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): September 16, 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 presentation 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 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Corporate Presentation by the Company for September 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: September 16, 2020

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

Exhibit 99.01

Investor Presentation
NASDAQ:TNXP

TONIX PHARMACEUTICALS

September 2020

Version P0248 9-16-20 (Doc 0714)

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.

Tonix Pharmaceuticals

- **Clinical-stage biopharmaceutical company**
  - Committed to discovering and developing innovative and proprietary new therapeutics
- **Focus on developing small molecules and biologics**
  - **Immunology**
    - Vaccines, immunosuppression, oncology, autoimmune diseases
  - **Central Nervous System (CNS)**
    - Pain, neurology, psychiatry, addiction

Our Pipeline – Immunology & Biodefense Portfolio

	CANDIDATES	INDICATION	STATUS
Immunology Portfolio	**TNX-1800**	**Covid-19 vaccine – Prioritized Program[1]**	**Preclinical**
	TNX-1810, TNX-1820, TNX-1830	Covid-19 vaccine[1]	Preclinical
	TNX-2300	Covid-19 vaccine[2]	Preclinical
	TNX-2600	Covid-19 vaccine[2]	Preclinical
	TNX-801	Smallpox and monkeypox preventing vaccine[3]	Preclinical
	TNX-1200	Smallpox and monkeypox preventing vaccine[4]	Preclinical
	TNX-1500	Organ Transplant Rejection/Autoimmune Conditions[5]	Preclinical
	TNX-1700	Gastric and pancreatic cancers[6]	Preclinical
	TNX-701	Radioprotection	Preclinical

[1]Live attenuated vaccine based on horsepox virus vector
[2]Live attenuated vaccine based on bovine parainfluenza virus vector; option for license with Kansas State University
[3]Live attenuated vaccine based on horsepox virus
[4]Live vaccine based on vaccinia virus
[5]anti-CD40L humanized monoclonal antibody
[6]recombinant trefoil factor 2 (TFF2) based protein; licensed from Columbia University

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	Phase 2 ready
	TNX-1300[2]	Cocaine Intoxication / Overdose	Phase 2
	TNX-601 CR[3]	Depression, PTSD, Neurocognitive Dysfunction from Corticosteroids	Phase 1
	TNX-1600[4]	Depression, PTSD and ADHD	Preclinical
	TNX-1900[5]	Migraine and craniofacial pain	Clinical – pre-IND[6]

[1]TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.
[2]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; licensed from Columbia University.
[3]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.
[4]Assets purchased from TRImaran Pharma; license agreement with Wayne State University
[5]Assets purchased from Trigemina; license agreement with Stanford University
[6]Two ex-U.S. Phase 2 trials have been completed using TNX-1900

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

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

- **Manufacturing agreement with FUJIFILM Diosynth**
  - Development for Good Manufacturing Practice (GMP) manufacturing for human trials
  - GMP clinical supply expected to be ready for human trials in 2021

- **Key Milestones:**
  - Results from small animals and non-human primate studies, including challenge with SARS-CoV-2, due 4Q 2020
  - Phase 1 safety study in humans expected to be initiated in 2021

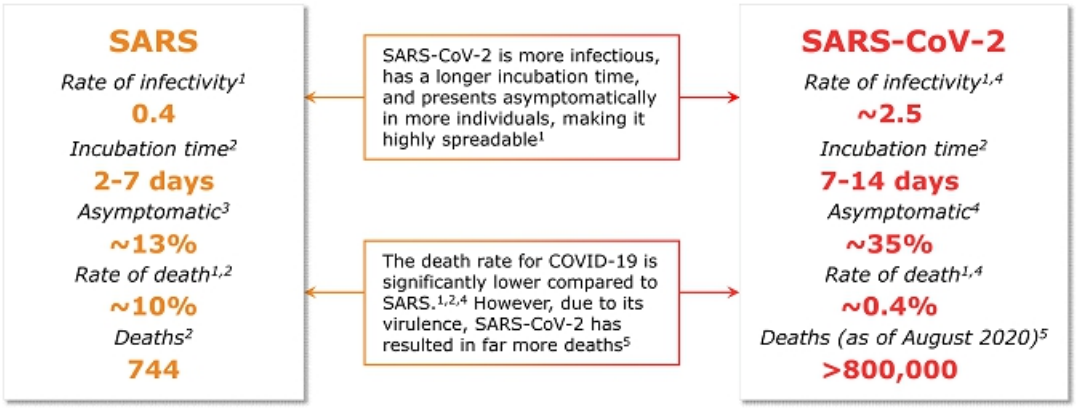
[1] TNX-1800 is at the pre-IND stage of development
[2] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

