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): December 14, 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))

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

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

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

Emerging growth company ☐

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

Item 7.01 Regulation FD Disclosure.

On December 14, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the U.S. Food and Drug Administration ("FDA") has cleared its Investigational New Drug ("IND") application to initiate a first-in-human clinical study for TNX-2100 (SARS-CoV-2 epitope peptide mixtures for intradermal administration), a skin test to measure delayed-type hypersensitivity (DTH), a measure of T cell immunity, to SARS-CoV-2 (CoV-2). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, 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 99.02 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. Other Events.

On December 14, 2021, the Company issued a press release announcing that the FDA cleared its IND application to initiate a first-in-human study for TNX-2100. TNX-2100 has the potential to provide important diagnostic, safety and predictive information, including durability of immune responses in vaccinated, convalescent and exposed individuals. One of the goals of clinical development of TNX-2100 will be to study the potential correlation of a positive skin test with protective immunity. A test that measures protective immunity has the potential to allow for a personalized approach to determining the need for vaccine boosters, which would reduce costs as well as risks associated with unnecessary vaccinations.

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 intellectual property rights and protections related to TNX-1700, the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

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

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press release of the Company, dated December 14, 2021
99.02	Corporate Presentation by the Company for December 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: December 14, 2021

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

Exhibit 99.1

Tonix Pharmaceuticals Announces IND Clearance for Skin Test (TNX-2100) to Measure SARS-CoV-2 Exposure and T Cell Immunity

First-in-Human Study Expected to be Initiated in the First Quarter of 2022

An Approved Test Would Lead to Identification of People Requiring Vaccine Boosters

CHATHAM, N.J., December 14, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application to initiate a first-in-human clinical study for TNX-2100 (SARS-CoV-2 epitope peptide mixtures for intradermal administration), a skin test to measure delayed-type hypersensitivity (DTH) to SARS-CoV-2 (CoV-2), the virus that causes COVID-19. DTH is a measure of T cell immunity. Tonix expects to initiate the clinical study in the first quarter of 2022.

“When fully developed, our proposed skin test has the potential to provide clinicians, patients, employers and public health officials with important diagnostic, safety and predictive information, including the durability of immune responses in vaccinated, convalescent and exposed individuals,” stated Seth Lederman, M.D., President and Chief Executive Officer of Tonix. “One of the goals of clinical development of TNX-2100 will be to study the potential correlation of a positive skin test with protective immunity. A test that measures protective immunity could allow for a personalized approach to determining the need for vaccine boosters which would reduce costs as well as risks associated with unnecessary vaccinations. In contrast, a one-size-fits-all booster strategy would be relatively more expensive and likely unsustainable.”

T cell immunity to SARS-CoV-2 is believed to provide an important element of protection against serious COVID-19 illness after infection with SARS-CoV-2. T cell immunity persists longer than antibody immunity and is sometimes present in the absence of a measurable antibody response. For example, T cell immunity has been detected in some individuals who do not make antibody responses and in others after their antibody responses have waned and become undetectable over time. A complete picture of a patient’s immune status would require assessment of both antibody titers and T cell immunity. Skin tests that elicit DTH responses are well-established methods for the detection of antigen-specific T cell responses. Tests of this kind are known as *in vivo* diagnostics because they require injection of small peptides into the skin. A positive result is evidenced by a skin reaction surrounding the site of the injection produced by local infiltration of functional antigen-specific T cells.

Dr. Lederman continued, “While the pandemic continues with new waves of infection from novel variants, the surveillance of immunity to COVID-19 disease is important in managing public health. Many experts expect COVID-19 to become endemic, so the need for COVID-19 immunity and disease surveillance will be ongoing.”

In parallel to developing TNX-2100 as a potential diagnostic tool, Tonix is developing TNX-1800, a live virus vaccine for COVID-19 designed to elicit primarily T cell immunity. Tonix has completed positive immune response and challenge studies in non-human primates and expects to start a Phase 1 study in humans in the second half of 2022, based on the FDA written responses of a pre-IND meeting.

