You may access these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov).

The preliminary prospectus, dated July 1, 2019, is available on the SEC Web site at <https://www.sec.gov/edgar/searchedgar/companysearch.html>.

Alternatively, we or any underwriter participating in the offering will arrange to send you the preliminary prospectus and, when available, the final prospectus and/or any supplements thereto if you contact Aegis Capital Corp., 810 Seventh Avenue, 18<sup>th</sup> Floor, New York, NY 10019.

This presentation shall not constitute an offer to sell, or the solicitation of an offer to buy, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state or jurisdiction. The offering will only be made by means of a prospectus pursuant to a registration statement that is filed with the SEC after such registration statement becomes effective.



## Offering Summary

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Issuer:	Tonix Pharmaceuticals Holding Corp.
Ticker / Exchange:	TNXP / Nasdaq Global Market
Offering Size:	Approximately \$10,400,000 (excluding 15% Over-Allotment)
Securities Issued:	Common Stock
Use of Proceeds:	<ul style="list-style-type: none"><li>• Fund Phase 3 development for lead product candidate, TNX-102 SL</li><li>• Advance the development of a recently in-licensed product candidate, TNX-1300</li><li>• Working capital and other general corporate purposes</li></ul>
Sole Book-Runner:	Aegis Capital Corp.



## Who we are:

- A clinical stage biopharmaceutical company dedicated to developing innovative treatments for patients and making meaningful contributions to society
- Focusing on small molecules and biologics to treat psychiatric, pain and addiction conditions as well as potential medical counter-measures to improve biodefense

## What we do:

- Target therapeutic areas with high need for improvement
  - Conditions with no, or inadequate treatments
  - Significant patient segments not well served by existing therapies
- Develop innovative treatment options
  - Scientifically unique and innovative
  - Supported by strong scientific rationale
  - Supported by preliminary clinical evidence and published literature
  - Utilize proven regulatory pathway and established clinical endpoint
  - Built on a foundation of proprietary intellectual property

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# CNS Candidates in Development

## Psychiatry, Pain and Addiction

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

Pipeline Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA <sup>1</sup> /BLA <sup>2</sup>	Market	
<b>TNX-102 SL<sup>3</sup></b> Cyclobenzaprine HCl sublingual tablets Protectic <sup>®</sup> formulation technology	Bedtime Treatment for PTSD – Tonmya <sup>4*</sup>	[Blue arrow spanning Preclinical, Phase 1, and Phase 2]						
	Bedtime Treatment for Fibromyalgia	[Blue arrow spanning Preclinical, Phase 1, and Phase 2]						
	Bedtime Treatment for Agitation in Alzheimer's	[Blue arrow spanning Preclinical and Phase 1]						
<b>TNX-1300<sup>5</sup></b> Cocaine esterase (recombinant from bacteria) i.v. formulation	Cocaine intoxication / overdose	[Green arrow spanning Preclinical, Phase 1, and Phase 2]						
<b>TNX-601</b> Tianeptine oxalate oral formulation	Daytime Treatment for PTSD	[Blue arrow spanning Preclinical and Phase 1]						
	Treatment of Neurocognitive Dysfunction from Corticosteroids	[Blue arrow spanning Preclinical and Phase 1]						

<sup>1</sup> NDA- New Drug Application; <sup>2</sup> BLA -Biologic Licensing Application; <sup>3</sup> TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication; <sup>4</sup> Tonmya has been conditionally accepted by the U.S. FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD; <sup>5</sup> TNX-1300 (TL72R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication

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# Biodefense Candidates in Development

Biodefense programs owned outright with no royalties due

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Pipeline Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA <sup>1</sup> /BLA <sup>2</sup>	Market
<b>TNX-801</b> Live horsepox virus (HPXV) vaccine from cell culture percutaneous (scarification) formulation	Smallpox-preventing vaccine						
<b>TNX-701</b> Radioprotection drug oral capsules	Protection from radiation injury						

<sup>1</sup>NDA- New Drug Application; <sup>2</sup>BLA - Biologic Licensing Application



