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): November 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.)**

26 Main Street, Suite 101, Chatham, New Jersey 07928
(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, 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 they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Information.

On November 16, 2020, the Company announced preliminary results following vaccination of non-human primates with TNX-1800 (modified horsepox virus, live vaccine), a live attenuated COVID-19 vaccine candidate engineered to express the SARS-CoV-2 (CoV-2) spike protein after vaccination. The research is part of an ongoing collaboration between the Company, the Southern Research Institute and the University of Alberta. All eight animals vaccinated with TNX-1800 manifested "takes", a skin reaction which is a validated biomarker of functional T cell immunity, and that vaccination was associated with neutralizing antibodies in each case.

Key features and results of the research include:

- **STUDY DESIGN:** The on-going study of non-human primates compares TNX-1800 (modified horsepox virus encoding CoV-2 spike protein) to TNX-801 (horsepox virus, live vaccine) at two doses. A control group received a placebo. Each of these five groups (TNX-1800 high and low dose; TNX-801 high and low dose and placebo) includes four animals.
- **NEUTRALIZING ANTI-CoV-2 ANTIBODIES:** At day 14 after a single vaccination, all eight of the TNX-1800 vaccinated animals made anti-CoV-2 neutralizing antibodies (≥1:40 titer) and, as expected, none of the eight TNX-801 vaccinated control animals, or any of the four animals in the placebo group, made anti-CoV-2 neutralizing antibodies (≤1:10 titer). The level of neutralizing anti-CoV-2 antibody production was similar between the low and high dose TNX-1800 groups ((1 x 106 Plaque Forming Units [PFU]) and 3 x 106 PFU, respectively).
- **TOLERABILITY:** TNX-1800 and TNX-801 were well tolerated at both doses.
- **SKIN TAKE BIOMARKER:** Further, as an expected additional outcome, all 16 animals vaccinated with either dose of TNX-1800 or the control TNX-801 manifested a "take", or cutaneous response, signaling that the horsepox vector elicited a strong T cell immune response.
- **DOSE:** These results support the expectation that TNX-1800 at the low dose of 1 x 106 PFU is an appropriate dose for a one-shot vaccine in humans, and indicate that 100 doses per vial is the target format for commercialization, which is suited to manufacturing and distribution at large scale.
- **CONCLUSIONS:** Together, these data show that TNX-1800 induces a strong immune response to CoV-2 in non-human primates. These data confirm that "take" is a biomarker of a strong immunological response to TNX-1800's vector, horsepox virus vaccine, and also indicate that "take" is predictive of a neutralizing antibody response to TNX-1800's cargo COVID-19 antigen, which is the CoV-2 spike protein.
- **NEXT PHASE:** In the second phase of the study, the TNX-1800 vaccinated and control animals will be challenged with CoV-2. Results are expected in the first quarter of 2021. A copy of the press release that discusses this matter is filed as Exhibit 99.02 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Corporate Presentation by the Company for November 2020
99.02	Press Release dated November 16, 2020, issued by the Company

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: November 16, 2020

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

Exhibit 99.01

Investor Presentation
NASDAQ:TNXP

TONIX PHARMACEUTICALS

November 2020

Version P0256 11-16-20 (Doc 0733)

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 biologics and small molecules**
  - **Immunology**
    - Vaccines, organ transplantation, 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)	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-1900[3]	Migraine and craniofacial pain	Clinical – pre-IND[4]
	TNX-601 CR	Depression, PTSD, Neurocognitive Dysfunction from Corticosteroids	Clinical – pre-IND[5]
	TNX-1600[6]	Depression, PTSD and ADHD	Preclinical

[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]Assets purchased from Trigemina; license agreement with Stanford University
[4]A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900
[5]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.
[6]Assets purchased from TRImaran Pharma; license agreement with Wayne State University

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

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

TNX-1800[1]: a COVID-19 Vaccine Candidate

- **Utilizes Tonix's proprietary horsepox virus as a vector**
  - Encodes a protein from SARS-CoV-2, the cause of COVID-19
  - Developed in collaboration with University of Alberta, Canada
- **Animal testing with Southern Research Institute**
  - Non-human primate immune response positive results reported in 4Q20
  - Small animal and non-human primate CoV-2 challenge testing data expected in 1Q21
- **Manufacturing agreement with FUJIFILM Diosynth**
  - Development for Good Manufacturing Practice (GMP) manufacturing for human trials
  - GMP[2] clinical supply expected to be ready for human trials in 2021[3]

[1]TNX-1800 (horsepox/Cov-2 spike live vaccine) is at the pre-IND stage of development
[2]Good Manufacturing Practice = GMP
[3]We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

TNX-1800 Vaccination of Non-Human Primates Elicited Anti-SARS-CoV-2 Neutralizing Antibodies and Skin Reaction or "Take" in All Eight Animals

STUDY DESIGN:

- Compares TNX-1800 (modified horsepox virus encoding CoV-2 spike protein) to TNX-801 (horsepox virus, live vaccine) at two doses in non-human primates. A control group received a placebo.
- Each of these five groups (TNX-1800 high and low dose; TNX-801 high and low dose and placebo) includes four animals.

NEUTRALIZING ANTI-CoV-2 ANTIBODIES:

- At Day 14 after a single vaccination, all eight of the TNX-1800 vaccinated animals made anti-CoV-2 neutralizing antibodies (≥1:40 titer).
- None of the eight TNX-801 vaccinated control animals, or any of the four animals in the placebo group, made anti-CoV-2 neutralizing antibodies (≤1:10 titer).
- Level of neutralizing anti-CoV-2 antibody production was similar between the low and high dose TNX-1800 groups ((1 x 10^6 Plaque Forming Units [PFU]) and 3 x 10^6 PFU, respectively.

