

**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): October 21, 2022

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(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))

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 Capital 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 2.02 Results of Operations and Financial Condition.

Tonix Pharmaceuticals Holding Corp. (the "Company") is disclosing selected preliminary operating results for the quarter ended September 30, 2022, and certain preliminary financial condition information as of September 30, 2022, as set forth below:

- The Company ended the third quarter with approximately \$140.0 million in cash and cash equivalents, and shares of common stock outstanding of 53,321,511 at September 30, 2022.
- The Company's net cash used in operating activities for the nine months ended September 30, 2022, was approximately \$75.8 million compared to \$53.1 million for the nine months ended September 30, 2021.
- The Company's capital expenditures for the nine months ended September 30, 2022, was approximately \$43.5 million compared to \$9.7 million for the nine months ended September 30, 2021.
- The Company's equity proceeds from the sale of common stock for the nine months ended September 30, 2022, was approximately \$84.8 million compared to \$168.6 million for the nine months ended September 30, 2021.
- As of October 20, 2022, the Company had 55,752,745 shares of common stock outstanding.

The above information is preliminary financial information for the third quarter of 2022 and subject to completion. The unaudited, estimated results for the third quarter of 2022 are preliminary and were prepared by the Company's management, based upon its estimates, a number of assumptions and currently available information, and are subject to revision based upon, among other things, quarter-end closing procedures and/or adjustments, the completion of the Company's interim consolidated financial statements and other operational procedures. This preliminary financial information is the responsibility of management and has been prepared in good faith on a consistent basis with prior periods. However, the Company has not completed its financial closing procedures for the quarter ended September 30, 2022, and its actual results could be materially different from this preliminary financial information, which preliminary information should not be regarded as a representation by the Company or its management.

as to its actual results for the quarter ended September 30, 2022. In addition, EisnerAmper LLP, the Company's independent registered public accounting firm, has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial information and does not express an opinion or any other form of assurance with respect to this preliminary financial information. During the course of the preparation of the Company's financial statements and related notes as of and for the quarter ended September 30, 2022, the Company may identify items that would require it to make material adjustments to this preliminary financial information. As a result, prospective investors should exercise caution in relying on this information and should not draw any inferences from this information. This preliminary financial information should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles and reviewed by the Company's auditors.

The Company currently expects to file its Quarterly Report on Form 10-Q, including its financial statements for the quarter ended September 30, 2022 on or about November 7, 2022.

Item 7.01 Regulation FD Disclosure.

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.

On October 26, 2022, the Company will present certain information regarding the Company and its product candidates at the 2022 ThinkEquity Conference (the "Presentation"). The Presentation, which may contain nonpublic information, is filed as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01 and 99.02 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Financial Statements and Exhibits.

The information included in Item 2.02 is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

| (d) | Exhibit No. | Description. |
|-----|-------------|---|
| | 99.01 | Corporate Presentation by the Company for October 2022 |
| | 99.02 | Presentation by the Company |
| | 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: October 21, 2022

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



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, 2021, as filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2022, 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.

Who We Are



OUR MISSION

Tonix Pharmaceuticals is committed to improving patient care by advancing science and developing **innovative therapies** which have the potential to address important **unmet needs** across **multiple therapeutic areas**



OUR VISION

Tonix strives to be a leader in providing **novel drug therapies and vaccines** to **patients in need** around the world

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Milestones: Recently Completed and Upcoming*

- ✓ 1st Quarter 2022 Topline data from Phase 3 RALLY study of TNX-102 SL for the management of fibromyalgia
- ✓ 2nd Quarter 2022 Phase 3 RESILIENT study start of TNX-102 SL for the management of fibromyalgia
- ✓ 3rd Quarter 2022 Phase 2 PREVAIL study start of TNX-102 SL for the treatment of Long COVID

Expected Data

- ❑ 2nd Quarter 2023 Interim analysis results of Phase 3 RESILIENT study of TNX-102 SL in fibromyalgia
- ❑ 2nd Quarter 2023 Interim analysis results of Phase 2 PREVAIL study of TNX-102 SL in Long COVID

Expected Clinical Trial Initiations

- ❑ 4th Quarter 2022 Phase 2 study start of TNX-102 SL for the treatment of PTSD in Kenya
- ❑ 4th Quarter 2022 Phase 2 study start of TNX-1900 for the treatment of migraine
- ❑ 1st Quarter 2023 Phase 2 study start of TNX-1300 for the treatment of cocaine intoxication
- ❑ 1st Quarter 2023 Phase 2 study start of TNX-601 ER for the treatment of major depressive disorder
- ❑ 1st Half 2023 Phase 1 study start of TNX-1500 for prevention of allograft rejection
- ❑ 1st Half 2023 Phase 1 study start of TNX-801 for prevention of monkeypox and smallpox in Kenya

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

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Pipeline Central Nervous System (CNS) Portfolio



| CANDIDATES* | INDICATION | STATUS / NEXT MILESTONE |
|-------------------------|--|---|
| TNX-102 SL ¹ | Fibromyalgia (FM) Posttraumatic Stress Disorder (PTSD) Long COVID (PASC ²) | Mid-Phase 3 Phase 2, Targeted 4Q 2022 Start Phase 2 |
| TNX-1300 ³ | Cocaine Intoxication <i>FDA Breakthrough Designation</i> | Mid-Phase 2, Targeted 1Q 2023 Start |
| TNX-1900 ⁴ | Migraine, Craniofacial Pain and Binge Eating Disorder | Phase 2, Targeted 4Q 2022 Start ⁵ |
| TNX-601 ER | Depression, PTSD, Neurocognitive Disorder from Steroids | Phase 2, Targeted 1Q 2023 Start ⁶ |
| TNX-1600 ⁷ | 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.

¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is also in development for Agitation in Alzheimer's Disease (AAD) and Alcohol Use Disorder (AUD). Both indications are Phase 2 ready.

²Post-Acute Sequelae of COVID-19.

³TNX-1300 (double-mutant cocaine esterase) was licensed from Columbia University.

⁴Acquired from Trigemina; license agreement with Stanford University; IND cleared for the prevention of migraine indication; Planned Binge Eating Disorder study is expected to be investigator initiated.

⁵A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900; Phase 2 for the prevention of migraine headache expected to start 4Q 2022

⁶A Phase 1 trial for formulation development was completed outside of the U.S. Phase 2 expected to start 1Q 2023

⁷Acquired 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.

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CNS PORTFOLIO

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Pipeline Rare Disease Portfolio



| CANDIDATES* | INDICATION | STATUS / NEXT MILESTONE |
|-----------------------|---|-------------------------|
| TNX-2900 ¹ | Prader-Willi Syndrome <i>FDA Orphan Drug Designation</i> | Preclinical |

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

¹Co-exclusive license agreement with French National Institute of Health and Medical Research (Inserm)

Pipeline Immunology and Immuno-Oncology portfolio



| CANDIDATES* | INDICATION | STATUS / NEXT MILESTONE |
|-----------------------|---|---------------------------------|
| TNX-1500 ¹ | Organ Transplant Rejection/ Autoimmune Conditions | Phase 1, Targeted 1H 2023 Start |
| TNX-1700 ² | Gastric and colorectal cancers | Preclinical |

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

¹anti-CD40L humanized monoclonal antibody

²Recombinant trefoil factor 2 (rTFF2) based protein; licensed from Columbia University

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RARE DISEASE & IMMUNOLOGY PORTFOLIOS

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Pipeline

Infectious Disease Portfolio



| CANDIDATES* | INDICATION | STATUS / NEXT MILESTONE |
|-----------------------|---|---------------------------------|
| TNX-801 ¹ | Smallpox and monkeypox vaccine | Phase 1, Targeted 1H 2023 Start |
| TNX-1850 ² | COVID-19 Vaccine (horsepox-based live virus vaccine) | Preclinical |
| TNX-2300 ³ | COVID-19 Vaccine | Preclinical |
| TNX-3600 ⁴ | COVID-19 Therapeutic Platform (monoclonal antibodies) | Preclinical |
| TNX-3700 ⁵ | COVID-19 Vaccine (zinc nanoparticle mRNA technology) | Preclinical |



INFECTIOUS DISEASE PORTFOLIO

*All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.
¹Live attenuated vaccine based on horsepox virus
²Live attenuated vaccine based on horsepox virus vector, expressed SARS-CoV-2 spike protein. TNX-1850 is based on the BA.2 variant spike protein.
³Live attenuated vaccine based on bovine parainfluenza (BPI) virus
⁴Fully human monoclonal antibody generated from COVID-19 convalescent patients
⁵COVID vaccine based on mRNA in zinc nanoparticle (ZNP) formulation with CD40L molecular trigger



CNS: KEY CANDIDATES

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TNX-102 SL*: Fibromyalgia Cyclobenzaprine Protectic® Sublingual tablets



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

Status: One Positive Phase 3 study RELIEF Completed

Second Phase 3 study RALLY missed primary endpoint

Confirmatory Phase 3 study RESILIENT is currently enrolling

Next Steps: Interim analysis results expected 2Q 2023

*TNX-102 SL has not been approved for any indication.

