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

FORM 8-K

CURRENT REPORT

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

Date of report (date of earliest event reported): November 6, 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, 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))

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 2.02 Results of Operations and Financial Condition

On November 8, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended September 30, 2021. A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Item 7.01 Regulation FD Disclosure.

On November 6, 2021, the Company presented an oral presentation of positive results from its Phase 3 clinical study, RELIEF, of TNX-102 SL for the management of fibromyalgia entitled, "*TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia in the RELIEF Study: Positive Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Efficacy and Safety Trial*" (the "Presentation") at the American College of Rheumatology Convergence 2021. Copies of the Presentation and press release which discusses this matter are furnished hereto as Exhibits 99.02 and 99.03, respectively, and incorporated herein by reference.

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 99.04 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.02, 99.03 and 99.04 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On November 6, 2021, the Company presented an oral presentation of previously announced positive results from its Phase 3 clinical study, RELIEF, of TNX-102 SL for the management of fibromyalgia entitled, "*TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia in the RELIEF Study: Positive Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Efficacy and Safety Trial"*. The study shows that there was a higher rate of responders to TNX-102 SL (47%) than to placebo (35%; p=0.006). Early discontinuation rates in the study were similar for TNX-102 SL and placebo (16.5% and 17.7%, respectively). In addition, TNX-102 SL was well tolerated with the most common adverse event from active treatment being oral hypoaesthesia, a sensory administration site reaction that is typically transient, was never rated as severe, and only led to one discontinuation of a trial participant. Topline results from RALLY, a second Phase 3 study for TNX-102 SL for the management of fibromyalgia, enrollment in which was stopped after an interim analysis showed that the study was not likely to meet its primary endpoint, are expected before year end. The

Company will determine the next steps in this program based on analysis of the RALLY data, which will include pharmacogenomic analyses of the RALLY and RELIEF studies.

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 results of the Phase 3 RELIEF and RALLY studies, 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 dated November 8, 2021, issued by the Company
99.02	ACR 2021 Oral Presentation
99.03	Press Release dated November 8, 2021, issued by the Company
99.04	Corporate Presentation by the Company for November 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: November 8, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Third Quarter 2021 Financial Results and Operational Highlights

Expansion of Internal Research and Development Capabilities Underway to Accelerate Infectious Disease Programs and Prepare for Future Pandemic Responses

COVID-19 Pipeline Progressing with First-in-Human Trial of TNX-2100 Novel Skin Test for SARS-CoV-2 Functional T cell Immunity Expected to Start this Quarter

Phase 2 Trial of TNX-1300 in Cocaine Intoxication Expected to Start this Quarter

At September 30, 2021, Cash and Cash Equivalents Totaled Approximately $183 Million

CHATHAM, NJ, November 8, 2021 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2021 and provided an overview of recent operational highlights.

"Our new infectious disease Research and Development Center (RDC) in Frederick, Md. is operational, and we have begun the build-out of our Advanced Development Center (ADC) in the New Bedford, Mass. Business Park -- two important milestones in our goal to becoming a leading innovator and manufacturer of vaccines, therapeutics and diagnostics for infectious diseases," said Seth Lederman, MD, President and CEO of Tonix.

"The facilities are designed to accelerate our current COVID-19 programs and provide us with the internal resources and capabilities to develop a broad-based infectious disease portfolio, including live virus vaccines and skin test diagnostics that specifically target new pathogens within the rapid response timeframe set forth in the American Pandemic Preparedness Plan, or AP3," he added.

AP3, which was recently released by the White House's U.S. Office of Science and Technology Policy calls for strengthening the nation's pandemic and biowarfare defenses, including the capability to develop vaccines against new pathogens within 100 days of the pathogen's sequence becoming available. This 100-day goal is a key component of preparedness for future pandemics. Tonix believes its new RDC and ADC will provide the capabilities to help address this need. The Company is also planning a Commercial Manufacturing Center (CMC) in Hamilton, Mont. to produce clinical-scale live virus vaccines and potentially other products for pandemic responses.

Dr. Lederman said, "Our portfolio of COVID-19 programs continues to advance. The COVID-19 portfolio currently includes a live virus vaccine candidate based on our recombinant pox virus (RPV) platform, a diagnostic skin test to measure functional T cell immunity, and therapeutic candidates for acute COVID-19 and Long COVID. We expect first-in-human testing of our SARS-CoV-2 diagnostic to measure T cell immunity to begin before year end, followed by the anticipated start of a Phase 2 trial in Long COVID and a Phase 1 trial for our T cell inducing vaccine in 2022."

As part of its infectious disease research and development programs, in the third quarter of 2021 Tonix expanded its research collaboration with Columbia University to better understand immune responses to SARS-CoV-2 in healthy individuals who have recovered from COVID-19. This work is expected to provide a foundation for tailoring vaccines and therapeutics to appropriate individuals with precision medicine.

Dr. Lederman added, "The Company's clinical calendar for our pipeline of central nervous system candidates includes the anticipated start this quarter of a Phase 2 trial of TNX-1300, an emergency antidote for cocaine intoxication, and the anticipated start of three additional Phase 2 studies in 2022, including TNX-601 CR in major depressive disorder, TNX-102 SL in posttraumatic stress disorder, and TNX-1900 in the prophylactic treatment of chronic migraine."

Recent Highlights—Facilities and Corporate

- In October 2021, Tonix held a ribbon-cutting ceremony at the Company's 48,000 square foot research and development center (RDC) in Frederick, Md., which is expected to provide internal capacity to discover and develop vaccines and antiviral drugs against COVID-19, its variants, and other infectious diseases. The ceremony was attended by federal, state and local officials, including U.S. Senator for Maryland Ben Cardin, U. S. Congressman David Trone representing Maryland's 6th Congressional District, Nan Mann representing U.S. Senator Chris Van Hollen, Maryland Department of Commerce Representatives Heather Gramm and Tamar Osterman, Maryland State Delegates Karen Lewis-Young and Kenneth Kerr, Frederick County Executive Jan Gardner, Frederick County Office of Economic Director Helen Propheter, the City of Frederick Mayor Michael O'Connor and the City of Frederick Director of Economic Development Richard Griffin. The center is operational with a dedicated staff of scientists and technicians. The main building was constructed as a biosafety level (BSL) -3 facility but has been operating at BSL-2. Tonix plans to make appropriate upgrades and seek certification for BSL-3 so that research may be conducted on live SARS-CoV-2 and other pathogens.

