UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): September 28, 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.)**

28 Main Street, 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.

On September 28, 2020, Tonix Pharmaceuticals Holding Corp (the "Company") issued a press release announcing that it completed the purchase of a 40,000 square foot facility in Massachusetts. A copy of the press release is attached hereto as Exhibit 99.01.

On September 29, 2020, the Company issued a press release announcing the outcome of the pre-planned interim analysis for the Phase 3 RELIEF study of the Company's TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) 5.6 mg product candidate for the management of fibromyalgia. A copy of the press release is attached hereto as Exhibit 99.02.

**TNX-102 SL is an investigational new drug and has not been approved for any indication.*

Also on September 29, 2020, 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 attached hereto as Exhibit 99.03.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.01, 99.02 and 99.03, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events.

On September 28, 2020, the Company announced that it completed the previously announced purchase of a 40,000 square foot facility in Massachusetts to house its new Advanced Development Center for accelerated development and manufacturing of vaccines, including vaccines for COVID-19. The Company expects the facility to be operational within 24 months with single-use bioreactors and purification suites with equipment for Good Manufacturing Practice production of vaccines for clinical trials, including when fully operational, the capability of producing sterile vaccines in glass bottles. In addition, research, development and supporting analytical capabilities are planned.

On September 29, 2020, the Company announced the outcome of the pre-planned interim analysis for the Phase 3 RELIEF study of the Company's TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg product candidate for the management of fibromyalgia. An independent statistical team conducted the unblinded interim analysis of the primary endpoint of the first 50 percent of randomized participants who entered the 14-week study. Based on the interim results, and the prespecified sample size re-estimation, the independent data monitoring committee ("IDMC") made the non-binding recommendation that the trial continue to completion with the addition of 210 participants to the original sample size of 470 participants, which is the maximum number of participants that could be added under the interim statistical analysis plan. Based on this information, the Company plans to complete the study with the 503 currently enrolled participants and to report topline results in the fourth quarter of 2020. The Company remains blinded to the interim analysis results.

The Company started enrolling participants in the RELIEF study in December 2019 and continued to enroll and study fibromyalgia sufferers through the onset and progression of the COVID-19 pandemic. The Company made changes to the protocol to conform to the U.S. Food and Drug Administration's ("FDA") guidance on research during the COVID-19 public health emergency. The Company is considering the possibility that the onset of the COVID-19 pandemic affected both the reporting and variability of fibromyalgia symptoms in the interim analysis cohort, or first half, of the RELIEF participants in a way that was not anticipated prior to the pandemic. The Company believes that it is also possible that the second half of the RELIEF participants, enrolled after April 22, 2020, may have been affected by the ongoing nature of the pandemic, but differently than the first half which comprised the interim analysis cohort. The interim analysis plan did not contemplate any differences between the interim analysis cohort and subsequent cohort. The possibility that there are differences between the cohorts is the basis for the Company's decision to complete the study without adding new participants, since the IDMC recommendation was based only on analysis of the interim analysis cohort. The Company is currently enrolling into a second potentially pivotal Phase 3 trial, F306 or the RALLY study. The trial design is very similar to the ongoing Phase 3 RELIEF study. The Company believes that recruiting participants to the ongoing RALLY study is a more efficient use of resources than expanding the RELIEF study. Based on the prior Phase 2 and Phase 3 studies in fibromyalgia at a lower dose, the Company believes that TNX-102 SL has potential as a novel non-opioid, centrally-acting analgesic for the millions of U.S. adults suffering with fibromyalgia. The Company expects the FDA to require two positive registration-quality clinical studies to support marketing approval. Topline data for the RALLY study is expected in the second half of 2021.

Forward- Looking Statements

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

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

Item 9.01. Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press release of the Company, dated September 28, 2020
99.02	Press release of the Company, dated September 29, 2020
99.03	Corporate Presentation by the Company for September 2020

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: September 29, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals Completes Purchase of Facility to
House *Advanced Development Center* (ADC) for Vaccine Programs
Facility Addresses the Shortage of Vaccine Production Capacity in the U.S.