About TNX-2100

TNX-2100 is a diagnostic product candidate in the pre-Investigational New Drug (IND) stage and has not been approved for any indication. TNX-2100 is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130), which are designed to represent different protein components of the SARS-CoV-2 virus. TNX-2110 (SARS-CoV-2 multi-antigen peptides) represents epitopes of multiple proteins from SARS-CoV-2. TNX-2120 (SARS-CoV-2 spike peptides) represents only the spike protein. TNX-2130 (SARS-CoV-2 non-spike peptides) represents non-spike proteins. Each of these three tests is expected to be administered as part of the same procedure, at separate locations on the forearm, and each is expected to elicit a DTH response after approximately 48 hours in individuals with pre-existing T cell immunity to peptides in that mixture. Individuals who have been infected by or exposed to SARS-CoV-2 would be expected to respond to all three mixtures. In contrast, a successfully vaccinated individual who has not been exposed or infected by SARS-CoV-2 would be expected to respond only to TNX-2120 (SARS-CoV-2 spike peptides), since the currently available vaccines only encode spike protein. In the planned clinical protocol for testing TNX-2100, positive skin test controls will be used to confirm that study participants have intact T cell immunity and are not immunodeficient.

The test is designed to be administered in the same manner as skin tests for tuberculosis, or TB, sold as Tubersol® or Aplisol® or generically as the Mantoux tuberculin purified protein derivative (PPD) test. A thin gauge needle is used to apply each of the three separate peptide mixtures into the skin, or intradermally, on the inner surface of the forearm between the wrist and the elbow. In a typical positive test, the skin surrounding the injection site is expected to become red, raised and hardened, or “indurated”, after approximately 48 hours. Induration above a threshold level would signify a positive result and the diameter of the induration would indicate the amount of T cell immunity to the test peptides. DTH skin test responses are believed to reflect functional in vivo immunity. Clinical trials are expected to correlate skin test results with clinical history to inform estimates about the sensitivity and specificity of the test as a marker of T cell immunity in individuals who are pre- and post-COVID-19 vaccination, recovered from COVID-19; or exposed but asymptomatic.

Discovered in 1882 by Robert Koch, the DTH reaction has been used for more than a century as a clinical test for T cell-mediated immune reactions[1]. In the 1940s, Landsteiner and Chase demonstrated that the reaction was mediated by the cellular and not the antibody arm of the immune system[2]. The DTH reaction has been shown to be dependent on the presence of memory T cells. Both the CD4+ and CD8+ T cells have been shown to participate in this response. DTH skin tests have been commonly used to detect T cell responses to tuberculosis, fungal pathogens, and mumps virus.

[1] *Black CA. Delayed type hypersensitivity: current theories with an historic perspective. Dermatol Online J. 1999;5:7.*
[2] *Landsteiner K, Chase MW. Studies on the sensitization of animals with simple chemical compounds: vii. Skin sensitization by intraperitoneal injections. J Exp Med. 1940;71:237.*

Tubersol® is a trademark of Sanofi Pasteur
Aplisol® is a trademark of Par Pharmaceutical, Inc.

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 also 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 first quarter of 2022. TNX-3500[5] (sangivamycin, i.v. solution) 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 the development of TNX-2100, 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 99.2

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.

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

PIPELINE

COVID, BIODEFENSE & IMMUNOLOGY PORTFOLIO

CANDIDATES	PORTFOLIO & INDICATION	STATUS / NEXT MILESTONE
	COVID	
TNX-1800[1]	COVID-19 Vaccine	Phase 1 start - 2H 2022
TNX-102 SL[2]	Long COVID-19 (Post-Acute Sequelae of COVID-19 or PASC)	Phase 2 start – 1H 2022
TNX-2100[3]	SARS-CoV-2 Diagnostic for T-Cell Immunity	First-in-human study – Q1 2022
TNX-3500[4]	COVID-19 Antiviral	Preclinical
TNX-3600[5]	COVID-19 Therapeutic	Preclinical
	BioDefense	
TNX-801[6]	Smallpox and monkeypox preventing vaccine	Preclinical
TNX-701	Radioprotection	Preclinical
	Immunology & Oncology	
TNX-1500[7]	Organ Transplant Rejection/ Autoimmune Conditions	Phase 1 start – 2H 2022
TNX-1700[8]	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, expressed SARS-CoV-2 spike protein.

[2]Pre-IND (Investigational New Drug) meeting with FDA completed; Company plans to start Phase 2 study in subset of patients whose symptoms overlap with fibromyalgia pending IND clearance.