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TNX-102 SL*: Long COVID (PASC) Cyclobenzaprine Protectic® Sublingual Tablets



PROFILE

Long COVID or Post-acute Sequelae of COVID-19 (PASC¹)

- Symptoms can include fatigue, sleep disorders, pain, fevers, shortness of breath, cognitive impairment described as "brain fog", gastrointestinal symptoms, anxiety, and depression²
- Can persist for months and can range in severity from mild to incapacitating
- Occurs in 30% of recovered COVID-19 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

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Long COVID (PASC)

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

Status: Phase 2 study PREVAIL is currently enrolling

Next Steps: Interim analysis results expected 2Q 2023

*TNX-102 SL has not been approved for any indication.

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Role of Infections in Triggering Fibromyalgia or Chronic fatigue (CFS)-Like Illnesses

- Symptoms of Long COVID, like multi-site pain, fatigue and insomnia, are the hallmarks of chronic pain syndromes like fibromyalgia and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).
- In August 2022, the HHS released the *National Research Action Plan on Long COVID*¹ which endorses the connection between Long COVID and chronic fatigue syndrome.

Infection initiates an autoreactive process, which affects several functions, including brain and energy metabolism²⁻⁷

- Infections can trigger any of these conditions in approximately 10% of exposed individuals
- The initial location of the infection determines the subsequent pain syndrome
- Any type of infectious diarrhea will trigger irritable bowel syndrome (IBS) in 10% to 20% of those exposed



¹Department of Health and Human Services, Office of the Assistant Secretary for Health. 2022. National Research Action Plan on Long COVID, 200 Independence Ave SW, Washington, DC 20201.

²Blomberg J, et al. Front Immunol. 2018;9:229. Published 2018 Feb 15.

³Warren JW, et al. Urology. 2008;71(6):1085-1090.

⁴Buskila D, et al. Autoimmun Rev. 2008;8(1):41-43.

⁵Hickie I, et al. BMJ. 2006;333(7568):575.

⁶Parry SD, et al. Am J Gastroenterol. 2003;98(9):1970-1975.

⁷Halvorson HA, et al. Am J Gastroenterol. 2006;101(8):1894-1942.

TNX-102 SL: Long COVID a.k.a Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)



- Long COVID is a heterogeneous condition that displays elements of nociplastic pain in many individuals, who experience otherwise unexplained¹⁻²:



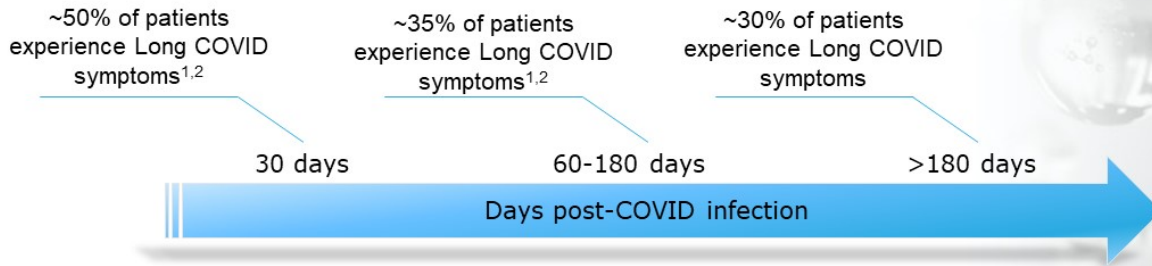
- Symptoms (multi-site pain, fatigue, sleep disorders and cognitive dysfunction) overlap with the key symptoms of fibromyalgia
- The primary outcome measure for fibromyalgia-type Long COVID will be decrease in multi-site pain measured by a daily diary

¹Bierle DM, et al. Central Sensitization Phenotypes in Post-Acute Sequelae of SARS-CoV-2 Infection (PASC): Defining the Post-COVID Syndrome. J Prim Care Community Health 2021;12:21501327211030826. doi: 10.1177/21501327211030826.

²Moghimi, N, et al. The Neurological Manifestations of Post-Acute Sequelae of SARS-CoV-2 Infection Curr Neurol Neurosci Rep. 2021;21(9):44. doi: 10.1007/s11910-02101130-1.



Prevalence of Long COVID ~30% of Recovered SARS-CoV-2 Patients after 6 Months



Long COVID (PASC) is more prevalent among patients^{1,2}:

- Requiring hospitalization (93% vs 23% for those not requiring hospitalization)
- With severe symptoms (2.25 times higher prevalence vs those with mild symptoms)

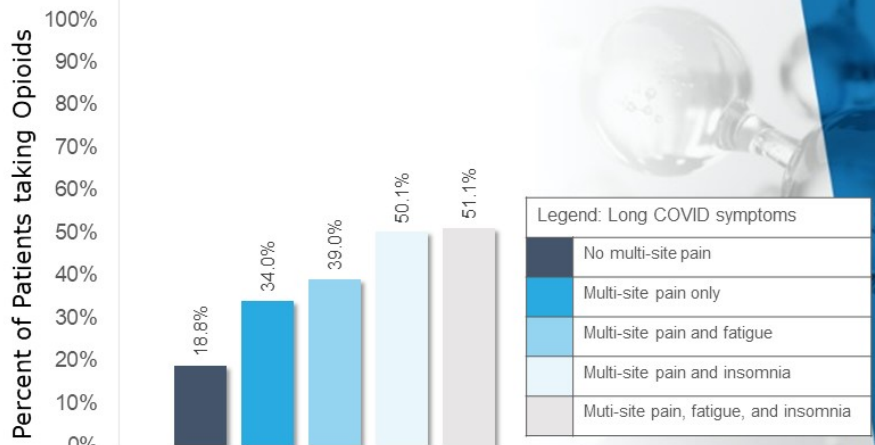
¹Hirschtick JL, et al. *Clinical Infectious Diseases*. 2021;73(11):2055-2064.
²Taquet M, et al. *PLoS Medicine*. 2021;18(9):e1003773.



Rate of Opioid Use in Long COVID Patients Potential Health Concern



- ▶ In only a few days some people can develop a physical dependence and addiction to opioids¹⁻²
- ▶ The USA Department of Labor estimates that **1 in 4 patients prescribed opioids long term will struggle with opioid addiction** adding to the already growing opioid crisis¹⁻²



Source: Harris, H, et al. Tonic data on file. 2022.; TriNetX Analytics

¹Shah, A, et al. *MMWR Morb Mortal Wkly Rep*. 2017;66:265-269.
²U.S. Department of Labor



TNX 102 SL*: Posttraumatic Stress disorder (PTSD)

Cyclobenzaprine Protectic® Sublingual Tablets



PROFILE

PTSD is a serious chronic psychiatric illness

- Defined as maladaptive prolonged stress response which occurs after experiencing severely injurious traumatic event(s)

Affects approximately 12 million Americans adults^{1,2}

Large unmet clinical need and limited effective therapies available

- Advances in pharmacological treatments beyond the currently approved SSRIs (e.g., Zoloft® (sertraline), Paxil® (paroxetine)) are needed³

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: PTSD

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

Status: One Phase 2 study (AtEase) completed

Two Phase 3 studies (HONOR, RECOVERY) conducted

Next Steps: 4Q 2022 Initiate Phase 2 Trial in Kenya

*TNX-102 SL has not been approved for any indication.

¹Goldstein RB, et al. The epidemiology of DSM-5 posttraumatic stress disorder in the United States: results from the National Epidemiologic Survey on Alcohol and Related Conditions-III. *Soc Psychiatry Psychiatr Epidemiol.* 2016;51(8):1137-1148.
²Pietrzak RH, et al. Prevalence and Axis I comorbidity of full and partial posttraumatic stress disorder in the United States: results from Wave 2 of the National Epidemiologic Survey on Alcohol and Related Conditions. *J Anxiety Disord.* 2011;25(3):456-465
³© 2022 Tonix Pharmaceuticals Holding Corp.

³Cain, C. K., et al. Targeting memory processes with drugs to prevent or cure PTSD. *Expert Opin Investig Drugs.* 2012; 21(9), 1323-1350

TNX-1300*: Cocaine Intoxication

Cocaine Esterase (CocE)



PROFILE

Cocaine is the main cause for drug-related ED visits¹

Cocaine use can cause irreversible structural damage to the heart and accelerate cardiovascular disease²

- In one survey of 94 long-term cocaine users, 71% had some form of cardiovascular disease³

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

Status: Mid-Phase 2

Next Steps: Initiate a new Phase 2 single-blind, placebo (+ usual care) controlled, randomized, potentially pivotal study in 1Q 2023, pending FDA agreement.

