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 21, 2021

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

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

26 Main Street, Suite 101, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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

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

Securities registered pursuant to Section 12(b) of the Act:

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

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

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

Item 7.01 Regulation FD Disclosure.

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

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

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description.**
99.01	Corporate Presentation by the Company for September 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 21, 2021

By: /s/ Bradley Saenger
Bradley Saenger

Chief Financial Officer

Exhibit 99.01

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, the 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. 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, 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

WHAT WE DO

OUR MISSION

ADVANCING THE SCIENCE AND UNDERSTANDING OF DISEASES

by developing **innovative therapies** that improve **population health**

by focusing on **unmet needs** in patient care

OUR STRATEGY

Using our integrated development engine, we advance innovative programs across multiple therapeutic areas into the clinic while maximizing asset potential

TONIX PHARMACEUTICALS

PIPELINE

COVID, BIODEFENSE & IMMUNOLOGY PORTFOLIO

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

CANDIDATES	PORTFOLIO & INDICATION	NEXT MILESTONE
	COVID	
TNX-1800	COVID-19 Vaccine[1]	Phase 1 start - 1H 2022
TNX-102 SL	Long COVID-19 (Post-Acute Sequelae of COVID-19 or PASC)[2]	Clinical - Pre-IND
TNX-2100	SARS-CoV-2 Diagnostic for T-Cell Immunity[3]	First-in-human study - Q4 2021
TNX-3500	COVID-19 Antiviral[4]	Preclinical
	BioDefense	
TNX-801[5]	Smallpox and monkeypox preventing vaccine	Preclinical
TNX-701	Radioprotection	Preclinical
	Immunology & Oncology	
TNX-1500[6]	Organ Transplant Rejection/ Autoimmune Conditions	Preclinical
TNX-1700[7]	Gastric and pancreatic cancers	Preclinical

**All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

[1]Live attenuated vaccine based on horsepox virus vector.
[2]Pre-IND meeting with the FDA completed and based on final meeting minutes, Company plans to file IND to support Phase 2 study in subset of patients whose symptoms overlap with fibromyalgia
[3]In vivo diagnostic: SARS-CoV-2 peptide epitope mixtures for intradermal administration to measure delayed-type hypersensitivity to SARS-CoV-2.
[4]Sangivamycin for injection.
[5]Live attenuated vaccine based on horsepox virus
[6]anti-CD40L humanized monoclonal antibody
[7]Recombinant trefoil factor 2 (rTFF2) based protein; licensed from Columbia University

TONIX PHARMACEUTICALS

PIPELINE
CNS PORTFOLIO

Candidates	INDICATION	STATUS
	CNS	
TNX-102 SL[1]	Fibromyalgia (FM) Posttraumatic Stress Disorder (PTSD) Long COVID (PASC[2])	Phase 3 Ongoing Phase 2 Clinical – Pre-IND[3]
TNX-1300[4]	Cocaine Intoxication / Overdose	Phase 2
TNX-1900[5]	Migraine and Craniofacial Pain	Clinical – pre-IND[6]
TNX-2900[7]	Prader-Willi Syndrome	Clinical – pre-IND
TNX-601 CR	Depression, PTSD, Neurocognitive Dysfunction from Steroids	Clinical – pre-IND[8]
TNX-1600[9]	Depression, PTSD and ADHD	Preclinical

**All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

[1]TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication. Long COVID/PASC program is also included in the COVID-19 Portfolio. Additional indications of Agitation in Alzheimer's Disease (AAD) and Alcohol Use Disorder (AUD) are Phase 2 ready.
[2]Post-Acute Sequelae of COVID-19.
[3]Pre-IND (Investigational New Drug) meeting with the FDA completed and based on final minutes Company plans to file IND to support Phase 2 study in patients whose symptoms overlap with fibromyalgia
[4]TNX-1300 (double-mutant cocaine esterase) is an investigational new biologic and has not been approved for any indication; licensed from Columbia University.
[5]Acquired from Trigemina; license agreement with Stanford University
[6]A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900; Phase 2 expected to start 1H'22
[7]Co-exclusive license agreement with French National Institute of Health and Medical Research (Inserm)
[8]TNX-601 CR is in the pre-IND stage in the U.S.; a Phase 1 trial for formulation development was completed outside of the U.S; Phase 2 expected to start 1H 2022
[9]Acquired from TRImaran Pharma; license agreement with Wayne State University[10]anti-CD40L humanized monoclonal antibody

ADHD = attention-deficit hyperactivity disorder; FM = fibromyalgia; IND = investigational new drug; PASC = post-acute sequelae of COVID-19; PTSD = posttraumatic stress disorder.

