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): April 13, 2020

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

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

509 Madison Avenue, Suite 1608, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TNXP	The NASDAQ Global Market

Item 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") updated its investor presentation, which is used to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.01 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Corporate Presentation by the Company for April 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: April 13, 2020

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

Exhibit 99.01

Investor Presentation

TONIX PHARMACEUTICALS

April 2020

Version P0225 4-10-20 (Doc 0617)

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: Lead Programs[1]

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:
  - 2nd Quarter 2020 – Expression of S protein and small animal response expected[5]
  - 3rd Quarter 2020 – Primate testing results expected[5]

TNX-102 SL for fibromyalgia (FM)

- Phase 3 clinical development – RELIEF study enrolling
- Sublingual cyclobenzaprine tablets
- Milestones:
  - 3rd Quarter 2020 - Interim analysis results expected[5]
  - 1st Half 2021 - Topline data 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

Public Health and Biodefense Preclinical Pipeline[1]

Pipeline Product	Targeted Indication(s)	Category
TNX-1800[2] Live modified horsepox virus (rHPXV/SARS-CoV-2-S[3]) vaccine from cell culture	**COVID-19[4] preventing vaccine**	**Public Health**
TNX-801[5] Live horsepox virus (sHPXV[6]) vaccine from cell culture	**Smallpox and monkeypox preventing vaccine**	**Biodefense**
TNX-1200 Live vaccinia virus (sVACV[7]) vaccine from cell culture	**Smallpox and monkeypox preventing vaccine**	**Biodefense**

[1] Experimental new medicines and biologics, not approved for any indication
[2] Collaboration with Southern Research
[3] Designed to express SARS-CoV-2 Spike (S) protein
[4] COVID-19 = Coronavirus disease 2019
[5] Collaboration with David Evans and Ryan Noyce at Univ. of Alberta, Canada
[6] Synthesized horsepox
[7] Synthesized vaccinia

TNX-801 (Synthesized Live Horsepox Virus): A Potential Smallpox and Monkeypox Preventing Vaccine

Pre-IND Stage

Potential improvement over current biodefense tools against smallpox

- ✓ Demonstrated protective vaccine activity in mice and macaques
- ✓ Collaboration with Professor David Evans and Dr. Ryan Noyce at University of Alberta

Currently approved smallpox and monkeypox vaccines

- ✓ Two vaccines are FDA approved for smallpox: Emergent BioSolutions' ACAM2000® (vaccinia) and Bavarian Nordic A/S's Jynneos® (MVA-BN) and only Jynneos is approved for monkeypox[1]

Regulatory strategy

- We intend to meet with FDA to discuss the most efficient and appropriate investigational plan to support the licensure
  - ✓ Planning non-inferiority, active comparator study using an FDA approved product

Targeting a Potential Public Health Issue

Material threat medical countermeasure under 21st Century Cures Act

- Qualifies for **Priority Review Voucher (PRV)** upon licensure[2]
  - ✓ **PRVs have no expiration date, are transferrable and have sold for ~$125 M**

[1]ACAM2000 is a registered trademark of Emergent BioSolutions and Jynneos is a registered trademark of Bavarian Nordic
[2]BLA/NDA priority 6-month review is expected.

Dr. Edward Jenner's *Inquiry* (1798)[1]

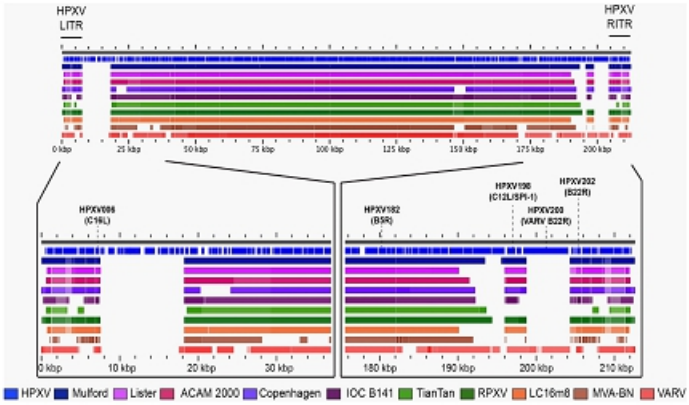
"There is a disease to which the **Horse** from his state of domestication is frequently subject. The Farriers have termed it *the Grease*. It is an inflammation and swelling in the heel, from which issues matter[2] possessing properties of a very peculiar kind, which seems capable of generating a disease in the Human Body (after it has undergone the modification[3] I shall presently speak of), which bears so strong a resemblance to the Small Pox, that I think it highly probable it may be the source of that disease."