When Fully Operational the ADC Is Expected to be Capable of Manufacturing Clinical Trial Quality Vaccines,
Including Vaccines Under Development for COVID-19

CHATHAM, N.J., September 28, 2020 -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, completed the purchase a 40,000 square foot facility in Massachusetts to house its new *Advanced Development Center* (ADC) for accelerated development and manufacturing of vaccines, including vaccines for COVID-19.

Tonix expects the facility to be operational within 24 months with single-use bioreactors and purification suites with equipment for Good Manufacturing Practice production of vaccines for clinical trials, including when fully operational, the capability of producing sterile vaccines in glass bottles. In addition, research, development and supporting analytical capabilities are planned.

Tonix currently is developing potential COVID-19 vaccines based on two live viral vector platforms: horsepox and bovine parainfluenza (BPI) virus. Four potential COVID-19 vaccines in development are based on the horsepox vector and two potential vaccines based on the BPI vector. Before year end the company expects to report results from an efficacy study of its lead COVID-19 candidate based on horsepox platform, TNX-1800, in which non-human primates are being challenged with SARS-CoV-2, the virus that causes COVID-19. The TNX-1800 vaccine is based on horsepox which is believed to be similar to the live attenuated single dose smallpox vaccine developed by Dr. Edward Jenner more than 200 years ago, which led to the eradication of smallpox. TNX-1800 is designed to express the SARS-CoV-2 spike protein and to elicit a predominately T cell response in order to provide long term immunity and prevent forward transmission.

“We are excited to have taken the first step in vertically integrating more of our development activities, but, even more importantly, adding a manufacturing capability for clinical trial quality vaccines. We believe this provides Tonix with a competitive advantage, especially in the current COVID-19 environment in which more domestic development and manufacturing capacity is needed,” commented Seth Lederman, M.D., Tonix’s President and Chief Executive Officer. “As a nation, we have a mandate to reduce our reliance on off-shore resources and we hope our plans become a siren call for others to join in fulfilling this objective. We expect that the U.S. government will maintain a sustained interest in pandemic preparedness based on the devastating effect of COVID-19 on the health of the U.S. population, on education and on the economy.”

The facility is located in the New Bedford Business Park, but the facility is in a section of the park that is actually located in the Town of Dartmouth, Massachusetts. The two municipalities work together to accommodate businesses located in the Dartmouth portion of the park as the roads are inaccessible through Dartmouth and municipal services are provided by the City of New Bedford.

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. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix 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. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). Both programs are Phase 2 ready, and 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 at www.tonixpharma.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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Exhibit 99.02

Tonix Pharmaceuticals Announces Plan to Complete the Phase 3 RELIEF Study of TNX-102 SL for Management of Fibromyalgia with Currently Enrolled Participants Based on Results of Interim Analysis

Topline Results of Full Study Expected Fourth Quarter 2020

RELIEF Study Protocol Was Formally Amended Mid-Study to Conform to FDA Guidance During COVID-19 Public Health Emergency

Currently Enrolled 503 Participants Represents More than Original Target of 470

Company is Currently Enrolling a Second Potential Pivotal Phase 3 Study (RALLY) of TNX-102 SL in Fibromyalgia, with Topline Data Expected Second Half of 2021

CHATHAM, N.J., September 29, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today the outcome of the pre-planned interim analysis for the Phase 3 RELIEF study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the management of fibromyalgia. An independent statistical team conducted the unblinded interim analysis of the primary endpoint of the first 50 percent of randomized participants who entered the 14-week study. Based on the interim results and the prespecified sample size re-estimation, the independent data monitoring committee (IDMC) made the non-binding recommendation that the trial continue to completion with the addition of 210 participants to the original sample size of 470 participants, which is the maximum number of participants that could be added under the interim statistical analysis plan. Based on this information, the Company plans to complete the study with the 503 currently enrolled participants and to report topline results in the fourth quarter of 2020. The Company remains blinded to the interim analysis results.