- Expected to enroll approximately 60 emergency department patients
- Primary endpoint: reduction of systolic blood pressure associated with acute cocaine intoxication identified at study baseline comparing TNX-1300 and standard of care after 60 minutes

FDA Breakthrough Therapy Designation

Awarded Cooperative Agreement Grant from National Institute on Drug Abuse (NIDA)

*TNX-1300 has not been approved for any indication.

¹Havakuk O et al. *J Am Coll Cardiol.* 2017;70:101-113.
²Phillips K et al. *Am J Cardiovasc Drugs.* 2009;9:177-196.
³Maceira AM et al. *J Cardiovasc Magn Reson.* 2014;16:26.
ED = emergency department.

TNX-601 ER*: Depression

Tianeptine Hemioxalate Extended-Release Tablets



PROFILE

A novel, oral, extended-release once-daily tablet

Mechanistically different from traditional monoaminergic treatments for depression

Indirectly modulates the glutamatergic system

- No direct binding to NMDA, AMPA, or kainate receptors

Treatment effect of tianeptine in depression is well-established

DEVELOPMENT PROGRAM

Market Entry: Major Depressive Disorder

Additional Indications: PTSD, Neurocognitive Disorder From Corticosteroids

Status: Phase 2 ready

Next Steps: Initiate a Phase 2 double-blind, placebo-controlled, parallel-group, randomized, potentially pivotal study in 1Q 2023.

Expected to enroll approximately 300 patients across 30 sites in the US.

Patents Issued

*TNX-601 ER has not been approved for any indication.

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

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TNX-1900*: Migraine

Intranasal Potentiated Oxytocin (OT) with Magnesium



PROFILE

Intranasal OT has potential utility in treating migraine¹

- 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^{2,3}

One billion individuals worldwide suffer from migraines

DEVELOPMENT PROGRAM

Market Entry: Chronic Migraine

Additional Indications: Acute Migraine, Craniofacial Pain, Insulin Resistance, Binge Eating Disorder

Status: Phase 2 ready⁴

Next Steps: 4Q 2022 Initiate Phase 2 Trial and Investigator Initiated Phase 2 Trial in Binge Eating Disorder

Patents Issued

*TNX-1900 has not been approved for any indication. CGRP = calcitonin gene-related peptide.

¹Tzabazis A, et al. Oxytocin and Migraine Headache. *Headache*. 2017 May;57 Suppl 2:64-75. doi: 10.1111/head.13082. PMID: 28485846.

²Antoni FA, Chadio SE. Essential role of magnesium in oxytocin-receptor affinity and ligand specificity. *Biochem J*. 1989 Jan 15;257(2):611-4. doi: 10.1042/bj2570611. PMID: 2539090; PMCID: PMC1135123

³Meyerowitz, J.G., et al. The oxytocin signaling complex reveals a molecular switch for cation dependence. *Nat Struct Mol Biol* (2022). (<https://doi.org/10.1038/s41594-022-00728-4>)

⁴A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900

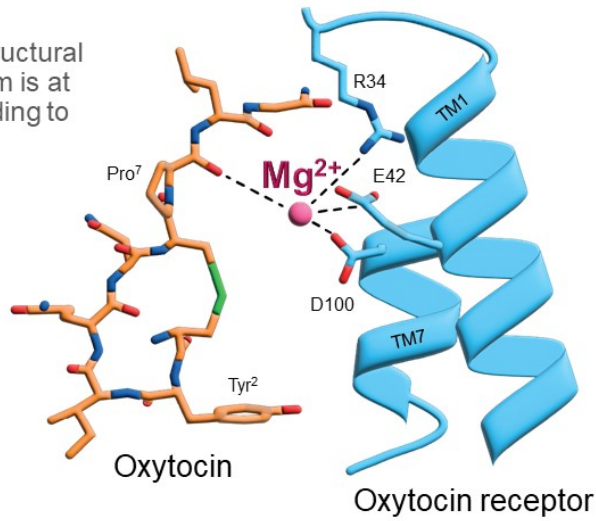
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TNX-1900 for Migraine Magnesium (Mg²⁺) is at the Core of Oxytocin Binding¹

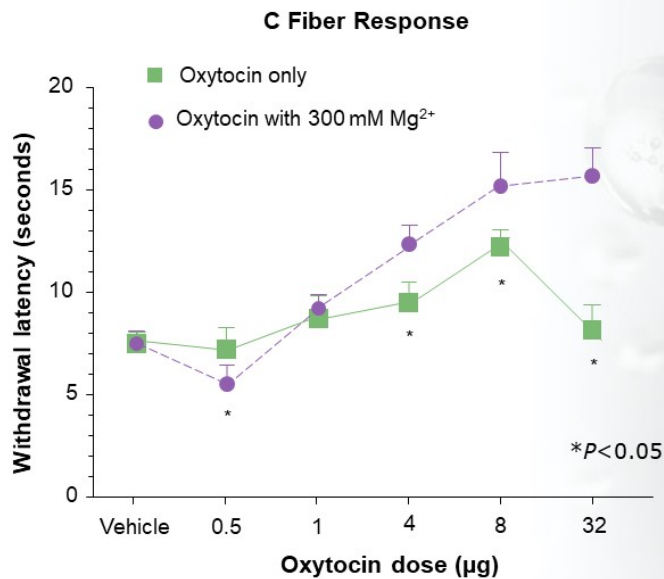
TNX-1900 contains magnesium: Recent structural studies show magnesium is at the core of oxytocin binding to oxytocin receptor¹



¹Adapted from Meyerowitz, J.G., Robertson, M.J., Barros-Álvarez, X. et al. The oxytocin signaling complex reveals a molecular switch for cation dependence. *Nat Struct Mol Biol* 29, 274–281 (2022). <https://doi.org/10.1038/s41594-022-00728-4>

TNX-1900 for Migraine Addition of Mg²⁺ Augments Oxytocin-Induced Analgesia in Animal Model

***in vivo* effect of Mg²⁺ ion addition with intranasal oxytocin-induced craniofacial analgesia on the withdrawal response time to noxious heat stimulation of the cheek of pre-inflamed rat**



Bharadwaj VN, et al. *Pharmaceutics*. 2022;14(5):1105.



RARE DISEASE: KEY CANDIDATES

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TNX-2900*: Hyperphagia in Prader-Willi Syndrome Intranasal Potentiated Oxytocin (OT) with Magnesium



RARE DISEASE PORTFOLIO

PROFILE

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

- Rare disease occurring in 1 in 10,000 to 1 in 30,000 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 off-target vasopressin receptors

DEVELOPMENT PROGRAM

Market Entry: Hyperphagia in Prader-Willi Syndrome

Additional Indications: Rare Hyperphagia Conditions

Status: Preclinical, granted orphan drug designation by FDA

Next Steps: pre-IND Meeting to seek agreement on development plans

Patents Issued

*TNX-2900 is in the pre-IND stage of development and has not been approved for any indication.



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TNX-1500*: Prevention of Allograft Rejection Next Generation α -CD40 Ligand (CD40L) Antibody

THE CD40-CD40L pathway is a pivotal immune system modulator and a well-established and promising treatment target

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

Second Generation: Eliminated the Fc γ R TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of Fc γ R while preserving FcRn function

- Expected to deliver efficacy without compromising safety

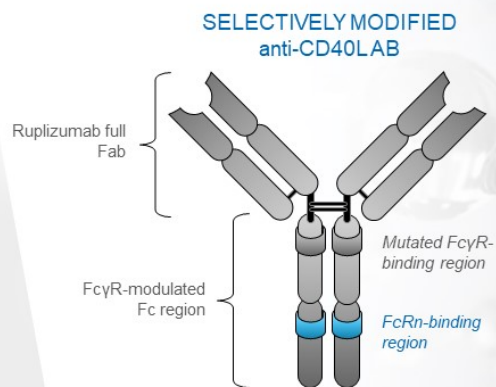
Status: Preclinical; collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

Next Steps: 1H 2023 Initiate Phase 1 Study

Patents Filed

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

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

*TNX-1500 is in the pre-IND stage of development and has not been approved for any indication.