# Management Team



**Seth Lederman, MD**  
President & CEO



**Gregory Sullivan, MD**  
Chief Medical Officer



**Bradley Saenger, CPA**  
Chief Financial Officer



**Jessica Morris**  
Chief Operating Officer







## TNX-102 SL Intellectual Property – U.S. Protection expected until 2034

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

- United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9636408 in May 2017, U.S. Patent No. 9956188 in May 2018, and U.S. Patent No. 10117936 in Nov 2018
- China National Intellectual Property Administration issued Chinese Patent No. ZL 201480024011.1 in April 2019
- Indonesian Patent Office issued Indonesian Patent No. IDP000055516 in January 2019
- Saudi Arabian Patent Office issued Saudi Patent No. 6088 in September 2018
- Japanese Patent Office (JPO) issued Japanese Patent No. 6310542 in March 2018
- New Zealand Intellectual Property Office (NZIPO) issued New Zealand Patent No. 631152 in August 2017
- 35 patent applications pending (5 being allowed in U.S., Australia, Europe, Taiwan, South Africa)

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

- NZIPO issued New Zealand Patent No. 631144 in March 2017 and Patent No. 726488 in January 2019
- Taiwanese Intellectual Property Office issued Taiwanese Patent No. I590620 in July 2017 and Patent No. I642429 in December 2018
- Australian Patent Office issued Australian Patent No. 2013274003 in October 2018
- JPO issued Japanese Patent No. 6259452 in Dec 2017
- 21 patent applications pending

### Method of use (PTSD) for cyclobenzaprine: Protection expected to 2030

- Hong Kong Patent Office issued Hong Kong Patent No. HK1176235 in September 2018
- USPTO issued U.S. Patent 9918948 in March 2018
- European Patent Office issued European Patent No. 250123481 in Sept 2017 (validated in 37 countries). Opposition filed in June 2018
- 1 patent application pending

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# Prevalence of PTSD Among Civilians and Veterans



**12 million** American adults annually<sup>1</sup>



**Women** more likely to develop than men<sup>1</sup>

<sup>1</sup> Gidycz et al., 2016 (adjusted for 2019); <sup>2</sup> Norris, PTSD Res Quar. 2013;

<sup>3</sup> Analysis of VA Health Care Utilization among Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn Veterans, from 1st Qtr FY 2002 through 2nd Qtr FY 2015, Washington, DC; Among 1.9M separated OEF/OIF/OND veterans, 1.2M have obtained VA healthcare; 685k evaluated by VA with possible mental disorder, and 379k diagnosed with PTSD.



## Unmet Need for Effective and Safe Therapies for Treatment of PTSD

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### **No FDA-approved products for PTSD since Pfizer's Zoloft® (sertraline) and GSK's Paxil® (paroxetine) circa 2000**

- Neither has shown efficacy in military-related PTSD
- Male PTSD patients often unresponsive or intolerant of current treatments
- Side effects relating to sexual dysfunction, sleep disruption and weight gain are commonly reported

### **PTSD is signature wound of last 25 years of war**

- Affects servicemember health and performance, force readiness, retention
- Believed to be the underlying cause of suicide in many cases



### **First investigational new drug to show treatment effect in military-related PTSD in two potential pivotal efficacy studies**

- Phase 2 study (P201/AtEase) showed Tonmya 5.6 mg had a signal of treatment effect at Week 12 as measured by CAPS-5<sup>1</sup>
- Phase 3 study (P301/HONOR) provided evidence of effectiveness as early as 4 weeks after treatment but diminished over time due to high placebo response
  - Retrospective analysis showed persistent effectiveness at Week 12 in subgroup with Time Since Trauma =9 years from screening
- Both studies can be used potentially as supportive evidence of efficacy and safety for Tonmya NDA submission
- No serious or unexpected adverse events related to Tonmya were reported

### **FDA feedback and acceptance of new Phase 3 study (P302/RECOVERY) received in November 2018<sup>2</sup>**

<sup>1</sup> CAPS-5 = Clinician-Administered PTSD Scale for DSM-5

<sup>2</sup> FDA Meeting Minutes, November 26, 2018



### **Tonmya is believed to treat PTSD by improving sleep *quality***

- The brain naturally processes memories during sleep
- PTSD sufferers' emotionally charged memories disturb sleep and disrupt the natural processing of memories during sleep
- Tonmya is believed to normalize memory processing and facilitate extinction consolidation (breaking the link between "triggers" and PTSD symptoms)

