**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): July 1, 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))

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. ☐

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 |

**Item 1.01 Entry into Material Definitive Agreement.**

On July 1**,** 2020, Tonix Pharmaceuticals Holding Corp. (the "Company") entered into a Purchase and Sale Agreement (the "Agreement") with the seller named therein (the "Seller"), pursuant to which the Company has agreed to purchase from Seller an approximately 40,000 square foot commercial building in Massachusetts (the "Property") for $4,000,000. The Company will pay $40,000 as an initial non-refundable deposit and an additional $40,000 non-refundable deposit upon the conclusion of a 60-day diligence period. The Company may terminate the Agreement prior to the closing of the sale of the Property for any reason. The Property is intended for use for research and development functions associated with the Company's product candidates.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2020.

A press release issued by the Company in connection with the Agreement is included as Exhibit 99.1 hereto.

*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 7.01 Regulation FD Disclosure.**

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 presentation is filed as Exhibit 99.02 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 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit No. | Description. |
|---|---|
| 99.01 | Press Release of the Company, dated July 7, 2020 |
| 99.02 | Corporate Presentation by the Company for July 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: July 7, 2020

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

**Exhibit 99.01**

**Tonix Pharmaceuticals Plans Massachusetts R&D Facility to Accelerate Clinical Development of Vaccines and Protein-Based Therapeutics**

**Tonix's *Advanced Development Center* Will House Laboratories Dedicated to Process and Analytical Development**

NEW YORK, July 7, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced its intent to purchase an approximately 40,000 square foot facility in Massachusetts to use as laboratories to enable R&D functions associated with its expanding portfolio of immunology candidates, including vaccines for COVID-19 and biological products for other disorders.

Tonix's Advanced Development Center is expected to expand and strengthen the Company's capabilities in process and analytical development. Tonix will continue working collaboratively in certain cases with outside partners, such as its current collaborations with Southern Research for preclinical testing and with FUJIFILM Diosynth Biotechnologies for the manufacturing of the TNX-801 and TNX-1800 vaccines for smallpox and COVID-19, respectively. Both vaccines utilize Tonix's proprietary live replicating virus platform, which is designed to potentially elicit a predominately T cell response, believed to be essential in conferring long-term vs. temporary immunity. Preclinical results from the TNX-1800 COVID-19 study in small animals and non-human primates are expected in the fourth quarter of this year. The R&D facility is expected to be operational in 2022.

"The Federal Government's 'Operation Warp Speed' for COVID-19, while critically important, has commandeered a large portion of America's biologics contract research and manufacturing facilities. As a country, the U.S. needs more domestic onshore capacity, and as a company Tonix needs more control over the speed with which we can make vaccines and biologics products suitable for clinical studies," said Seth Lederman, MD, Chief Executive Officer of Tonix.

Dr. Lederman continued, "This is a significant step that we believe will add to our competitive advantage in responding quickly to emerging infectious diseases utilizing our growing range of vaccine technologies and protein-based therapeutic platforms. We view having our own in-house facilities for R&D as a strategic capability and we foresee a potential scarcity of available domestic capacity. In addition, R&D resources in foreign countries may not fit with our strategy to develop products related to emerging biodefense threats or critical public health needs."

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of 2020. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix's lead CNS candidate, TNX-102 SL** (cyclobenzaprine HCl sublingual tablets), is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth quarter 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 program for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor) , a new molecular entity being developed as a treatment for PTSD, 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-1800, TNX-801, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have 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; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2019, as filed with the Securities and Exchange Commission (the “SEC”) on March 24, 2020, and periodic 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. The information set forth herein speaks only as of the date thereof.

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**Exhibit 99.02**

# Investor Presentation
## NASDAQ:TNXP



TONIX PHARMACEUTICALS

July 2020

**Version P0235 7-1-20 (Doc 0661)**

# 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; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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.