“We plan to complete the Phase 3 RELIEF study without adding new participants,” commented Seth Lederman, M.D., President and Chief Executive Officer. “We started enrolling RELIEF in December 2019 and continued to enroll and study fibromyalgia sufferers through the onset and progression of the COVID-19 pandemic. We made changes to the protocol to conform to the U.S. Food and Drug Administration’s (FDA’s) guidance on research during the COVID-19 public health emergency. We need to consider the possibility that the onset of the COVID-19 pandemic affected both the reporting and variability of fibromyalgia symptoms in the interim analysis cohort, or first half, of the RELIEF participants in a way that was not anticipated prior to the pandemic. It is also possible that the second half of the RELIEF participants, enrolled after April 22, 2020, may have been affected by the ongoing nature of the pandemic, but differently than the first half which comprised the interim analysis cohort. The interim analysis plan did not contemplate any differences between the interim analysis cohort and subsequent cohort. The possibility that there are differences between the cohorts is the basis for our decision to complete the study without adding new participants, since the IDMC recommendation was based only on analysis of the interim analysis cohort. We believe that recruiting participants to the ongoing RALLY study is a more efficient use of resources than expanding the RELIEF study. Based on the prior Phase 2 and Phase 3 studies in fibromyalgia at a lower dose, we believe that TNX-102 SL has potential as a novel non-opioid, centrally-acting analgesic for the millions of U.S. adults suffering with fibromyalgia.”

Dr. Lederman continued, “Fibromyalgia is a significant treatment market in which the annual sales of approved drugs grew to more than $9 billion before Cymbalta® and Lyrica® went off patent. The dollar value of the fibromyalgia drug market has since decreased because of generic substitution, but the number of sufferers has not. We believe many are dissatisfied with available drug treatments. Poor tolerability is often a reason why patients give up taking the currently approved drugs. As many as one-third of fibromyalgia patients end up on chronic opiates. TNX-102 SL has the potential to provide relief from the pain and dysfunction of fibromyalgia with good tolerability and without addictive potential. We look forward to assessing top-line data from RELIEF in the fourth quarter of 2020.”

Tonix is currently enrolling into a second potentially pivotal Phase 3 trial, F306 or the RALLY study, to study TNX-102 SL for the management of fibromyalgia, with topline data expected in the second half of 2021. The trial design is very similar to the ongoing Phase 3 RELIEF study. The Company expects the FDA to require two positive registration-quality clinical studies to support marketing approval.

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 6-12 million adults in the U.S., and physicians and patients report common dissatisfaction with currently marketed products. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

About the Phase 3 RELIEF and RALLY Studies

The RELIEF and RALLY studies are double-blind, randomized, placebo-controlled trials designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets). The two-arm trials each targeted enrolling 470 participants at approximately 40 U.S. sites. For the first two weeks of treatment, there is a run-in period in which participants start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all participants have the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint is daily diary pain severity score change (TNX-102 SL 5.6 mg vs. placebo) from baseline (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

Additional details about the RELIEF study are available at clinicaltrials.gov (NCT04172831).

Additional details about the RALLY study are available at clinicaltrials.gov (NCT04508621).

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*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 at www.tonixpharma.com.

Forward Looking Statements

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Exhibit 99.03

Investor Presentation
NASDAQ:TNXP

TONIX PHARMACEUTICALS

September 2020

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Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to failure to obtain U.S. Food and Drug Administration clearances or approvals and noncompliance with its regulations; our need for additional financing; delays and uncertainties caused by the global COVID-19 pandemic; substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

Tonix Pharmaceuticals

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

Our Pipeline – Immunology & Biodefense Portfolio

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

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

Our Pipeline – CNS Portfolio

	CANDIDATES	INDICATION	STATUS
CNS Portfolio	**TNX-102 SL[1]**	**Fibromyalgia (FM) - Lead Program**	**Phase 3 – ongoing**
		PTSD	Phase 3 – ongoing
		Agitation in Alzheimer's	Phase 2 ready
		Alcohol Use Disorder	Phase 2 ready
	TNX-1300[2]	Cocaine Intoxication / Overdose	Phase 2
	TNX-601 CR[3]	Depression, PTSD, Neurocognitive Dysfunction from Corticosteroids	Phase 1
	TNX-1600[4]	Depression, PTSD and ADHD	Preclinical
	TNX-1900[5]	Migraine and craniofacial pain	Clinical – pre-IND[6]