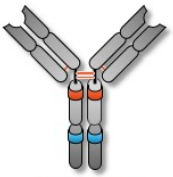
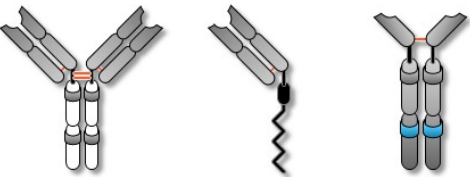
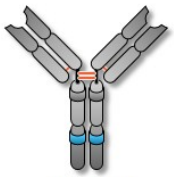


IMMUNOLOGY PORTFOLIO

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Third-Generation α -CD40L Engineered to Decrease Risk of Thrombosis



| First-generation anti-CD40L mAbs | Second-generation anti-CD40L mAbs | Third-generation anti-CD40L mAbs* |
|--|---|--|
|  <p>Ruplizumab</p> <p>Constant fragment (Fc) domain interacted with FcγRIIA (CD32A), which suggested a mechanism for the increased risk of thrombosis.^{1,2}</p> |  <p>Aglycosyl Ruplizumab Dapirolizumab Letolizumab</p> <p>Second-generation anti-CD40L mAbs exhibited dramatically reduced binding to FcγRIIA³⁻⁵ but had other issues, including decreased efficacy.⁶⁻⁸</p> |  <p>TNX-1500</p> <p>TNX-1500 is engineered to target CD40L therapeutically while reducing FcγRIIA binding and thereby lowering the potential for thrombosis.¹⁻⁸</p> |

*Sanofi's SAR441344 and Eledon's tegoprubart (f.k.a., AT-1501) also are Fc-modified

¹Inwald DP, et al. *Circ Res*. 2003;92(9):1041-1048.

²Robles-Carrillo L, et al. *J Immunol*. 2010;185(3):1577-1583.

³Shock A, et al. *Arthritis Res Ther*. 2015;17(1):234.

⁴Xie JH, et al. *J Immunol*. 2014;192(9):4083-4092.

⁵Ferrant JL, et al. *Int Immunol*. 2004;16(11):1583-1594.

⁶ClinicalTrials.gov identifier: NCT02273960. Updated July 16, 2019. Accessed June 1, 2021. <https://clinicaltrials.gov/ct2/show/results/NCT02273960?view=results>

⁷Walters J. *Biocentury*; October 26, (2018). <https://www.biocentury.com/article/298908/biogen-ucb-report-phase-ii-b-miss-for-lupus-candidate-dapirolizumab>

⁸Company data.

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Development and Regulatory Strategy

- **1st Indication – Kidney allotransplantation (human to human)**
 - Replacement for nephrotoxic CNI's (calcineurin inhibitors, e.g. Prograf® (tacrolimus)¹, Neoral® (cyclosporin)²
 - Similar development path to the successful development of BMS's Nulojix® (belatacept)³, CTLA-4/Ig biologic
 - Clinical development may combine with Nulojix or Rapamune® (rapamycin/sirolimus)⁴
- **2nd Indication – Heart or kidney xenotransplant (pig to human)**
 - CD40L:CD40 blockade considered essential
 - The engineered pig organ is also considered a biologic
- **3rd Indication – Lou Gehrig's Disease, or ALS⁵**
 - Animal models show strong activity; competitor Eledon (ELDN) is pursuing ALS as primary indication
- **4th Indication (and beyond) – Autoimmune disease (e.g., Systemic Lupus Erythematosus, Rheumatoid Arthritis, Progressive Systemic Sclerosis)**
 - These indications require large studies; SLE and RA would represent very large target markets

¹http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/050708s027,050709s02.1bl.pdf

²<http://www.novartis.us/sites/www.novartis.us/files/neoral.pdf>

³https://packageinserts.bms.com/vpi/pi_nulojix.pdf

⁴<https://labeling.pfizer.com/showlabeling.aspx?id=139>

⁵Amyotrophic Lateral Sclerosis

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TNX-1700*: Gastric and Colorectal Cancers Recombinant Trefoil Factor 2 (rTFF2) Fusion Protein

POTENTIAL NEW CANCER TREATMENT

- TNX-1700 (rTFF2) has effects on cancer by altering the tumor micro-environment
- Mechanism of action: suppresses myeloid-derived suppressor cells and activates anti-cancer CD8+ T cells
- Potential synergy with anti-PD-1 or anti-PD-L1 monoclonal antibodies (mAbs)

PRECLINICAL EVIDENCE FOR INHIBITING GROWTH OF CANCER CELLS

- Data showed that TFF2-CTP augmented the efficacy of mAb anti-PD-1 therapy. Anti-PD-1 in combination with TFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice.

LICENSED FROM COLUMBIA UNIVERSITY

- Developing in partnership under sponsored research agreement

DEVELOPMENT PROGRAM

Market Entry: Immuno-oncology, combination therapy with PD1 blockers for gastric and colorectal cancer

Status: Preclinical

Next Steps: Animal studies ongoing

Patents Filed

*TNX-1700 is in the pre-IND stage of development and has not been approved for any indication.



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**INFECTIOUS
DISEASE: KEY
CANDIDATES**

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TNX-801: Monkeypox and Smallpox Vaccine Live Virus Platform Development Program

APPLICATION OF LIVE VIRUS PLATFORM

- TNX-801 is a cloned version of horsepox¹ (without any insert) purified from cell culture
- In addition to being a potential addition to the U.S. Strategic National Stockpile, TNX-801 serves as the basis for the RPV/horsepox platform

ANIMAL TESTING OF TNX-801 WITH SOUTHERN RESEARCH INSTITUTE

- Non-human primate monkeypox challenge testing: positive data reported in 1Q 2020²

DEVELOPED IN COLLABORATION WITH UNIVERSITY OF ALBERTA

- Proprietary synthetic biology approach and vector system

DEVELOPMENT PROGRAM

Market Entry: Monkeypox and Smallpox Vaccine

Status: Preclinical, Pre-IND

Next Steps: Developing GMP manufacturing for TNX-801; initiate Phase 1 Trial, 1H 2023 in Kenya

Patents Filed

*TNX-801 is in the pre-IND stage of development and has not been approved for any indication.

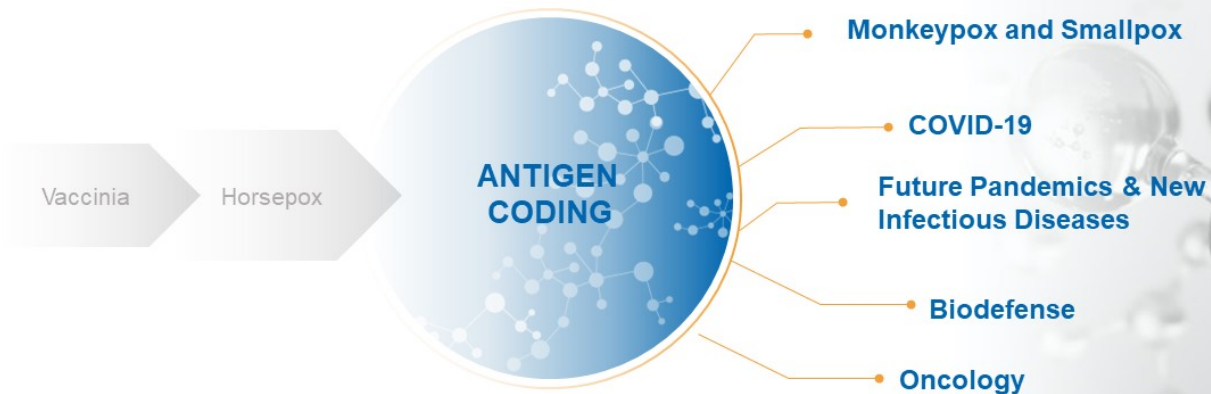
¹Noyce RS, et al. Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. PLoS One. 2018 Jan 19; 13(1):e0188453.

²Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (schPV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (<https://content.equisolve.net/tonixpharma/media/10929ac274fb5f5204f5cf41d59a121.pdf>)

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Live Virus Vaccine Platform: Recombinant Pox Vaccine (RPV) Technology for Emerging Infectious Diseases and Oncolytics



RPV VECTOR BELIEVED SIMILAR TO EDWARD JENNER'S VACCINE¹⁻³

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

¹Shrick, L. N Engl J Med 2017; 377:1491-1492. DOI: 10.1056/NEJMc1707600

²Esparza, J. Vaccine. 2020 Jun 19; 38(30): 4773-4779. doi: 10.1016/j.vaccine.2020.05.037