SKIN *TAKE* BIOMARKER:

- All 16 animals vaccinated with either dose of TNX-1800 or the control TNX-801 manifested a "take", or cutaneous response, signaling that the horsepox vector elicited a strong T cell immune response.

TNX-1800 Vaccination of Non-Human Primates Findings, Conclusions and Next Phase

TOLERABILITY:

- TNX-1800 and TNX-801 were well tolerated at both doses.

DOSE:

- Supports the expectation that TNX-1800 at the low dose of 1 x 10^6 PFU is an appropriate dose for a one-shot vaccine in humans.
- Indicates that 100 doses per vial is the target format for commercialization, which is suited to manufacturing and distribution at large scale.

CONCLUSIONS:

- Data show that TNX-1800 induces a strong immune response to CoV-2 in non-human primates.
- Data confirm that "take" is a biomarker of a strong immunological response to TNX-1800's vector, horsepox virus vaccine, and also indicate that "take" is predictive of a neutralizing antibody response to TNX-1800's cargo COVID-19 antigen, which is the CoV-2 spike protein.

NEXT PHASE:

- In the second phase of the study, the TNX-1800 vaccinated and control animals will be challenged with CoV-2. Results are expected in the first quarter of 2021.

TNX-1800[1]: Engineered for Long-term Immunity

- **Based on "vaccinia" vaccine developed more than 200 years ago by Dr. Edward Jenner to prevent smallpox**
  - Eradicated smallpox (only viral disease ever eradicated)
  - Elicits durable (many decades) T cell immunity
  - Single dose protection without adjuvants
  - Manufacturable at scale
  - Minimal "cold chain" supply issues
  - Glass-sparing packaging owing to small unit dose

- **Genetic analysis of early vaccines indicates that Tonix's "horsepox" is closely related to Edward Jenner's "vaccinia"**
  - Modern "vaccinia" evolved during the 220 years it was propagated by primitive methods – for over 120 years before "viruses" were identified

[1]TNX-1800 (horsepox/Cov-2 spike live vaccine) is at the pre-IND stage of development

Why Use a Horsepox Platform for a Vaccine?

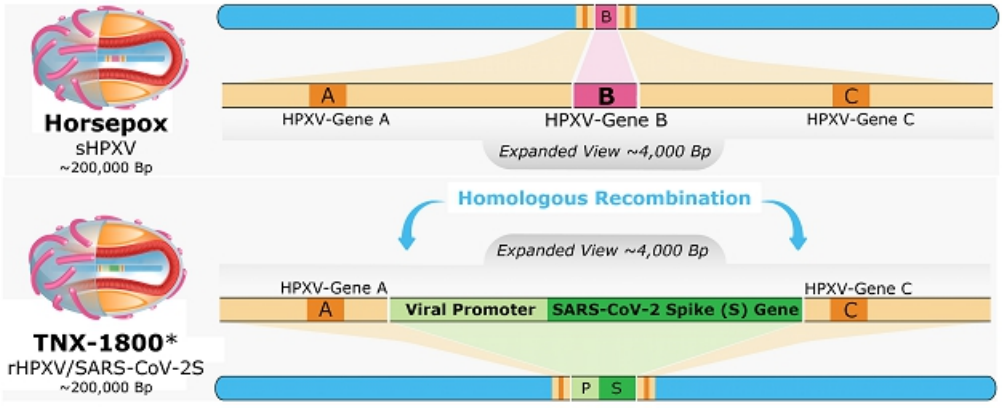
Horsepox can be engineered to express foreign genes

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

Potential advantages of horsepox over vaccinia

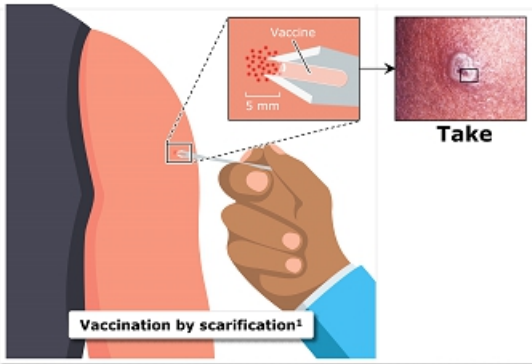
- Maintains strong immunogenicity with potentially improved tolerability
- Relative to non-replicating vaccinia, horsepox's replication in human cells provides direct antigen presentation, which is expected to trigger a T cell immune response, by Class I Major Histocompatibility Complex (MHC) Antigens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

Vaccinia Induces a Skin Reaction Called "Take" – Described by Dr. Edward Jenner



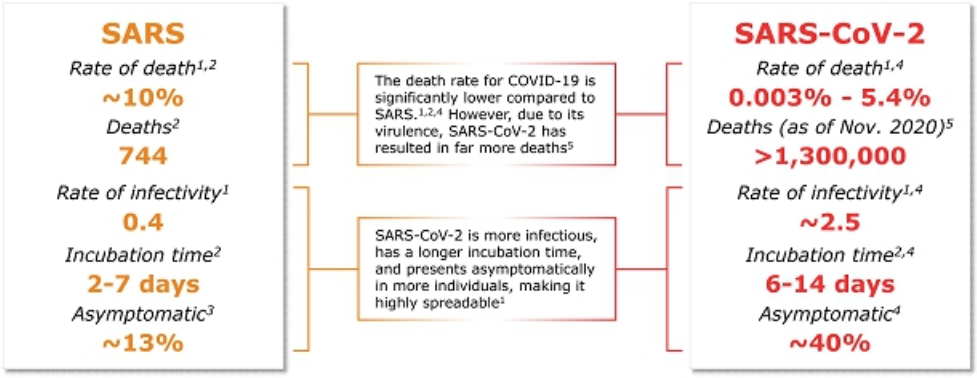
Take

- **Biomarker of protection**
  - Smallpox was eradicated using this marker
  - Revaccination indicated for recipients without "take"
- **Measure of T cell immunity**
  - No need for blood draws or complex laboratory studies
  - No other functional T cell assay is approved or in clinical use for vaccination