[1]TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.
[2]TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication; licensed from Columbia University.
[3]TNX-601 CR is in the pre-IND stage in the U.S.; a Phase 1 trial for formulation development was recently completed outside of the U.S.
[4]Assets purchased from TRImaran Pharma; license agreement with Wayne State University
[5]Assets purchased from Trigemina; license agreement with Stanford University
[6]Two ex-U.S. Phase 2 trials have been completed using TNX-1900

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

Utilizes Tonix's proprietary horsepox virus as a vector

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

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

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

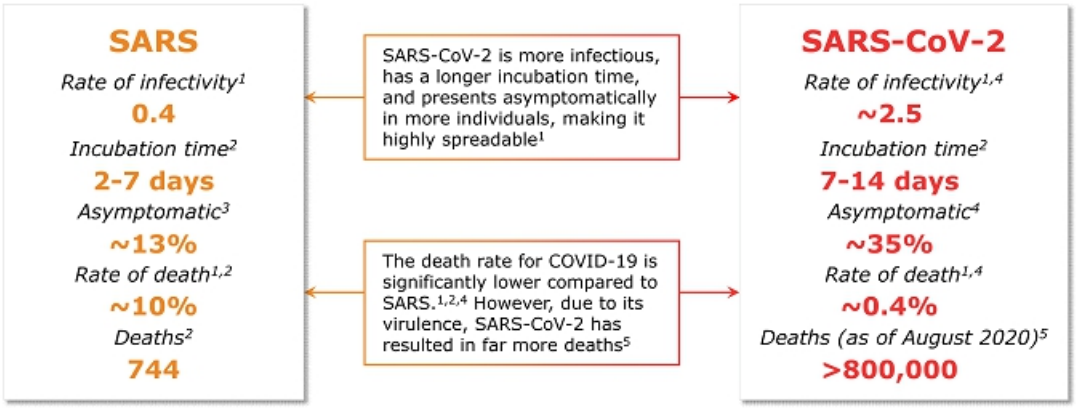
[1] TNX-1800 is at the pre-IND stage of development
[2] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

COVID-19 Vaccine Landscape

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

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

Unique Challenges of SARS-CoV-2



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

Why Use a Horsepox Platform for a Vaccine?

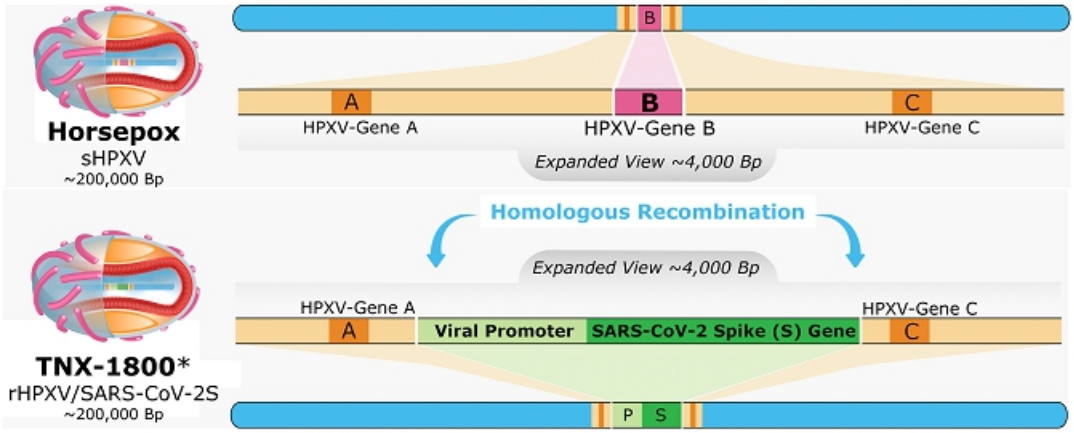
Horsepox can be engineered to express foreign genes