### **Tonmya is *NEITHER* a benzodiazepine nor a narcotic**

- The active ingredient of Tonmya, cyclobenzaprine, does **NOT** interact with the same receptors as traditional hypnotic sleep drugs associated with retrograde amnesia; is **NOT** an opiate

### **Tonmya is non-addictive**

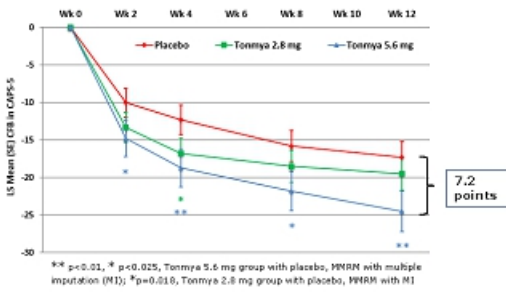
- Cyclobenzaprine is the active ingredient of an orally ingested immediate release tablet (Flexeril®), approved 40 years ago
- Flexeril's current labeling indicates no abuse and dependence concern at higher doses than Tonmya (15-30 mg/day v. 5.6 mg/day); NDA can be filed without drug abuse and dependency assessment studies

### **Once-daily sublingual dose taken at bedtime enhances patient adherence**

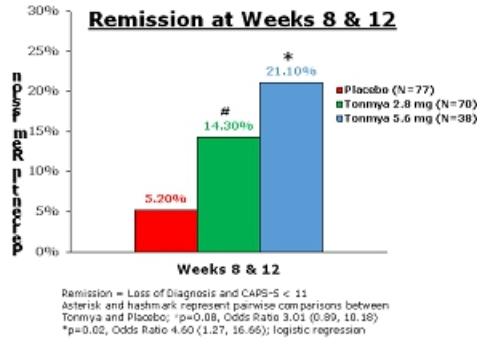


# Tonmya Phase 2 Dose-Effect in Military-Related PTSD<sup>1</sup>

## PTSD Symptoms (CAPS-5<sup>2</sup> Score)



## Remission at Weeks 8 & 12



<sup>1</sup> Completed Phase 2 P201/AtEase study: Retrospective analysis of Tonmya 5.6 mg on CAPS-5 =33 (high-moderate) subgroup. Primary analysis of P201/AtEase, based on Tonmya 2.8 mg in participants with entry CAPS-5 =29 (moderate PTSD severity), was not statistically significant.  
<sup>2</sup> CAPS-5 = Clinician administered PTSD Scale for DSM-5

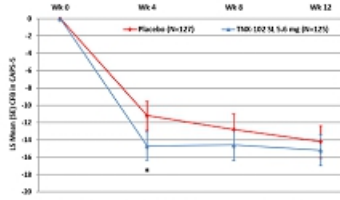


# Primary Outcome (CAPS-5) in Phase 3 (mITT) and 9 Years Time Since Trauma Subgroups

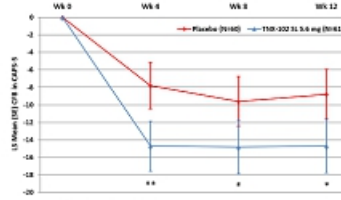
## Phase 3 P301/HONOR Study<sup>1</sup>

Modified intent to treat (mITT) population

Time Since Trauma (TST) = 9 yrs



~50% mITT Population



\*p=0.019, TNX-102 SL 5.6 mg group v. placebo, using mixed model repeated measures (MMRM) with multiple imputation (MI)

\*\*p=0.004, \*p=0.039, #p=0.059, TNX-102 SL 5.6 mg group v. placebo, using NMRM with MI

<sup>1</sup>Phase 3 P301/HONOR study: stopped in July 2018. Separation on primary endpoint did not cross pre-specified study continuation threshold at Week 12 in the interim analysis at ~50% randomization; no safety or tolerability issues discovered.