- In August 2021, Tonix announced that it commenced construction on its Advanced Development Center (ADC) for the development and manufacturing of Good Manufacturing Practice or GMP live-virus vaccines to support Phase 1 and 2 clinical trials. The facility, located in New Bedford, Mass., is planned to be BSL-2 and expected to be operational in the first half of 2022. A groundbreaking ceremony held August 3, 2021 was attended by federal, state and local officials, including U.S. Representative Bill Keating, Massachusetts Housing and Economic Development Secretary Mike Kennealy and New Bedford Mayor Jon Mitchell.

- Tonix also intends to build a Commercial Manufacturing Center (CMC) in Hamilton, Mont. where it purchased approximately 44 acres of land. The CMC will focus on developing and manufacturing commercial scale live-virus vaccines and is also intended to be BSL-2. Construction is expected to be initiated for the CMC in 2022. Together, the Company expects these three facilities may qualify the RPV platform for programs that are designed to carry out the goals of AP3.

Highlights—Key Product Candidates*

COVID-19 Pipeline

TNX-1800 (live virus vaccine based on Tonix's recombinant pox virus vector): COVID-19 vaccine designed as a single-administration vaccine to elicit T cell immunity

- In March 2021, positive efficacy results from a study of TNX-1800 in which non-human primates were vaccinated with TNX-1800 and challenged with live SARS-CoV-2 were reported. TNX-1800 was found to induce protection against infection in the upper airway, which suggests an ability to inhibit forward transmission. Tonix has completed a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) and expects to begin a Phase 1 study using TNX-1800 in humans in the second half of 2022.

TNX-2100 (diagnostic skin test): SARS-CoV-2 epitope peptide mixtures for intradermal administration to measure the delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2

- Tonix expects to initiate a first-in-human clinical study in the fourth quarter of 2021. TNX-2100, designed to measure functional *in vivo* T cell immunity to SARS-CoV-2, is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130). Tonix's proposed skin test has the potential to serve as: 1) a biomarker for cellular (T-cell mediated) immunity and protective immunity; 2) a method to stratify participants in COVID-19 vaccine trials by immune status; 3) an endpoint in COVID-19 vaccine trials, and 4) a biomarker of durability of vaccine protection.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): small molecule for the treatment of Long COVID Syndrome or Post-Acute Sequelae of COVID-19 (PASC)

- Tonix has completed a pre-IND meeting with the FDA and intends to initiate a Phase 2 study in patients with Long Covid in the first half of 2022 following IND clearance.

TNX-3500 (sangivamycin): antiviral inhibitor of SARS-CoV-2 for the treatment of COVID-19 and potential other viral disorders

- Tonix intends to conduct further nonclinical animal studies prior to submitting an IND and initiating a Phase 1 study.

Immunology Pipeline

TNX-1500 (anti-CD154 monoclonal antibody): third generation monoclonal antibody as first line monotherapy for preventing or treating organ transplant rejection and treating autoimmune disorders.

- Tonix expects to start a Phase 1 study in the second half of 2022. Preliminary results from an ongoing experiment in heart transplants indicated that TNX-1500 appeared to have comparable efficacy to historical experiments using the chimeric mouse-primate anti-CD40L monoclonal antibody based on mu5c8 and no evidence of thrombosis has been observed.

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): small molecule for the management of fibromyalgia

- The positive Phase 3 study, called RELIEF, achieved statistical significance on the primary endpoint in December, 2020. Tonix initiated a second Phase 3 study, RALLY in September 2020. Based on disappointing efficacy results at the interim analysis of RALLY in July 2021, the Company stopped enrolling new participants. Topline results from RALLY are expected before the end of 2021. The Company will determine the next steps in this program based on analysis of the RALLY data, which will include pharmacogenomic analyses of RALLY and RELIEF.

TNX-102 SL for the treatment of Posttraumatic Stress Disorder (PTSD)

- Tonix completed a meeting with the FDA to discuss potential new endpoints for the indication of treatment of PTSD, and expects to begin enrolling a Phase 2 study of TNX-102 SL in police in Kenya in the first quarter of 2022.

TNX-1300 (recombinant double mutant cocaine esterase): biologic for life-threatening cocaine intoxication

- Tonix expects to initiate a Phase 2 open-label safety study in an emergency department setting to study TNX-1300 in the fourth quarter of 2021. Results of a positive Phase 2 study of volunteer cocaine users in a controlled laboratory setting were reported prior to Tonix licensing the technology. TNX-1300 has been granted Breakthrough Therapy designation (BTD) by the FDA.

TNX-601 CR (tianeptine oxalate and naloxone controlled-release tablets): small molecule for the treatment of major depressive disorder, PTSD and neurocognitive dysfunction associated with corticosteroid use.

- Tonix previously completed a Phase 1 trial for formulation development outside of the U.S. Based on official minutes from a pre-IND meeting with the FDA, the Company expects to initiate a Phase 2 study for the treatment of depression in the first half of 2022.

TNX-1900 (intranasal potentiated oxytocin): small peptide for migraine, craniofacial pain, insulin resistance and related disorders

- Tonix intends to initiate a Phase 2 study of TNX-1900 for the prophylactic treatment of chronic migraine in the U.S. in the second half of 2022. A Phase 2 trial under an investigator-initiated IND was completed in the U.S. using the TNX-1900 formulation prior to Tonix's acquisition of the program.

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

Recent Highlights--Financial

As of September 30, 2021, Tonix had $183.0 million of cash and cash equivalents, compared to $77.1 million as of December 31, 2020. Cash used in operations was approximately $12.9 million for the three months ended September 30, 2021, compared to $15.3 million for the three months ended September 30, 2020.

Third Quarter 2021 Financial Results

R&D expenses for the third quarter of 2021 were $13.1 million, compared to $8.8 million for the same period in 2020. This increase is predominately due to increased manufacturing expenses of $1.8 million, non-clinical expenses of $1.6 million, employee-related expenses of $1.0 million and regulatory/legal expenses of $0.6 million offset by a decrease in clinical expenses of $0.7 million.

