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): June 5, 2020

TONIX PHARMACEUTICALS HOLDING CORP.
(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

509 Madison Avenue, Suite 306, 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 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") will present certain information regarding its product candidates (the "Presentation") at the 2020 BIO International Convention being held June 8, 2020 to June 12, 2020. The Presentation, which may contain nonpublic information, is filed as Exhibit 99.01 hereto and incorporated herein by reference.

The Company updated its investor presentation (the "Corporate 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. The Corporate Presentation, which may contain nonpublic information, is filed as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibits 99.01 and 99.02 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 it 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.

Forward- Looking Statements

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

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

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description.**
99.01	Presentation by the Company.
99.02	Corporate Presentation by the Company for June 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: June 5, 2020

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

Exhibit 99.01

Bio International - 2020
NASDAQ:TNXP

TONIX PHARMACEUTICALS

Seth Lederman, CEO
June 8-11, 2020

Version P0232 5-27-20 (Doc 0640)

Cautionary Note on Forward-Looking Statements

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

Tonix Pharmaceuticals

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

	CANDIDATES	INDICATION	STATUS
CNS Portfolio	TNX-102 SL	**Fibromyalgia (FM) - Lead Program**	**Phase 3 – ongoing**
		PTSD	Phase 3 – ongoing
		Agitation in Alzheimer's	Phase 2 ready
		Alcohol Use Disorder	Pre-IND
	TNX-1300	Cocaine Intoxication / Overdose	Phase 2
	TNX-601 CR	Major depression	Phase 1
		PTSD	Phase 1
		Neurocognitive Dysfunction from Corticosteroids	Phase 1
	TNX-1600	Depression, PTSD and ADHD	Preclinical
Immunology Portfolio	**TNX-1800**	**Covid-19 vaccine – Prioritized Program**	**Pre-clinical**
	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

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}, α_1, H_1)	Complimentary trimodal mechanism of action with less risk of off-target interference

TNX-102 SL:
Results from Completed 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

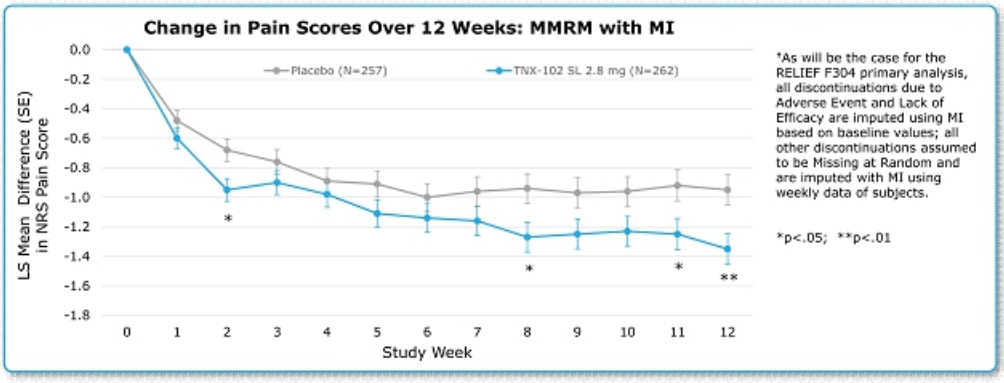
TNX-102 SL 2.8 mg: Efficacy Signal in Completed FM Trials

		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 = jumpt to control; MMRM = Multiple measures repeated models

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

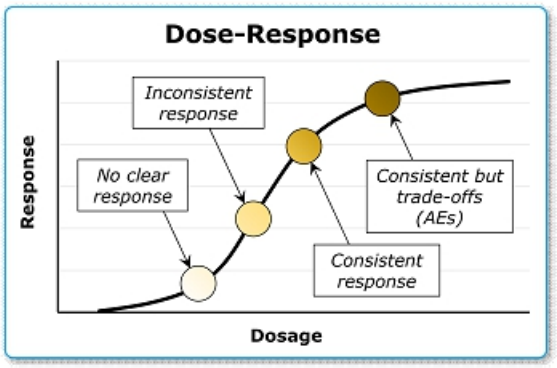
- A retrospective analysis conducted using Mean Pain Analysis, MMRM with MI† demonstrated a significant effect on pain, even though the dose was 2.8 mg



Where Are We on the Dose-Response Curve?