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

Potential advantages of horsepox over vaccinia

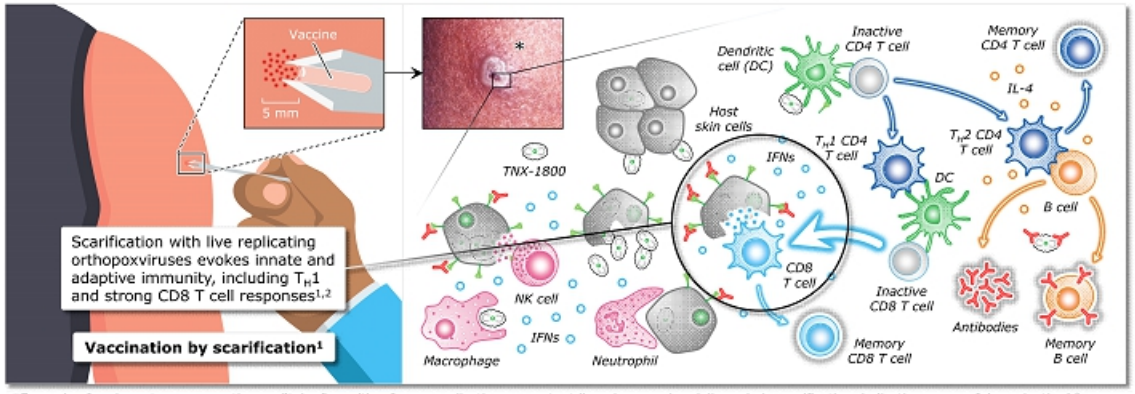
- Maintains strong immunogenicity with potentially improved tolerability
- Relative to non-replicating vaccinia, horsepox's replication in human cells provides direct antigen presentation, which is expected to trigger a T cell immune response, by Class I Major Histocompatibility Complex (MHC) Antigens
- Horsepox may behave differently than vaccinia as a vector, in part because of its different repertoire of genes that modulate immune responses and host range

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



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

TNX-1800 is Designed to Induce Robust T_H1 Cellular Immunity



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

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

Contrasting T cell and Antibody Immunity

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

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

TNX-1800 Development Status

Southern Research will address two key questions:

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

Manufacturing development for GMP virus initiated

- Clinical development will require manufacturing for clinical supplies

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

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

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

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

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

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

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

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

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

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

Overview of TNX-102 SL*

Protectic® proprietary formulation of cyclobenzaprine that supports sublingual administration

◇ Scientific Rationale for Protectic® Formulation ◇

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

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

TNX-102 SL: Differentiation from Oral Formulations

FEATURE	BENEFIT	ADVANTAGE
Cyclobenzaprine	40+ years as oral medication	Established safety record
Formulation: Protectic®	Allows submucosal absorption	Not achievable with oral formulation
Administration: sublingual	Bypasses gut	Avoids first-pass metabolism; reduced formation of "activating" metabolite
Pharmacokinetic profile	Rapid absorption (peak at ~4 hours, low trough levels 8-24 hours)	Desired profile for nighttime action
Dose: low (2.8 to 5.6 mg)	Recruitment of high affinity receptors (5-HT_{2A}, α_1, H_1)	Complimentary trimodal mechanism of action with less risk of off-target interference