*Developing novel therapies for humanity*

- A clinical-stage biopharmaceutical company committed to discovering and developing innovative and proprietary new therapeutics that address the needs of patients
- We focus on developing small molecules and biologics:
  - CNS (pain, neurology, psychiatry, addiction)
  - Immunology (vaccines, immunosuppression, oncology, autoimmune disease)

# Our Pipeline – CNS Portfolio



| | CANDIDATES | INDICATION | STATUS |
|---|---|---|---|
| CNS Portfolio | **TNX-102 SL[1]** | **Fibromyalgia (FM) - Lead Program** | **Phase 3 – ongoing** |
| | | PTSD | Phase 3 – ongoing |
| | | Agitation in Alzheimer's | Phase 2 ready |
| | | Alcohol Use Disorder | Pre-IND[2] |
| | TNX-1300[3] | Cocaine Intoxication / Overdose | Phase 2 |
| | TNX-601 CR[4] | Major depression | Phase 1 |
| | | PTSD | Phase 1 |
| | | Neurocognitive Dysfunction from Corticosteroids | Phase 1 |
| | TNX-1600 | Depression, PTSD and ADHD | Preclinical |
| | TNX-1900 | Migraine and craniofacial pain | Clinical – pre-IND[5] |

[1]TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.
[2]Pre-Investigational New Drug (IND) meeting completed in October 2019 with FDA. 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,
[3]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.
[4]TNX-601 CR is in the pre-IND stage in the U.S.; a Phase 1 trial for formulation development was recently completed outside of the U.S.
[5]Two ex-U.S. Phase 2 trials have been completed using TNX-1900

# Our Pipeline – Immunology Portfolio



| | CANDIDATES | INDICATION | STATUS |
|---|---|---|---|
| Immunology Portfolio | **TNX-1800** | **Covid-19 vaccine – Prioritized Program** | **Preclinical** |
| | TNX-801 | Smallpox and monkeypox preventing vaccine | Preclinical |
| | TNX-1200 | Smallpox and monkeypox preventing vaccine | Preclinical |
| | TNX-1500 | Organ Transplant Rejection/Autoimmune Conditions | Preclinical |
| | TNX-1700 | Gastric and pancreatic cancers | Preclinical |

# TNX-1800[1], a SARS-CoV-2 Vaccine



Utilizes Tonix's proprietary horsepox virus as a vector

- Designed to express a protein from SARS-CoV-2, the cause of COVID-19
- Collaboration with Southern Research

**◇ Status of Vaccines for COVID-19 ◇**

- No vaccines are currently available
- Many vaccines are being developed
  - *However, uncertainty exists around efficacy, and importantly, safety*
- Global response will require multiple vaccines developed in parallel
  - *Contingencies are needed*

[1]TNX-1800 is at the pre-IND stage of development

# Why Use a Horsepox Platform for a Vaccine?



## Horsepox can be engineered to express foreign genes

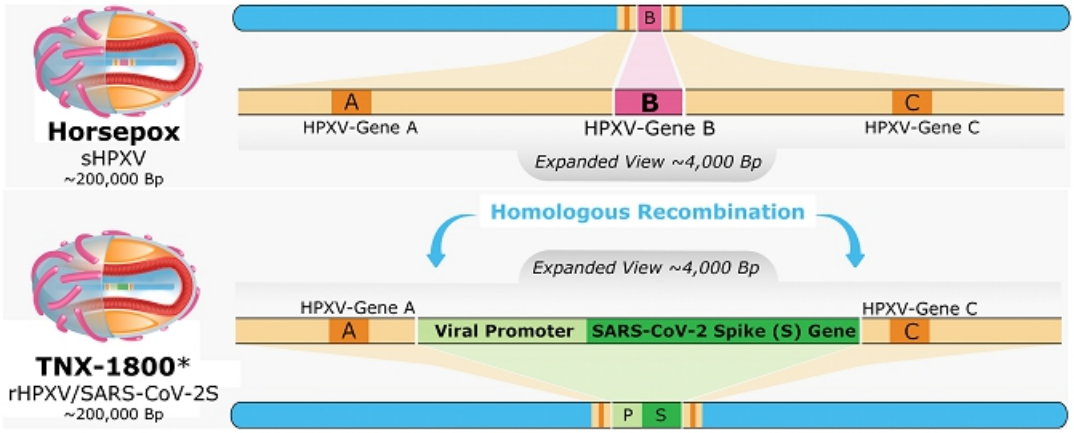
- Lack of persistence or genomic integration in the host
- Strong immunogenicity as a vaccine
- Readily manufacture at scale
- Live, replicating vaccine – direct antigen presentation