"In this Dairy Country a great number of Cows are kept, and the office of milking is performed indiscriminately by Men and Maid Servants. One of the former having been appointed to apply dressings to the heels of a **Horse** affected with *the Grease*, and not paying due attention to cleanliness, incautiously bears his part in milking the Cows, with some particles of the infectious matter adhering to his fingers. When this is the case, it commonly happens that a disease is communicated to the Cows, and from the Cows to the Dairy-maids, which spreads through the farm until most of the cattle and domestics feel its unpleasant consequences. The disease has obtained the name of the *Cow Pox*."

[1]Jenner, E. "An Inquiry Into the Causes and Effects of the *Variolae Vaccinae*, a Disease Discovered in Some of the Western Counties of England, Particularly Gloucestershire, and Known by the Name of the Cow Pox (p 2 & 3.)

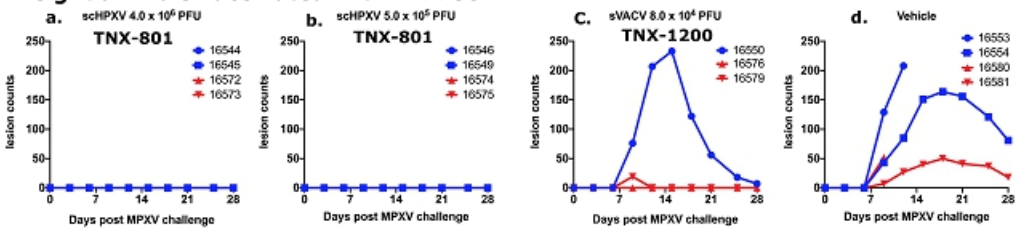
Relationship Between Horsepox, Certain Vaccinia Strains and Variola

Legend: Alignment of orthopoxvirus genomes and location of horsepox (HPXV) genes within telomeres. Orthopoxvirus genomes were aligned using the program GView (https://server.gview.ca). The actual nucleotide sequence of each gene within the genome was compared to the coding sequence (CDS) of each gene within the horsepox (HPXV) reference genome (NCBI Accession DQ792504) and the following orthopoxvirus genomes (VACV Mulford 1902 - MF477237; VACV Lister - AY678276; VACV ACAM2000 - AY313847; VACV Copenhagen - M35027; VACV IOC-B141 - KT184690; VACV TianTan -KC207810; Rabbitpox virus (RPXV) Utrecht -AY484669; MVA-BN - DQ983238; VACV LC16m8 - AY678275; Variola virus (VARV) (Bangladesh 1975 - L22579). The white gaps in the HPXV reference sequence represent non-coding sequences within the genome. The percent identity (PID) cutoff was set to 85%, meaning that only matches with PID values over 85% are displayed. Abbreviations: BLAST = Basic Local Alignment Search Tool; LITR = left inverted terminal repeat (ITR); RITR= right ITR.



No Overt Clinical Signs Observed in TNX-801 Vaccinated Macaques After MPXV Challenge[1]

No monkeypox lesions observed after monkeypox (MPXV) challenge in any of the eight animals vaccinated with TNX-801



Legend: Cynomolgus macaques (4 per group), were vaccinated *via* scarification using a bifurcated needle. Two different doses of TNX-801 (scHPXV) vaccine were tested (panel a and b); one dose of TNX-1200 (sVACV)(panel c); or vehicle (panel d). After monkeypox (MPXV) challenge, no lesions were seen in any of the 8 animals vaccinated with TNX-801 (panel a and b). One animal in the TNX-1200 arm died from unrelated causes, and two of three remaining animals showed lesions by Day 69 (panel c). All four vehicle vaccinated animals developed lesions (panel d). Clinical signs of systemic monkeypox infections were seen in all 4 vehicle-vaccinated animals (panel d) by Day 69, but TNX-801 and TNX-1200 vaccinated animals were protected. In Panels a-d, blue symbols are male animals and red are female.
Methods: 4 of 4 animals in the $4x10^6$ PFU dose, and 3 of 4 animals in the $5x10^5$ PFU dose groups exhibited a "take" at Day 7 after a single vaccination. A take is a biomarker of protective immunity. In the TNX-1200 (sVACV) arm only 1 of 4 animals exhibited a take after a single vaccination. The animals that did not present a take were revaccinated on Day 14: the one TNX-801 animal was revaccinated with $5x10^5$ PFU TNX-801 and the 3 TNX-1200 animals were revaccinated with $2.4x10^5$ PFU TNX-1200. All but one of the TNX-1200 animals subsequently produced a take. Tolerability was comparable for TNX-801 and TNX-1200.