Basic Pharmacology

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



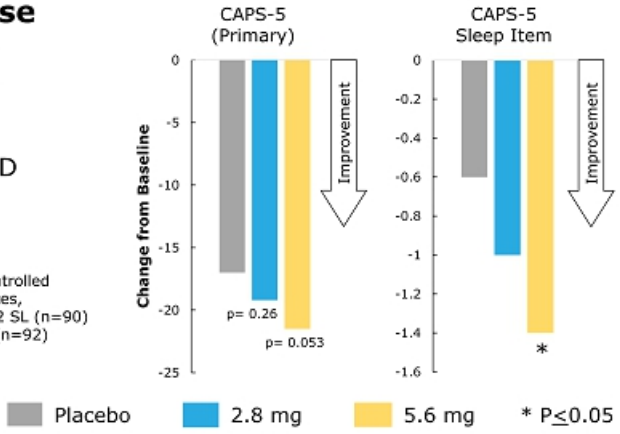
*Trade off's are increases in adverse events, side-effects and drug-drug interactions

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)

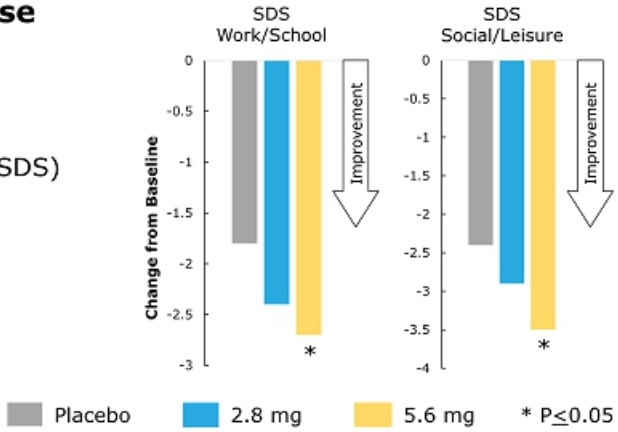
* Phase 2 study (AtEase), a randomized, placebo-controlled study of 231 patients with PTSD at 25 U.S. clinical sites, receiving a sublingual dose of either 2.8 mg TNX-102 SL (n=90) or 5.6 mg TNX-102 SL (n=49) compared to placebo (n=92)



Dose Response from Phase 2 PTSD Study

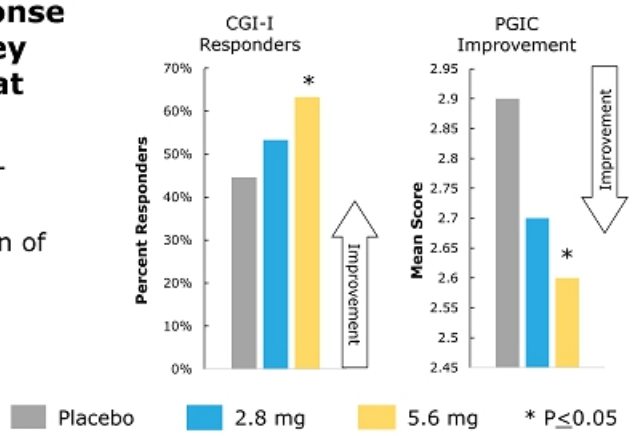
Consistent Dose-response Across Primary and Key Secondary Endpoints at Week 12

- 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)



Placebo 2.8 mg 5.6 mg * P≤0.05

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 1Q 2021 if no delays
  - Potential pivotal efficacy study to support NDA approval

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*

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

Why Use a Horsepox Platform for a Vaccine?