## Potential advantages of horsepox over vaccinia

- Maintains strong immunogenicity with potentially improved tolerability
- Relative to non-replicating vaccinia, horsepox's replication in human cells provides direct antigen presentation by Class I Major Histocompatibility Complex (MHC) Antigens
- Horsepox may behave differently than vaccinia as a vector, in part because of its different repertoire of genes that modulate immune responses and host range

# TNX-1800 is Based on a Horsepox Virus (HPXV) Vector Designed to Express SARS-CoV-2 S Protein

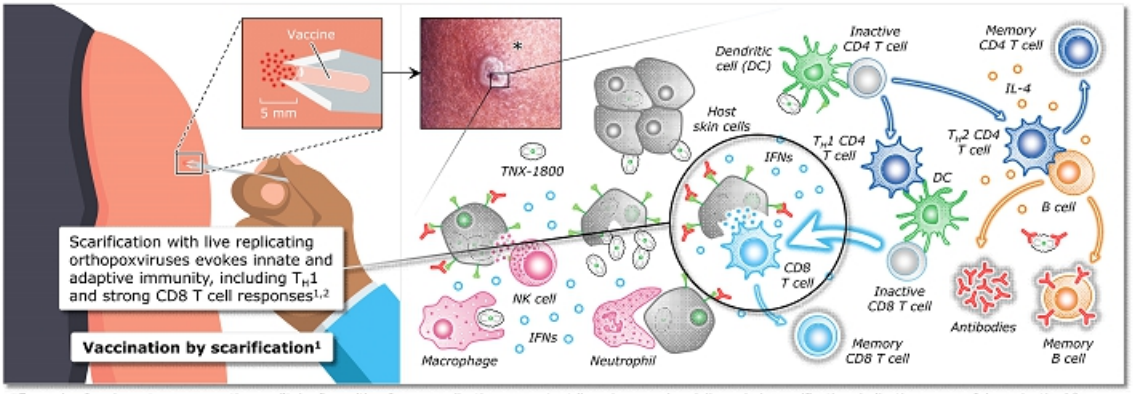





*TNX-1800 is at the pre-IND stage of development

# TNX-1800 is Designed to Induce Robust $T_H1$ Cellular Immunity






*Example of major cutaneous reaction, or "take," resulting from a replication-competent live-virus vaccine delivered via scarification, indicating successful vaccination[1,3]

1.Fulginiti VA, et al. *Clin Infect Dis.* 2003;37(2):241-250.
2.Liu L, et al. *Nature Med.* 2010;16(2):224-228.
3.Centers for Disease Control and Prevention. Accessed April 15, 2020. https://phil.cdc.gov/Details.aspx?pid=3276

# TNX-1800 Development Status



Southern Research will address two key questions:

1. Will vaccination of animals elicit an immune response to the S protein?
   - 4th Quarter 2020 –Small animal response expected[1]
2. Will immune response protect non-human primates against a challenge with SARS-CoV-2 virus?
   - 4th Quarter 2020 – Primate testing results expected[1]

Manufacturing development for GMP virus initiated

- Clinical development will require manufacturing for clinical supplies

[1] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

# Overview of TNX-102 SL*



Protectic® proprietary formulation of cyclobenzaprine that supports sublingual administration