G&A expenses for the third quarter of 2021 were $5.5 million, compared to $3.2 million for the same period in 2020. The increase is primarily due to an increase in employee-related expenses of $1.3 million.

Net loss available to common stockholders was $18.5 million, or $0.05 per share, basic and diluted, for the third quarter of 2021, compared to net loss of $12.0 million, or $0.09 per share, basic and diluted, for the third quarter of 2020. The basic and diluted weighted average common shares outstanding for the third quarter of 2021 was 366,425,157, compared to 127,199,834 shares for the third quarter of 2020.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL[1] (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300[2] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800[3], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study in the fourth quarter of 2021, pending IND clearance. TNX-3500[5] (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

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

[2] *TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[3] *TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.*

[4] *TNX-2100 is an investigational new biologic and has not been approved for any indication.*

[5] *TNX-3500 is an investigational new drug at the pre-IND stage of development and has 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, the risks related to the operation of research and manufacturing facilities, 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
COSTS AND EXPENSES:				
Research and development	$ 13,082	$ 8,813	$ 46,542	$ 24,060
General and administrative	5,453	3,186	16,291	9,428
	18,535	11,999	62,833	33,488
Operating loss	(18,535)	(11,999)	(62,833)	(33,488)
Interest income, net	7	9	99	46
Net loss	(18,528)	(11,990)	(62,734)	(33,442)
Warrant deemed dividend	—	—	—	(451)
Preferred stock deemed dividend	—	—	—	(1,260)
Net loss available to common stockholders	$ (18,528)	$ (11,990)	$ (62,734)	$ (35,153)
Net loss per common share, basic and diluted	$ (0.05)	$ (0.09)	$ (0.19)	$ (0.49)

Weighted average common shares outstanding, basic and diluted	366,425,157	127,199,834	329,550,525	71,329,221

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	September 30, 2021	December 31, 2020[1]
Assets		
Cash and cash equivalents	$ 182,970	$ 77,068
Prepaid expenses and other	12,112	10,921
Total current assets	195,082	87,989
Other non-current assets	19,692	10,194
Total assets	$ 214,774	$ 98,183
Liabilities and stockholders' equity		
Total liabilities	$ 12,556	$ 10,535
Stockholders' equity	202,218	87,648
Total liabilities and stockholders' equity	$ 214,774	$ 98,183

[1]The condensed consolidated balance sheets for the year ended December 31, 2020 has been derived from the audited financial statements but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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Exhibit 99.02

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Disclosures

- Presenting author Gregory Sullivan MD is an officer of Tonix Pharmaceuticals Inc (Tonix)
- Dr. Sullivan holds stock and stock options in Tonix
- Tonix owns composition of matter and use patents for the investigational product in the RELIEF trial and its use for the fibromyalgia indication
- TNX-102 SL (sublingual cyclobenzaprine) is an investigational new drug that is not approved for any indication

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Evidence-Based Medicine (EBM) or Key References

- Moldofsky H, Harris HW, Archambault WT, Kwong T, Lederman S. Effects of bedtime very low dose cyclobenzaprine on symptoms and sleep physiology in patients with fibromyalgia syndrome: a double-blind randomized placebo-controlled study. J Rheumatol. 2011 Dec;38(12):2653-63. doi: 10.3899/jrheum.110194. Epub 2011 Sep 1. PMID: 21885490.

- Choy EH. The role of sleep in pain and fibromyalgia. Nat Rev Rheumatol. 2015 Sep;11(9):513-20. doi: 10.1038/nrrheum.2015.56. Epub 2015 Apr 28. PMID: 25907704.

- Sullivan GM, Gendreau RM, Gendreau J, Peters P, Peters A, Engels J, Daugherty BL, Vaughn B, Weathers FW, Lederman S. Randomized clinical trial of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related PTSD and the role of sleep quality in treatment response. Psychiatry Res. 2021 Jul;301:113974. doi: 10.1016/j.psychres.2021.113974. Epub 2021 Apr 30. PMID: 33979763.

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Trial TNX-CY-F304 ('RELIEF' Study)

- **General Study Design:** Phase 3, Randomized, Multicenter (39), Parallel Group, Double-Blind, Placebo-Controlled 14 Week Study
- **Objectives:** To evaluate efficacy and safety of bedtime TNX-102 SL in fibromyalgia (FM)
- **Investigational Product (IP):** TNX-102 SL (sublingual cyclobenzaprine) is a tricyclic drug that potently binds and antagonizes: hydroxytryptamine-2A, α1-adrenergic, H1-histaminergic, and M1-muscarinic acetylcholine receptors
- **Study Visits:** Screening, Baseline, and four treatment (Weeks 2, 6, 10 & 14/ET) visits
- **IP Dosage:** first 2 weeks on 1 tablet (TNX-102 SL 2.8 mg); at Week 2 visit the dose is increased to 2 tablets providing 5.6 mg of TNX-102 SL at bedtime for 12 weeks
- **Patient Population:** diagnosis of primary FM as defined by 2016 Revision to the 2010/2011 FM diagnostic criteria (ACR Preliminary Diagnostic Criteria)
- **Exclusionary Medications:** duloxetine, milnacipran, pregabalin, gabapentin, tramadol, tapentadol, muscle relaxants, tricyclic antidepressants, MAOIs, trazodone, narcotics/opioids, naltrexone, benzodiazepines, anticonvulsants (exception for migraine), sodium oxybate, ketamine, CGRP/CGRP-R meds, and all other cyclobenzaprine

Demographics

Variable	Placebo N=255	TNX-102 SL N=248	Total N=503
Age, years (mean, SD)	49.3 (10.2)	50.0 (9.4)	49.6 (9.8)
Sex, female	247 (96.9%)	232 (93.5%)	479 (95.2%)
Ethnicity, Hispanic/Latino	42 (16.5%)	43 (17.3%)	85 (16.9%)
Race			
White or Caucasian	216 (84.7%)	222 (89.5%)	438 (87.1%)
Black or African American	20 (7.8%)	19 (7.7%)	39 (7.8%)
All Other	19 (7.5%)	7 (2.8%)	26 (5.9%)
BMI (kg/m^2)	31.6 (6.3)	32.4 (6.6)	32.0 (6.4)
Education, some college or greater	212 (83.1%)	205 (82.7%)	417 (82.9%)
Employed, currently	158 (62.0%)	182 (73.4%)	340 (67.6%)
Unable to work due to fibromyalgia	15 (5.9%)	16 (6.5%)	31 (6.2%)
Duration of fibromyalgia, years	9.0 (8.1)	9.2 (8.4)	9.1 (8.2)