[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]Humanized monoclonal antibody generated from COVID-19 convalescent patients

[6]Live attenuated vaccine based on horsepox virus

[7]anti-CD40L humanized monoclonal antibody

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

PIPELINE
CNS PORTFOLIO

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 start – 1Q 2022 Phase 2 start – 1H 2022[3]
TNX-1300[4]	Cocaine Intoxication / Overdose	Phase 2 start – 4Q 2021
TNX-1900[5]	Migraine and Craniofacial Pain	Phase 2 start – 2H 2022[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; IND cleared
[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

COVID-19: THE MISSING PIECES

DELTA VARIANT IS SURGING IN THE US – OMICRON VARIANT IS POISED TO SPREAD

- **Vaccines: early vaccines slowed pandemic, but are showing limitations**
  - Short term protection – requirement for boosters; uncertain protection against variants
- **Anti-viral drugs: only remdesivir is available**
  - Pfizer's PAXLOVID™[1] looks promising; Merck's molnupiravir did not show benefit in 2nd cohort[2]
- **Anti-SARS-CoV-2 monoclonal antibodies: increasing adoption**
  - Concerns about whether monoclonals will work on new variants
- **Tests: measurement of functional T cell immunity is a new frontier**
- **Long COVID: no approved treatment for 'Long Covid'**

[1]PAXLOVID™ (PF-07321332; ritonavir)
[2]Merck Says Its Covid Pill Is Less Effective in a Final Analysis - The New York Times (nytimes.com)

COVID-19 VACCINES: WHERE WE ARE TODAY

Durability of protection
- Vaccinated people lose protection, starting at 6 months[1]
- Increasing rates of "breakthrough" COVID
- White House advocating booster vaccinations with mRNA vaccines at 6 months

Effect on forward transmission (spread of infection to others)
- Concerns about whether vaccinated people can be infectious to others

Detecting vaccine failure
- Need a strategy for identifying individuals at risk after vaccination

No recognized, clinical applicable biomarker of vaccine protection
- Best proxy is neutralizing antibodies, which are hard to measure

Current and future variants (e.g., delta, omicron variants)
- Less protection from existing vaccines
- Unknown effectiveness for future variants

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

COVID-19 VACCINES: WHERE DO WE GO FROM HERE?

mRNA vaccines have slowed pandemic, but may not be a long-term solution

- Vaccinated people lost protection, increasing rates of "breakthrough" COVID
- COVID is becoming endemic; vaccination of entire world every 6 months not practical

Operation Warp Speed (OWS) identified 4 types of vaccines:

1. RNA/DNA – Pfizer is fully approved by the FDA[1] and Moderna has EUA
2. Subunit – NovaVax has good data, but manufacturing issues – not available
3. Non-replicating – J&J has EUA; AstraZeneca widely used ex-US
4. Live Virus Vaccines – none were ultimately adopted by OWS

Live Virus Vaccines

- Merck was developing two programs: VSV and Measles, but they were not included in OWS and were abandoned in January 2021[2]

[1]COMIRNATY is the brand name for the Pfizer-BioNTech COVID-19 vaccine
[2]https://www.merck.com/news/merck-discontinues-development-of-sars-cov-2-covid-19-vaccine-candidates-continues-development-of-two-investigational-therapeutic-candidates/

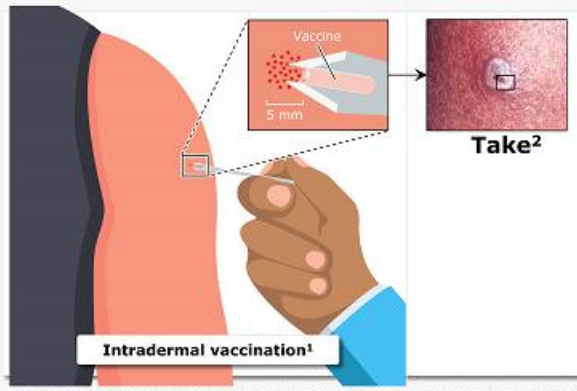
TONIX PHARMACEUTICALS

LIVE VIRUS VACCINES: DEVELOPMENT RATIONALE

- **Control of smallpox, measles, mumps, rubella, chickenpox and other viral conditions**
  - Prevent 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 cold chain required for shipping and storage**
- **Live virus vaccines are the oldest vaccine technology**
  - Starting with Edward Jenner's smallpox vaccine, the first vaccine, eradicated smallpox