**◇ Scientific Rationale for Protectic® Formulation ◇**

- Engenders unique pharmacokinetic and pharmacodynamic properties that emphasize sleep properties of cyclobenzaprine while minimizing undesirable properties
- Potential therapeutic value in a constellation of disorders where sleep disturbances are:
  - Co-morbid
  - Involved in the onset, progression and severity of the disease

*TNX-102 SL is in clinical stage of development and not approved for any indication

# TNX-102 SL: Differentiation from Oral Formulations



| FEATURE | BENEFIT | ADVANTAGE |
|---|---|---|
| Cyclobenzaprine | 40+ years as oral medication | Established safety record |
| Formulation: Protectic® | Allows submucosal absorption | Not achievable with oral formulation |
| Administration: sublingual | Bypasses gut | Avoids first-pass metabolism; reduced formation of "activating" metabolite |
| Pharmcaokinetic profile | Rapid absorption (peak at ~4 hours, low trough levels 8-24 hours) | Desired profile for nighttime action |
| Dose: low (2.8 to 5.6 mg) | Recruitment of high affinity receptors (5-$HT_{2A}$, $\alpha_1$, $H_1$) | Complimentary trimodal mechanism of action with less risk of off-target interference |

# TNX-102 SL: Results from Completed Fibromyalgia (FM) Trials



***Completed Trials in FM:***
- Phase 2 (F202 BESTFIT) – 205 patients randomized
- Phase 3 (F301 AFFIRM) – 519 patients randomized

***Topline Efficacy Results:***
- Studies did not achieve statistical significance in the primary efficacy endpoint

***More In-Depth Results:***
- Both studies showed efficacy signals justifying continued development in FM

***Safety:***
- Well tolerated; side effects consistent with known side effects of cyclobenzaprine

# TNX-102 SL 2.8 mg: Efficacy Signal in Completed FM Trials



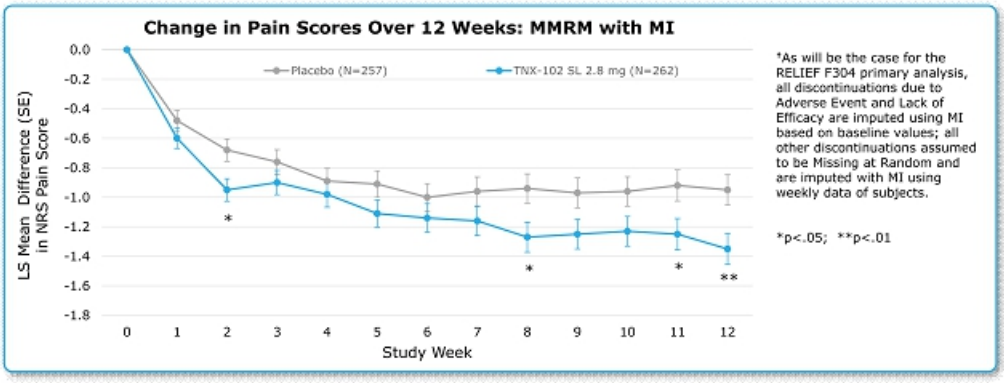
| | | Phase 2b F202 (BESTFIT)<br>*Dose: 2.8 mg* | Phase 3 F301 (AFFIRM)<br>*Dose: 2.8 mg* |
|---|---|---|---|
| **Primary Endpoint:**<br>Pain Relief at Week 12 | Pre-specified pain endpoint | Change in daily pain score (ANCOVA with JTC/MI*)<br>**Trend: p=0.172** | Responder analysis 30% pain reduction (Logistic regression)<br>**Trend: p=0.095** |
| | Post hoc analysis | Responder analysis ≥30% pain reduction (Logistic Regression)<br>**p=0.033** | • Imbalance in missing data and individuals with missing data treated as 'non-responder'<br>• Current FDA statistical guidance on handling missing data: analysis with MMRM with MI*<br>**p=0.005** |
| **Key Secondary Endpoints:**<br>Global improvement or improvement in symptoms and function | Patient Global Impression of Change (PGIC) | **p=0.025** | **p=0.038** |
| | Fibromyalgia Impact Questionnaire-Revised (FIQ-R) total score | **p=0.015 (ANCOVA)** | **P<0.001** |
| | PROMIS Sleep Disturbance instrument | **p=0.004 (ANCOVA)** | **P<0.001** |
| | FIQ-R Pain Item | **p=0.004** | **P<0.001** |