CNS PORTFOLIO

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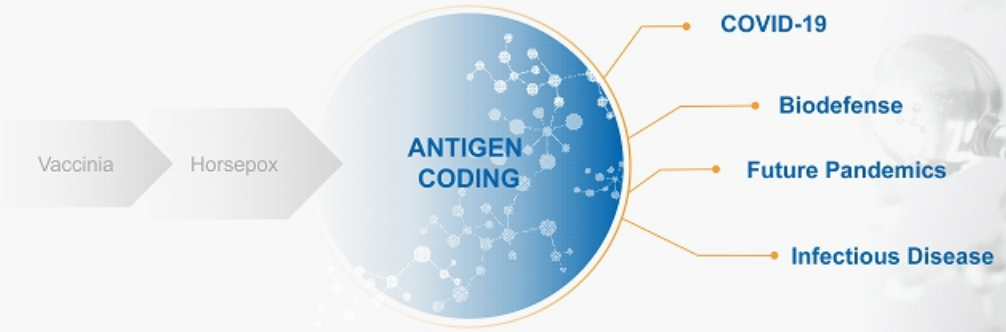
KEY CANDIDATES: COVID, BIODEFENSE & IMMUNOLOGY

RECOMBINANT POX VACCINE (RPV) PLATFORM:
NEW VACCINE TECHNOLOGY FOR EMERGING DISEASES



Using Proven Science To Address Challenging Disease States, We Have Created A Programmable Technology Platform Aimed At Combating Future Threats To Public Health

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

TONIX PHARMACEUTICALS

RPV PLATFORM PROFILE

POTENTIALLY LONGER DURABILITY DUE TO POX-ENGINEERED ARCHITECTURE

- Enables broad CD8 T-cell response, resulting in strong immune response

PROGRAMMABLE VECTOR DESIGN FOR USE IN DIFFERENT DISEASE MODELS

- Responsive to new variants
- Wide range of clinical applications: pandemic, biodefense, infectious disease, smallpox, oncology

VIRUS-BASED SCIENCE IS WELL ESTABLISHED

- Streamlined development
- Ability to vertically integrate development and manufacturing
- Highly concentrated non–cold-chain products

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

TONIX PHARMACEUTICALS

TNX-1800 COVID-19 VACCINE
RPV PLATFORM DEVELOPMENT PROGRAM

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

ESTABLISHES RPV PLATFORM

- Encodes a protein from SARS-CoV-2, the cause of COVID-19
- Provides a novel, variant-reflexive alternative to mRNA products

ANIMAL TESTING WITH SOUTHERN RESEARCH INSTITUTE

- Non-human primate immune response: positive results reported in Q4 2020
- Non-human primate CoV-2 challenge testing: positive data reported in Q1 2021

MANUFACTURING AGREEMENT WITH FUJIFILM DIOSYNTH

- Development for GMP manufacturing for human trials
- GMP clinical supply expected to be ready for human trials in 1H 2022

Patents Filed

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Vaccine

Additional Indications: Future Pandemic, Infectious Disease, Smallpox, Cancer

Status: Preclinical

Next Steps: 1H 2022 Initiate Phase 1 Study

TONIX PHARMACEUTICALS

RPV PLATFORM: WHAT MAKES TNX-1800 DIFFERENT FROM MRNA VACCINES

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

CRITERIA	mRNA VACCINES	TNX-1800*
Number of shots	Two	One
Duration	8 months	Years / decades
Boosters	Recommended	Likely not required
Protection from variants	Variants	Expected
Forward transmission	Unknown for variants like delta	Likely prevents
Biomarker	None	Yes – "Take"
Manufacturing	Complex	Conventional
Glass-sparing packaging	No	Yes
Shipping and storage	Cold chain	Standard refrigeration
Protection from smallpox	No	Yes

** Characterizations of TNX-1800 show in table represent expectations.*

TONIX PHARMACEUTICALS

US TRENDS IN COVID-19 VACCINE BOOSTER DEVELOPMENT

CURRENT US GOVERNMENT STANCE IS BOOSTERS MAY BE NEEDED POST- PFIZER OR MODERNA VACCINATION[1]