TONIX PHARMACEUTICALS

VACCINIA INDUCES A SKIN REACTION CALLED "TAKE" – DESCRIBED BY DR. EDWARD JENNER



- **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

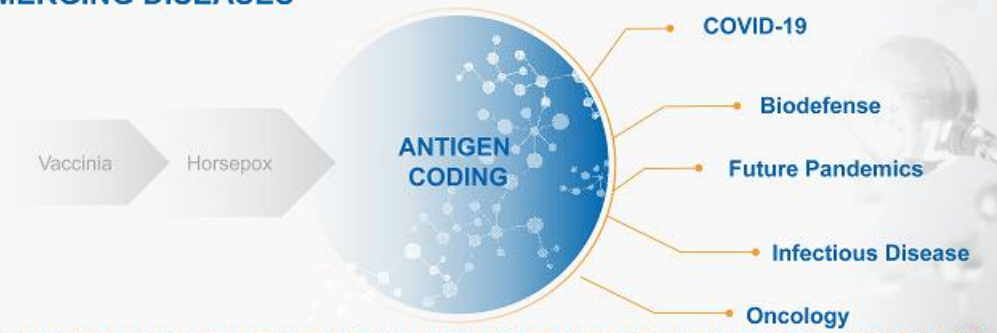
*Example of major cutaneous reaction, or "take," resulting from a replication-competent live-virus vaccine with intradermal delivery, indicating successful vaccination[1,2]

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

TONIX PHARMACEUTICALS

LIVE VIRUS VACCINE PLATFORM:

NEW RECOMBINANT POX VACCINE (RPV) TECHNOLOGY FOR EMERGING DISEASES



RPV VECTOR BELIEVED SIMILAR TO EDWARD JENNER'S VACCINE[1-3]

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

[1]Shrick, L. N Engl J Med 2017; 377:1491-1492. DOI: 10.1056/NEJMc1707800
[2]Esparza, J. Vaccine. 2020 Jun 19; 38(30): 4773–4779. doi: 10.1016/j.vaccine.2020.05.037
[3]Brinkmann, A. Genome Biol. 2020; 21: 286. doi: 10.1186/s13059-020-02202-0

TONIX PHARMACEUTICALS

LIVE VIRUS RECOMBINANT POX VACCINE (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
- Multi-dose packaging, standard cold-chain products

TNX-1800 COVID-19 VACCINE
LIVE VIRUS PLATFORM DEVELOPMENT PROGRAM

ESTABLISHES LIVE VIRUS 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

DEVELOPED IN COLLABORATION WITH UNIVERSITY OF ALBERTA AND MANUFACTURING AGREEMENT WITH FUJIFILM DIOSYNTH

- 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

LIVE VIRUS PLATFORM: WHAT MAKES TNX-1800 DIFFERENT FROM MRNA VACCINES

CRITERIA	mRNA VACCINES	TNX-1800*
Number of shots	Two	One
Duration	6 months	Years / decades
Boosters	Recommended	Likely not required
Protection from variants	Variants	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-1800 show in table represent expectations.*

LIVE VIRUS 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: 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

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/-1800 (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
    - CDC 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/

US TRENDS IN COVID-19 VACCINE BOOSTER DEVELOPMENT

CURRENT US GOVERNMENT STANCE IS BOOSTERS RECOMMENDED POST- PFIZER MODERNA, AND J&J VACCINATIONS[1,2]

- CDC, FDA, White House, COVID-19 Response Team stated that immunity wanes and booster vaccines should be used in all adults and most children
- FDA has authorized and CDC approved a single booster shot of the Pfizer-BioNTech and Moderna COVID-19 vaccines for Americans age 18 and older, six months after second dose
- 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

Testing protective immunity to assess personalized need for vaccine boosters is expected to be more cost effective and reduce risks with unnecessary vaccination

[1] www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html
[2] https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

ASSESSING ANTI-SARS-COV-2 PROTECTIVE IMMUNITY

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

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TNX-2100*: SARS-COV-2 DIAGNOSTIC TO MEASURE T-CELL IMMUNITY

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

- Q1 2022: Plan to initiate first-in-human clinical testing
- 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.