*MI=multiple imputation; JTC = jumpt to control; MMRM = Multiple measures repeated models

# Results from F301 (AFFIRM) Using Current FDA Statistical Guidance on Handling of Missing Data



- A retrospective analysis conducted using Mean Pain Analysis, MMRM with MI† demonstrated a significant effect on pain, even though the dose was 2.8 mg

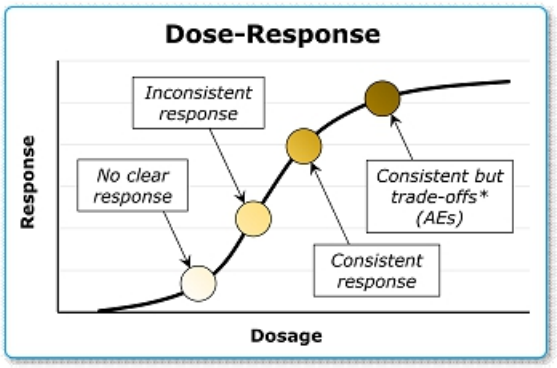


# Where Are We on the Dose-Response Curve?



**Basic Pharmacology**

- Dose can make the difference in the strength of the response




*Trade off's are increases in adverse events, side-effects and drug-drug interactions

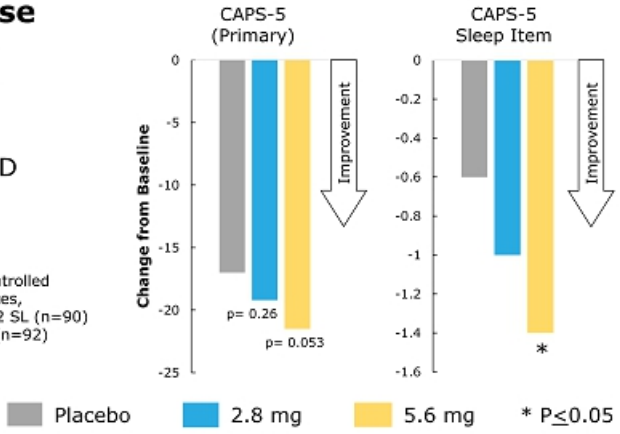
# Dose Response from Phase 2 PTSD Study*



## Consistent Dose-response Across Primary and Key Secondary Endpoints at Week 12

- Clinician Administered PTSD Scale for DSM-5 (CAP-5)

* Phase 2 study (AtEase), a randomized, placebo-controlled study of 231 patients with PTSD at 25 U.S. clinical sites, receiving a sublingual dose of either 2.8 mg TNX-102 SL (n=90) or 5.6 mg TNX-102 SL (n=49) compared to placebo (n=92)