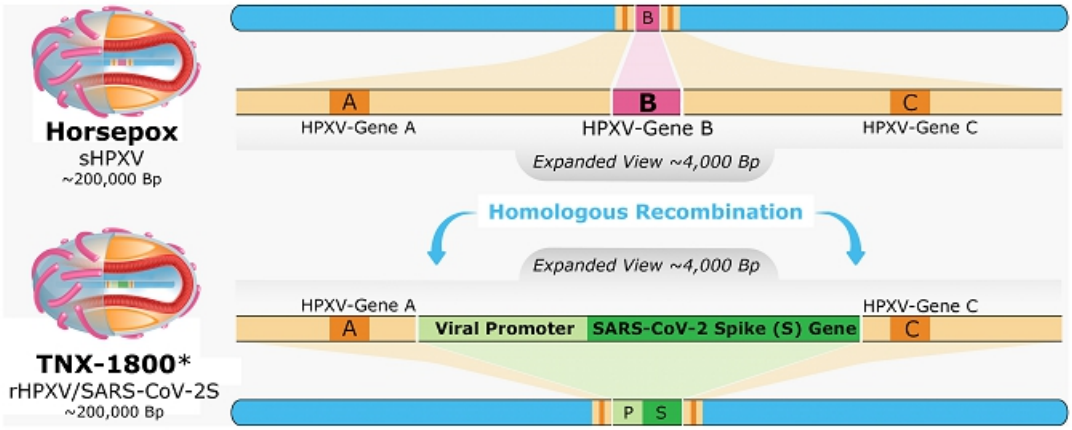
Horsepox can be engineered to express foreign genes

- 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 MHC
- Horsepox may behave differently 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



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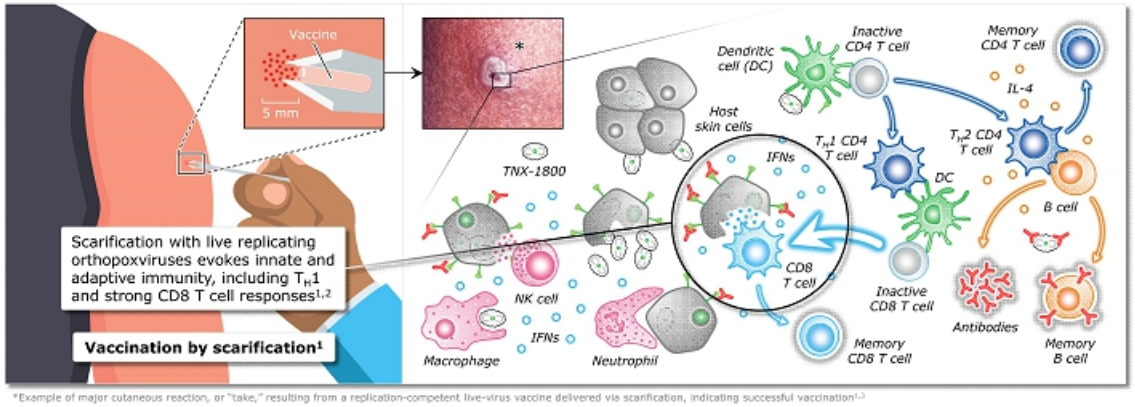
TNX-1800 is Designed to Induce Robust T_H1 Cellular Immunity



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

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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

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]
    - 1st Quarter 2021 - Topline data expected[5]
- **TNX-1800 potential vaccine for COVID-19[2,3]**
  - Pre-clinical 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

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!

Exhibit 99.02

Investor Presentation
NASDAQ:TNXP

TONIX PHARMACEUTICALS

June 2020

Version P0233 6-5-20 (Doc 0645)