- CDC, FDA, White House, COVID-19 Response Team stated that immunity wanes and booster vaccines are being considered
- FDA advisory committee has voted in favor of a Pfizer booster shot for those 65 and older as well as high-risk individuals
- J&J vaccine duration under review

BOOSTER DEVELOPMENT ACTIVITY

- Pfizer applied for FDA approval of potential boosters based on a Phase 3 clinical trial in which participants were given a booster between 4.8 and 8 months after completing the two-dose primary regimen[2]
- J&J and Moderna also developing boosters[3-4]

IMPORTANCE OF TESTING PROTECTIVE IMMUNITY

- Personalized approach to determine need for vaccine boosters
- More cost effective
- Reduces risk with unnecessary vaccination
- One-size-fits-all booster strategy is expensive and unlikely unsustainable

[1]www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html
[2]www.investors.pfizer.com/investor-news/press-release-details/2021/Pfizer-and-BioNTech-Initiate-Rolling-Submission-of-Supplemental-Biologics-License-Application-to-U.S.-FDA-for-Booster-Dose-of-COMIRNATY-in-Individuals-16-and-Older/default.aspx
[3]www.jnj.com/johnson-johnson-announces-data-to-support-boosting-its-single-shot-covid-19-vaccine
[4]investors.modernatx.com/news-releases/news-release-details/moderna-announces-submission-initial-data-us-fda-its-covid-19

RPV PLATFORM & COVID-19 VACCINE
INTERNAL DEVELOPMENT & MANUFACTURING CAPABILITIES

Infectious Disease R&D Center (RDC) – Frederick, MD

- Function: Accelerated development of vaccines and antiviral drugs against COVID-19, its variants and other infectious diseases
- Description: ~48,000 square feet, BSL-2, currently operated by Southern Research
- Status: Acquisition expected to close in the fourth quarter of 2021

Advanced Development Center (ADC) – New Bedford, MA

- Function: Development and clinical scale manufacturing of live-virus vaccines to support Phase 1 and Phase 2 trials
- Description: ~45,000 square feet, under construction, planned BSL-2
- Status: Expected to be operational in first half 2022

Architectural Rendering

Commercial Manufacturing Center (CMC) – Hamilton, MT

- Function: Commercial scale manufacturing of live-virus vaccines
- Description: ~44 acre green field site, planned BSL-2
- Status: Planning for initiation of construction in 2022

Architectural Rendering

ASSESSING ANTI-SARS-COV-2 PROTECTIVE IMMUNITY

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

TWO TYPES OF IMMUNITY

- *Antibodies* – can be measured in a blood test, but anti-SARS-CoV-2 antibodies are not predictive of protection
- *T cell* – can be measured in a blood test, but requires sophisticated lab, unknown if predictive

NEUTRALIZING ANTIBODIES – APPEAR TO CORRELATE WITH PROTECTION[1]

- Not part of standard antibody tests
- Requires culture of antibodies with live SARS-CoV-2; possibly "pseudo-type" assays

FUNCTIONAL T CELL IMMUNITY

- *in vivo* – classic skin test – correlation with protection under investigation[2,3]

[1]Krammer, F. (2021) Nature Medicine. 27:1145–1153. https://www.nature.com/articles/s41591-021-01432-4.pdf
[2]Barrios, Y et al. Clinical Immunol. (2021) 226:108730
[3]Barrios, Y et al. Vaccines (2021) 9:575

TONIX PHARMACEUTICALS

TNX-2100*: COVID-19 DIAGNOSTIC TO CONFIRM T-CELL IMMUNITY

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

MEASURES THE PRESENCE AND STRENGTH OF FUNCTIONAL IN VIVO T-CELL IMMUNITY

- Designed to elicit delayed-type hypersensitivity in individuals who have been exposed to SARS-CoV-2 or successfully vaccinated
- SARS-CoV-2 epitope peptide mixtures for intradermal administration (Skin Test)

POTENTIALLY SCALABLE FOR WIDESPREAD USE

- Many tests[†] for T-cell immunity to SARS-CoV-2 require specialized laboratories and are not amendable to standardization
- Adaptive Biotech's T Detect™ COVID-19 test received FDA EUA based on genetic analysis of T-cell receptors

DEVELOPMENT PLANS

- Q4 2021: Plan to initiate first-in-human clinical testing pending clearance of IND
- Patents filed

*TNX-2100 is in the pre-IND stage of development and has not been approved for any indication.
[†]Intracellular cytokine staining (ICS) measured by flow cytometry after in vitro stimulation of purified peripheral blood mononuclear cells.