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

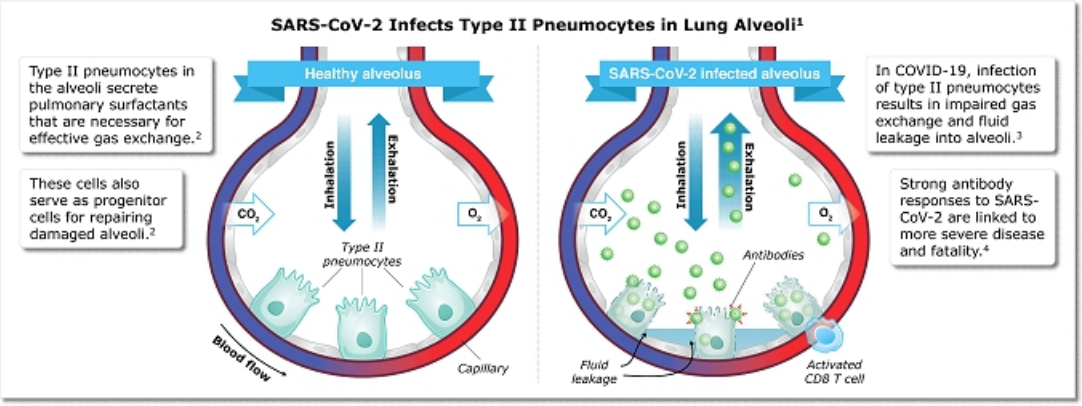
1.Fulginiti VA, et al. *Clin Infect Dis.* 2003;37(2):241-250.
2.Liu L, et al. *Nature Med.* 2010;16(2):224-228.
3.Centers for Disease Control and Prevention. Accessed April 15, 2020. https://phil.cdc.gov/Details.aspx?pid=3276

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 November 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html
5. Johns Hopkins University. Accessed November, 2020. https://coronavirus.jhu.edu/map.html

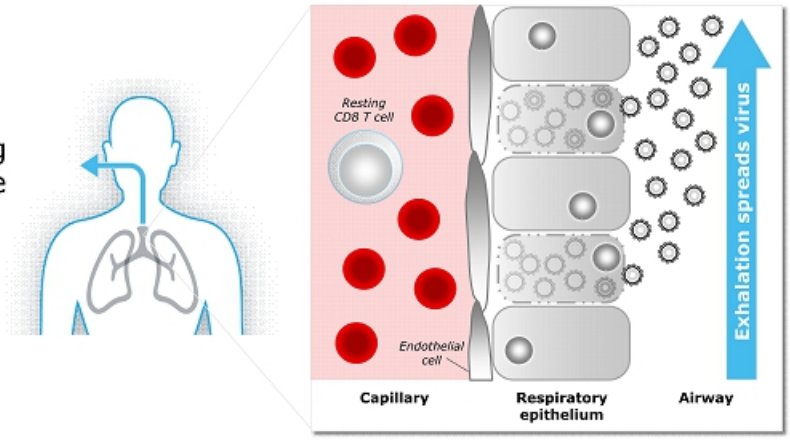
Infection of Type II Pneumocytes Can Lead to Lethal Respiratory Illness



1. Knudsen L, et al. *Histochem Cell Biol*. 2018;150(6):661-676.
2. Mason RJ. *Am J Physiol Lung Cell Mol Physiol*. 2020;319(1):L115-L120.
3. Xu Z, et al. *Lancet Respir Med*. 2020;8(4):420-422.
4. Lee WS, et al. *Nat Microbiol*. 2020;5:1185-1191.

SARS-CoV-2 Hijacks the Respiratory System to Spread Contagious Virus

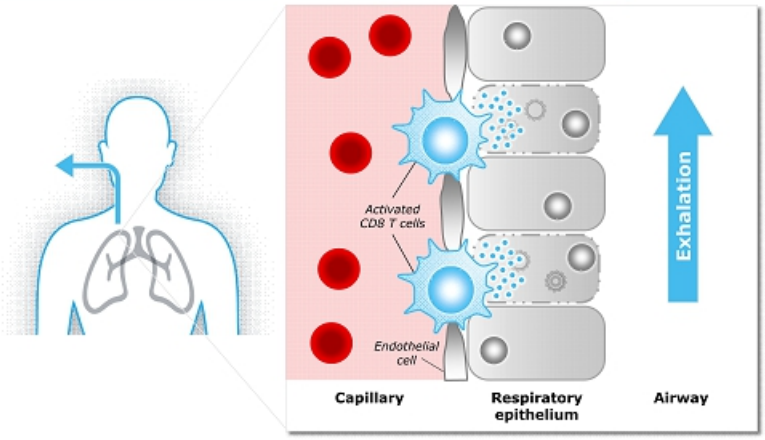
- Virus factories release virions by continuous budding
- Breathing, speaking or coughing has the potential to release virions into the air and transmit infection to others



Bar-On YM, et al. eLife. 2020;9:e57309.

CoV-2 Specific T Cells Kill the Virus Factories

- Natural immunity or vaccine protection has the potential to decrease forward transmission
- T cells specifically kill virally infected cells



Bar-On YM, et al. eLife. 2020;9:e57309.