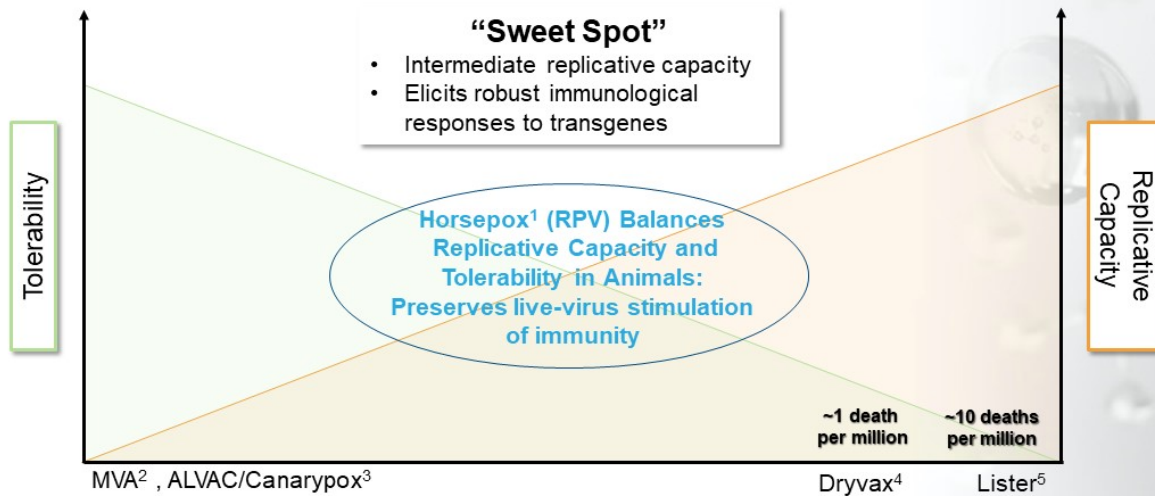
³Brinkmann, A. Genome Biol. 2020; 21: 286. doi: 10.1186/s13059-020-02202-0

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Spectrum of Pox-Virus Replicative Capacity Horsepox Has Lower Replicative Capacity in Human Cells



MVA = Modified Vaccinia virus Ankara

¹Tonix Pharmaceuticals. June 1, 2022. Accessed Sept 30, 2022. ir.tonixpharma.com/news-events/press-releases/detail/1318/tonix-pharmaceuticals-announces-issuance-of-u-s-patent-for

²Volz A, et al. *Adv Virus Res.* 2017;97:187-243.

³Kim, JH, et al. *Annual Review of Medicine* 2015, 66: 423-437.

⁴Belongia EA, et al. *Clin Med Res.* 2003;1(2):87-92.

⁵Kretzschmar M, et al. *PLoS Med.* 2006;3(8):e272.

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Vaccinia and Horsepox Induce a Skin Reaction Called a “Take” Described by Dr. Edward Jenner

Intradermal vaccination¹

Take²

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

¹Example of major cutaneous reaction, or “take,” resulting from a replication-competent live-virus vaccine with intradermal delivery, indicating successful vaccination^{1,2}

¹Fulginiti VA, et al. *Clin Infect Dis.* 2003;37(2):241-250.

²Centers for Disease Control and Prevention. Accessed April 15, 2020. <https://phil.cdc.gov/Details.aspx?pid=3276>

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TNX-1850*: COVID-19 Vaccine

Live Virus Platform Development Program



APPLICATION OF LIVE VIRUS PLATFORM

- First version TNX-1800 encodes spike protein from SARS-CoV-2, Wuhan strain
- Planned new version TNX-1850 encode spike protein from SARS-CoV-2 BA.2 strain¹

ANIMAL TESTING OF TNX-1800 WITH SOUTHERN RESEARCH INSTITUTE

- Non-human primate immune response: positive results reported in 4Q 2020
- Non-human primate CoV-2 challenge testing: positive data reported in 1Q 2021

DEVELOPED IN COLLABORATION WITH UNIVERSITY OF ALBERTA

- Proprietary synthetic biology approach and vector system

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Vaccine

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

Status: Preclinical

Next Steps: Developing TNX-1850 (BA.2) version

Patents Filed

*TNX-1850 is in the pre-IND stage of development and has not been approved for any indication.

¹Brennan, Z. Endpoints March 2, 2022 (<https://endpts.com/weaker-omicron-variant-is-great-news-for-the-world-but-bad-news-for-covid-related-clinical-trials/>)

Live Virus Platform: What Makes TNX-1850 Different from mRNA Vaccines



| CRITERIA | mRNA VACCINES | TNX-1850 |
|--------------------------|----------------------|------------------------|
| Number of shots | Two | One |
| Duration | 6 months | Years / decades |
| Boosters | Recommended | Likely not required |
| Protection from variants | Decreased | Expected |
| Forward transmission | Unknown for variants | 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-1850 shown in table represent expectations.

TNX-2300*: COVID-19 Vaccine

Live Virus Vaccine Based on Bovine Parainfluenza (BPI) Virus



LIVE VIRUS VACCINE¹⁻⁵

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

ANIMAL TESTING OF TNX-2300 ONGOING

- Non-human primate immune response: positive results reported in 4Q 2020
- Non-human primate CoV-2 challenge testing: positive data reported in 1Q 2021

DEVELOPED IN COLLABORATION WITH KANSAS STATE UNIVERSITY (KSU)

- Uses a novel live attenuated vaccine vector platform, BPI, and the CD40-ligand to stimulate T cell immunity

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Vaccine

Additional Indications: Future Pandemic, Infectious Diseases

Status: Preclinical

Next Steps: Animal studies with KSU to test the effect of co-expression of the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity.

Patents Filed

*TNX-2300 is in the pre-IND stage of development and has not been approved for any indication.

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

TNX-3600*: COVID-19 Therapeutics

Fully Human Monoclonal Antibody Platform



PROFILE

Collaboration with Columbia University

Human monoclonal antibodies (mAbs) generated from COVID-19 convalescent patients

Potential monotherapies

- Plan to seek indication similar to current EUA therapeutic mAbs for treating individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease

Potential combination therapy with other antibodies

- Combination therapies for other anti-CoV-2 monoclonal antibodies are believed to have reduced the emergence of drug resistant viral strains

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Therapeutic

Additional Indications: Symptomatic COVID in patients with risk factors for poor outcome

Status: Preclinical

Next Steps: Study inhibition of SARS CoV-2 variants in tissue culture

Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants¹, we seek to contribute to a broad set of monoclonal antibodies from a variety of patients, that can be scaled up quickly and potentially combined with other monoclonal antibodies.

*TNX-3600 is in the pre-IND stage of development and has not been approved for any indication.

¹Waltz, E. Nature. "Does the World Need an Omicron Vaccine?" 28 Jan 2022 <https://www.nature.com/articles/d41586-022-00199-z>



TNX-3700*: COVID-19 Vaccine Zinc Nanoparticle (ZNP) Formulation for mRNA Vaccines

PROFILE

Collaboration with Kansas State University

ZNP technology is a potential replacement for the Lipid Nanoparticle (LNP) technology of current mRNA vaccines

Potential improved stability

- Plan to seek initial indications as booster, similar to the current EUA and FDA approved mRNA vaccines
- Improved stability would facilitate shipping and storage

Addresses limitations in current mRNA vaccines which require ultra-cold storage and shipping

- Stability issues limit use in less developed countries

DEVELOPMENT PROGRAM

Market Entry: Booster for COVID-19 Vaccines

Additional Indications: COVID-19 vaccine for naïve individuals

Status: Preclinical

Next Steps: Research at K-State on CoV-2 spike based vaccine in tissue culture and animals

Patents Filed

*TNX-3700 is in the pre-IND stage of development and has not been approved for any indication.

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Live Virus RPV Platform 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 with some areas designated BSL-3
- **Status:** Operational



Advanced Development Center (ADC) – North Dartmouth, MA

- **Function:** Development and clinical scale manufacturing of live-virus vaccines
- **Description:** ~45,000 square feet, BSL-2
- **Status:** Operational as of 4Q 2022



Commercial Manufacturing Center (CMC) – Hamilton, MT

- **Function:** Phase 3 and Commercial scale manufacturing of live-virus vaccines
- **Description:** ~44 acre green field site, planned BSL-2
- **Status:** Planning for site enabling work in 2022



Architectural Rendering

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American Pandemic Preparedness Plan (AP3)

• “Platforms” – Foundation of Pandemic Response

- Key element of AP3 from White House Office of Science and Technology Policy or OSTP^{1,2}
 - 100 days to human trials
 - Technologies that do not require sterile injection

• TNX-801/TNX-1850 (live virus RPV) platform addresses OSTP requirements^{1,2}

- Our goal is to be able to test new live virus vaccines against novel pathogens within the 100 days of obtaining sequence
 - RDC is equipped to make new vaccines
 - ADC will be equipped to make clinical trial material
 - CMC is planned to make commercial scale material

¹ Sept 3, 2021 (<https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf>)

² Sept 3, 2021 (<https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/>)

FUTURE OUTLOOK

Key Development Partners



TNX-1500: ALLOGRAFT REJECTION

TNX-1300: COCAINE INTOXICATION
TNX-1700: GASTRIC AND COLORECTAL CANCERS
TNX-3600: MONOCLONAL ANTIBODIES FOR COVID-19 TREATMENT



TNX-1900: MIGRAINE & OTHER INDICATIONS

TNX-801: SMALLPOX AND MONKEYPOX VACCINE
TNX-1850: COVID-19 VACCINE



TNX-2900: PRADER-WILLI SYNDROME

TNX-3700: COVID-19 VACCINE (ZINC NANOPARTICLE mRNA TECHNOLOGY)
TNX-2300: BOVINE PARAINFLUENZA VIRUS

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Milestones: Recently Completed and Upcoming*