[1]Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

TNX-801 (live horsepox virus vaccine for percutaneous (scarification) administration)

Vaccine based on sequence of isolated horsepox clone[1,2]
- No new gene elements and coding sequence is identical to environmental horsepox isolate
- May be considered "primordial" since Left and Right ITRs are "complete"
- In contrast, modern vaccinia strains contain deletions and mutations

Small plaque size in culture
- Appears similar to CDC publication of 1976 horsepox isolate[3]

Substantially decreased virulence in mice[2]
- Relative to a vaccinia vaccine strain

Protects macaques from monkeypox[4]
- No overt sign of clinical symptoms and no lesions in 8/8 animals at two doses of TNX-801

Historical evidence for horsepox-like vaccines
- Jenner and others demonstrated their horse originated vaccine was protective against variola in challenge studies with variola (what was then called "variolation")
- Used when smallpox was endemic

Horsepox has not been reported in >40 years
- Improved hygiene in animal husbandry led to its elimination
- Probable natural hosts are rodents
- Horse-to-cow transmission by human vector reported by Jenner

[1]Tulman ER, et al. (2006) *J Virol.* 80(18):9244-58.PMID:16940536
[2]Noyce RS, et al. (2018) *PLoS One.* 13(1):e0188453.
[3]Trindale GS et al. *Viruses* (2016) (12). pii: E328. PMID:27973399
[4]Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

Potential for Use of Horsepox as a Vector Platform for other Infectious Diseases

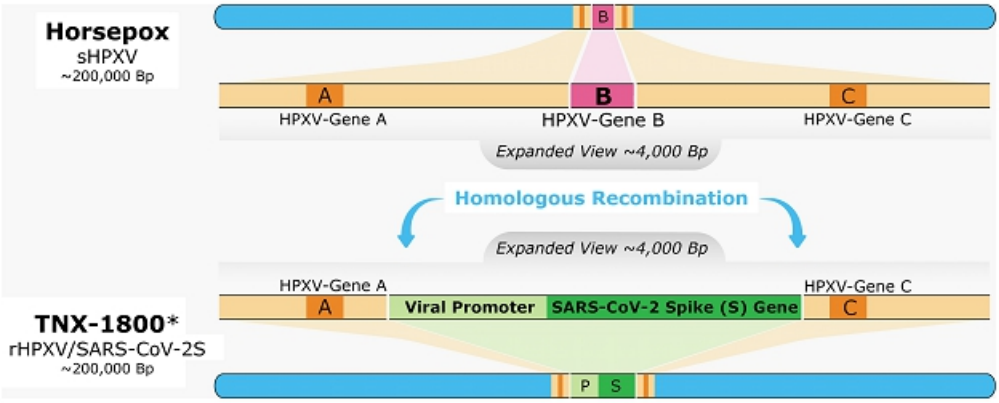
Horsepox can be engineered to express foreign genes and serve as a platform for vaccine development

- Large packaging capacity for exogenous DNA inserts (i.e. encoding antigens)
- Precise virus-specific control of exogenous gene insert expression
- Lack of persistence or genomic integration in the host
- Strong immunogenicity as a vaccine
- Ability to rapidly generate vector/insert constructs
- 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 Designed to Express SARS-CoV-2 Spike Protein



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

Potential for Use of Horsepox as a Vector Platform for a SARS-CoV-2 Vaccine

Strong immunogenicity for adaptive and innate immunity – believed important in SARS