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

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

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

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

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

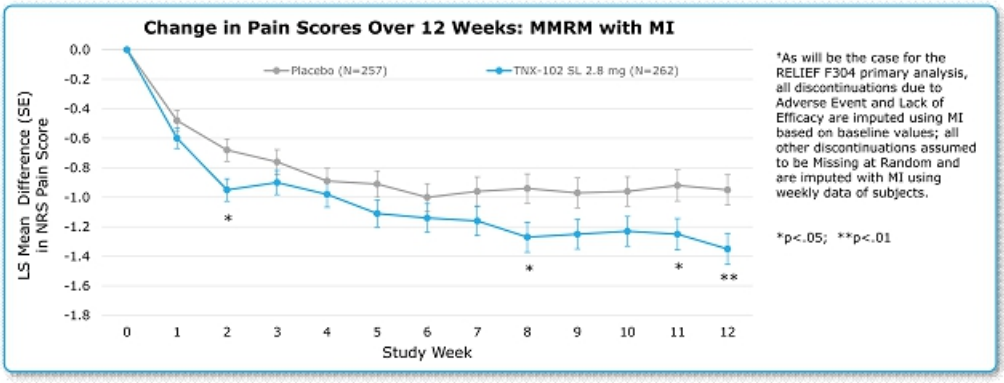
TNX-102 SL 2.8 mg: Efficacy Signal in Completed FM Trials

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

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

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

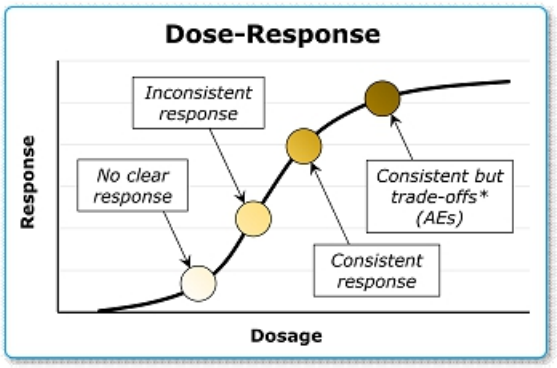
- A retrospective analysis conducted using Mean Pain Analysis, MMRM with MI† demonstrated a significant effect on pain, even though the dose was 2.8 mg



Where Are We on the Dose-Response Curve?

Basic Pharmacology

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

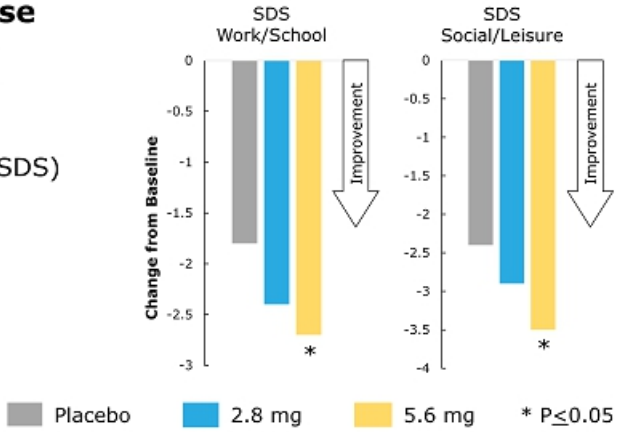


*Trade off's are increases in adverse events, side-effects and drug-drug interactions

Dose Response from Phase 2 PTSD Study

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

- Sheehan Disability Score (SDS)



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

Dose-related AEs:

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

		P201			P301	
		Placebo (N=94)	2.8 mg (N=93)	5.6 mg (N=50)	Placebo (N=134)	5.6 mg (N=134)
Systemic Adverse Event * #	Somnolence	6.4%	11.8%	16.0%	9.0%	15.7%
	Dry Mouth	10.6%	4.3%	16.0%		
	Headache	4.3%	5.4%	12.0%		
	Insomnia	8.5%	7.5%	6.0%		
	Sedation	1.1%	2.2%	12.0%		
Local Administration Site Reaction * #	Hypoaesthesia oral	2.1%	38.7%	36.0%	1.5%	37.3%
	Paresthesia oral	3.2%	16.1%	4.0%	0.7%	9.7%
	Glossodynia	1.1%	3.2%	6.0%		
	Product Taste Abnormal				3.0%	11.9%

*Only adverse events (AEs) are listed that are at a rate of ≥ 5% in any TNX-treated group

*No values in a row for either study means the AE in the active group(s) in that study was at a rate of <5%

TNX-102 SL 5.6 mg for Fibromyalgia: Phase 3 F304/RELIEF Study

- **Interim Analysis Completed in September 2020**
  - Tonix will complete the RELIEF study with the currently-enrolled sample size of 503 participants
  - 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
  - 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

Approved Fibromyalgia Pharmacotherapies

Pfizer

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

Lilly

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

Abbvie (developed by Forest Laboratories)

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

Other Fibromyalgia Pharmacotherapies in Development in the U.S.