- ✓ 1st Quarter 2022 Topline data from Phase 3 RALLY study of TNX-102 SL for the management of fibromyalgia
- ✓ 2nd Quarter 2022 Phase 3 RESILIENT study start of TNX-102 SL for the management of fibromyalgia
- ✓ 3rd Quarter 2022 Phase 2 PREVAIL study start of TNX-102 SL for the treatment of Long COVID

Expected Data

- ❑ 2nd Quarter 2023 Interim analysis results of Phase 3 RESILIENT study of TNX-102 SL in fibromyalgia
- ❑ 2nd Quarter 2023 Interim analysis results of Phase 2 PREVAIL study of TNX-102 SL in Long COVID

Expected Clinical Trial Initiations

- ❑ 4th Quarter 2022 Phase 2 study start of TNX-102 SL for the treatment of PTSD in Kenya
- ❑ 4th Quarter 2022 Phase 2 study start of TNX-1900 for the treatment of migraine
- ❑ 1st Quarter 2023 Phase 2 study start of TNX-1300 for the treatment of cocaine intoxication
- ❑ 1st Quarter 2023 Phase 2 study start of TNX-601 ER for the treatment of major depressive disorder
- ❑ 1st Half 2023 Phase 1 study start of TNX-1500 for prevention of allograft rejection
- ❑ 1st Half 2023 Phase 1 study start of TNX-801 for prevention of monkeypox and smallpox in Kenya

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

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Management Team



Seth Lederman, MD
Co-Founder, CEO & Chairman



Gregory Sullivan, MD
Chief Medical Officer



Bradley Saenger, CPA
Chief Financial Officer



Jessica Morris
Chief Operating Officer



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**INVESTOR
PRESENTATION**

ThinkEquity Conference 2022

NASDAQ: TNXP

Version P0385 October 26, 2022 (Doc 1111)

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Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate” and “intend,” among others. These forward-looking statements are based on Tonix’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, 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, 2021, as filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2022, 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.

Who We Are



OUR MISSION

Tonix Pharmaceuticals is committed to improving patient care by advancing science and developing **innovative therapies** which have the potential to address important **unmet needs** across **multiple therapeutic areas**



OUR VISION

Tonix strives to be a leader in providing **novel drug therapies and vaccines** to **patients in need** around the world

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What We Do



DIVERSE PIPELINE

Tonix's core focus is on **central nervous system** disorders, but we also target unmet needs across multiple therapeutic areas including **immunology, infectious disease** and **rare disease**. Tonix is currently enrolling participants in one Phase 3 trial and one Phase 2 trial. We expect six additional clinical trials to commence in the next 12 months.



STRATEGIC PARTNERSHIPS

Partnering strategically with other **biotech companies, world-class academic and non-profit research organizations** to bring innovative therapeutics to market faster.



IN-HOUSE CAPABILITIES

Investment in domestic, **in-house, R&D and manufacturing** to accelerate development timelines and improve the ability to respond to pandemics.



FINANCIAL POSITION

Tonix had **\$145.5 M of cash** as of 6/30/22. Tonix has no debt.

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Pipeline: Key Programs

| Therapeutic Area | Candidates* | Indication | Status/Next Milestone |
|--------------------|-------------------------|--|---|
| CNS | TNX-102 SL ¹ | Fibromyalgia (FM) Posttraumatic Stress Disorder (PTSD) Long COVID (PASC ²) | Mid-Phase 3 Phase 2, Targeted 4Q 2022 Start Phase 2 |
| CNS | TNX-1300 ³ | Cocaine Intoxication <i>FDA Breakthrough Designation</i> | Mid-Phase 2, Targeted 1Q 2023 Start |
| CNS | TNX-1900 ⁴ | Migraine, Craniofacial Pain and Binge Eating Disorder | Phase 2, Targeted 4Q 2022 Start ⁵ |
| CNS | TNX-601 ER | Depression, PTSD, Neurocognitive Dysfunction from Steroids | Phase 2, Targeted 1Q 2023 Start ⁶ |
| Rare Disease | TNX-2900 ⁷ | Prader-Willi Syndrome <i>FDA Orphan Drug Designation</i> | Preclinical |
| Immunology | TNX-1500 ⁸ | Organ Transplant Rejection/ Autoimmune Conditions | Phase 1, Targeted 1H 2023 Start |
| Immunology | TNX-1700 ⁹ | Gastric and colorectal cancers | Preclinical |
| Infectious Disease | TNX-801 ¹⁰ | Smallpox and monkeypox vaccine | Phase 1, Targeted 1H 2023 Start |
| Infectious Disease | TNX-1850 ¹¹ | COVID-19 Vaccine (horsepox-based live virus vaccine) | Preclinical |

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

¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is also in development for Agitation in Alzheimer's Disease (AAD) and Alcohol Use Disorder (AUD). Both indications are Phase 2 ready.

²Post-Acute Sequelae of COVID-19.

³TNX-1300 (double-mutant cocaine esterase) was licensed from Columbia University.

⁴Acquired from Trigemina; license agreement with Stanford University; IND cleared for the prevention of migraine indication; Planned Binge Eating Disorder study is expected to be investigator initiated.

⁵A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900; Phase 2 for the prevention of migraine headache expected to start 4Q 2022.

⁶TNX-601 ER 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 1Q 2023.

⁷Co-exclusive license agreement with French National Institute of Health and Medical Research (Inserm)

⁸Anti-CD40L humanized monoclonal antibody

⁹Recombinant trefoil factor 2 (TFF2) based protein; licensed from Columbia University

¹⁰Live attenuated vaccine based on horsepox virus

¹¹Live attenuated vaccine based on horsepox virus vector, expressed SARS-CoV-2 spike protein. TNX-1850 is based on the BA.2 variant spike protein.

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**CNS:
KEY CANDIDATES**

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TNX-102 SL*

Cyclobenzaprine (Protectic®) Pipeline in a Product

A unique, sublingual formulation of cyclobenzaprine designed to optimize delivery and absorption

Potent binding and antagonist activities at the serotonin-5-HT_{2A}, α 1-adrenergic, histaminergic-H₁, and muscarinic-M₁ receptors to facilitate restorative sleep

Innovative and proprietary PROTECTIC® Rapid drug exposure following nighttime administration

Differentiators:

Relative to Oral Cyclobenzaprine

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

Relative to Standard of Care

- Potential for better tolerability while maintaining efficacy

Patents Issued

*TNX-102 SL has not been approved for any indication.

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Fibromyalgia

Status: Mid-Phase 3

- One Positive Phase 3 study (RELIEF) Completed
- Second Phase 3 study (RALLY) missed primary endpoint
- Confirmatory Phase 3 study (RESILIENT) is currently enrolling

Next Steps: Interim analysis results expected 2Q 2023

Long COVID

Status: Phase 2

- Phase 2 study (PREVAIL) is currently enrolling

Next Steps: Interim analysis results expected 2Q 2023

Posttraumatic Stress Disorder (PTSD)

Status: Mid-Phase 2

- One Phase 2 study (AtEase) completed
- Two Phase 3 studies (HONOR, RECOVERY) conducted

Next Steps: Initiate Phase 2 Trial in Kenya 4Q 2022

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TNX-102 SL*: Fibromyalgia Cyclobenzaprine Protectic® Sublingual Tablets

PROFILE

Fibromyalgia (FM) is a chronic pain disorder resulting from amplified sensory and pain signaling within the CNS.

- Affects an estimated 6-12 million adults in the U.S., approximately 90% of whom are women¹.
- Symptoms include chronic widespread pain, nonrestorative sleep, fatigue, and cognitive dysfunction.
- Patients struggle with daily activities, have impaired quality of life, and frequently are disabled.
- Physicians and patients report common dissatisfaction with currently marketed products.

Patents Issued

¹American Chronic Pain Association (www.theacpa.org, 2019)

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DEVELOPMENT PROGRAM

Market Entry: Fibromyalgia

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

Status: One Positive Phase 3 study RELIEF completed

Second Phase 3 study RALLY missed primary endpoint

Confirmatory Phase 3 study RESILIENT is currently enrolling

Next Steps: Interim analysis results expected 2Q 2023

*TNX-102 SL has not been approved for any indication.