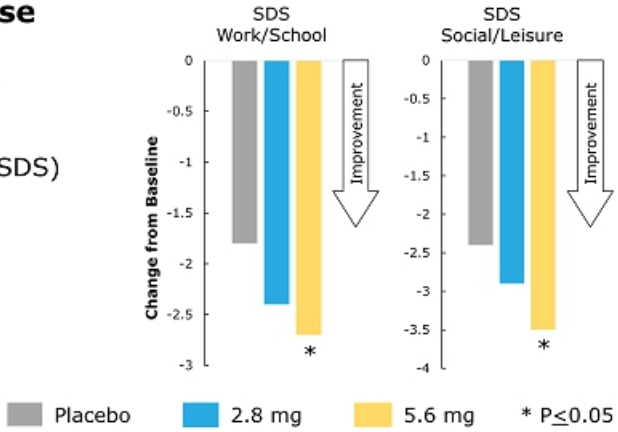


# Dose Response from Phase 2 PTSD Study



## Consistent Dose-response Across Primary and Key Secondary Endpoints at Week 12

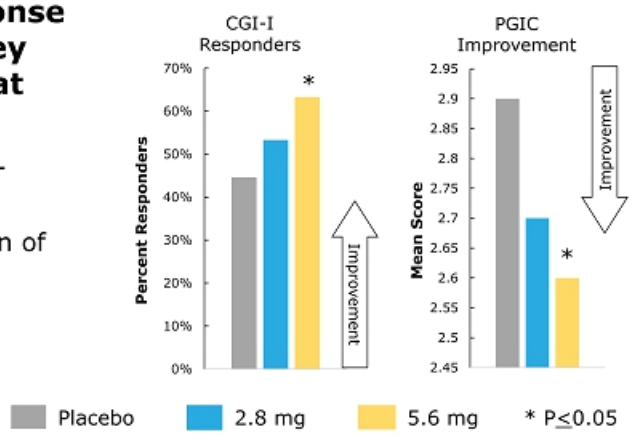
- Sheehan Disability Score (SDS)



# Dose Response from Phase 2 PTSD Study



- **Consistent Dose-response Across Primary and Key Secondary Endpoints at Week 12**
  - Clinical Global Impression-Improvement (CGI-I)
  - Patients' Global Impression of Change (PGIC)



# Effect of Dose on Adverse Events (AEs) in the P201/AtEase and P301/HONOR PTSD Studies



**Dose-related AEs:**

- AE profiles are comparable between FM and PTSD studies at 2.8 mg
- No serious and unexpected AEs in PTSD at either 2.8 or 5.6 mg doses
- No unique systemic AEs observed for 5.6 mg dose (but generally, a modest increase in frequency)
- Severity and incidence of oral hypoesthesia (oral numbness) are not dose related

| | | P201 | | | P301 | |
|---|---|---|---|---|---|---|
| | | Placebo (N=94) | 2.8 mg (N=93) | 5.6 mg (N=50) | Placebo (N=134) | 5.6 mg (N=134) |
| **Systemic Adverse Event * #** | 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 Reaction * #** | Hypoaesthesia oral | 2.1% | 38.7% | 36.0% | 1.5% | 37.3% |
| | Paresthesia 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%

# TNX-102 SL:
# On-going Phase 3 Study in FM (F304/RELIEF)



- **Key changes to protocol from previous Phase 3 trial in FM**
  - Exclusive use of higher dose of 5.6 mg (2 x 2.8 mg)
  - Primary endpoint: mean pain improvement
  - Analysis: MMRM with MI
- **Clear guidance from FDA to advance fibromyalgia program using higher dose (5.6 mg)**
- **Long-term safety of 5.6 mg dose from PTSD studies expected to support FM NDA**
- **Study is progressing on schedule**
  - First patient enrolled in the new Phase 3 RELIEF study in December 2019
  - Achieved 50% enrollment in April 2020
  - Optional interim analysis results expected September 2020; topline results in 4Q 2020 if no delays
  - Potential pivotal efficacy study to support NDA approval