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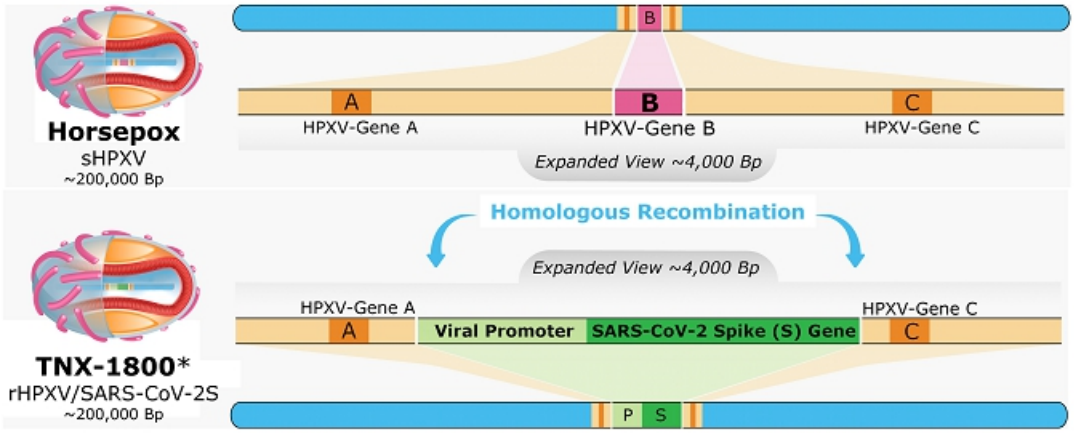

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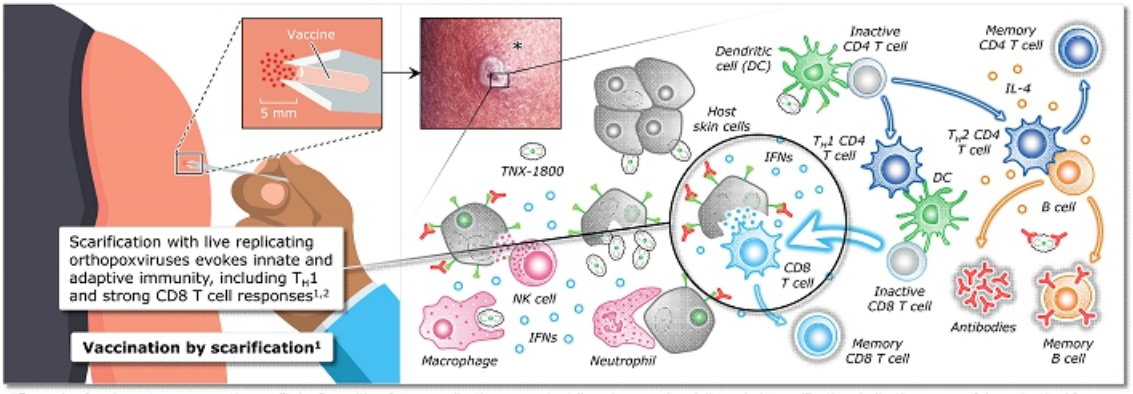

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TNX-102 SL: Differentiation from Oral Formulations

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}, α_1, H_1)	Complimentary trimodal mechanism of action with less risk of off-target interference

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More In-Depth Results:
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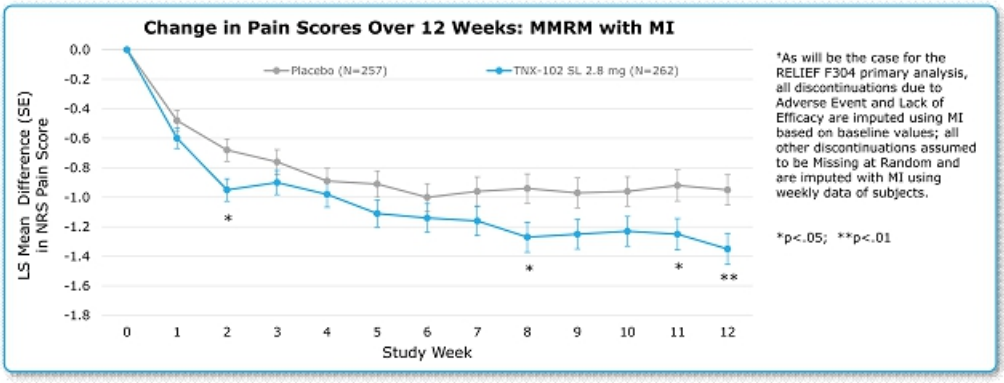
TNX-102 SL 2.8 mg: Efficacy Signal in Completed FM Trials