Primary Efficacy Endpoint Analysis

Endpoint: change from baseline to Week 14 endpoint in diary NRS weekly average of daily self-reported average pain severity

Visit Statistic	Placebo (N = 255) Value	Placebo (N = 255) Change from Baseline	TNX-102 SL (N = 248) Value	TNX-102 SL (N = 248) Change from Baseline
Baseline				
Mean (SD)	**6.0 (1.08)**		**6.1 (1.06)**	
Week 14				
LS mean (SE) [1]	4.6 (0.12)	**-1.5 (0.12)**	4.2 (0.12)	**-1.9 (0.12)**
95% CI [1]	(4.3, 4.8)	(-1.7, -1.3)	(3.9, 4.4)	(-2.1, -1.7)
Difference in LS mean (SE)				**-0.4 (0.16)**
95% CI for difference in LS mean				(-0.7, -0.1)
p-value for difference				**0.010**

* p <0.0452, adjusted p-value necessary for significance due to alpha-spend from an interim analysis; for Week 14 results, Cui, Hung, & Wang methodology used to combine p-values for interim and post-interim subjects

[1] Least squares means, differences, and CIs were based on an MMRM with fixed, categorical effects of treatment, center, study week, and treatment-by-study week interaction, as well as the fixed covariates of baseline value and baseline value-by-study week interaction. Missing values for Week 14 were imputed with multiple imputation, accounting for the reasons for study discontinuation (if due to adverse events or lack of efficacy, considered missing not-at-random. Abbreviations: CI = confidence interval; LS = least squares; MMRM = mixed model repeated measures; SD = standard deviation; SE = standard error

Responder Rates

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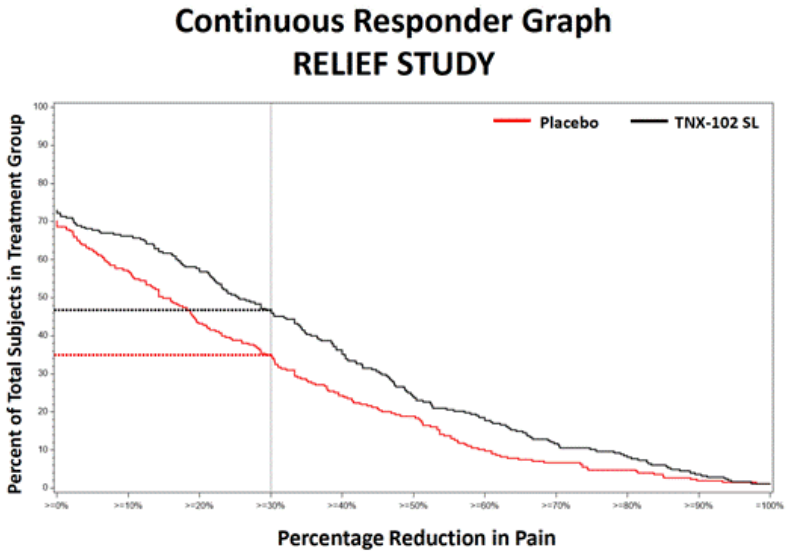
Continuous Responder Graph shows a selected percent pain reduction rate (x-axis) for responder status versus percent of responders in each treatment group (y-axis)

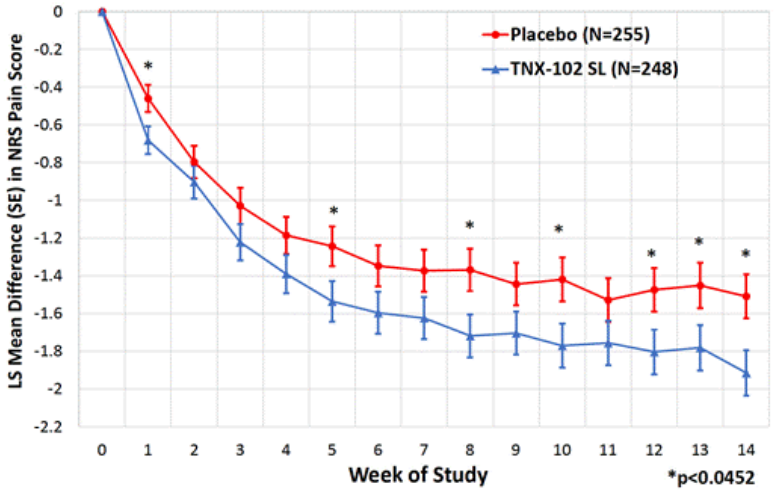
<u>For a ≥30% Pain Reduction Responder Analysis:</u>

- Choose ≥30% on x-axis
- On y-axis find
  - TNX-102 SL at 46.8%
  - Placebo at 34.9%
  - Logistic Regression Odds Ratio (95% CI) of **1.67 (1.16, 2.40), p=0.006**



Pain Reduction by Daily Diary Across 14 Weeks of Study

- Note: in addition to statistically significant pain reduction at Week 14, TNX-102 SL separated from Placebo at Weeks 1, 5, 8, 10, 12, & 13; all p<0.0452



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Key Secondary Efficacy Endpoint Analyses

- Sequential test procedure to adjust for multiplicity applied to primary and key secondary endpoints; hierarchy of key secondaries:
  - **PGIC**, responder analysis, proportion with '2' or '1' at Week 14
  - **FIQR Symptoms** domain, change from baseline at Week 14
  - **FIQR Function** domain, change from baseline at Week 14
  - **PROMIS Sleep Disturbance** (8a), change from baseline at Week 14
  - **PROMIS Fatigue** (8a), change from baseline at Week 14
  - **Sleep Quality** by daily diary, change from baseline at Week 14

FIQR = Fibromyalgia Impact Questionnaire – Revised; PGIC = Patient Global Impression of Change ('2' = much improved; '1' = very much improved); PROMIS = Patient-Reported Outcomes Measurement Information System