# Tonix Pharmaceuticals: Lead Programs[1]



- **TNX-102 SL for fibromyalgia (FM)**
  - Phase 3 clinical development – RELIEF study enrolling
  - Sublingual cyclobenzaprine tablets at higher dose of 5.6 mg
  - Milestones:
    - September 2020 – Optional interim analysis results expected[5]
    - 4th Quarter 2020 - Topline data expected[5]
- **TNX-1800 potential vaccine for COVID-19[2,3]**
  - Preclinical stage
  - Live virus vaccine designed on our horsepox vaccine platform[4] to express the SARS-CoV-2 Spike (S) protein
  - Milestones:
    - 4th Quarter 2020 –Small animal response expected[5]
    - 4th Quarter 2020 – Primate testing results expected[5]

[1] Experimental new medicines and biologics, not approved for any indication
[2] Collaboration with Southern Research
[3] COVID-19 = Coronavirus disease 2019
[4] TNX-801 is unmodified horsepox virus, which is in development as a vaccine to protect against smallpox and monkeypox
[5] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

# 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
- IND application submitted in 2Q 2020 to support a Phase 2 POC Study[3]

[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
[3] We cannot predict whether the global COVID-19 pandemic will impact the timing of this milestone.

# 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 a bacterium (*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]**

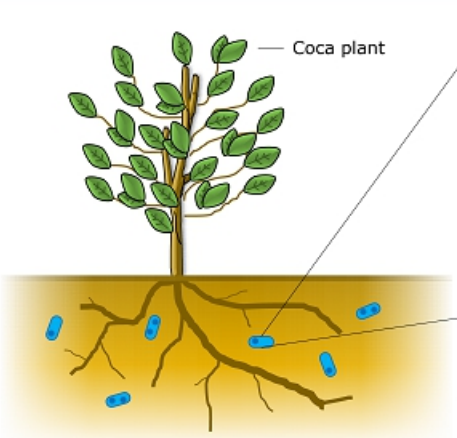
- Volunteer cocaine abusers received cocaine 50 mg *i.v.* infusion over 10 minutes
- TNX-1300 given one minute after completion of cocaine infusion
  - Rapidly reversed the physiologic effects of cocaine; cocaine plasma exposures dropped by 90% within two minutes
  - Well tolerated with the most frequently 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.*

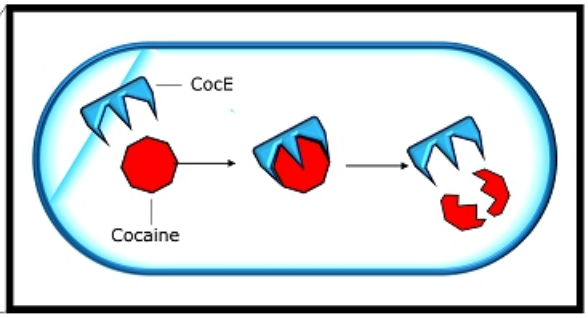
[1] Gao D et al, Mol Pharmacol. 2009. 75(2):318-23.
[2] Bresler MM et al, Appl Environ Microbiol. 2000. 66(3):904-8.
[3] Nasser AF et al, J Addict Dis, 2014;33(4):289-302.

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






Cocaine is derived from the coca plant[1]



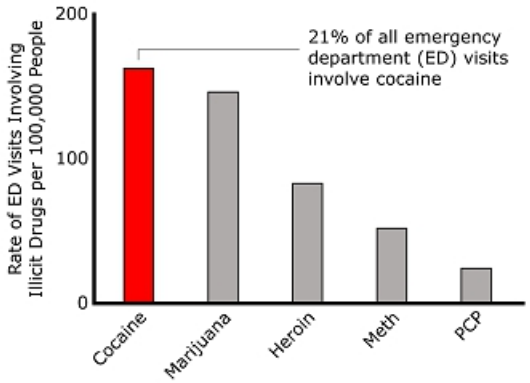

*Rhodococcus* bacteria living in the roots of the coca plant use CocE to metabolize cocaine[1]

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

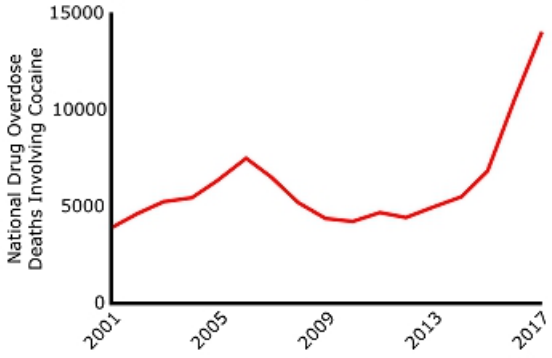
[1]Narasimhan D et al. *Future Med Chem*. 2012.