		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 = jumpt to control; MMRM = Multiple measures repeated models

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

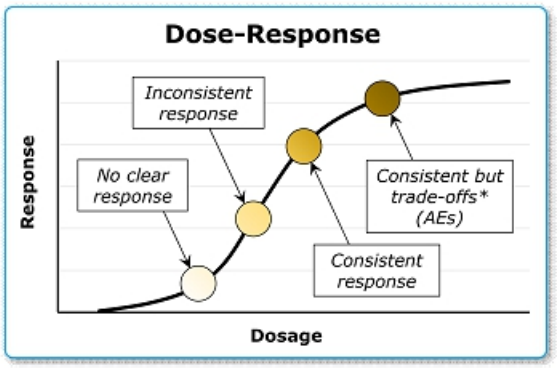
- A retrospective analysis conducted using Mean Pain Analysis, MMRM with MI† demonstrated a significant effect on pain, even though the dose was 2.8 mg



Where Are We on the Dose-Response Curve?

Basic Pharmacology

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



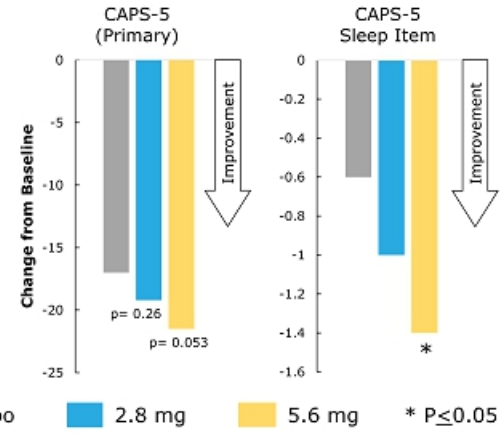
*Trade off's are increases in adverse events, side-effects and drug-drug interactions

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)

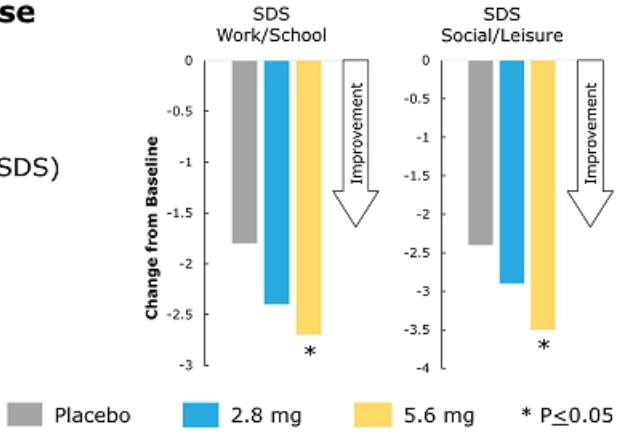


Placebo 2.8 mg 5.6 mg * P≤0.05

Dose Response from Phase 2 PTSD Study

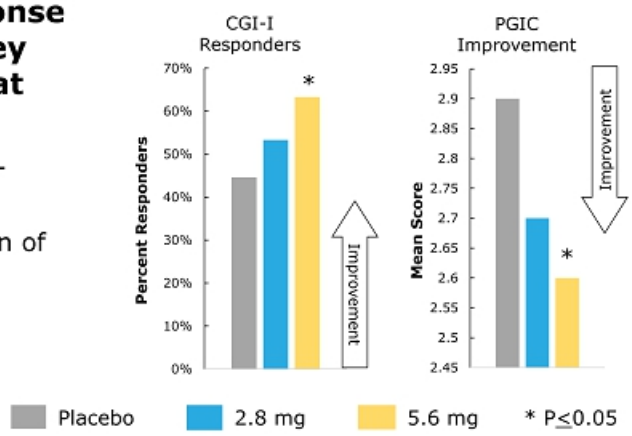
Consistent Dose-response Across Primary and Key Secondary Endpoints at Week 12