TONIX PHARMACEUTICALS

TNX-3500*: COVID-19 ANTIVIRAL TREATMENT
SANGIVAMYCIN

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

PROFILE

New variants heighten need for therapeutics

NIH Treatment Guidelines for COVID-19 are mixed on use of remdesivir

Potential monotherapy antiviral[1]
- 65 times more potent than remdesivir in inhibiting SARS-CoV-2 in cell culture infectivity studies (dose to achieve IC_{90})[2]

Potential combination therapy with remdesivir
- TNX-3500 antiviral effect is additive when combined with remdesivir and reduces the amount of each drug necessary for an IC_{90}
- Combination therapies for other viruses have reduced the emergence of drug resistant viral strains

Patents Filed

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Antiviral

Additional Indications: MERS, Ebola, Lassa, Oncology

Status: Preclinical

Next Steps: Q3 2021 Initiate Animal Studies

MERS = Middle East Respiratory Syndrome; NIH = National Institutes of Health; PK = pharmacokinetics.

*TNX-3500 is in the pre-IND stage of development and has not been approved for any indication.

1. Bennett RP et al. *Viruses*. 2020;13(1):52. doi: 10.3390/v13010052.
2. Data on file, live virus BSL-4 testing conducted by NIAID in collaboration with OyaGen.

TONIX PHARMACEUTICALS

TNX-102 SL: LONG COVID (PASC)
CYCLOBENZAPRINE PROTECTIC® SUBLINGUAL TABLETS

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

PROFILE

Long COVID or Post-acute Sequelae of COVID-19 (PASC) – What is it?

- Symptoms can include fatigue, sleep disorders, pain, fevers, shortness of breath, cognitive impairment described as "brain fog", gastrointestinal symptoms, anxiety, and depression
- Can persist for months and can range in severity from mild to incapacitating
- Occurs in 30% of patients
- Typically associated with moderate or severe COVID-19, Long COVID can occur after mild COVID-19 or even after asymptomatic SARS-CoV-2 infection

To address the urgent need for PASC therapies, Congress awarded the National Institutes of Health $1.15 billion to study Long COVID.

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Long COVID (PASC)

Status: Clinical – pre-IND; FDA minutes from pre-IND meeting received in Q3 2021

Next Steps: Submit IND for treating subset of Long COVID patients whose symptoms overlap with fibromyalgia in Q1 2022

1Feb. 24, 2021 - White House COVID-19 Response Team press briefing; Feb 25, 2021 - policy brief from the World Health Organization on long COVID 2Nalbandian, Ani, et al. "Post-acute COVID-19 syndrome." Nature Medicine (2021): 1-15. 3Clauw DJ, et al. Pain. 2020 Aug; 161(8): 1694–1697. 4Cox, D. "Why are women more prone to long Covid?." The Guardian. 13 Jun 2021 https://www.theguardian.com/society/2021/jun/13/why-are-women-more-prone-to-long-covid Silriggs, Andrew, and Anna Vassall. "Count the cost of disability caused by COVID-19." (2021): 502-505. 6The NIH provision of Title III Health and Human Services, Division M--Coronavirus Response and Relief Supplemental Appropriations Act, 2021, of H.R. 133, The Consolidated Appropriations Act of 2021. The bill was enacted into law on 27 December 2020, becoming Public Law 116-260.

TONIX PHARMACEUTICALS

TNX-1500
NEXT GENERATION CD40 LIGAND ANTIBODY

COVID BIODEFENSE AND IMMUNOLOGY PORTFOLIO

THE CD40-CD40L PATHWAY IS A PIVOTAL IMMUNE SYSTEM MODULATOR AND IS A WELL-ESTABLISHED AND PROMISING TREATMENT TARGET TO MORE SAFELY PREVENT ALLOGRAFT REJECTION[1]

First Generation: Development *halted due to thromboembolic (TE) complications—blood clots*—traced to Fc gamma receptor (FcγR)

Second Generation: Eliminated the FcγR TE complication but *potency and half life was reduced, limiting utility*

Third Generation: Re-engineered to better modulate the binding of FcγR while preserving FcRn function

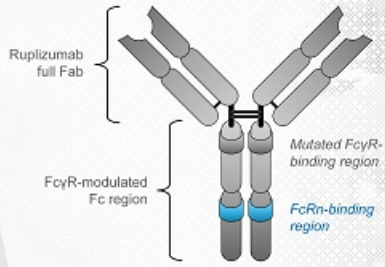
- Expected to deliver efficacy without compromising safety

Status: Preclinical; collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

Next Steps: 2H 2022 Initiate Phase 1 Study

Patents Filed

SELECTIVELY MODIFIED ANTI-CD40L AB



Contains the full ruplizumab Fab and the engineered Fc region that modulates FcγR-binding, while preserving FcRn function.