COVID-19 Vaccine Landscape

- **We expect more than one vaccine will be approved by FDA**
  - Different vaccines for different individuals
- **More than 150 vaccines in development**
  - Diversity of approaches is important since protective immunity is not yet understood
  - Technologies range from never tested before to 220 years old
  - Uncertainty exists around efficacy, durability and importantly, safety
- **Live attenuated vector systems in development include:**
  - Tonix (horsepox), Tonix (bovine parainfluenza), Merck (measles[1]- and VSV[2]-based), Zydus Cadila (measles-based)

[1]Measles-based vaccine, acquisition of Themis, collaboration with Institute Pasteur
[2]VSV = vesicular stomatitis virus; collaboration with IAVI = International AIDS Vaccine Initiative

Unique Challenges of SARS-CoV-2



1. Ceccarelli M, et al. *Eur Rev Med Pharmacol Sci.* 2020;24:2781-2783.
2. Rabaan AA, et al. *Le Infezioni in Medicina.* 2020;28(2):174-184.
3. Wilder-Smith A, et al. *Emerg Infect Dis.* 2020;11(7):1142-1145.
4. Centers for Disease Control and Prevention. Accessed June 9, 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html
5. Johns Hopkins University. Accessed June 11, 2020. https://coronavirus.jhu.edu/map.html

Why Use a Horsepox Platform for a Vaccine?

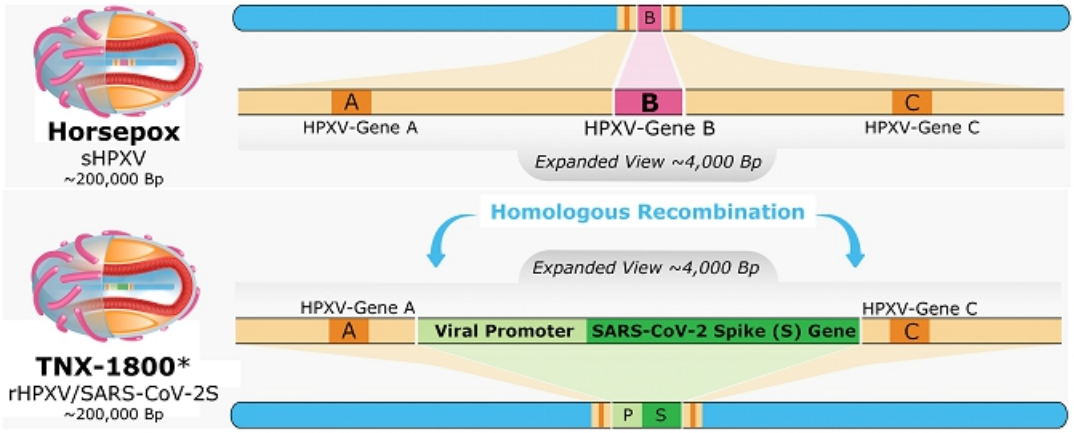
Horsepox can be engineered to express foreign genes