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SMALL MOLECULE COVID-19 THERAPEUTICS

The only COVID-19 antiviral that is FDA approved is Remdesivir/Veklury®
- Gilead – Intravenous (*i.v.*) medicine
- FDA approved for patients who are at least 12 years old and require hospitalization
- May shorten the time to recover from acute COVID-19
- World Health Organization has recommended against its use[1]
- Resistance reported[2]

Anti-virals in Phase 3 development
- Pfizer – PAXLOVID™ (PF-07321332; ritonavir) - oral protease C3L inhibitor
- Merck/Ridgeback – molnupiravir, oral, in Phase 3 development with US gov't supply agreement[3]

Concerns about anti-viral efficacy
- Remdesivir resistance reported[2]
- Molnupiravir efficacy was not repeated in second cohort of Phase 3 trial[4]

[1] *World Health Organization (2021). Therapeutics and COVID-19: living guideline, 6 July 2021 (Report).* hdl:10665/342368. Therapeutics and COVID-19: living guideline, 6 July 2021 (who.int)
WHO/2019-nCoV/therapeutics/2021.2
[2] https://yaledailynews.com/blog/2021/12/02/yale-scientists-identify-remdesivir-resistance-in-immunocompromised-covid-19-patient/
[3] www.merck.com/news/merck-announces-supply-agreement-with-u-s-government-for-molnupiravir-an-investigational-oral-antiviral-candidate-for-treatment-of-mild-to-moderate-covid-19
[4] www.merck.com/news/merck-announces-supply-agreement-with-u-s-government-for-molnupiravir-an-investigational-oral-antiviral-candidate-for-treatment-of-mild-to-moderate-covid-19

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COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

TNX-3500*: COVID-19 ANTIVIRAL TREATMENT
SANGIVAMYCIN

PROFILE

New variants heighten need for therapeutics

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

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

Potential combination therapy with remdesivir[1,2]
- 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: 1H 2022 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. Bennett, RP et al. *JCI Insight*. 2021 in press preview 10.1172/jci.insight.153165

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MONOCLONAL ANTIBODY COVID-19 THERAPEUTICS

Monoclonal antibodies (mAbs) (EUA) – 4 granted US Emergency Use Authorization[1]

- Regeneron/Genentech - REGEN-COV® Casirivimab/imdevimab[2]
- Vir/GSK – XEVURDY® (sotrovimab)[3]
- Eli Lilly – Bamlanivimab/etesevimab[4] - US distribution halted[5]
- AstraZeneca – Evusheld (Tixagevimab/cilgavimab) – EUA for long term prophylaxis

New mAbs under development[6]

- AstraZeneca – AZD7442 – EUA request submitted[7]
- Brii Biosciences – BRII-196 and BRII-198[8]
- Adagio Therapeutics – ADG20[9]
- Many other companies[10]

Concerns about efficacy of mAbs against new variants

- Delta and Omicron variants have many changes in the spike protein, which is the target of current mAbs[11]
- Antibodies are being studies for activity against new variants

[1]Indicated for individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease
[2]www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19
[3]www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19
[4]www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0
[5]www.fiercepharma.com/pharma/lilly-s-covid-antibody-combo-halted-nationwide-dealing-huge-blow-to-blockbuster-program
[6]Dolgin, E. *Nature Biotechnology* **volume 39**, pages783–785 (2021) https://doi.org/10.1038/s41587-021-00980-x
[7]https://www.cnbc.com/2021/11/18/astrazeneca-antibody-drug-83percent-effective-at-preventing-covid-trial.html
[8]https://endpts.com/brii-bio-gets-all-hands-on-deck-for-covid-19-antibody-hunt-leveraging-chinese-partners-work-with-recovered-patients/
[9]https://endpts.com/qa-lilman-gerngross-explains-why-his-covid-mab-will-have-an-edge-over-an-already-crowded-field/
[10]e.g., Centivax, Corat Therapeutics, IDBiologics, Leyden Labs, Memo Therapeutics and SpikImm
[11]Dec 7, 2021 Glaxo Says Its Covid-19 Antibody Drug Works Against Omicron - WSJ

COVID, BIODEFENSE AND IMMUNOLOGY PORTFOLIO

TNX-3600*: COVID-19 THERAPEUTIC
HUMANIZED MONOCLONAL ANTIBODY

PROFILE

Collaboration with Columbia University

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

Potential monotherapy

- 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; 1H 2022 Initiate Animal Studies

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

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

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 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

To address the urgent need for PASC therapies, Congress awarded the National Institutes of Health $1.15 billion to study Long COVID.[3]

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

Patents Issued

[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.