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1. Camilleri B, et al. *Exp Clin Transplant.* 2016;14(5):471-483.

TONIX PHARMACEUTICALS

KEY CANDIDATES: CNS

TNX-102 SL: FIBROMYALGIA
CYCLOBENZAPRINE PROTECTIC® SUBLINGUAL TABLETS

CNS PORTFOLIO

PROFILE

A unique formulation of cyclobenzaprine designed to optimize delivery and absorption

Innovative and proprietary PROTECTIC® Rapid drug exposure following nighttime administration

- Lower daytime exposure
- Avoids first-pass metabolism
  - Reduces risk of pharmacological interference from major metabolite

Clinical trial program designed to examine treatment of core Fibromyalgia symptoms

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Fibromyalgia

Additional Indications: PTSD, Agitation in Alzheimer's, Alcohol Use Disorder, Long COVID

Status: One Positive Phase 3 study (RELIEF) Completed

Next Steps: Second Phase 3 Study Ongoing; topline data expected Q4 2021

TONIX PHARMACEUTICALS

TNX-102 SL: FIBROMYALGIA
CYCLOBENZAPRINE PROTECTIC® SUBLINGUAL TABLETS PROGRAM UPDATE

CNS PORTFOLIO

Phase 3 Study, RALLY (F306)

- July 2021: Tonix stopped enrollment in the RALLY study following an unblinded, pre planned interim analysis by the Independent Data Monitoring Committee (IDMC).
- Based on interim analysis results of the first 50% (n=337) enrolled participants, the IDMC recommended stopping the trial as TNX-102 SL is unlikely to demonstrate a statistically significant improvement in the primary endpoint.
- Tonix will currently allow enrolled participants (n= 514) to complete the treatment period.
- 4th quarter 2021: topline results expected, following completion of study for currently enrolled participants

Following analysis of results from the full RALLY study, Tonix will determine next steps for fibromyalgia program.

TNX 102-SL Development Beyond Fibromyalgia

- Development efforts continue in PTSD, Agitation in Alzheimer's, Alcohol Use Disorder, Long COVID

TONIX PHARMACEUTICALS

TNX-601 CR: PSYCHIATRY
TIANEPTINE OXALATE AND NALOXONE

CNS PORTFOLIO

PROFILE

A novel, oral, controlled release once-daily tablet

Mechanistically different from traditional MAOI treatments for depression

Indirectly modulates the glutamatergic system

- Bypasses interaction with NMDA, AMPA, or kainate receptors

Naloxone added to deter parenteral abuse

Treatment effect of tianeptine in depression is well-established

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Major Depressive Disorder

Additional Indications: PTSD, Neurocognitive Disorder From Corticosteroids

Status: Clinical – pre-IND

Next Steps: 1H 2022 Initiate Phase 2 Trial

AMPA=α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid; MAOI=monoamine oxidase inhibitors; NMDA=N-methyl-D-aspartate.

TONIX PHARMACEUTICALS

TNX-1900: MIGRAINE
INTRANASAL POTENTIATED OXYTOCIN (OT) WITH MAGNESIUM

CNS PORTFOLIO

PROFILE

Intranasal OT has potential utility in treating migraine[1]

- Intranasal OT reaches the trigeminal ganglion
- Preclinical evidence of OT blocking CGRP release and suppressing pain
- Association of low OT levels during and preceding migraine episodes
- Novel non-CGRP antagonist approach to treatment

Magnesium is known to potentiate the binding of OT to its receptor[2]

One billion individuals worldwide suffer from migraines

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Chronic Migraine

Additional Indications: Neuropathic Pain

Status: Clinical – pre-IND[3]

Next Steps: 1H 2022 Initiate Phase 2 Trial

1. Tzabazis et al., 2017.
2. Antoni and Chadio, 1989.
3. A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900

CGRP = calcitonin gene-related peptide.