Axsome Therapeutics - AXS-14

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

Aptinyx - NYX-2925

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

Teva - Ajovy®

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

*licensed from Pfizer, Jan 2020

Highlights of Lead Programs[1]

- **TNX-1800 potential vaccine for COVID-19[2]**
  - Preclinical stage
  - Live virus vaccine designed on our horsepox vaccine platform[4] to express the SARS-CoV-2 Spike (S) protein
  - Milestones:
    - 4th Quarter 2020 –Small animal response results expected[4]
    - 4th Quarter 2020 – Primate testing results expected[4]
    - 2021 – Initiation of Phase 1 human safety study expected[4]
- **TNX-102 SL for fibromyalgia (FM)**
  - Phase 3 clinical development – RELIEF and RALLY studies
  - Sublingual cyclobenzaprine tablets at higher dose of 5.6 mg
  - Milestones:
    - September 2020 – Enrollment initiated in new Phase 3 RALLY study
    - September 2020 – Interim analysis completed
    - Fourth quarter 2020 - Topline data expected from RELIEF study[4]
    - Second half 2021 - Topline data expected from RALLY study[4]

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

Opportunities to Expand TNX-102 SL to Other Indications

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

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

Psychiatric Disorders

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

Psychiatric Symptoms of Neurological Disorders

- Agitation in Alzheimer's
- Psychosis in Parkinson's, Alzheimer's and other dementias

Chronic Pain States

- Chronic wide-spread pain (fibromyalgia)
- Osteoarthritis

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

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

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

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

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

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

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

Prevalence

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

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

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

[1]Rose, K.et al. (2015). *American Journal of Alzheimer's Disease & Other Dementias, 30*:78
[2]Shih, Y. H., et al. (2017). *Journal of the American Medical Directors Association, 18*, 396.
[3]Canevelli, M., et al. (2016). *Frontiers in medicine, 3*.
[4]The Alzheimer's Association, 2017 Alzheimer's Disease Facts and Figures: https://www.alz.org/facts/
[5]FDA comments on final protocol received October 2018

TNX-102 SL: Potential Treatment for Alcohol Use Disorder (AUD)

AUD is a chronic relapsing brain disease

- Characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using

Sleep disturbance is extremely common in alcohol recovery[1]

- Significantly impacts daytime cognition, mood, and ability to participate in alcohol treatment, and is associated with increased risk of relapse

Prevalence

- An estimated 36 million adults in the U.S. have AUD[2]

Three FDA-approved medications

- Remains an unmet need due to compliance and safety issues

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

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

[1]Arnedt et al, J Addict Dis. 2007 ; 26(4): 41–54
[2]Grant et al, JAMA Psychiatry 2015; 72(8): 757-766; www.census.gov

TNX-1300* for the Treatment of Cocaine Intoxication

Recombinant protein that degrades cocaine in the bloodstream[1]

- Double-mutant cocaine esterase (CocE)
- CocE was identified in a bacterium (*Rhodococcus*) that use cocaine as its sole source of carbon and nitrogen and that grow in soil surrounding coca plants[2]
- CocE catalyzes the breakdown of cocaine into metabolites ecgonine methyl ester and benzoic acid