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 Upcoming Milestones

Southern Research studies will address two key questions:

1. Will vaccination of animals elicit an immune response to the S protein?
   - 4th Quarter 2020 - Non-human primate immune response positive results reported
2. Will immune response protect animals against a challenge with SARS-CoV-2 virus?
   - 1st Quarter 2021 – Non-human primate and small animal results expected[1]

Detailed analysis of primates planned, including:

- Major cutaneous reaction or "take" in primates
- In vitro stimulation of T cells
- Neutralizing antibodies

[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

Data from small animals to measure efficacy in challenge studies using SARS-COV-2 are expected in the second quarter of 2021

[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

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

Three Recent PTSD Trials Testing TNX-102 SL (cyclobenzaprine sublingual tablets)

Phase 2 P201 "AtEase" – Military-related PTSD[1]

- **Reported May 2016 (mITT, N=231)**
- 3 groups: Placebo (n= 92), TNX 2.8 mg (n= 90) and TNX 5.6 mg (n=49)
- Primary endpoint (2.8 mg dose): CAPS-5 CFB, Week 12: MMRM, *P*=0.26 (two-sided)
- Secondary endpoints (5.6 mg dose): CAPS-5 (*P* =0.053), **PGIC (*P*=0.035)** and CGI-I (*P*=0.041)

Phase 3 P301 "HONOR" – Military-related PTSD[2]

- **Discontinued August 2018 (randomized, N=358) due to "futility" at interim analysis (IA)**
- 2 groups at IA: Placebo (n= 125) and TNX 5.6 mg (n= 127)
- Primary endpoint (5.6 mg dose): CAPS-5 CFB, Week 12: MMRM with MI, *P*=0.60 (two-sided)
- Secondary endpoints (5.6 mg dose): **PGIC (*P*=0.020)** and CGI-I (*P* =0.34)

Phase 3 P302 "RECOVERY" – Civilian PTSD[3]

- **Stopped enrollment in Feb 2020 (randomized, N=192) when interim analysis recommended stop for "futility"**
- 2 groups: Placebo (n ~ 96) and TNX 5.6 mg (n ~ 96)
- **Remains blinded**

[1]ClinicalTrials.gov Identifier: NCT02277704
[2]ClinicalTrials.gov Identifier: NCT03062540
[3]ClinicalTrials.gov Identifier: NCT03841773

Abbreviations: CAPS-5 = Clinician-Administered PTSD Scale for DSM-5; CFB = change from baseline; CGI = Clinician Global Impression - Improvement; PGIC = Patient Global Impression of Change; mITT = modified Intent-to-Treat; MMRM = mixed model repeated measures; MI = multiple imputation

Effect of Dose on Adverse Events (AEs) at 5.6 mg in 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%

Common Themes from Three Recent PTSD Trials Testing TNX-102 SL

- **Consistent nominal improvement on sleep item on CAPS-5**
  - E6 sleep disturbance item
  - Supported by nominal benefits in PROMIS Sleep Disturbance
  - Evidence of "target engagement", appropriate dosing and pharmacokinetics
- **High placebo response measured by CAPS-5 change from baseline**
  - Studies appear to have provided "enhanced" standard of care
- **Drug separation from placebo at Week 4 was not sustained at Week 12[1]**
  - Continued trend of improvement in placebo groups throughout courses of studies
- **Patient Global Impression of Change (PGIC) consistently improved at Week 12**
  - Patient self-assessment is not tied to disease constructs of CAPS-5/DSM-5
  - Clinician Global Impression of Improvement (CGI-I) also tended to improvement, although was more correlated with CAPS-5 change relative to that seen with PGIC

[1]In P201, 2.8 mg dose was nominally positive at Week 4; in P301, 5.6 mg dose nominally positive at Week 4

Multi-dimensional Analyses

"21st Century Cures Act" addressed use of novel trial designs, simulations and analyses

- Requiring guidance and encouraging increased reliance on novel and adaptive clinical trial designs, including use of modeling and simulation (sec 3021(b)(2))
- Then-FDA Commissioner Gottlieb expressed strong interest in the use of these innovative tools to expedite product development

Practical and ethical considerations motivate efficient extraction of data from trials with the lowest N's

- Excessively large studies, needlessly:
  - Increase the cost of developing drugs and discourage innovation
  - Delay the approval, marketing and availability of effective drugs
  - Prolong the exposure of participants to ineffective drugs
  - Sometimes show statistically significant effects that are not *clinically* meaningful
- "Adequate and well controlled" implies that drug approvals should be based on reasonably sized RCTs that show a statistically significant ($p < 0.05$) probability that drug benefit did NOT occur by chance

Proposed Analysis: Randomization Honoring Non-Parametric Combination of Tests (RHNPCOT)[1]

Honors the actual randomization method of the study
- Uses modern analyses and simulations which are advocated by 21st Century Cures Act

Preserves information from 20 dimensional CAPS-5
- Unlike "total CAPS-5" which collapses data into one dimension

Measure of benefit from all of the CAPS-5 items
- Not a "trimmed" CAPS-5 with fewer items
- No *a posteriori* selection, elimination or weighting of measurements

Assesses PTSD improvement at the Syndromal Level – not Symptom Level
- Not pseudo-specific

Efficient use of data with smaller numbers of study participants
- Ethical (not exposing volunteers unnecessarily) and practical (allows for reasonably sized studies)
- Provides benefit of statistical methods that weren't practical before computers

Concordant with Patient Global Impression of Change (PGIC)
- Patient reported yardstick of benefit – not connected to theoretical constructs of nosology
- PGIC is clinically meaningful