- 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)



Placebo 2.8 mg 5.6 mg * P≤0.05

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%

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]
    - 1st Quarter 2021 - 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

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 1Q 2021 if no delays
  - Potential pivotal efficacy study to support NDA approval

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]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

Pre-IND meeting with the FDA completed in October 2019

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

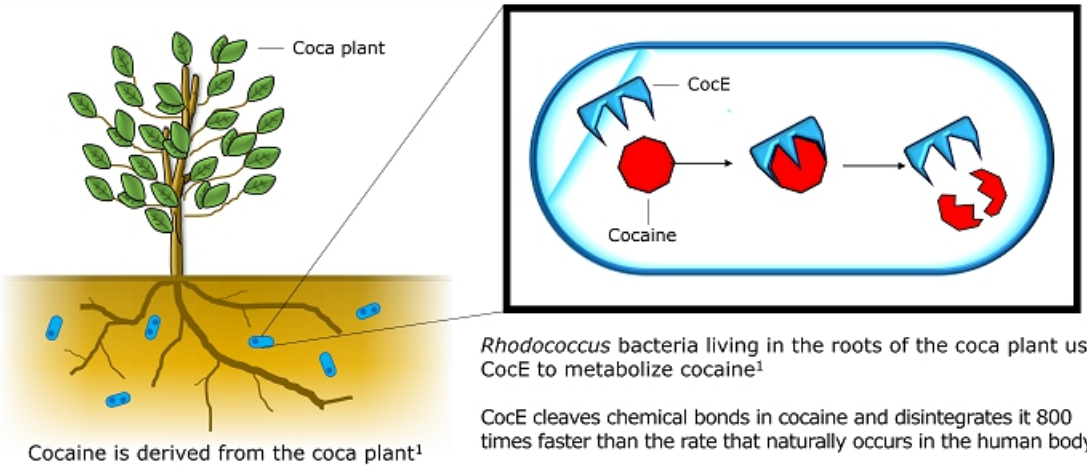
Phase 2 study completed by Rickett Benckiser (TNX-1300 was formerly RBP-8000)[3]

- 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]

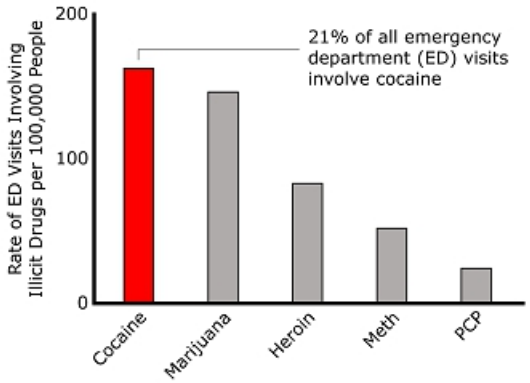
Rhodococcus bacteria living in the roots of the coca plant use CocE to metabolize cocaine[1]

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

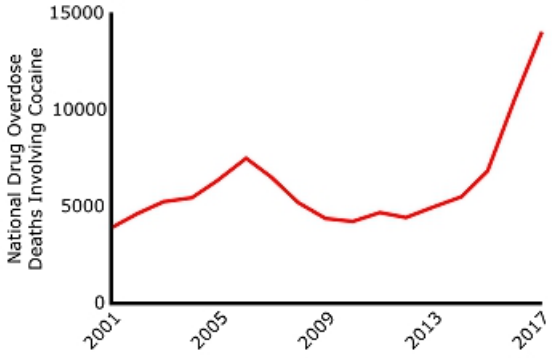
[1]Narasimhan D et al. *Future Med Chem*. 2012.

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 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

Public Health

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

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**
  FDA official meeting minutes confirmed plan to submit IND application for a Phase 2 Proof of Concept study

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**	**Expect to submit 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**	**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 Quarter 2021**	**Topline data from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia expected**
❑ **1st Half 2021**	**Expect to initiate Phase 2 study of TNX-601 CR in depression, ex-U.S.**

[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!