# 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[1] (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 2020[2]
- Plan for Phase 2 study in depression in 2021[2]

## 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)

[1] TNX-601 CR (tianeptine oxalate controlled release tablets) is in the pre-IND stage in the U.S. and has not been approved for any indication.
[2] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones.

# 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**

- Tianeptine 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

# Psychiatry, Immunology and Oncology Preclinical Pipeline[1]



| Pipeline Product | Indication(s) | Category |
|---|---|---|
| **TNX-1600**<br>Triple reuptake inhibitor[2] | **Daytime treatment for Depression, PTSD and ADHD[3]** | **Psychiatry** |
| **TNX-1500**<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** |

[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) – licensed from Wayne State University
[3] ADHD = attention deficit hyperactivity disorder
[4] Recombinant Trefoil Family Factor 2 – licensed from Columbia University

# Pipeline Summary – by Select Therapeutic Areas



## Pain

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

## Psychiatry

- **TNX-102 SL – (sublingual cyclobenzaprine) for PTSD**
  Phase 3/RECOVERY
- **TNX-102 SL – (sublingual cyclobenzaprine) for agitation in Alzheimer's**
  Phase 2-ready
  *FDA Fast Track designation*
- **TNX-601 CR – (tianeptine oxalate) for depression and PTSD**
  Phase 2-ready
- **TNX-1600 – (triple reuptake inhibitor) for PTSD, Depression and ADHD**
  Preclinical

## Addiction Medicine

- **TNX-1300 – (cocaine esterase) for cocaine intoxication**
  Phase 2
  *FDA Breakthrough Therapy designation*
- **TNX-102 SL – (sublingual cyclobenzaprine) for alcohol use disorder**
  Submitted IND application for a Phase 2 Proof of Concept study

## Neurology

- **TNX-1900 – (intranasal oxytocin) for migraine**
  Clinical – pre-IND stage

# Pipeline Summary – by Select Therapeutic Areas (continued)



**Public Health**

- **TNX-1800 (live modified horsepox vaccine) for preventing COVID-19**
  Preclinical

**Biodefense**

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

# Milestones – Recently Completed and Upcoming[1]



| | |
|---|---|
| ☑ 4th Quarter 2019 | Confirmed once-daily dosing for TNX-601 CR in PK study |
| ☑ 4th Quarter 2019 | Enrolled first patient in TNX-102 SL Phase 3 F304/RELIEF study for management of fibromyalgia |
| ☑ February 2020 | Interim analysis results reported from TNX-102 SL Phase 3 P302/RECOVERY study in PTSD |
| ☑ 2nd Quarter 2020 | Submitted IND application for TNX-102 SL to support Phase 2 POC study in AUD |
| ❑ **September 2020 expected** | **Interim analysis results from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia** |
| ❑ **4th Quarter 2020** | **Topline data from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia expected** |
| ❑ **4th Quarter 2020** | **Expect small animal data from TNX-1800 in COVID-19 model** |
| ❑ **4th Quarter 2020** | **Expect primate data from TNX-1800 in COVID-19 model** |
| ❑ **1st Half 2021** | **Expect to initiate Phase 2 study of TNX-601 CR in depression** |

[1] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones.

# Management Team



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TARGENT X | Fusilev (levoleucovorin) for injection | vela

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TONIX PHARMACEUTICALS

# *Thank You!*