- Humoral immunity against Spike protein is sufficient to protect against SARS-CoV in mice[1,2]
- T cells are sufficient to clear SARS-CoV in mice[3]
- T cells can protect mice from SARS-CoV after vaccination with vaccinia-virus encoding a SARS Spike protein peptide[3,4]
- T cell response to Spike protein is durable (>1 year) in humans post-SARS[5]
- Innate immunity can clear SARS-CoV from mice[6]
- Interferon responses are important for mice to limit SARS-CoV in mice[7]

Collaboration with Southern Research

- Southern Research will develop and test TNX-1800, which is designed to express Spike (S) protein from the virus that causes COVID-19, which is called SARS-CoV-2.
- We plan to test whether vaccination of animals with TNX-1800 will elicit an immune response to the S protein from SARS-CoV-2 and if so, whether such an immune response will protect mice and non-human primates against a challenge with SARS-CoV-2 virus
- We expect to receive data from small animal experiments in the second quarter of 2020 and from primates in the third quarter of 2020[8]

Further Development

- The further development of TNX-1800 for human clinical trials will require manufacturing according to Good Manufacturing Practice, or GMP

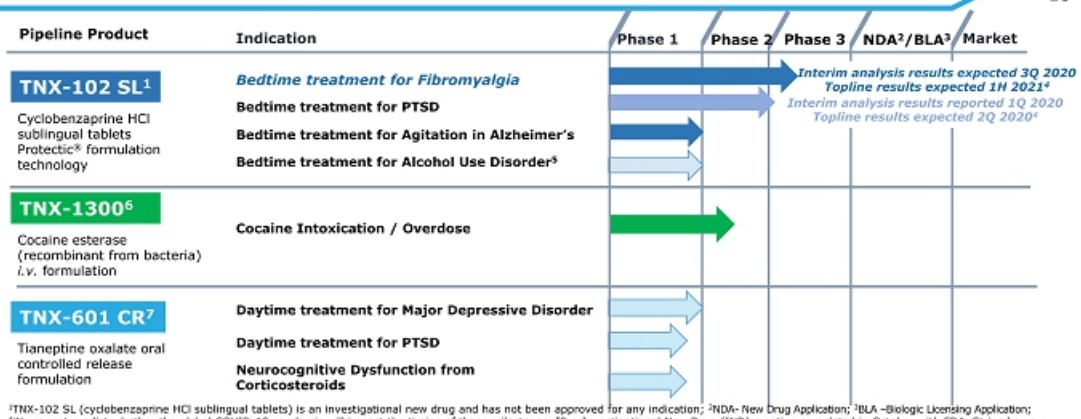
[1]Yang ZY, *et al.* (2004) *Nature.*;428:561–564.
[2]Enjuanes L, *et al.* (Review) (2008) *Virus Res.* 133:45–62.
[3]Zhao J *et al.* (2010) *J Virol* 84(18):9318-9325.
[4]Channappanavar R, *et al.* (2014) *J Virol* 88(19):11034-11044.

[5]Yang L-T *et al.* (2006) *Clinical Immunology* 120, 171—178.
[6]Glass WG, *et al.* (2004) *J Immunol.* 173:4030–4039.
[7]Hogan RJ, *et al.* (2004) *J Virol.* 78:11416–11421.
[8]We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

CNS Candidates in Clinical Development

Pain, Psychiatry and Addiction

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



¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication; ²NDA- New Drug Application; ³BLA –Biologic Licensing Application; ⁴We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones. ⁵Pre-Investigational New Drug (IND) meeting completed in October with FDA. Striped arrow reflects that TNX-102 SL for AUD is in the pre-IND stage; upon receiving FDA clearance of an IND application, it will be Phase 2 POC ready as it is expected to qualify for the 505(b)(2) pathway for approval; ⁶TNX-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; ⁷Striped arrows reflect that TNX-601 CR is in the pre-IND stage in the U.S.; a Phase 1 study for formulation development was recently completed outside of the U.S.