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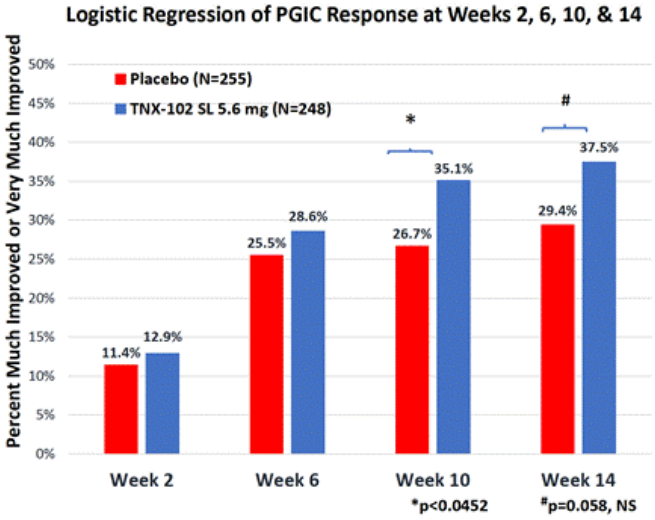
Patient Global Impression of Change

- At Week 14, greater proportion of responders to TNX-102 SL, at 37.5% versus Placebo, at 29.4%; however, did not achieve statistical significance
- Remaining secondary endpoints in hierarchy automatically considered non-significant regardless of the p-value
- Note: Week 10 separated at p<0.0452



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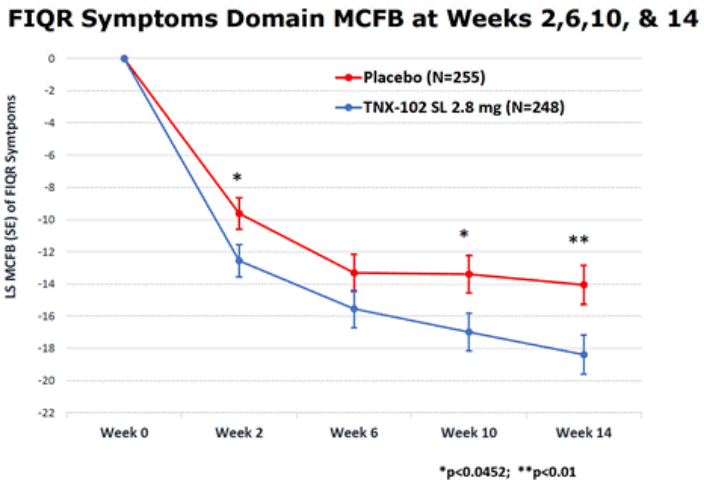
FIQR Symptoms Domain

- On Fibromyalgia Impact Questionnaire – Revised Symptoms Domain at Week 14 TNX-102 SL separated from placebo by -4.3 (1.6) units, p=0.007
- Note: Week 2 p=0.020 and Week 10 p=0.019



Fibromyalgia Impact Questionnaire – Revised: Symptoms & Impact Items

- **Broad range** of FM symptoms and both global impact items demonstrated TNX-102 SL separated from placebo at $p<0.0452$
- Only level of anxiety and balance problems were $p>0.0452$
- **Syndromal coverage** of core FM symptoms:
  - widespread pain
  - fatigue/low energy
  - sleep disturbance
  - mood disturbance
  - memory problems
  - sensory sensitivity

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Week 14 FIQR Please rate your...(last 7 days)	TNX-102 SL LS MCFB (SE)	Placebo LS MCFB (SE)	Difference in LS Means (SE)	p-value
Level of Pain	-2.3 (0.15)	-1.9 (0.15)	-0.5 (0.20)	0.014*
Level of Energy	-2.1 (0.16)	-1.3 (0.16)	-0.7 (0.22)	<0.001***
Level of Stiffness	-2.4 (0.17)	-1.8 (0.17)	-0.6 (0.23)	0.009**
Quality of Sleep	-3.1 (0.20)	-2.1 (0.20)	-0.9 (0.26)	<0.001***
Level of Depression	-1.1 (0.14)	-0.4 (0.13)	-0.7 (0.18)	<0.001***
Level of Memory Problems	-1.6 (0.16)	-1.0 (0.16)	-0.6 (0.21)	0.004**
Level of Anxiety	-1.2 (0.16)	-0.9 (0.16)	-0.4 (0.22)	0.084
Level of Tenderness to Touch	-2.4 (0.19)	-1.8 (0.19)	-0.6 (0.25)	0.017*
Level of Balance Problems	-1.4 (0.15)	-1.1 (0.15)	-0.3 (0.19)	0.149
Level of (Sensory) Sensitivity^	-2.4 (0.18)	-1.8 (0.18)	-0.5 (0.23)	0.021*
FM over the last 7 days...				
Prevented Accomplishing Goals	-2.6 (0.18)	-1.9 (0.18)	-0.7 (0.24)	0.003**
Completely Overwhelmed Me	-2.1 (0.18)	-1.5 (0.18)	-0.7 (0.24)	0.005**

^to loud noises, bright lights, odors, and cold *p<0.0452; **p<0.01; ***p<0.001
Abbreviations: FIQR = Fibromyalgia Impact Questionnaire – Revised; FM = fibromyalgia; LS = least squares; MCFB = mean change from baseline; p = probability; SE = standard error

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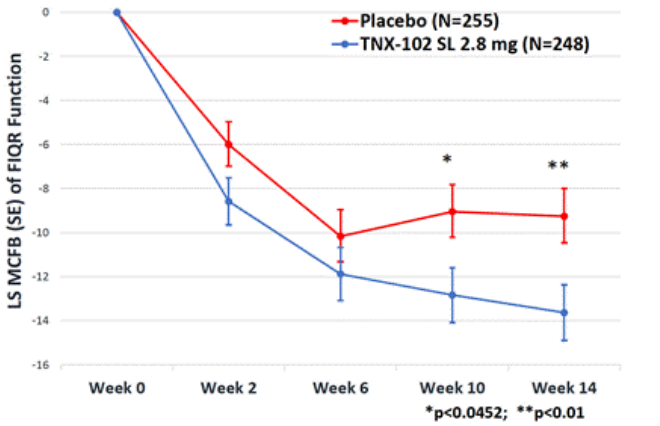
FIQR Function Domain