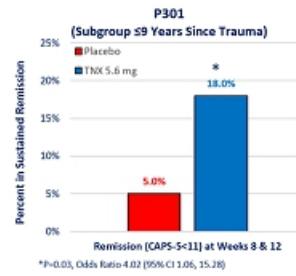
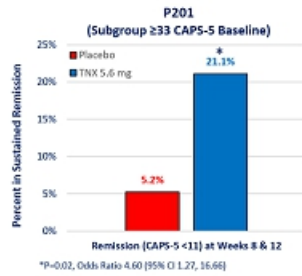
# Sustained Remission in Phase 2 and Phase 3 Studies: Retrospective Analyses of P201 Entry CAPS-5 $\geq 33$ and P301 $\geq 9$ Years Since Trauma Subgroups

Remission is a clinical state that is essentially asymptomatic

**In order to confirm remission:**

- Determined rates of participants who met remission status at both Week 8 and Week 12

**Rate of remission in  $\geq 9$  years since trauma group in P301 is similar to baseline CAPS-5  $\geq 33$  group in P201<sup>1</sup>**



<sup>1</sup> Majority of P201 participants were  $\geq 9$  years since trauma and  $\sim 80\%$  of P201 participants and all of P301 participants were  $\geq 33$  CAPS-5 at baseline





# Adverse Events (AEs) in P201/AtEase and P301/HONOR Studies

Category of Adverse Reaction Preferred Term	P201			P301	
	Placebo (N=94)	TNX 2.8 mg (N=93)	TNX 5.6 mg (N=50)	Placebo (N=134)	TNX 5.6 mg (N=134)
<b>Systemic Adverse Events**</b>					
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%		
<b>Local Administration Site Reactions**</b>					
Hypoesthesia 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 or unexpected AEs in P201 or P301 related to Tonmya

- 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



# New Phase 3 P302/RECOVERY Study – Initiated 1Q 2019

### General study characteristics:

- Randomized, double-blind, placebo-controlled study with baseline CAPS-5<sup>1</sup> = 33 in approximately 30 U.S. sites
- Enrollment restricted to study participants with PTSD who experienced an index trauma = 9 years from the date of screening
- Both civilian and military-related PTSD to be included

**Tonmya once-daily at bedtime**  
5.6 mg (2 x 2.8 mg tablets) *N* = 125

**Placebo once-daily at bedtime**  
*N* = 125

— 12 weeks —

### Primary endpoint:

- CAPS-5<sup>1</sup> mean change from baseline at Week 4 (Tonmya 5.6 mg vs. placebo)

### Key Secondary endpoints include:

- CAPS-5 mean change from baseline at Week 12 (Tonmya 5.6 mg vs. placebo)
- Change from baseline Clinical Global Impression – Severity scale
- Change from baseline Sheehan Disability Scale total score

### Potential pivotal efficacy study to support NDA approval

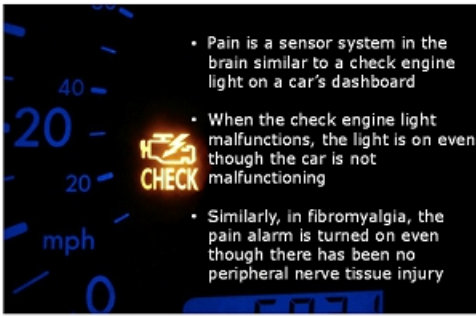
<sup>1</sup>CAPS-5 = Clinician-Administered PTSD Scale for DSM-5

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# Fibromyalgia is a Chronic, Debilitating Disorder that Imposes a Significant Societal and Economic Burden

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

- Pain is a sensor system in the brain similar to a check engine light on a car's dashboard
- When the check engine light malfunctions, the light is on even though the car is not malfunctioning
- Similarly, in fibromyalgia, the pain alarm is turned on even though there has been no peripheral nerve tissue injury

- **Fibromyalgia is considered a neurobiological disorder characterized by<sup>1</sup>: 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<sup>1</sup>
- **Causes significant impairment in all areas of life<sup>2</sup>**
  - 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<sup>3</sup>

<sup>1</sup>Phillips K & Clauw DJ. Best Pract Res Clin Rheumatol 2011;25:141.