[1] https://www.stat.berkeley.edu/~stark/Seminars/npc-tonix-20.slides.pdf

Future Plans: TNX-102 SL for PTSD

Pharmacogenomics on study participants

- P302 had high percentage of participant DNA collected
- P301 has a subset of participant DNA available
- Exome sequencing to focus on:
  - Drug metabolizing enzymes
  - Neurotransmitter receptors and transporters
  - Genes related to sleep quality
  - Genes related to fear extinction memory processing

Plan to propose new analysis for primary endpoint in next PTSD studies

- Statistical analysis plan to use RHNPCOT for primary analysis

P3 Study in US

- Protocol in development

P3 Study on Kenyan Police

- Protocol in development with Moi University – expected start date 3Q 2021

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

Completed Trials in FM at 2.8 mg:
- 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 5.6 mg for Fibromyalgia: Phase 3 F304/RELIEF Study

- **Interim Analysis Completed in September 2020**
  - Independent data monitoring committee (IDMC) made a non-binding recommendation to continue the trial with the addition of 210 participants to the original sample size of 470, the maximum number that could be added per the interim statistical analysis plan
  - Tonix will complete the RELIEF study with the currently-enrolled sample size of 503 participants
  - Topline results of full study expected in fourth quarter 2020
- **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**

TNX-102 SL 5.6 mg for Fibromyalgia: Phase 3 F304/RELIEF Study – Interim Analysis Completed

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia in approximately 40 U.S. sites (full sample size N=503)
- Adaptive Design: one unblinded interim analysis based on 50% of randomized participants

TNX-102 SL once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets)[1] *N= ~251*

Placebo once-daily at bedtime
N= ~251

14 weeks

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 completed in September 2020

Topline results expected fourth quarter 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

TNX-102 SL Intellectual Property – U.S. Protection expected until 2035

Composition of matter (eutectic): **Protection expected to 2034/2035**	• United States Patent and Trademark Office (USPTO) issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020 • European Patent Office (EPO) issued European Patent No. 2968992 in December 2019 (validated in 37 countries). Opposition filed in October 2020 by Hexal AG • China National Intellectual Property Administration issued Chinese Patent No. ZL 201480024011.1 in April 2019 • Japanese Patent Office (JPO) issued Japanese Patent No. 6310542 in March 2018, Patent No. 6614724 in November 2019, and Patent No. 6717902 in June 2020 • 10 granted patents (Indonesia, Saudi Arabia, New Zealand, Australia, Mexico, Taiwan, Israel, South Africa) • 31 patent applications pending (4 being allowed in U.S., China, Israel, South Africa)
Composition of matter (sublingual): **Protection expected to 2033**	• NZIPO issued New Zealand Patent No. 631144 in March 2017 and Patent No. 726488 in January 2019 • Taiwanese Intellectual Property Office issued Taiwanese Patent No. I590820 in July 2017, Patent No. I642429 in December 2018 and Patent No. I683660 in February 2020 • Australian Patent Office issued Australian Patent No. 2013274003 in October 2018 and Patent No. 2018241128 in September 2020 • JPO issued Japanese Patent No. 6259452 in December 2017 • 20 patent applications pending

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

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-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

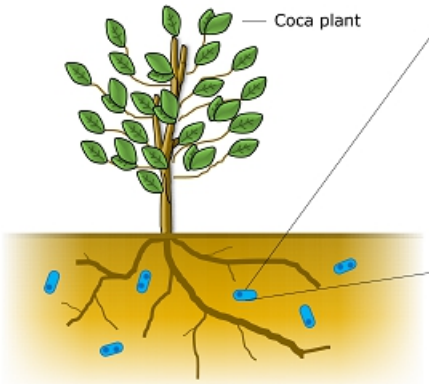
Phase 2 study completed by Reckitt Benckiser (TNX-1300 was formerly RBP-8000)[3]

- 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)

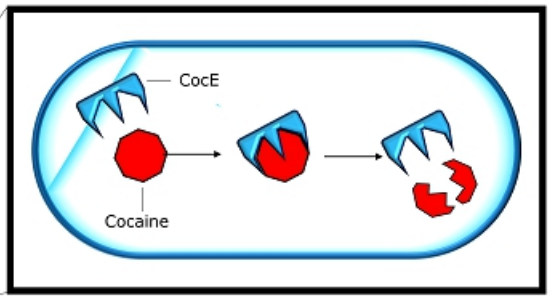
**TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

[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.

TNX-1300 Development Plan

- **Targeting to initiate a Phase 2 open-label, randomized pilot study of TNX-1300 in the first quarter of 2021**
- **Emergency department (ED) setting with patients coming in for treatment of cocaine and/or polysubstance intoxication**
- **Objectives**
  - Primary: To evaluate the safety of TNX-1300 in the ED setting
  - Secondary:
    - To evaluate TNX-1300 in the management of cardiovascular (CV) and other signs and symptoms associated with cocaine intoxication compared to usual care (UC) alone
    - To demonstrate reduction of plasma cocaine, cocaethylene, and ecgonine methyl ester levels after TNX-1300 administration and compare cocaine and cocaethylene levels of TNX-1300 group to those in UC alone

TNX-1900 for the Treatment of Migraine and Craniofacial Pain – Overview

Novel intranasal oxytocin formulation being developed as a prophylactic treatment for chronic migraine

- Based on a propriety formulation of oxytocin*, a naturally occurring human hormone that acts as a neurotransmitter in the brain

Clinical and preliminary research has shown that low oxytocin levels in the body can lead to increase in headache frequency, and that increased oxytocin levels can relieve headaches

- Certain other chronic pain conditions are also associated with decreased oxytocin levels

Oxytocin when delivered via the nasal route, results in enhanced binding of oxytocin to receptors on neurons in the trigeminal system, inhibiting transmission of pain signals

Intranasal oxytocin has been shown in animals that it can also block CGRP release, a pathway known to be critical to the pathogenesis of migraine attacks.