TONIX PHARMACEUTICALS

TNX-2900: PRADER-WILLI SYNDROME
INTRANASAL POTENTIATED OXYTOCIN (OT) WITH MAGNESIUM

CNS PORTFOLIO

PROFILE

Prader-Willi Syndrome is the most common genetic cause of life-threatening childhood obesity

- Orphan disease occurring in 1 in 15,000 births

Symptoms include lack of suckling as infants, poor muscle strength, and constant hunger (hyperphagia)

- In animal models, OT has improved suckling and suppressed hunger
  - Tonix's patented potentiated OT formulation is believed to increase specificity for OT receptors relative to vasopressin receptors

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Prader-Willi Syndrome

Additional Indications: Rare, Orphan Hyperphagia Conditions

Status: pre-IND

Next Steps: Submit applications to the FDA for Orphan Drug and Fast Track designations for TNX-2900

TONIX PHARMACEUTICALS

TNX-1300: COCAINE INTOXICATION
COCAINE ESTERASE (CoCe)

CNS PORTFOLIO

PROFILE

Cocaine is the main cause for drug-related ED visits[1]

Cocaine use can cause irreversible structural damage to the heart and accelerate cardiovascular disease[2]

- In one survey of 94 long-term cocaine users, 71% had some form of cardiovascular disease[3]

CoCe is a recombinant protein that degrades cocaine in the bloodstream

- **Rapidly reverses physiologic effects of cocaine**
- **Drops plasma exposure by 90% in 2 minutes**

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Cocaine Intoxication

Additional Indications: Cocaine Overdose

Status: Phase 2 Open Label

Next Steps: Q4 2021 Initiate Trial

FDA Breakthrough Therapy Designation

1. Havakuk O et al. *J Am Coll Cardiol*. 2017;70:101-113.
2. Phillips K et al. *Am J Cardiovasc Drugs*. 2009;9:177-196.
3. Maceira AM et al. *J Cardiovasc Magn Reson*. 2014;16:28.
4. Richards JR. *Am J Cardiol*. 2018;121:393.

ED = emergency department.

TONIX PHARMACEUTICALS

KEY DEVELOPMENT PARTNERS

Massachusetts General Hospital · Harvard Medical School

TNX-1500: ALLOGRAFT REJECTION

Columbia University

TNX-1300: COCAINE INTOXICATION
TNX-1700: GASTRIC AND PANCREATIC CANCERS

Stanford University · Université de Genève

TNX-1900: MIGRAINE & OTHER INDICATIONS

University of Alberta · SR Southern Research

TNX-1800: COVID-19 VACCINE

InsermTransfert · CHU de Toulouse · Aix Marseille université

TNX-2900: PRADER-WILLI SYNDROME

TONIX PHARMACEUTICALS

MILESTONES:
RECENTLY COMPLETED AND UPCOMING*

- ✓ 4th Quarter 2020 Positive topline data from TNX-102 SL Phase 3 F304/RELIEF study in fibromyalgia reported
- ✓ 1st Quarter 2021 Non-human primate positive efficacy data from TNX-1800 in COVID-19 models reported
- ✓ 3rd Quarter 2021 Interim analysis of TNX-102 SL Phase 3 F306/RALLY study in fibromyalgia reported

Data

- ❑ 4th Quarter 2021 Topline data from TNX-102 SL Phase 3 F306/RALLY study in fibromyalgia expected

Clinical Trial Initiations – Three New Trials This Year

- ❑ 4th Quarter 2021 Phase 2 OL safety study of TNX-1300 in ED setting for cocaine intoxication expected
- ❑ 4th Quarter 2021 Phase 2 study of TNX-102 SL for the treatment of PTSD in Kenya expected
- ❑ 4th Quarter 2021 First-in-human clinical study of TNX-2100 for SARS-CoV-2 skin test expected
- ❑ 1st Half 2022 Phase 1 safety study of TNX-1800 for COVID-19 expected
- ❑ 1st Half 2022 Phase 2 study of TNX-1900 for the treatment of migraine expected
- ❑ 1st Half 2022 Phase 2 study of TNX-601 CR for the treatment of major depressive disorder expected
- ❑ 2nd Half 2022 Phase 1 study of TNX-1500 for prevention of allograft rejection expected

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

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TARGENT X · Fusilev (levoleucovorin) for injection · vela pharm

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