<sup>2</sup>Schaefer et al., Pain Pract. 2015.

<sup>3</sup>Robinson et al, Pain Medicine 2013;14:1400.



## Large Need for New Fibromyalgia Therapies that Provide Broad Symptom Improvement with Better Tolerability

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- **Currently-approved medications may have side effects that limit long-term use<sup>1</sup>**
  - 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<sup>2</sup>
  - The typical patient has tried six different medications<sup>3</sup>
- **Substantial off-label use of narcotic painkillers and prescription sleep aids<sup>3</sup>**
- **TNX-102 SL is a non-opioid, centrally-acting analgesic that may provide a new therapeutic option for fibromyalgia patients**

<sup>1</sup> Nuesch et al, Ann Rheum Dis 2013;72:955-62.

<sup>2</sup> Robinson RL, et al, Pain Medicine 2012;13:1366.

<sup>3</sup> Patent Trends: "Fibromyalgia", Decision Resources, 2011.

**Recombinant protein that degrades cocaine in the bloodstream<sup>1</sup>**

- Double-mutant cocaine esterase

**Phase 2 study completed by Rickett Benckiser (TNX-1300 was formerly RBP-8000)<sup>2</sup>**

- 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)

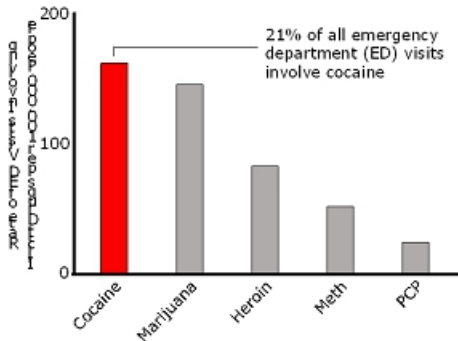
*\*TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

<sup>1</sup> Gao D et al, Mol Pharmacol. 2009. 75(2):318-23.

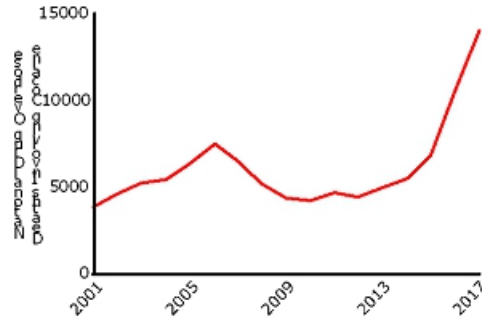
<sup>2</sup> Nasser Ali et al, J Addict Dis, 2014;33(4):289-302.

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

Cocaine is involved in more emergency department (ED) visits than any other illicit substance<sup>1</sup>



Drug overdose deaths involving cocaine have increased dramatically in recent years<sup>2</sup>



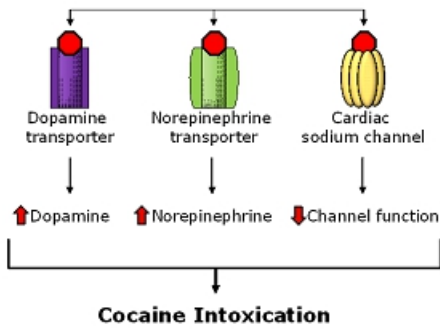
1. CBHSQ, DAWN 2011. Rockville, MD: SAMHSA; 2013.  
2. NIDA. Overdose death rates. <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

Note: Figures are for illustrative purposes

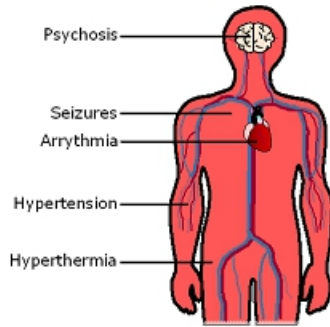


# Cocaine Intoxication Is the Result of Cocaine's Activity at Multiple Targets

In addition to dopamine transporters, cocaine also blocks other targets<sup>1</sup>



The effects of cocaine intoxication include<sup>1</sup>:



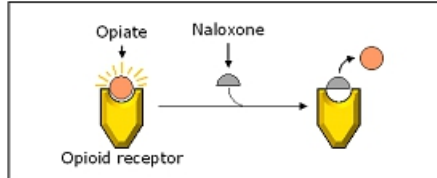
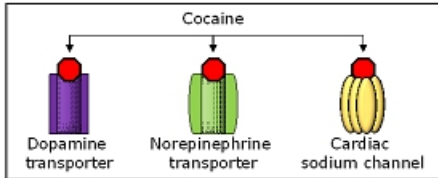
1. Bohn et al. *NB/Pharmacol*. 2013.