- On Fibromyalgia Impact Questionnaire – Revised Function Domain at Week 14 TNX-102 SL separated from Placebo by -4.4 (1.7) units, p=0.009
- Note: Week 10 p=0.016
- Slope remains downward after Week 6 for active but not for Placebo

FIQR Function Domain MCFB at Weeks 2,6,10, & 14



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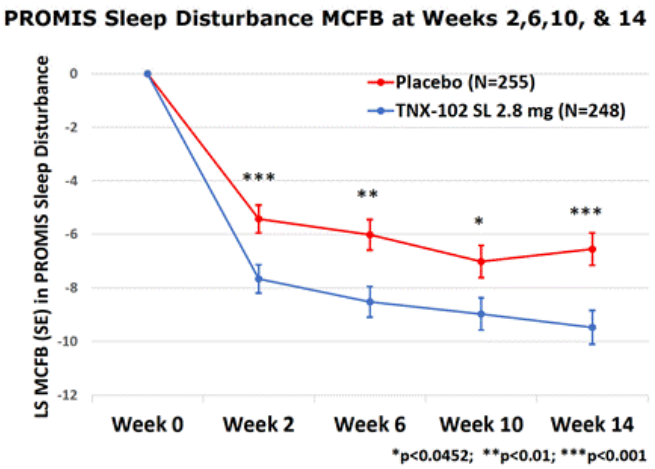
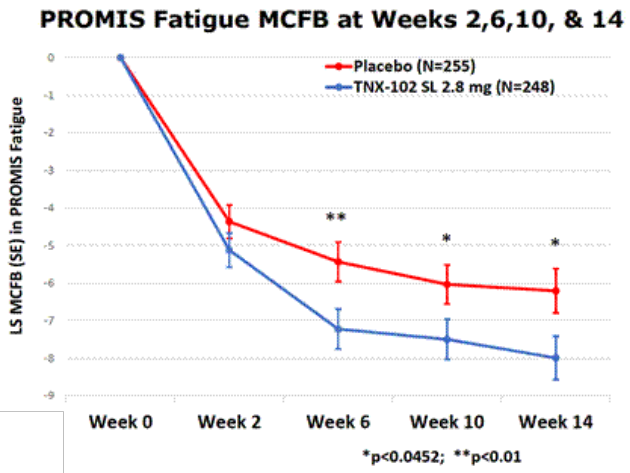
PROMIS Sleep Disturbance Instrument

- On PROMIS Sleep Disturbance instrument T-scores at Week 14 TNX-102 SL separated from placebo by -2.9 (0.82) units, p<0.001
- Note: Week 2 p<0.001, Week 6 p=0.001, Week 10 p=0.014



PROMIS Fatigue Instrument

- On PROMIS Fatigue instrument T-scores at Week 14 TNX-102 SL separated from placebo by -1.8 (0.76) units, p=0.018
- Note: Week 6 p=0.008, Week 10 p=0.032



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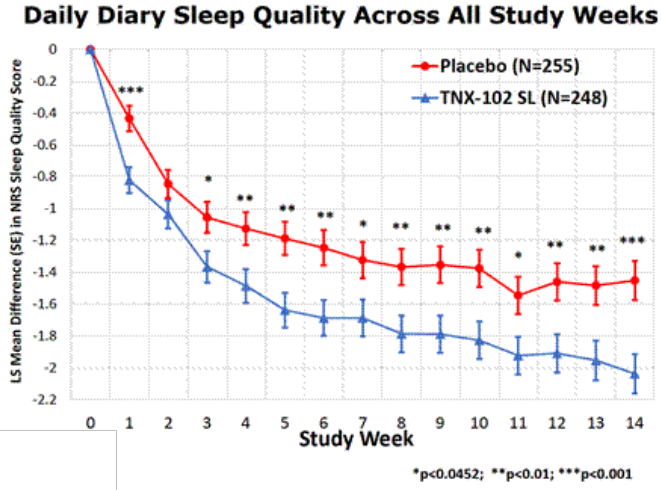
Sleep Quality by Daily Diary

- Sleep Quality by weekly averages of daily diary NRS scores at Week 14 separated for TNX-102 SL from placebo by -0.6 (0.17) units, p<0.001
- All weeks except Week 2 were p<0.0452



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Safety

Exposure

Mean (SD) treatment duration (days): **TNX-102 SL 88.9** (26.2); **Placebo 88.7** (24.9)
Mean (SD) study days drug taken: **TNX-102 SL 77.1** (25.2); **Placebo 75.9** (23.6)

Treatment-Emergent Adverse Events (TEAEs) Rated as Severe

TNX-102 SL 4.4% of all TEAEs in group; Placebo 3.5% of all TEAEs in group

Incidence of Oral TEAEs

TNX-102 SL 40.7%; Placebo 9.0%

Discontinued Study Drug Due to TEAE

TNX-102 SL 8.9%; Placebo 3.9%

Serious Adverse Effects

TNX-102 SL 2 SAEs; Placebo 5 SAEs; none deemed related to study drug

Completion rates

TNX-102 SL 83.5%; Placebo 82.3%

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Treatment Emergent Adverse Events (TEAEs)

All TEAEs at a rate of ≥ 3% in the TNX-102 SL group

	TNX-102 SL	Placebo	Total
Oral Cavity Adverse Events			
Hypoaesthesia oral	43 (17.3%)	1 (0.4%)	44 (8.7%)
Paraesthesia oral	14 (5.6%)	1 (0.4%)	15 (3.0%)
Dysgeusia	13 (5.2%)	1 (0.4%)	14 (2.8%)
Glossodynia	9 (3.6%)	2 (0.8%)	11 (2.2%)
Dry mouth	8 (3.2%)	7 (2.7%)	15 (3.0%)
Systemic Adverse Events			
Sedation	9 (3.6%)	1 (0.4%)	10 (2.0%)
Fatigue	9 (3.6%)	4 (1.6%)	13 (2.6%)

Conclusions

- TNX-102 SL reduced pain in fibromyalgia significantly more than Placebo (p=0.010) over 14 weeks of treatment
- 30% pain responder analysis demonstrated greater responders with TNX-102 SL at 46.8% than with Placebo at 34.9% (p=0.006)
- TNX-102 SL had broad syndromal effects across core fibromyalgia symptoms of widespread pain, fatigue, sleep disturbance, memory disturbance, mood disturbance, and sensory sensitivity
- Most common adverse event from active treatment is oral hypoaesthesia, a sensory administration site reaction that is typically transient, never rated as severe, and lead to only 1 discontinuation
- TNX-102 SL was very well tolerated, with the two highest rates of systemic adverse events, sedation and fatigue, both at 3.6%
- Only 16.5% of TNX-102 SL group discontinued early (17.7% on Placebo)

Acknowledgements

Mary Kelley[1], Annabelle Iserson[1], Perry Peters[1], Ashild Peters[1], Candace Flint[1], Judy Gendreau[2], Herb Harris[1], Ben Vaughn[3], and Seth Lederman[1]

[1]Tonix Pharmaceuticals, Inc., New York, NY,
[2]Gendreau Consulting LLC, Poway, CA
[3]Rho, Inc, Chapel Hill, NC

And a big thank you to all the participants in our trial!