*Oxytocin is approved by the U.S. Food and Drug Administration (FDA) as Pitocin®, an intravenous infusion or intramuscular injection drug, for use in pregnant women to induce labor. An intranasal form of oxytocin was marketed by Novartis to assist in nursing as Syntocinon®, but the product was withdrawn and the New Drug Application (NDA) has been discontinued.

TNX-1900 for the Treatment of Migraine – Prevalence

One billion individuals worldwide suffer from migraines (~14% of population)[1]

Migraine is the second leading cause of years lived with disability[1]

In U.S., the estimated cost of all migraine headaches was $78 billion in 2014[2]

- Approximately 30% of those costs ($23 billion) were direct medical costs

Chronic migraine (≥ 15 headaches / month) effects about 1-2% of individuals[3]

- 75-150 million individuals worldwide
- 3-7 million in the U.S.

CGRP antibodies are the only migraine specific prophylaxis drugs approved in decades

- Requires parenteral administration (systemic effects on peripheral CGRP pathways)
- Long term safety concerns with prolonged systemic blockade of CGRP receptor[4]

[1] GBD 2016 Headache Collaborators, Global, regional, and national burden of migraine and tension-type headache, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016, Lancet Neurol 2018; 17: 954–76
[2] Gooch, C. L., et al., The Burden of Neurological Disease in the United States: A Summary Report and Call to Action. Ann Neurol. 2017; 81:479-484
[3] Natoli et al., Global prevalence of chronic migraine: a systematic review, Cephalagia, 2010, 30:599-609
[4] Robbins, At Stake: The Possible Long-Term Side Effects of CGRP Antagonists, https://www.practicalpainmanagement.com/pain/headache/stake-possible-long-term-side-effects-cgrp-antagonists, accessed November 8, 2020.

TNX-1900 for the Treatment of Migraine – Mechanism of Action

Preclinical research showed that nasally applied TNX-1900 selectively inhibits the activity of trigeminal pain-sensing nerve cells and blocks the release of CGRP

- TNX-1900 is believed to interrupt pain signals at the trigeminal ganglia by suppressing electrical impulses, a potentially different activity than drugs that just block CGRP

Migraine attacks are caused, in part, by the release of CGRP from pain-sensing nerve cells that are part of the trigeminal system

- The CGRP binds to receptors on other nerve cells and starts a cascade of events that eventually results in a severe headache. This, in turn, reduces various kinds of trigeminal nerve associated pain and prevents CGRP from acting at receptors in the central nervous system that are involved in migraine.

We believe targeted delivery of oxytocin could translate into selective blockade of CGRP release in the trigeminal ganglion and not throughout the body, which could be a potential safety advantage over systemic CGRP inhibition

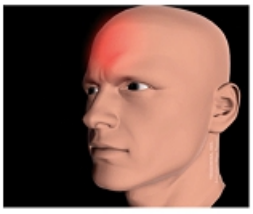
- In addition, daily dosing is more quickly reversible, in contrast to monthly or quarterly dosing, giving physicians and their patients greater control

TNX-1900 for the Treatment of Migraine – Mechanism of Action (continued)

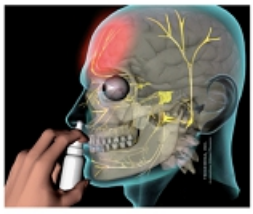
CGRP: NEUROTRANSMITTER THAT HAS BEEN VALIDATED AS KEY MIGRAINE TARGET

TNX-1900 believed to partially block release of CGRP in the trigeminal nerve

Proprietary Nasal to Brain Delivery



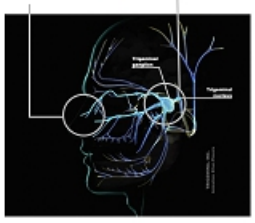
HEAD PAIN



PATIENT USES TNX-1900

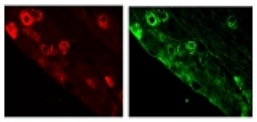
Permeates nasal mucosa

Transported to trigeminal system and brain



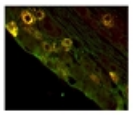
TARGETED DELIVERY

Oxytocin Receptors Co-Localize with CGRP in most Trigeminal Ganglia Neurons



Oxytocin Receptors CGRP

Overlay of Oxytocin Receptors and CGRP Staining



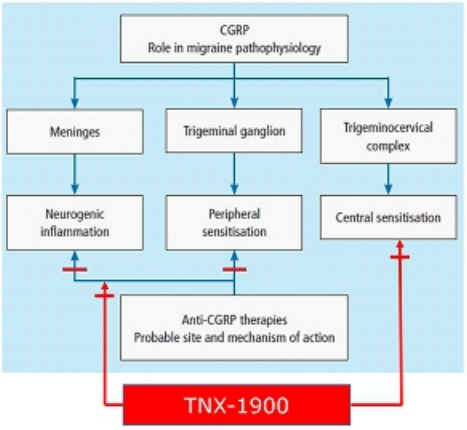
Abbrev. CGRP, calcitonin gene-related peptide

TNX-1900: Mechanism of Action (continued)

In animal models, intranasal oxytocin concentrates in the trigeminal system

Inhibits trigeminal neuronal firing, and decreases CGRP (and PACP) release onto meningeal vasculature and within the brainstem

- **Believed to have effects on:**
  - Neurogenic inflammation
  - Peripheral sensitization, where CGRP otherwise promotes neuronal-glial signaling of pain to trigeminal ganglion
  - Central sensitization, in which CGRP otherwise causes sensitization of NMDA receptor, reducing threshold for glutamate – creating allodynia
- **Anti-CGRP antibodies may only work on inflammation and peripheral sensitization**
  - Due to poor blood brain barrier penetration



Abbrev. CGRP, calcitonin gene-related peptide; PACP, pituitary adenylate cyclase-activating peptide
Figure adapted from Krishnaswamy R et al. Anti-CGRP monoclonal antibodies: breakthrough in migraine therapeutics. Progress in Neurology and Psychiatry. Vol 23.03, July-Sept, 2019.