# Pharmacotherapies for Cocaine Intoxication Have Not Been Effective

## Treatments for opiates not effective for cocaine:

	Cocaine	Opiates
MOA of Toxicity	Complex; mediated by multiple targets with distinct biological functions <sup>1</sup>	Simple; mediated by opioid receptors <sup>2</sup>
Pharmacology	Antagonist <sup>1</sup>	Agonists <sup>2</sup>
Pharmacotherapy	<b>No FDA-approved medication exists<sup>1</sup></b>	Naloxone <sup>2</sup>



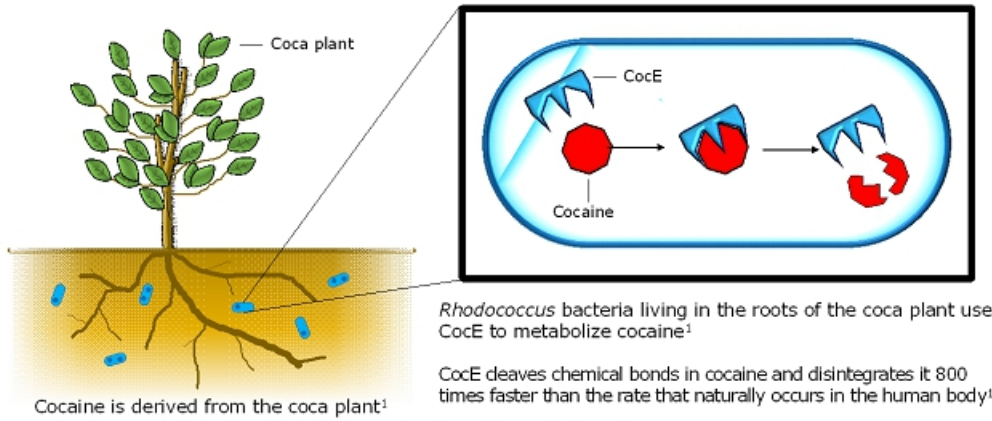
1. Brim et al. *Hor Pharmacol*, 2011.  
2. Melchior et al. *Eur J Pharmacol*, 2003.  
3. Narasimhan et al. *Future Medicinal Chemistry*, 2012.





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

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

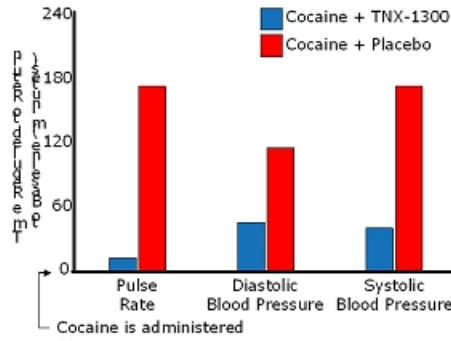
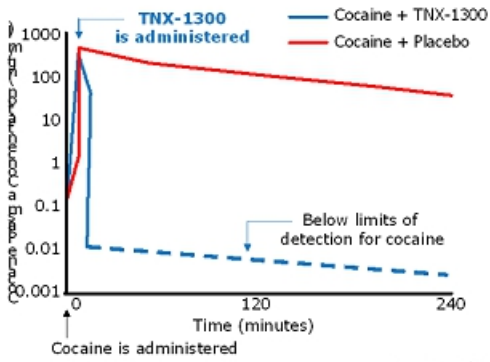
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# TNX-1300 (CocE) Accelerates Recovery From Cocaine Intoxication in Humans

TNX-1300 cleaves cocaine in humans and removes it from the blood circulation<sup>1</sup> (N=29)