Exhibit 99.03

Tonix Pharmaceuticals Presents Positive Results from Phase 3 RELIEF Study of TNX-102 SL for the Management of Fibromyalgia at the American College of Rheumatology Convergence 2021

CHATHAM, N.J., November 8, 2021 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an oral presentation of positive results from its Phase 3 clinical study, RELIEF, of TNX-102 SL for the management of fibromyalgia. A copy of the presentation is available under the IR Events tab of the Investors section of the Tonix website at www.tonixpharma.com.

The presentation, titled, "*TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia in the RELIEF Study: Positive Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Efficacy and Safety Trial"* by Dr. Gregory Sullivan, Chief Medical Officer of Tonix, reports that TNX-102 SL met its pre-specified primary endpoint in the Phase 3 RELIEF trial, significantly reducing daily pain compared to placebo (p=0.01) in participants with fibromyalgia. Also, when the primary endpoint was analyzed as a ≥30% pain responder analysis, there was a higher rate of responders to TNX-102 SL (47%) than to placebo (35%; p=0.006). TNX-102 SL at 5.6 mg also showed activity in key secondary endpoints demonstrating improvements in sleep quality, mitigation of fatigue, and fibromyalgia-specific functional recovery.

Early discontinuation rates were similar for TNX-102 SL and placebo (16.5% and17.7%, respectively). In addition, TNX-102 SL was well tolerated with the most common adverse event from active treatment being oral hypoaesthesia, a sensory administration site reaction that is typically transient, was never rated as severe, and only lead to one discontinuation.

"Results of the Phase 3 RELIEF trial demonstrated that TNX-102 SL had broad syndromal effects across core fibromyalgia symptoms of widespread pain, fatigue, memory and sleep disturbance," said Seth Lederman, M.D., President and Chief Executive Officer. "The positive Phase 3 RELIEF study achieved statistical significance on the primary endpoint in December, 2020. We had started a second Phase 3 study, RALLY in September 2020. Based on disappointing efficacy results at the interim analysis of RALLY in July 2021, we stopped enrolling new participants. Topline results from RALLY are expected before year end. The Company will determine the next steps in this program based on analysis of the RALLY data, which will include pharmacogenomic analyses of RALLY and RELIEF."

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., approximately 90% of whom are women. 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. Physicians and patients report common dissatisfaction with currently marketed products.

About TNX-102 SL

TNX-102 SL is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride which provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. As a multifunctional agent with potent binding and antagonist activities at the serotonin$_{2A}$, α_1-adrenergic, histaminergic-H_1, and muscarinic-M_1 receptors, TNX-102 SL is in clinical development as a daily bedtime treatment for fibromyalgia, PTSD, alcohol use disorder and agitation in Alzheimer's disease. The U.S. Patent and Trademark Office (USPTO) has issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in these patents are important elements of Tonix's proprietary TNX-102 SL composition. These patents are expected to provide TNX-102 SL, upon NDA approval, with U.S. market exclusivity until 2034/2035.

About the Phase 3 RELIEF Study

The RELIEF study has been completed and TNX-102 SL achieved a statistically significant benefit as measured by the primary, prespecified endpoint of improvement over placebo in daily pain. The RELIEF study was a double-blind, randomized, placebo-controlled Phase 3 trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia. The two-arm trial targeted enrollment of 470 participants, at approximately 40 U.S. sites. RELIEF completed final enrollment of 503 participants. The first two weeks of treatment were 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 had 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 was 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 completed RELIEF study are available at clinicaltrials.gov (NCT04172831).

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL[1] (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300[2] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800[3], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study in the fourth quarter of 2021, pending IND clearance. TNX-3500[5] (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

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

[2] *TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[3] *TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.*

[4] *TNX-2100 is an investigational new biologic and has not been approved for any indication.*

[5] *TNX-3500 is an investigational new drug at the pre-IND stage of development and has 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, 2020, as filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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 99.04

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	STATUS / NEXT MILESTONE
	COVID	
TNX-1800	COVID-19 Vaccine[1]	Phase 1 start - 2H 2022
TNX-102 SL	Long COVID-19 (Post-Acute Sequelae of COVID-19 or PASC)[2]	Phase 2 start – 1H 2022
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	Phase 1 start – 2H 2022
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 (Investigational New Drug) meeting with the FDA completed; 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

CNS PORTFOLIO

Candidates	INDICATION	STATUS / NEXT MILESTONE
	CNS	
TNX-102 SL[1]	Fibromyalgia (FM) Posttraumatic Stress Disorder (PTSD) Long COVID (PASC[2])	Phase 3 Ongoing Phase 2 Phase 2 start – 1H 2022[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	Preclinical
TNX-601 CR	Depression, PTSD, Neurocognitive Dysfunction from Steroids	Phase 2 start – 1H 2022[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; 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 2H'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

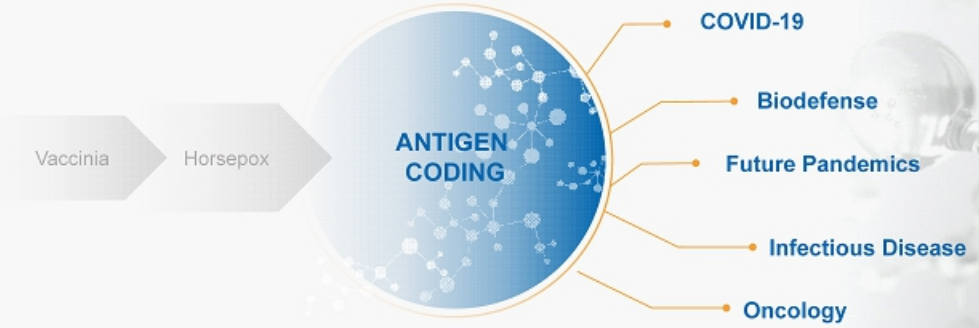
ADHD = attention-deficit hyperactivity disorder; FM = fibromyalgia; IND = investigational new drug; PASC = post-acute sequelae of COVID-19; PTSD = posttraumatic stress disorder.