TNX-1900 for the Treatment of Migraine – Development Status

In June 2020, Tonix acquired a proprietary formulation of nasal oxytocin solution for intranasal delivery from Trigemina

Also acquired migraine and pain treatment technologies of Trigemina, Inc. and assumed license for some of technologies from Stanford University

A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900

Completed by Trigemina prior to acquisition

Tonix intends to submit an IND application for this program to the FDA in the first quarter of 2021

Targeting start of a Phase 2 study of TNX-1900 for the prophylactic treatment of chronic migraine in the U.S. in the second quarter of 2021

- Primary endpoint expected to be mean change in number of migraine headache days from the last 28 days of baseline to the last 28 days of treatment in each treatment group

Pipeline[1] Summary – by Select Therapeutic Areas

Public Health	Biodefense	Transplantation/ Autoimmunity	Oncology
• **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	• **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	• **TNX-1500 (anti-CD40-Ligand) for preventing rejection of solid organ transplants** Preclinical • **TNX-1500 (anti-CD40-Ligand) for treating autoimmune disease** Preclinical	• **TNX-1700 (rTFF2[2]) for treatment of gastric and pancreatic cancer** Preclinical

[1] Experimental new medicines and biologics, not approved for any indication
[2] Recombinant Trefoil Family Factor 2 – licensed from Columbia University

Pipeline[1] Summary – by Select Therapeutic Areas (continued)

Pain

- **TNX-102 SL (sublingual cyclobenzaprine) for fibromyalgia**
  Phase 3/RELIEF
  Phase 3/RALLY
- **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 and naloxone) for depression and PTSD**
  Clinical - Pre-IND stage
- **TNX-1600 (triple reuptake inhibitor[2]) for PTSD, Depression and ADHD[3]**
  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

[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

Milestones – Recently Completed and Upcoming[1]

☑ September 2020	Interim analysis of TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia completed
☑ 4th Quarter 2020	Non-human primate immune response positive results reported
❑ **4th Quarter 2020**	**Topline data from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia expected**
❑ **2021**	**Initiation of Phase 1 safety study of TNX-1800 for COVID-19 expected**
❑ **1st Quarter 2021**	**Small animal & non-human primate efficacy data from TNX-1800 in COVID-19 models expected**
❑ **1st Quarter 2021**	**Initiation of Phase 2 open-label safety study of TNX-1300 in ED setting**
❑ **1st Quarter 2021**	**Submission of IND application for TNX-1900 for the treatment of migraine**
❑ **2nd Quarter 2021**	**Initiation of Phase 2 study of TNX-1900 for the treatment of migraine**
❑ **2nd Quarter 2021**	**Small animal efficacy data from TNX-2300 in COVID-19 models expected**
❑ **2nd 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 Fusilev 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

Tonix Pharmaceuticals Reports Positive Immune Response Results from COVID-19 Vaccine Candidate TNX-1800, Following Vaccination of Non-Human Primates

Anti-SARS-CoV-2 Neutralizing Antibodies Elicited in All Eight TNX-1800 Vaccinated Animals

Skin Reaction or "Take", a Validated Biomarker of Functional T cell Immunity, Elicited in All Eight TNX-1800 Vaccinated Animals

CHATHAM, NJ, November 16, 2020 - Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced preliminary results following vaccination of non-human primates with TNX-1800 (modified horsepox virus, live vaccine), a live attenuated COVID-19 vaccine candidate engineered to express the SARS-CoV-2 (CoV-2) spike protein after vaccination. The research is part of an ongoing collaboration between Southern Research Institute, the University of Alberta and Tonix.

"We are pleased that all eight animals vaccinated with TNX-1800 manifested "takes", a skin reaction which is a validated biomarker of functional T cell immunity, and that vaccination was associated with neutralizing antibodies in each case," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "'Take' has a long history as a validated biomarker for T cell immunity. 'Take' is important because it is otherwise difficult and costly to measure the T cell response to a vaccine. Vaccines that elicit a strong T cell response, like horsepox and closely related vaccinia, have been established to provide long-term, durable immunity and to block forward transmission. Single dose horsepox and vaccinia vaccination led to the eradication of smallpox, which, like CoV-2, is transmitted by the respiratory route. In the successful campaign to eradicate smallpox, 'take' was used as a biomarker for protective immunity."

Dr. Lederman continued, "Our hope and our goal is to produce a vaccine that will provide long term immunity with a single dose using a proven technology that can be readily scaled up for manufacturing and that does not require a costly and cumbersome cold chain for distribution and storage. These results encourage us to advance TNX-1800 to human Phase 1 trials in 2021, when we expect to have Good Manufacturing Practice, or cGMP, quality TNX-1800 available. We have previously announced that our manufacturing partner is FUJIFILM Diosynth Biotechnologies."