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

Potential advantages of horsepox over vaccinia

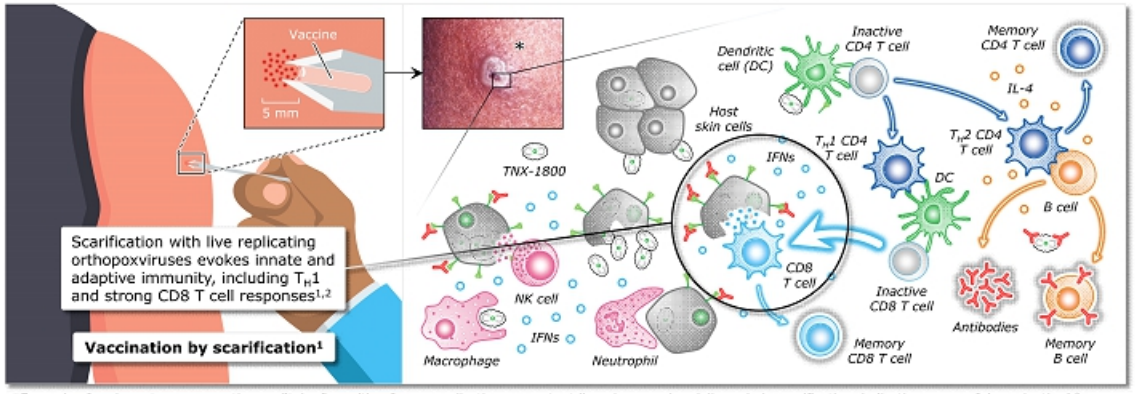
- Maintains strong immunogenicity with potentially improved tolerability
- Relative to non-replicating vaccinia, horsepox's replication in human cells provides direct antigen presentation, which is expected to trigger a T cell immune response, by Class I Major Histocompatibility Complex (MHC) Antigens
- 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

Contrasting T cell and Antibody Immunity

- **T cell immunity**
  - ***Durable or long-lived (many years)***
  - Recognize fragments of pathogens on the surfaces of infected cells
  - Cannot recognize pathogens directly
  - Potential to clear viral infections (by killing infected cells)
  - Potential to block forward transmission (contagion) by infected people

- **Antibody immunity**
  - ***Temporary or short-lived (typically 3-6 months)***
  - Recognize pathogens directly
  - Potential to block viral entry (by recognizing pathogens)
  - Can only recognize virally infected cells that express viral surface proteins

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

2nd SARS-CoV-2 Vaccine Platform: Bovine Parainfluenza (BPI) Virus

Collaboration with Kansas State University to develop a vaccine candidate for the prevention of COVID-19

- Utilizes a novel live attenuated vaccine vector platform and the CD40-ligand to stimulate T cell immunity
- TNX-2300[1] and TNX-2600[1] drive expression of CoV-2 spike and CD40-L

Live attenuated vaccines based on bovine parainfluenza virus[2-6]

- Previously has been shown to be an effective antigen delivery vector in humans, notably well tolerated in infants and children
- Vector is well suited for mucosal immunization using a nasal atomizer, but it can also be delivered parenterally

[1]Pre-IND stage of development
[2]Halle, AA *et al. J Gen. Virology* (2003) 84:2153–2162
[3]Halle, AA *et al. J Virology* (2000) 74 (24): 11626–11635
[4]Karron RA *et al. J Inf Dis* (1995) 171: 1107-14
[5]Karron RA *et al. Vaccine* (2012) 30: 3975– 3981
[6]Schmidt AC *et al. J Virology* (2001) 75(10): 4594–4603

Live, Attenuated Virus Vaccines for Other Infectious Diseases[1]

- **Long term, durable immunity**
  - Expected to stimulate T cells and provide years to decades of protection
- **Single administration, scalable manufacturing**
  - Low dose is amplified by replication, mRNA and protein synthesis at vaccination site
- **Block forward transmission (infectivity)**
  - Key to conferring herd immunity and protecting immunocompromised

[1]For example, the eradication of smallpox, containment of measles, mumps, and rubella

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
Pharmacokinetic 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}, α_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