TONIX PHARMACEUTICALS

TONIX PHARMACEUTICALS

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 2H 2022

Patents Filed

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Vaccine

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

Status: Preclinical

Next Steps: 2H 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.*

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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 should be used in certain cases
- FDA has authorized a single booster shot of the Pfizer-BioNTech and Moderna COVID-19 vaccines for those 65 and older as well as high-risk individuals.
- FDA has authorized a single booster shot of the J&J vaccine for everyone who received the initial J&J vaccine two or more months ago

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 likely unsustainable

[1]www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

TONIX PHARMACEUTICALS

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; currently BSL-2 but being converted to BSL-3
- Status: Operational; acquisition completed on October 1st, 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

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

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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: Q4 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[1]) – 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[2]
- 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.[3]

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: Start Phase 2 study for treating subset of Long COVID patients whose symptoms overlap with fibromyalgia in 1H 2022

[1]Feb. 24, 2021 - White House COVID-19 Response Team press briefing; Feb 25, 2021 - policy brief from the World Health Organization on long COVID
[2]Nalbandian, Ani, et al. "Post-acute COVID-19 syndrome." Nature Medicine (2021): 1-15.
[3]The 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*

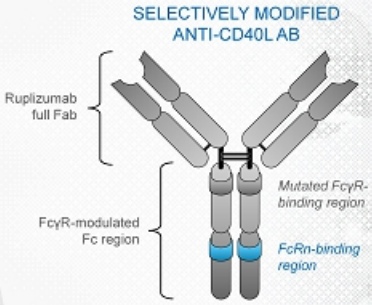
Third Generation: Re-engineered to better modulate the binding of FcγR while preserving FcRn function

- 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



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: 2H 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

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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;16:26.

ED = emergency department.


FUTURE OUTLOOK
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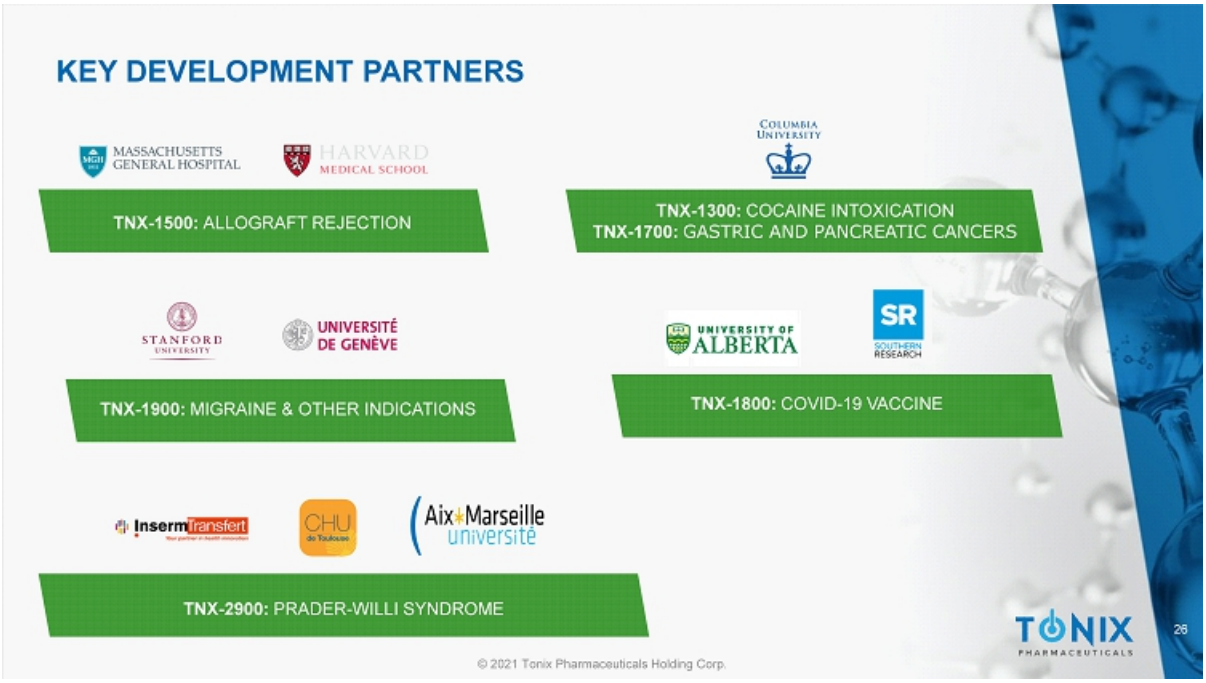
KEY DEVELOPMENT PARTNERS
MASSACHUSETTS GENERAL HOSPITAL
HARVARD MEDICAL SCHOOL
TNX-1500: ALLOGRAFT REJECTION
COLUMBIA UNIVERSITY
TNX-1300: COCAINE INTOXICATION
TNX-1700: GASTRIC AND PANCREATIC CANCERS
STANFORD UNIVERSITY
UNIVERSITÉ DE GENÈVE
TNX-1900: MIGRAINE & OTHER INDICATIONS
UNIVERSITY OF ALBERTA
SR SOUTHERN RESEARCH
TNX-1800: COVID-19 VACCINE
Inserm Transfert
CHU de Toulouse
Aix Marseille université
TNX-2900: PRADER-WILLI SYNDROME
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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

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

TONIX PHARMACEUTICALS

MANAGEMENT TEAM

Seth Lederman, MD
Co-Founder, CEO & Chairman

TARGENT Fusilev vela

Gregory Sullivan, MD
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Jessica Morris
Chief Operating Officer

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THANK YOU
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