TNX-1300 accelerates recovery from cocaine intoxication without inducing serious side effects<sup>1</sup>



1. Nasser A et al., J Addict Dis, 2014.

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Note: Figures are for illustrative purposes

# **TNX-601 (Tianeptine Oxalate): A Potential Clinical Candidate for PTSD**

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**Pre-IND  
Candidate**

**Targeting a  
Condition with  
Significant  
Unmet Need**

## **Targeted as a 1<sup>st</sup> line monotherapy for PTSD: oral formulation for daytime dosing**

- ✓ **Leverages expertise in PTSD (clinical and regulatory experience, market analysis, etc.)**
- ✓ **Mechanism of Action (MOA) is different from TNX-102 SL**

- Tianeptine sodium (amorphous), first marketed for depression in France in 1989, is approved as an antidepressant in the EU, Russia, Asia and Latin America; established post-marketing experience
- Identified new oxalate salt with improved pharmaceutical properties ideal for reformulation
- Preliminary human pharmacokinetic and safety data (non-IND study) from selected formulation expected in second half 2019

## **Patents and patent applications directed to tianeptine**

- Issued patent directed to methods of treating cognitive impairment associated with corticosteroid treatment
- Patent application directed to oxalate salt

## **Clinical evidence for PTSD**

- Several studies have shown tianeptine to be active in the treatment of PTSD<sup>1-4</sup>

<sup>1</sup> Francišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693

<sup>2</sup> Rumyantseva GM and Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761

<sup>3</sup> Aleksandrovskii IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]

<sup>4</sup> Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747



# TNX-801 (Synthesized Live Horsepox Virus): A Smallpox-Preventing Vaccine Candidate

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## Pre-IND Stage

### Potential improvement over current biodefense tools against smallpox

- ? Leverages Tonix's government affairs effort
- ? Collaboration with Professor David Evans and Dr. Ryan Noyce at University of Alberta
- ? Demonstrated protective vaccine activity in mice
- ? Patent application on novel vaccine submitted

### Regulatory strategy

- We intend to meet with FDA to discuss the most efficient and appropriate investigational plan to support approval, either:
  - ? Application of the "Animal Rule", or
  - ? Conducting an active comparator study using ACAM2000
- Good Manufacturing Practice (GMP) viral production process in development

## Targeting a Potential Public Health Issue

### Material threat medical countermeasure under 21<sup>st</sup> Century Cures Act

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

\*BLA/NDA priority 6-month review is expected.

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## Milestones – Recently Completed and Upcoming

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- November 2018 Received FDA minutes confirming agreement on the design of P302/RECOVERY study
- March 2019 Met with FDA to discuss new FM Phase 3 study design using TNX-102 SL 5.6 mg
- March 2019 P302/RECOVERY study initiated
- April 2019 Received FDA formal minutes with clear guidance and support on new Phase 3 FM study
- May 2019 In-licensed TNX-1300, product candidate in Phase 2 development for cocaine intoxication
- Second Half 2019 Preliminary human pharmacokinetic and safety data (non-IND study) from selected TNX-601 (tianeptine oxalate) formulation expected
- First Half 2020 Topline data from P302/RECOVERY study expected



### **Two Phase 3 Programs in indications affecting millions of Americans**

- Tonmya for PTSD: affects 12 million adults in U.S.; currently conducting Phase 3 trial with data expected next year; bedtime treatment
- TNX-102 SL for Fibromyalgia: affects between 5-10 million adults in U.S.; in Phase 3 development

### **Two Phase 2 Programs in indications for which there is no FDA-approved drug available**

- TNX-1300 for Cocaine Intoxication: biologic; ready for Phase 2
- TNX-102 SL for Agitation in Alzheimer's Disease: ready for Phase 2/3

### **Pipeline products to improve biodefense and leverage PTSD expertise**

- TNX-601: tianeptine oxalate in formulation development for daytime treatment of PTSD
- TNX-801: smallpox-preventing vaccine in preclinical development; demonstrated protective vaccine activity in mice; GMP viral production process in development
- TNX-701: oral radioprotection drug in preclinical development; demonstrated radioprotective effect in mice



*Thank you!*