Key features and results:

- **STUDY DESIGN**: This on-going study of non-human primates compares TNX-1800 (modified horsepox virus encoding CoV-2 spike protein) to TNX-801 (horsepox virus, live vaccine) at two doses. A control group received a placebo. Each of these five groups (TNX-1800 high and low dose; TNX-801 high and low dose and placebo) includes four animals.
- **NEUTRALIZING ANTI-CoV-2 ANTIBODIES**: At day 14 after a single vaccination, all eight of the TNX-1800 vaccinated animals made anti-CoV-2 neutralizing antibodies (≥1:40 titer) and, as expected, none of the eight TNX-801 vaccinated control animals, or any of the four animals in the placebo group, made anti-CoV-2 neutralizing antibodies (≤1:10 titer). The level of neutralizing anti-CoV-2 antibody production was similar between the low and high dose TNX-1800 groups ((1 x 10^6 Plaque Forming Units [PFU]) and 3 x 10^6 PFU, respectively).
- **TOLERABILITY**:TNX-1800 and TNX-801 were well tolerated at both doses.
- **SKIN *TAKE* BIOMARKER**: Further, as an expected additional outcome, all 16 animals vaccinated with either dose of TNX-1800 or the control TNX-801 manifested a "take", or cutaneous response, signaling that the horsepox vector elicited a strong T cell immune response.
- **DOSE:** These results support the expectation that TNX-1800 at the low dose of 1 x 10^6 PFU is an appropriate dose for a one-shot vaccine in humans, and indicate that 100 doses per vial is the target format for commercialization, which is suited to manufacturing and distribution at large scale.
- **CONCLUSIONS**: Together, these data show that TNX-1800 induces a strong immune response to CoV-2 in non-human primates. These data confirm that "take" is a biomarker of a strong immunological response to TNX-1800's vector, horsepox virus vaccine, and also indicate that "take" is predictive of a neutralizing antibody response to TNX-1800's cargo COVID-19 antigen, which is the CoV-2 spike protein.
- **NEXT PHASE**: In the second phase of the study, the TNX-1800 vaccinated and control animals will be challenged with CoV-2. Results are expected in the first quarter of 2021.

About TNX-1800

TNX-1800 is a live modified horsepox virus vaccine for percutaneous administration that is designed to express the Spike protein of the SARS-CoV-2 virus and to elicit a predominant T cell response. Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. Tonix's TNX-1800 vaccine candidate is administered percutaneously using a two-pronged, or "bifurcated" needle. TNX-1800 is based on a horsepox vector, which is a live replicating, attenuated virus that elicts a strong immune response. The major cutaneous reaction or "take" to vaccinia vaccine was described by Dr. Edward Jenner in 1796 and has been used since then as a biomarker for protective immunity to smallpox, including in the World Health Organization's (WHO) accelerated smallpox eradication program that successfully eradicated smallpox in the 1960's. The "take" is a measure of functional T cell immunity validated by the eradication of smallpox, a respiratory-transmitted disease caused by variola. Tonix's proprietary horsepox vector is believed to be more closely related to Jenner's vaccinia vaccine than modern vaccinia vaccines, which appear to have evolved by deletions and mutations to a phenotype of larger plaque size in tissue culture and greater virulence in mice. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been explored as platforms for vaccine development because they possess; (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) readily manufacturable at scale, and (7) ability to provide direct antigen presentation. Relative to vaccinia, horsepox has substantially decreased virulence in mice[1]. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, that can be manufactured using conventional cell culture systems, with the potential for mass scale production and packaging in multi-dose vials.

About Southern Research

Founded in 1941, Southern Research (SR) is an independent, 501(c)(3) nonprofit, scientific research organization with more than 400 scientists and engineers working across three divisions: Drug Discovery, Drug Development, and Engineering. SR has supported the pharmaceutical, biotechnology, defense, aerospace, environmental, and energy industries. SR works on behalf of the National Institutes of Health, the U.S. Department of Defense, the U.S. Department of Energy, NASA and other major aerospace firms, utility companies, and other external academic, industry and government agencies. SR pursues entrepreneurial and collaborative initiatives to develop and maintain a pipeline of intellectual property and innovative technologies that positively impact real-world problems. SR has numerous ongoing drug discovery programs, which encompass drug discovery programs to combat various forms of cancer, Alzheimer's, schizophrenia, opioid use disorder, human immunodeficiency virus, disease, Parkinson's, tuberculosis, influenza, and others. SR's strong history, which includes over 75 years of successful collaborations to solve complex problems, has led to the discovery of seven FDA-approved cancer drugs—a number rivaling any other U.S. research institute. Furthermore, experts at SR are well-equipped to assist with the challenging landscapes of drug design and development technologies and market viability. SR is headquartered in Birmingham, Alabama with additional laboratories and offices in Frederick, Maryland.

Further information about SR can be found athttps://southernresearch.org/

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[1] Noyce RS, et al. (2018) PLoS One. 13(1):e0188453

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 a live replicating vaccine 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 this year and the first quarter of 2021. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.. Tonix is also developing TNX-2300* and TNX-2600*, live replicating vaccine candidates for the prevention of COVID-19 but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects topline data in the Phase 3 RELIEF study in the fourth quarter of 2020. Tonix is also currently enrolling participants in the Phase 3 RALLY study for the management of fibromyalgia using TNX-102 SL, and the results are expected in second half of 2021. TNX-102 SL is also in development for PTSD, agitation in Alzheimer's disease (AAD) and alcohol use disorder (AUD). The PTSD program is in Phase 3 development, while AAD and AUD are Phase 2 ready The AAD program has FDA Fast Track designation. 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 life-threatening 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-2300, TNX-2600, 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 atwww.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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