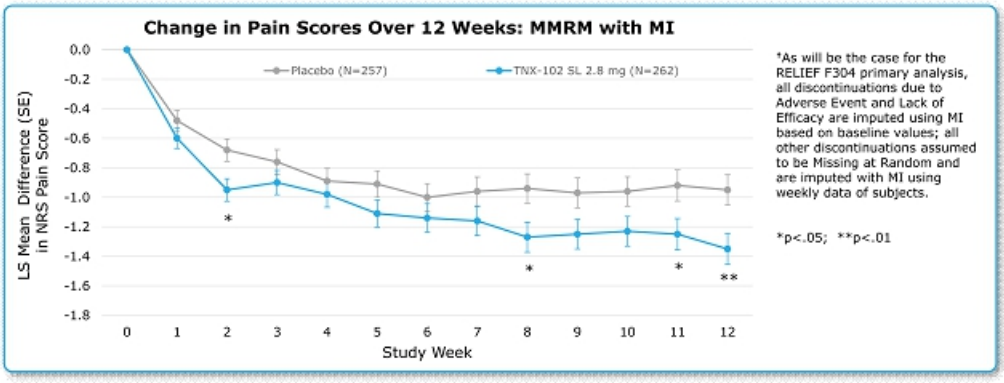
TNX-102 SL 2.8 mg: Efficacy Signal in Completed FM Trials

		Phase 2b F202 (BESTFIT) *Dose: 2.8 mg*	Phase 3 F301 (AFFIRM) *Dose: 2.8 mg*
Primary Endpoint: Pain Relief at Week 12	Pre-specified pain endpoint	Change in daily pain score (ANCOVA with JTC/MI*) **Trend: p=0.172**	Responder analysis ≥30% pain reduction (Logistic regression) **Trend: p=0.095**
	Post hoc analysis	Responder analysis ≥30% pain reduction (Logistic Regression) **p=0.033**	• Imbalance in missing data and individuals with missing data treated as 'non-responder' • Current FDA statistical guidance on handling missing data: analysis with MMRM with MI* **p=0.005**
Key Secondary Endpoints: 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 = jump to control; MMRM = Multiple measures repeated models

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

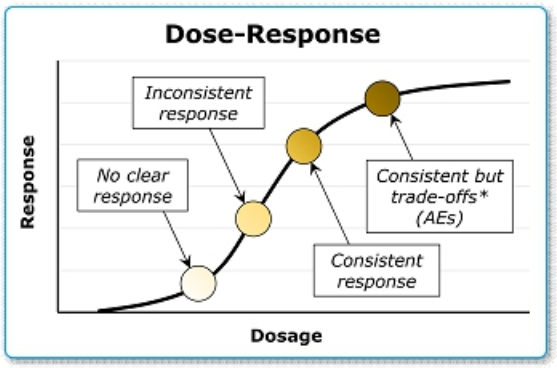
- A retrospective analysis conducted using Mean Pain Analysis, MMRM with MI† demonstrated a significant effect on pain, even though the dose was 2.8 mg



Where Are We on the Dose-Response Curve?

Basic Pharmacology

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

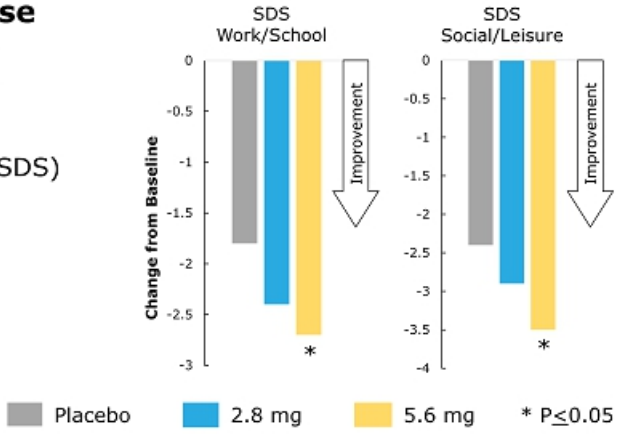


*Trade off's are increases in adverse events, side-effects and drug-drug interactions