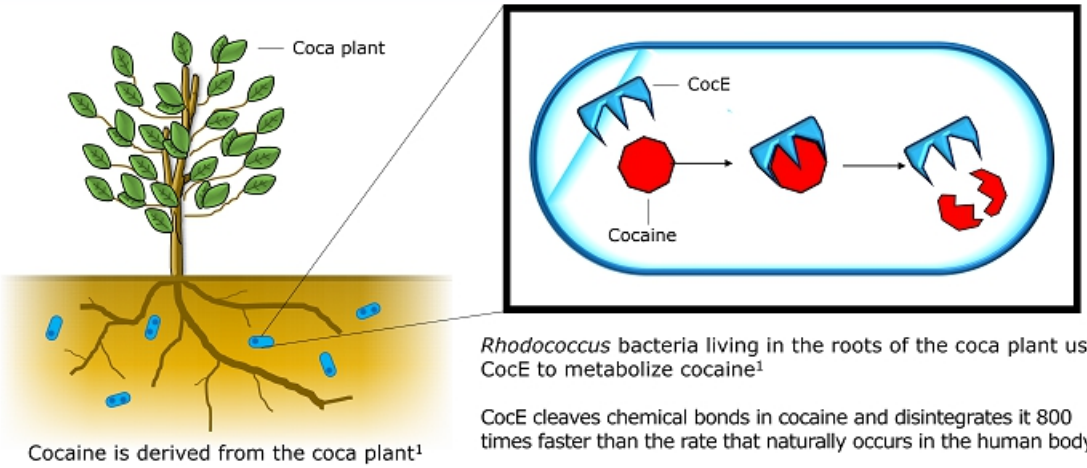
Phase 2 study completed by Rickett Benckiser (TNX-1300 was formerly RBP-8000)[3]

- Volunteer cocaine abusers received cocaine 50 mg *i.v.* infusion over 10 minutes
- TNX-1300 given one minute after completion of cocaine infusion
  - Rapidly reversed the physiologic effects of cocaine; cocaine plasma exposures dropped by 90% within two minutes
  - Well tolerated with the most frequently reported adverse events being gastrointestinal disorders (including dry mouth, nausea); nervous systems disorders (including headache, dizziness) and skin and subcutaneous tissue disorders (including hyperhidrosis, dermatitis)

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

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

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



Cocaine is derived from the coca plant[1]

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

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

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

Psychiatry, Immunology and Oncology Preclinical Pipeline[1]

Pipeline Product	Indication(s)	Category
TNX-1600 Triple reuptake inhibitor[2]	**Daytime treatment for Depression, PTSD and ADHD[3]**	**Psychiatry**
TNX-1500 Anti-CD154 monoclonal antibody	**Prevention and treatment of organ transplant rejection** **Treatment of autoimmune conditions**	**Transplant** **Autoimmunity**
TNX-1700 rTFF2[4]	**Treatment for gastric and pancreatic cancers**	**Oncology**

[1] Experimental new medicines and biologics, not approved for any indication
[2] (2S,4R,5R)-5-(((2-aminobenzo[d]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2H-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine) – licensed from Wayne State University
[3] ADHD = attention deficit hyperactivity disorder
[4] Recombinant Trefoil Family Factor 2 – licensed from Columbia University

Pipeline Summary – by Select Therapeutic Areas

Pain

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

Addiction Medicine

- **TNX-1300 (cocaine esterase) for cocaine intoxication**
  Phase 2
  FDA Breakthrough Therapy designation
- **TNX-102 SL (sublingual cyclobenzaprine) for alcohol use disorder**
  Phase 2 ready

Neurology

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

Pipeline Summary – by Select Therapeutic Areas (continued)

Public Health

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

Biodefense

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

Milestones – Recently Completed and Upcoming[1]

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

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

Management Team

Seth Lederman, MD
President & CEO

TARGENT X · Fusilev (levoleucovorin) for injection · vela

Gregory Sullivan, MD
Chief Medical Officer

Columbia University Department of Psychiatry · New York State Psychiatric Institute

Bradley Saenger, CPA
Chief Financial Officer

Shire · VERTEX · Steward · pwc

Jessica Morris
Chief Operating Officer

Deutsche Bank · svb Silicon Valley Bank · American Capital

TONIX PHARMACEUTICALS

Thank You!