TNX-102 SL

- Novel sublingual formulation of cyclobenzaprine HCl[1] designed for long-term daily use at bedtime
- Rapid absorption
- Transmucosal absorption bypasses first pass liver metabolism
- Dynamic pharmacokinetic profile with increase in cyclobenzaprine concentration during sleep induction and decrease leading up to awakening
- Cyclobenzaprine is the active ingredient of oral (swallowed) muscle relaxants, Flexeril® and Amrix®

TNX-102 SL is believed to treat fibromyalgia by improving sleep *quality,* in contrast to sleep *quantity*

- **Quality** involves restorative properties of sleep
- **Quantity** is time spent asleep
- TNX-102 SL targets clinical conditions for which improved sleep quality may have a therapeutic benefit
- Reduction in disease-specific symptoms with sleep improvement as a secondary endpoint

[1] Cyclobenzaprine is the active ingredient of oral (swallowed) muscle relaxants, Flexeril® and Amrix®

TNX-102 SL Intellectual Property – Patent Protection expected until 2035

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

- 10 patents issued worldwide; 35 patent applications pending

Composition of matter (sublingual): protection expected to 2033

- 6 patents issued worldwide; 21 patent applications pending

Fibromyalgia

Fibromyalgia is considered a neurobiological disorder characterized by[1]: chronic widespread pain, non-restorative sleep, fatigue, diminished cognition

Believed to result from inappropriate pain signaling in central nervous system in the absence of peripheral injury[1]

An estimated 6-12 million adults in the U.S. have fibromyalgia[2]

Causes significant impairment in all areas of life[3]

- Lower levels of health-related quality of life – reduced daily functioning
- Interference with work (loss of productivity, disability)

Fewer than half of those treated for fibromyalgia receive complete relief from the three FDA-approved drugs[4]

Inflicts substantial strain on the healthcare system

- Average patient has 20 physician office visits per year[5]
- Annual direct medical costs are twice those of non-fibromyalgia individuals[6]

[1] Phillips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.
[2] American Chronic Pain Association (www.theacpa.org, 2019)
[3] Schaefer et al., Pain Pract, 2015.

[4] The three drugs with FDA approval for the treatment of fibromyalgia: Pregabalin (Lyrica®); Duloxetine (Cymbalta®); Milnacipran (Savella®)
[5] Robinson et al, Pain Medicine 2013;14:1400.
[6] White et al, J Occupational Environ Med 2008;50:13.

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

Currently-approved medications may have side effects that limit long-term use[1]

High rates of discontinuation, switching and augmentation

- Attempts to treat multiple symptoms and/or avoid intolerable side effects
- Average of 2-3 medications used simultaneously[2]
- Typical patient has tried six different medications[3]
- Medication-related side effects may be similar to fibromyalgia symptoms

Substantial off-label use of narcotic painkillers and prescription sleep aids[3]

- Among those diagnosed, more than one-third have used prescription opioids as a means of treatment[4]

TNX-102 SL is a non-opioid, centrally-acting analgesic that could provide a new therapeutic option for fibromyalgia patients

[1] Nuesch et al, Ann Rheum Dis 2013;72:955-62.
[2] Robinson RL et al, Pain Medicine 2012;13:1366.
[3] Patient Trends: Fibromyalgia", Decision Resources, 2011.
[4] Berger A, Dukes E, Martin S, Edelsberg J, Oster G, Int J Clin Pract, 2007; 61(9):1498-1508.

Potential Role of Sleep Quality in Fibromyalgia

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

Believed to result from inappropriate pain signaling in central nervous system

- Absence of peripheral injury[1]

Pain is a sensor system in the brain

- When the system malfunctions, the pain alarm is turned on even through there has been no peripheral nerve tissue injury

Improving sleep quality is believed to reduce pain and fatigue in FM

- Suggesting sleep dysfunction is pathogenic in FM

TNX-102 SL acts as a non-opioid, centrally-acting analgesic to aid in the management of fibromyalgia

[1] Philips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.

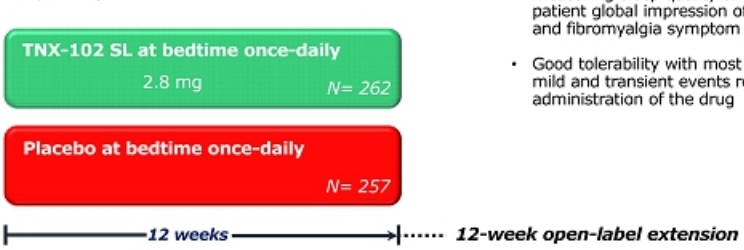
Phase 3 F301/AFFIRM[1] Study Results of TNX-102 SL 2.8 mg in Fibromyalgia

General study characteristics:

Randomized, double-blind, placebo-controlled trial in fibromyalgia at 35 U.S. sites (N=519)

Primary endpoint: Mean Pain

Mean change from baseline at Week 12 (TNX-102 SL 2.8 mg vs. placebo)



Efficacy analyses:

- Primary endpoint (30% responder analysis), p=0.095
- Key Secondary Endpoint: mean pain improvement after 12 weeks of treatment) (MMRM statistical method), p< 0.001
- Significant improvements in other secondary endpoints measuring sleep quality and sleep disturbances, fatigue, patient global impression of change, global physical health, and fibromyalgia symptom and function domains
- Good tolerability with most common adverse events generally mild and transient events related to the sublingual administration of the drug

[1]ClinicalTrials.gov Identifier NCT02436096

Phase 3 AFFIRM (F301) Study Results:
Mean Pain Analyzed by Mixed Model Repeated Measures (MMRM), with and without Multiple Imputation (MI)

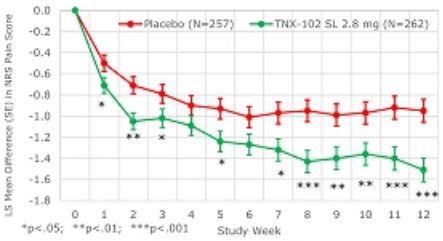
Pre-specified secondary analysis of AFFIRM:

- Mean Pain Analysis, MMRM
- TNX-102 SL N=262; Placebo N=257
- Difference in Least Square Mean (SE): -0.6 (0.15); 95% CI (-0.8, -0.3); p<0.001

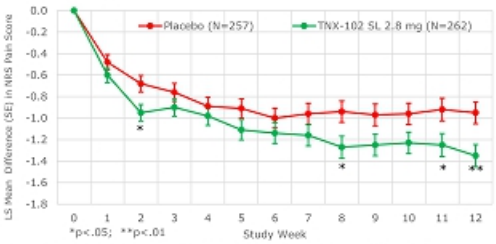
Retrospective analysis of AFFIRM:

- Mean Pain Analysis, MMRM with MI[a]
- TNX-102 SL N=262; Placebo N=257
- Difference in Least Square Mean (SE): -0.4 (0.14); 95% CI (-0.7, -0.1); p=0.005
- Tonix intends to use MMRM with MI for analyzing the primary endpoint for the new RELIEF (F304) study, in line with current FDA statistical guidance on handling of missing data

Change in Pain Scores Over 12 Weeks: MMRM



Change in Pain Scores Over 12 Weeks: MMRM with MI



[a]As will be the case for the RELIEF F304 primary analysis, all discontinuations due to Adverse Event and Lack of Efficacy are imputed using MI based on baseline values; all other discontinuations assumed to be Missing at Random and are imputed with MI using weekly data of subjects.

TNX-102 SL for Fibromyalgia
New Phase 3 Study: Higher (2x) Dose, New Primary Endpoint

Clear guidance from FDA to advance fibromyalgia program using higher dose (5.6 mg)

Long-term safety of 5.6 mg dose collected in PTSD studies expected to support fibromyalgia NDA

Retrospective analysis of mean pain improvement after 12 weeks of treatment showed statistically significant improvement using both statistical methods: MMRM ($p < 0.001$) and MMRM with MI ($p < 0.01$)

- MMRM with MI to be used going forward

First patient enrolled in the new Phase 3 RELIEF study in December 2019

Common Adverse Events (AEs) Related to TNX-102 SL in prior Posttraumatic Stress Disorder (PTSD) Studies

	P201			P301	
Category of Adverse Reaction Preferred Term	Placebo (N=94)	TNX 2.8 mg (N=93)	TNX 5.6 mg (N=50)	Placebo (N=134)	TNX 5.6 mg (N=134)
Systemic Adverse Events*#					
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 Reactions*#					
Hypoaesthesia oral	2.1%	38.7%	36.0%	1.5%	37.3%
Paraesthesia oral	3.2%	16.1%	4.0%	0.7%	9.7%
Glossodynia	1.1%	3.2%	6.0%		
Product Taste Abnormal				3.0%	11.9%

#only adverse events (AEs) are listed that are at a rate of ≥ 5% in any TNX-treated group
*no values in a row for either study means the AE in the active group(s) in that study was at a rate of <5%