Dose Response from Phase 2 PTSD Study

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

- Sheehan Disability Score (SDS)



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 5.6 mg for Fibromyalgia: Phase 3 F304/RELIEF Study

- **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 ahead of schedule**
  - First participant enrolled in the new Phase 3 RELIEF study in December 2019
  - Completed enrollment in July 2020
  - Interim analysis results expected September 2020; topline results expected 4Q 2020 if no delays
  - Potential pivotal efficacy study to support NDA approval

TNX-102 SL 5.6 mg for Fibromyalgia: Phase 3 F304/RELIEF Study – Enrollment Completed Ahead of Schedule

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia in approximately 40 U.S. sites (N=470)
- Adaptive Design: one 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 September 2020

Topline results expected 4Q 2020

Potential pivotal efficacy study to support NDA approval

[1]Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

TNX-102 SL 5.6 mg for Fibromyalgia: Phase 3 F306/RALLY Study – Enrollment Initiated

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia in approximately 40 U.S. sites (N=470)

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

Potential for topline results in second half 2021

Potential pivotal efficacy study to support NDA approval

[1]Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

Approved Fibromyalgia Pharmacotherapies

Pfizer

- Drug: Lyrica® or pregabalin (U.S. patent expired in 2018)
- Approved: 2004
- Mechanism: modulates nerve impulses involved in the transmission of pain through selective binding to the alpha2-delta protein of the voltage-gated calcium channels in CNS tissues
- Peak Sales: Approximately $5 billion (including all approved indications)

Lilly

- Drug: Cymbalta® or duloxetine (U.S. patent expired 2014)
- Approved: 2004
- Mechanism: serotonin and norepinephrine reuptake inhibitor (SNRI)
- Peak Sales: Approximately $5 billion (including all approved indications)

Abbvie (developed by Forest Laboratories)

- Drug: Savella® or milnacipran (patent expires 2021)
- Approved: 2009
- Mechanism: serotonin and norepinephrine reuptake inhibitor (SNRI)
- Peak Sales: $400 million (fibromyalgia indication only)

Other Fibromyalgia Pharmacotherapies in Development in the U.S.

Axsome Therapeutics - AXS-14

- Drug: esreboxetine
- Mechanism: Selective norepinephrine reuptake inhibitor
- Developmental Stage: At least mid-Phase 3 (Phase 2 and Phase 3 trial positive*)

Aptinyx - NYX-2925

- Drug: ((2S, 3R)-3-hydroxy-2-((R)-5-isobutyryl-1-oxo-2,5-diazaspiro(3.4)octan-2-yl)butanamide)
- Mechanism: NMDA receptor modulator
- Developmental Stage: Phase 2 study is "active, not recruiting"

Teva - Ajovy®

- Drug: fremanezumab
- Anti-CGRP antibody
- Developmental Stage: Phase 2 proof-of-concept study "recruiting"

*licensed from Pfizer, Jan 2020

Highlights of Lead Programs[1]

- **TNX-1800 potential vaccine for COVID-19[2]**
  - 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 results expected[4]
    - 4th Quarter 2020 – Primate testing results expected[4]
    - 2021 – Initiation of Phase 1 human safety study expected[4]
- **TNX-102 SL for fibromyalgia (FM)**
  - Phase 3 clinical development – RELIEF study fully enrolled
  - Sublingual cyclobenzaprine tablets at higher dose of 5.6 mg
  - Milestones:
    - September 2020 – Enrollment initiated in new Phase 3 RALLY study
    - September 2020 – Interim analysis results expected from RELIEF study[4]
    - 4th Quarter 2020 - Topline data expected from RELIEF study[4]

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

Opportunities to Expand TNX-102 SL 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]Rosa, 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

FDA cleared Tonix's IND application for initiation of a Phase 2 proof-of-concept study

- Program expected to qualify for 505(b)(2) pathway for FDA approval

[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 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