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CNS PORTFOLIO



Phase 3 RESILIENT Study Design

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia
- U.S. sites only, expected to enroll approximately 470 patients
- One unblinded interim analysis based on 50% of randomized participants

Primary Endpoint:

- Daily diary pain severity score change from baseline to Week 14 (TNX-102 SL vs. placebo)
 - Weekly averages of the daily numerical rating scale scores
 - Analyzed by mixed model repeated measures with multiple imputation (MMRM with MI)

TNX-102 SL once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets)*

*Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

Placebo once-daily at bedtime

14 weeks

TNX-102 SL*: Long COVID (PASC) Cyclobenzaprine Protectic® Sublingual Tablets



PROFILE

Long COVID or Post-acute Sequelae of COVID-19 (PASC¹)

- Symptoms can include fatigue, sleep disorders, pain, fevers, shortness of breath, cognitive impairment described as “brain fog”, gastrointestinal symptoms, anxiety, and depression²
- Can persist for months and can range in severity from mild to incapacitating
- Many core symptoms of Long COVID overlap with fibromyalgia
- Occurs in approximately 13% of recovered COVID-19 patients⁵
 - As many as 40% of Long COVID patients experience multi-site pain, a hallmark of fibromyalgia^{3,4}
- Typically associated with moderate or severe COVID-19, Long COVID can occur after mild COVID-19 or even after asymptomatic SARS-CoV-2 infection

DEVELOPMENT PROGRAM

Market Entry: Fibromyalgia-Type Long COVID (PASC)

Additional Indications: Fibromyalgia, PTSD, Agitation in Alzheimer’s, Alcohol Use Disorder

Status: Phase 2 study PREVAIL is currently enrolling

Next Steps: Interim analysis results expected 2Q 2023

Patents Issued

*TNX-102 SL has not been approved for any indication.

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, Anj, et al. "Post-acute COVID-19 syndrome." Nature Medicine (2021): 1-15.

³Harris, H, et al. Tonix data on file. 2022

⁴TriNetX Analytics

⁵September 1, 2022- CDC - <https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html> © 2022 Tonix Pharmaceuticals Holding Corp.



Phase 2 PREVAIL Study Design

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia-type Long COVID
- Approximately 30 sites in the U.S. and is expected to enroll approximately 470 patients
- One unblinded interim analysis based on 50% of randomized participants

Primary Endpoint:

- Daily self-reported worst pain intensity change from baseline at Week 14 (TNX-102 SL vs. placebo)
 - Weekly averages of the daily numerical rating scale scores
 - Analyzed by mixed model repeated measures with multiple imputation (MMRM with MI)

TNX-102 SL once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets)*

*Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

Placebo once-daily at bedtime

14 weeks

TNX 102 SL*: Posttraumatic Stress disorder (PTSD) Cyclobenzaprine Protectic® Sublingual Tablets



PROFILE

PTSD is a serious chronic psychiatric illness

- Defined as maladaptive prolonged stress response which occurs after experiencing severely injurious traumatic event(s)

Affects approximately 12 million Americans adults^{1,2}

Large unmet clinical need and limited effective therapies available

- Advances in pharmacological treatments beyond the currently approved SSRIs (e.g., Zoloft® (sertraline), Paxil® (paroxetine)) are needed³

DEVELOPMENT PROGRAM

Market Entry: PTSD

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

Status: One Phase 2 study (AtEase) completed

Two Phase 3 studies (HONOR, RECOVERY) conducted

Next Steps: 4Q 2022 Initiate Phase 2 Trial in Kenya

Patents Issued

*TNX-102 SL has not been approved for any indication.

¹Goldstein RB, et al. The epidemiology of DSM-5 posttraumatic stress disorder in the United States: results from the National Epidemiologic Survey on Alcohol and Related Conditions-III. Soc Psychiatry Psychiatr Epidemiol. 2016;51(8):1137-1148.

²Pietrzak RH, et al. Prevalence and Axis I comorbidity of full and partial posttraumatic stress disorder in the United States: results from Wave 2 of the National Epidemiologic Survey on Alcohol and Related Conditions. J Anxiety Disord. 2011;25(3):456-465

³Cain, C. K., et al. Targeting memory processes with drugs to prevent or cure PTSD. Expert Opin Investig Drugs. 2012; 21(9), 1323-1350

TNX-1300*: Cocaine Intoxication Cocaine Esterase (CocE)



PROFILE

Cocaine is the main cause for drug-related ED visits¹

Cocaine use can cause irreversible structural damage to the heart and accelerate cardiovascular disease²

- In one survey of 94 long-term cocaine users, 71% had some form of cardiovascular disease³

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

Differentiators:

Rapidly metabolizes cocaine in the bloodstream; no other product currently on the market for this indication

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Cocaine Intoxication

Status: Mid-Phase 2

Next Steps: Initiate a new Phase 2 single-blind, placebo (+ usual care) controlled, randomized, potentially pivotal study in 1Q 2023, pending FDA agreement.

- Expected to enroll approximately 60 emergency department patients
- Primary endpoint: reduction of systolic blood pressure associated with acute cocaine intoxication identified at study baseline comparing TNX-1300 and standard of care after 60 minutes

FDA Breakthrough Therapy Designation

Awarded Cooperative Agreement Grant from National Institute on Drug Abuse (NIDA)



¹Havakuk O et al. *J Am Coll Cardiol.* 2017;70:101-113.
²Phillips K et al. *Am J Cardiovasc Drugs.* 2009;9:177-196.
³Maceira AM et al. *J Cardiovasc Magn Reson.* 2014;16:26.
ED = emergency department.

TNX-601 ER*: Depression Tianeptine Hemioxalate Extended-Release Tablets



PROFILE

A novel, oral, extended-release once-daily tablet

Mechanistically different from traditional monoaminergic treatments for depression

Indirectly modulates the glutamatergic system

- No direct binding to NMDA, AMPA, or kainate receptors

Treatment effect of tianeptine in depression is well-established

Differentiators:

Once daily dosing; unique MOA; Tianeptine sodium IR has similar efficacy but fewer side effects than traditional anti-depressants

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Major Depressive Disorder

Additional Indications: PTSD, Neurocognitive Disorder From Corticosteroids

Status: Phase 2 ready

Next Steps: Initiate a Phase 2 double-blind, placebo-controlled, parallel-group, randomized, potentially pivotal study in 1Q 2023.

Expected to enroll approximately 300 patients across 30 sites in the US.

*TNX-601 ER has not been approved for any indication.



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



TNX-1900*: Migraine Intranasal Potentiated Oxytocin (OT) with Magnesium

PROFILE

Intranasal OT has potential utility in treating migraine¹

- 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^{2,3}

One billion individuals worldwide suffer from migraines

Differentiator:

Novel non-CGRP antagonist approach to treatment

DEVELOPMENT PROGRAM

Market Entry: Chronic Migraine

Additional Indications: Acute Migraine, Craniofacial Pain, Insulin Resistance, Binge Eating Disorder

Status: Phase 2 ready⁴

Next Steps: 4Q 2022 Initiate Phase 2 Trial and Investigator Initiated Phase 2 Trial in Binge Eating Disorder

Patents Issued

*TNX-1900 has not been approved for any indication. CGRP = calcitonin gene-related peptide.

¹Tzabazis A, et al. Oxytocin and Migraine Headache. *Headache*. 2017 May;57 Suppl 2:64-75. doi: 10.1111/head.13082. PMID: 28485846.

²Antoni FA, Chadio SE. Essential role of magnesium in oxytocin-receptor affinity and ligand specificity. *Biochem J*. 1989 Jan 15;257(2):611-4. doi: 10.1042/bj2570611. PMID: 2539090; PMCID: PMC1135123

³Meyerowitz, J.G., et al. The oxytocin signaling complex reveals a molecular switch for cation dependence. *Nat Struct Mol Biol* (2022). (<https://doi.org/10.1038/s41594-022-00728-4>)

⁴A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900



TNX-2900*: Hyperphagia in Prader-Willi Syndrome Intranasal Potentiated Oxytocin (OT) with Magnesium



RARE DISEASE PORTFOLIO

PROFILE

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

- Rare disease occurring in 1 in 10,000 to 1 in 30,000 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 off-target vasopressin receptors

Differentiator:

No approved therapeutic currently on the market for hyperphagia in PWS

DEVELOPMENT PROGRAM

Market Entry: Hyperphagia in Prader-Willi Syndrome

Additional Indications: Rare Hyperphagia Conditions

Status: Preclinical, granted orphan drug designation by FDA

Next Steps: pre-IND meeting to seek agreement on development plans

Patents Issued

*TNX-2900 is in the pre-IND stage of development and has not been approved for any indication.

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IMMUNOLOGY: KEY CANDIDATES

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TNX-1500*



Next Generation α -CD40 Ligand (CD40L) Antibody

The CD40-CD40L pathway is a pivotal immune system modulator and a well-established and promising treatment target

Differentiators: Expected to deliver efficacy without compromising safety

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

Second Generation: Eliminated the Fc γ R TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of Fc γ R while preserving FcRn function.

*TNX-1500 is in the pre-IND stage of development and has not been approved for any indication. Patents filed.