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TNX-1500
NEXT GENERATION CD40 LIGAND ANTIBODY

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)

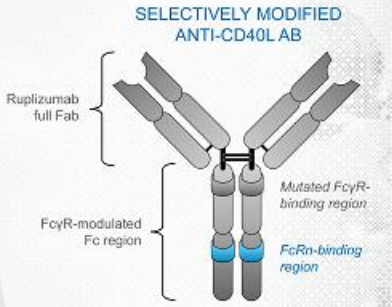
Second Generation: Eliminated the FcγR TE complication but *potency and half life was reduced, limiting utility*

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



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

Patents Filed

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

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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 (RALLY/F306): clinical phase completed, and topline data expected 1Q 2022. Confirmatory Phase 3 planned for 1H 2022

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=336) enrolled participants, the IDMC recommended stopping the trial as TNX-102 SL is unlikely to demonstrate a statistically significant improvement in the primary endpoint.
- Clinical phase of study completed, with 514 participants enrolled overall – 399 completers; topline results expected 1Q 2022
- Confirmatory Phase 3 study (F307) planned 1H 2022

Following analysis of F306 results, including pharmacogenetic comparison of F304 and F306, Tonix may modify F307 protocol

TNX 102-SL Development Beyond Fibromyalgia

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

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TNX-601 CR: PSYCHIATRY
TIANEPTINE OXALATE AND NALOXONE

CNS PORTFOLIO

PROFILE

A novel, oral, controlled 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

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.

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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: Acute Migraine, Craniofacial Pain, Insulin Resistance

Status: Clinical – IND cleared[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.

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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 off-target vasopressin receptors

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Prader-Willi Syndrome

Additional Indications: Rare, Orphan Hyperphagia Conditions

Status: pre-IND; orphan drug designation application submitted to FDA

Next Steps: Submit application to the FDA for Fast Track designation

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TNX-1300: COCAINE INTOXICATION
COCAINE ESTERASE (CoCe)

CNS PORTFOLIO

PROFILE

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

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

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

CoCe is a recombinant protein that degrades cocaine in the bloodstream

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

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Cocaine Intoxication

Additional Indications: Cocaine Overdose

Status: Phase 2 Open Label

Next Steps: Q4 2021 Initiate Trial

FDA Breakthrough Therapy Designation

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

ED = emergency department.

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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
TNX-3600: MONOCLONAL ANTIBODIES FOR COVID-19 TREATMENT

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

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

Data

- ❑ 1st Quarter 2022 Topline data from TNX-102 SL Phase 3 F306/RALLY study in fibromyalgia expected

Expected Clinical Trial Initiations

- ❑ 4th Quarter 2021 Phase 2 OL safety study start of TNX-1300 in ED setting for cocaine intoxication
- ❑ 1st Quarter 2022 First-in-human clinical study start of TNX-2100 for SARS-CoV-2 skin test
- ❑ 1st Quarter 2022 Phase 2 study start of TNX-102 SL for the treatment of PTSD in Kenya
- ❑ 1st Half 2022 Phase 3 study start of TNX-102 SL for the management of fibromyalgia
- ❑ 1st Half 2022 Phase 2 study start of TNX-102 SL for the treatment of Long COVID
- ❑ 1st Half 2022 Phase 2 study start of TNX-601 CR for the treatment of major depressive disorder
- ❑ 2nd Half 2022 Phase 2 study start of TNX-1900 for the treatment of migraine
- ❑ 2nd Half 2022 Phase 1 study start of TNX-1800 for COVID-19
- ❑ 2nd Half 2022 Phase 1 study start of TNX-1500 for prevention of allograft rejection

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

MANAGEMENT TEAM

Seth Lederman, MD
Co-Founder, CEO & Chairman

TARGENT X | Fusilev (levoleucovorin) for injection | vela

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THANK YOU