AE profiles are comparable between fibromyalgia and PTSD studies

- Tolerability of TNX-102 SL 2.8 mg in two fibromyalgia studies (F201 and F301) comparable to Phase 2 PTSD study
- No serious and unexpected AEs related to TNX-102 SL at 2.8 mg or 5.6 mg
- Systemic AEs are comparable between studies and also consistent with those described in approved oral cyclobenzaprine product labeling
- Severity and incidence of oral hypoesthesia (oral numbness) are not dose related and similar in both studies

TNX-102 SL 5.6 mg for Fibromyalgia:
New Phase 3 F304/RELIEF[1] Study Enrolling

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia in approximately 40 U.S. sites (N=470)
- Adaptive Design: one planned 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)[2] *N= ~235*

Placebo once-daily at bedtime
N= ~235

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 results expected 3Q 2020[3]

Topline results expected 1H 2021 based on currently-planned sample size[3]

Potential pivotal efficacy study to support NDA approval

[1]ClinicalTrials.gov Identifier: NCT04172831
[2]Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose
[3]We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

Summary of PTSD Clinical Trials with TNX-102 SL

Phase 2 "AtEase Study" (P201)(Military population)

- 2.8 mg and 5.6 mg treatment doses
- Not significant on primary endpoint
- Median Time Since Index Trauma - 6.0 years
- Stronger activity observed at 5.6 mg treatment dose

Phase 3 "HONOR Study" (P301)(Military population)

- 5.6 mg treatment dose
- Not significant on primary endpoint
- Median Time Since Index Trauma – 9.5 years
- Stopped at Interim Analysis (separation on primary endpoint at Week 12 did not cross pre-specified study continuation threshold)
- However, activity observed in retrospective analysis for subset with trauma ≤9 years before screening

Phase 3 "RECOVERY Study" (P302)(Civilian and Military population)

- Stopped enrollment at Interim Analysis – futility or unlikely to show improvement over placebo
- Trauma ≤9 years before screening
- Data still blinded – expect topline in 2Q 2020[1]

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

TNX-102 SL for PTSD: Phase 3 P302/RECOVERY[1] Study
Expecting Topline Results in 3Q 2020

General study characteristics:

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

Interim Analysis Result was Futility

- Unlikely to reach statistical significance on primary endpoint based on first 127 patients randomized
- Enrollment stopped
- Enrolled patients will continue in trial until completion

Primary endpoint:

- CAPS-5[2] mean change from baseline at Week 12 (TNX-102 SL 5.6 mg vs. placebo)

Key Secondary endpoints include:

- Change from baseline Clinical Global Impression – Severity scale
- Change from baseline Sheehan Disability Scale total score

Interim analysis results reported 1Q 2020[4]

Topline data expected 2Q 2020[4]

[1]ClinicalTrials.gov Identifier: NCT03841773
[2]CAPS-5 = Clinician-Administered PTSD Scale for DSM-5
[3]Target enrollment – enrollment stopped at less than 250 after interim analysis
[4]We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

Opportunities to Expand to Other Indications

Role of sleep disturbance more established in common psychiatric and neurological/pain disorders

- Recognized as a core symptom of many of these disorders
- Traditional sleep medications, which increase sleep quantity, may not provide benefit (benzodiazepines in major depression) or are contraindicated

Psychiatric Disorders
- Stress Disorders (PTSD)
- Mood Disorders (Depression)
- Anxiety Disorders
- Addiction (Alcohol Use Disorder)

Psychiatric Symptoms of Neurological Disorders
- Agitation in Alzheimer's
- Psychosis in Parkinson's, Alzheimer's and other dementias

Chronic Pain States
- Chronic wide-spread pain (fibromyalgia)
- Osteoarthritis

Growing recognition that there are many disorders where sleep disturbances may have a role in the pathophysiology (cardiovascular, metabolic, neurologic)

- Sleep quality plays a homeostatic role *in several disorders*

TNX-102 SL: Potential Treatment for Agitation in Alzheimer's Disease (AAD)

Agitation is one of the most distressing and debilitating of the behavioral complications of Alzheimer's disease

- Includes emotional lability, restlessness, irritability and aggression[1]

Link between disturbed sleep and agitation in Alzheimer's[1-3]

- Agitation is commonly diurnal (e.g., "sundowning")