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Prevention of Allograft Rejection

Status: Preclinical

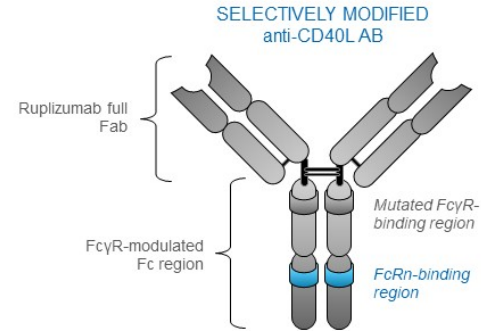
- Collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

Next Steps: Initiate Phase 1 study 1H 2023

Autoimmune Disease

Status: Potential future indication

- These indications require large studies, but represent large target markets



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

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TNX-1700*: Gastric and Colorectal Cancers Recombinant Trefoil Factor 2 (rTFF2) Fusion Protein



IMMUNOLOGY PORTFOLIO

POTENTIAL NEW CANCER TREATMENT

- TNX-1700 (rTFF2) has effects on cancer by altering the tumor micro-environment
- Mechanism of action: suppresses myeloid-derived suppressor cells and activates anti-cancer CD8+ T cells
- Potential synergy with anti-PD-1 or anti-PD-L1 monoclonal antibodies (mAbs)

PRECLINICAL EVIDENCE FOR INHIBITING GROWTH OF CANCER CELLS

- Data showed that TFF2-CTP augmented the efficacy of mAb anti-PD-1 therapy. Anti-PD-1 in combination with TFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice.

LICENSED FROM COLUMBIA UNIVERSITY

- Developing in partnership under sponsored research agreement

Patents Filed

DEVELOPMENT PROGRAM

Market Entry: Immuno-oncology, combination therapy with PD1 blockers for gastric and colorectal cancer

Status: Preclinical

Next Steps: Animal studies ongoing

Differentiator: No product yet identified consistently augments PD1 effects on cold tumors

*TNX-1700 is in the pre-IND stage of development and has not been approved for any indication.

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INFECTIOUS DISEASE: KEY CANDIDATES



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TNX-801 & TNX-1850*

Recombinant Pox Vaccine (RPV)
Platform Using Live Virus Technology



Differentiators:

- **Live virus vaccines are the most established vaccine technology**
 - Starting with Edward Jenner's smallpox vaccine, the first vaccine, which eradicated smallpox
 - Prevents forward transmission
 - Effective in eliciting durable or long-term immunity
- **Economical to manufacture at scale**
 - Low dose because replication amplifies dose in vivo
 - Single shot administration
- **Standard refrigeration required for shipping and storage**

*TNX-801 and TNX-1850 are in the pre-IND stage of development and has not been approved for any indication. Patents filed.
 †Noyce RS, et al. Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. PLoS One. 2018; Jan 19; 13(1):e0198453.
 ‡Brennan, Z. Endpoints March 2, 2022 (<https://endpts.com/weaker-omicron-variant-is-great-news-for-the-world-but-bad-news-for-covid-related-clinical-trials/>)

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Monkeypox and Smallpox Vaccine

Status: Preclinical

- TNX-801 is a cloned version of horsepox¹ (without any insert) purified from cell culture

Next Steps: Developing GMP manufacturing; Initiate Phase 1 Trial 1H 2023 in Kenya

COVID-19 Vaccine

Status: Preclinical

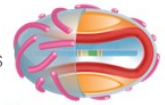
- First version TNX-1800 encodes spike protein from SARS-CoV-2, Wuhan strain
- Planned new version TNX-1850 encode spike protein from SARS-CoV-2 BA.2 strain²

Next Steps: Developing TNX-1850 (BA.2) version

TNX-801*
schPXV (Horsepox)
212,811 bp



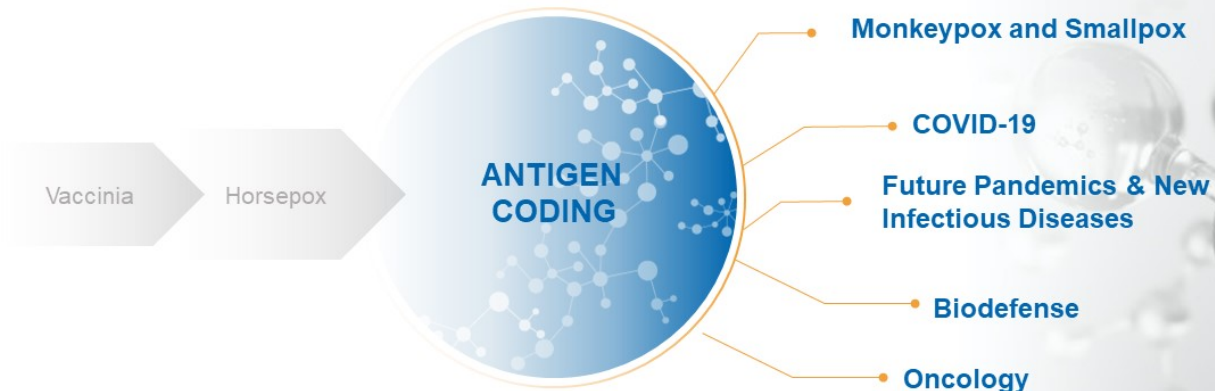
TNX-1800
rHPXV/SARS-CoV-2 S
210,963 bp



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Live Virus Vaccine Platform: Recombinant Pox Vaccine (RPV) Technology for Emerging Infectious Diseases and Oncolytics



RPV VECTOR BELIEVED SIMILAR TO EDWARD JENNER'S VACCINE¹⁻³

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

¹Shrick, L. N Engl J Med 2017; 377:1491-1492. DOI: 10.1056/NEJMc1707600
²Esparza, J. Vaccine. 2020 Jun 19; 38(30): 4773-4779. doi: 10.1016/j.vaccine.2020.05.037
³Brinkmann, A. Genome Biol. 2020; 21: 286. doi: 10.1186/s13059-020-02202-0



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 with some areas designated BSL-3
- **Status:** Operational



Advanced Development Center (ADC) – North Dartmouth, MA

- **Function:** Development and clinical scale manufacturing of live-virus vaccines
- **Description:** ~45,000 square feet, BSL-2
- **Status:** Operational as of 4Q 2022



Commercial Manufacturing Center (CMC) – Hamilton, MT

- **Function:** Phase 3 and Commercial scale manufacturing of live-virus vaccines
- **Description:** ~44-acre green field site, planned BSL-2
- **Status:** Planning for site enabling work in 2022



Architectural Rendering



FUTURE OUTLOOK

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Milestones: Recently Completed and Upcoming*

- ✓ 1st Quarter 2022 Topline data from Phase 3 RALLY study of TNX-102 SL for the management of fibromyalgia
- ✓ 2nd Quarter 2022 Phase 3 RESILIENT study start of TNX-102 SL for the management of fibromyalgia
- ✓ 3rd Quarter 2022 Phase 2 PREVAIL study start of TNX-102 SL for the treatment of Long COVID

Expected Data

- 2nd Quarter 2023 Interim analysis results of Phase 3 RESILIENT study of TNX-102 SL in fibromyalgia
- 2nd Quarter 2023 Interim analysis results of Phase 2 PREVAIL study of TNX-102 SL in Long COVID

Expected Clinical Trial Initiations

- 4th Quarter 2022 Phase 2 study start of TNX-102 SL for the treatment of PTSD in Kenya
- 4th Quarter 2022 Phase 2 study start of TNX-1900 for the treatment of migraine
- 1st Quarter 2023 Phase 2 study start of TNX-1300 for the treatment of cocaine intoxication
- 1st Quarter 2023 Phase 2 study start of TNX-601 ER for the treatment of major depressive disorder
- 1st Half 2023 Phase 1 study start of TNX-1500 for prevention of allograft rejection
- 1st Half 2023 Phase 1 study start of TNX-801 for prevention of monkeypox and smallpox in Kenya

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

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Key Development Partners



TNX-1500: ALLOGRAFT REJECTION

TNX-1300: COCAINE INTOXICATION
TNX-1700: GASTRIC AND COLORECTAL CANCERS
TNX-3600: MONOCLONAL ANTIBODIES FOR COVID-19 TREATMENT



TNX-1900: MIGRAINE & OTHER INDICATIONS

TNX-801: SMALLPOX AND MONKEYPOX VACCINE
TNX-1850: COVID-19 VACCINE



TNX-2900: PRADER-WILLI SYNDROME

TNX-3700: COVID-19 VACCINE (ZINC NANOPARTICLE mRNA TECHNOLOGY)
TNX-2300: BOVINE PARAINFLUENZA VIRUS



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Management Team



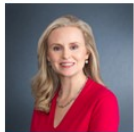
Seth Lederman, MD
 Co-Founder, CEO & Chairman



Gregory Sullivan, MD
 Chief Medical Officer



Bradley Saenger, CPA
 Chief Financial Officer



Jessica Morris
 Chief Operating Officer



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THANK YOU

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