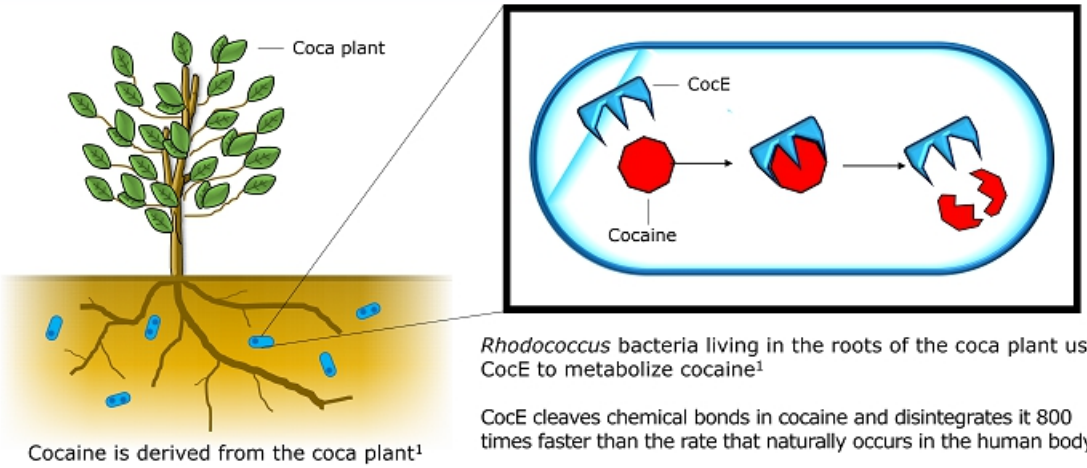
Phase 2 study completed by Rickett Benckiser (TNX-1300 was formerly RBP-8000)[3]

- 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.

Psychiatry, Immunology and Oncology Preclinical Pipeline[1]

Pipeline Product	Indication(s)	Category
TNX-1600 Triple reuptake inhibitor[2]	**Daytime treatment for Depression, PTSD and ADHD[3]**	**Psychiatry**
TNX-1500 Anti-CD154 monoclonal antibody	**Prevention and treatment of organ transplant rejection** **Treatment of autoimmune conditions**	**Transplant** **Autoimmunity**
TNX-1700 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
- **TNX-1900 (intranasal oxytocin) for craniofacial pain**
  Clinical – pre-IND stage

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**
  Phase 2 ready

Neurology

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

Pipeline Summary – by Select Therapeutic Areas (continued)

Public Health

- **TNX-1800, TNX-1810, TNX-1820 & TNX-1830 (live modified horsepox vaccine) for preventing COVID-19**
  Preclinical
- **TNX-2300 and TNX-2600 (live bovine parainfluenza 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

Tonix Financial Overview

NASDAQ: TNXP	
Cash and cash equivalents, June 30, 2020	$55.0 million
Net proceeds from common stock offering - July 15, 2020	$9.6 million
Warrant exercises subsequent to June 30, 2020	$2.4 million

Milestones – Recently Completed and Upcoming[1]

☑ 3rd Quarter 2020	IND application cleared by FDA for initiation of Phase 2 POC study of TNX-102 SL for AUD
☑ September 2020 for the	Enrollment initiated in second potentially pivotal Phase 3 trial, the F306/RALLY study, of TNX-102 SL management of fibromyalgia
❑ **September 2020**	**Interim analysis results from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia expected**
❑ **4th Quarter 2020**	**Topline data from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia expected**
❑ **4th Quarter 2020**	**Small animal data from TNX-1800 in COVID-19 model expected**
❑ **4th Quarter 2020**	**Primate data from TNX-1800 in COVID-19 model expected**
❑ **2021**	**Initiation of Phase 1 safety study of TNX-1800 for COVID-19 expected**
❑ **Second Half 2021**	**Topline data from TNX-102 SL Phase 3 F306/RALLY study in fibromyalgia expected**

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

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 Silicon Valley Bank | American Capital

TONIX PHARMACEUTICALS

Thank You!