Prevalence

- Agitation is likely to affect more than half of the 5.3 million Americans who currently suffer from moderate to severe Alzheimer's disease; expected to nearly triple by 2050[4]

Significant unmet need with no FDA approved drugs for the treatment of AAD

Proposed Phase 2 study can potentially serve as a pivotal efficacy study to support NDA approval[5]

[1]Rose, K.et al. (2015). *American Journal of Alzheimer's Disease & Other Dementias*, *30*:78
[2]Shin, 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 1H 2020 for a Phase 2 Proof of Concept 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

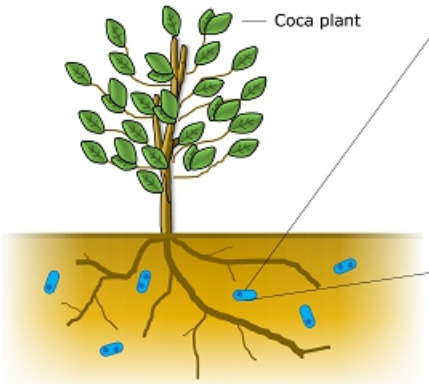
Phase 2 study completed by Rickett Benckiser (TNX-1300 was formerly RBP-8000)[3]

- 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)

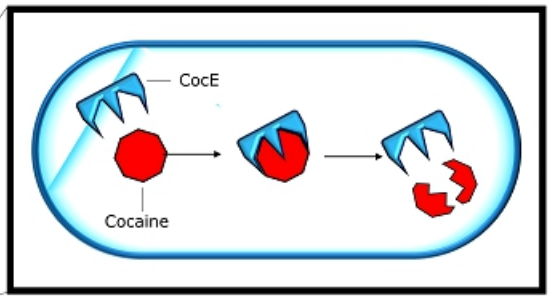
**TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

[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]



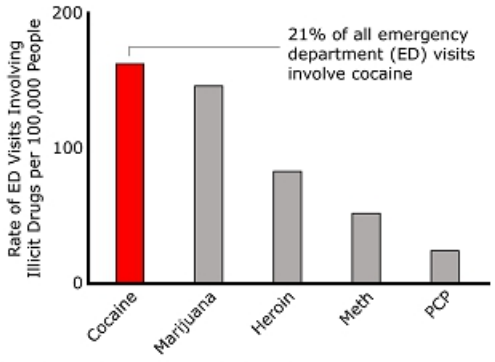
Rhodococcus bacteria living in the roots of the coca plant use CocE to metabolize cocaine[1]

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

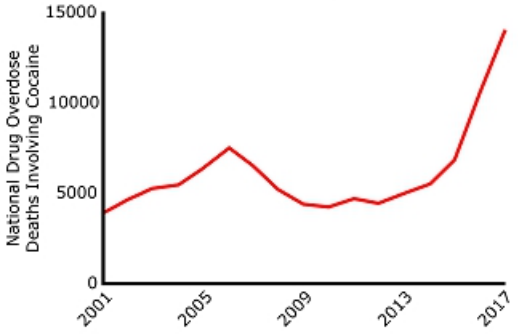
[1]Narasimhan D et al. *Future Med Chem*. 2012.

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, ex-U.S., 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] Franciškoviċ 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**
  Pre-clinical

Psychiatry

- **TNX-102 SL – (sublingual cyclobenzaprine) for PTSD**
  Phase 3/RECOVERY
  FDA Breakthrough Therapy designation
- **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, ex-U.S.
- **TNX-1600 – (triple reuptake inhibitor) for PTSD, Depression and ADHD**
  Pre-clinical

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

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
❑ **2rd Quarter 2020**	**Expect to submit IND application for TNX-102 SL to support Phase 2 POC study in AUD**
❑ **2rd Quarter 2020**	**Expect small animal data from TNX-1800 in COVID-19 model**
❑ **3rd Quarter 2020**	**Expect primate data from TNX-1800 in COVID-19 model**
❑ **3rd Quarter 2020 expected**	**Interim analysis results from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia**
❑ **1st Half 2021**	**Expect to initiate Phase 2 study of TNX-601 CR in depression, ex-U.S.**
❑ **1st Half 2021**	**Topline data from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia expected**

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

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TARGENT | Fusilev (levleucovorin) for injection | vela

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Thank you!