

**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): **May 15, 2026**

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.)

200 Connell Drive, Berkeley Heights, New Jersey, 07922
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(862) 799-8599**

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 Select 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 May 15, 2026, Tonix Pharmaceuticals Holding Corp. (the “Company”) presented certain data from the Phase 1 trial for its TNX-4800 product candidate for protection against Lyme disease at the Global Lyme Alliance. A copy of the presentation is attached hereto as Exhibit 99.01.

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

Item 8.01 Other Events.

On May 15, 2026, the Company presented the following analysis of pharmacokinetic data from the Phase 1 trial for TNX-4800 at the Global Lyme Alliance in connection with the proposed adaptive Phase 2 field study for TNX-4800, planned for the first half of 2027, pending agreement by the U.S. Food and Drug Administration:

- Simulation of a two-dose regimen (350 mg subcutaneous administration on Day 1 and 56 Days) of TNX-4800 were presented that predict mean serum levels for participants in the field study. Predictions were quantified for the time in days for serum levels to decrease below four serum levels, referred to as Minimum Effective Concentrations (“MECs”), of 10 µg/mL, 15 µg/mL, 20 µg/mL and 5 µg/mL. Days to MEC were: MEC₁ (10 µg/mL): 196 days; MEC₂ (15 µg/mL): 161 days; MEC₃ (20 µg/mL): 136 days; MEC₄ (5 µg/mL): 265 days.
- The simulations and predictions support the feasibility of a two-dose 350 mg regimen maintaining a minimal mean serum level above MEC 10 µg/mL for six months following the initial dose, the proposed primary endpoint for the field study.

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 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	TNX-4800: A Long-Acting, Bactericidal, Human Monoclonal Antibody to Prevent Lyme Disease in the U.S.
	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: May 15, 2026

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

TNX-4800: A Long-Acting, Bactericidal, Human Monoclonal Antibody to Prevent Lyme Disease in the U.S.

Zeil Rosenberg MD, MPH
Executive Vice President, Medical
Tonix Pharmaceuticals

Global Lyme Alliance

PO6143 May 15, 2026 1660

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Cautionary Note on Forward-Looking Statements

Certain statements in this presentation 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 failure to successfully launch and commercialize TONMYA® and any of our approved products; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2025, as filed with the Securities and Exchange Commission (the “SEC”) on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. All of Tonix’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

Tonix Pharmaceuticals – Transforming Medicine for the Future

3 FDA Approved Products

Tonmya[®]
(cyclobenzaprine HCl)
sublingual tablets 2.8mg

tosymra[®]
(sumatriptan nasal spray) 10 mg

Zembrace[®] SYMTOUCH[®]
(sumatriptan injection) 3 mg

Therapeutic Areas of Focus:

- CNS
- Infectious Disease
- Immunology
- Rare Disease



Nasdaq TNXP

- ~\$185.5 M cash as of March 31, 2026
- No debt

Fully Integrated

- Research
- Development
- Manufacturing
- Commercial

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Partnerships

with major Universities
and the U.S. Federal
Government



First FDA-Approved Treatment for Fibromyalgia in Over 15 Years

Tonmya[®]
(cyclobenzaprine HCl)
sublingual tablets 2.8mg

First-in-class, First-line Medicine
Unique, Sublingual, Proprietary Formulation Supports:
Efficacy, Absorption, and Tolerability



Current Treatments

Limited approved and effective options

High rate of patient and HCP dissatisfaction

Off-label opioids often used

TONMYA

Distinct mechanism of action versus current therapies

Robust efficacy

Generally well-tolerated

TONMYA (cyclobenzaprine HCl sublingual tablets) is indicated for the treatment of fibromyalgia in adults

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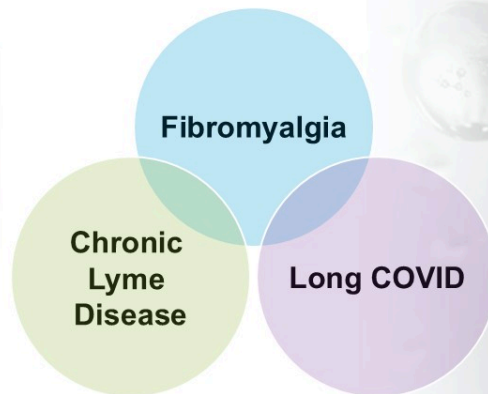
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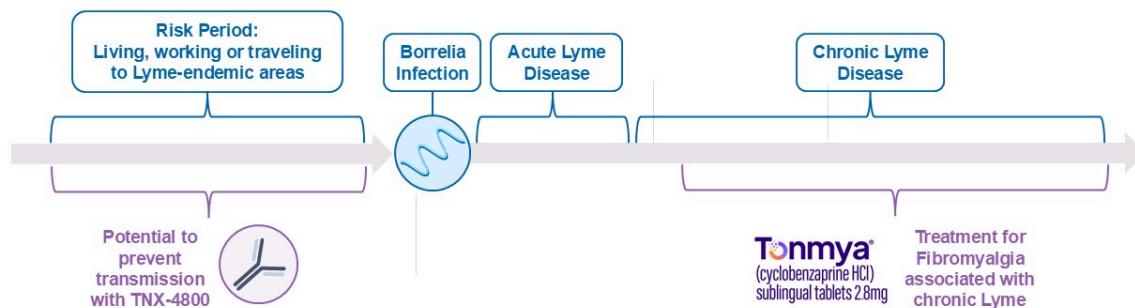
Overlap of Fibromyalgia and Chronic Lyme Disease

**Fibromyalgia is a
diagnosable condition in:**

- ✓ *Long COVID*
- ✓ *Chronic Lyme disease*
- ✓ *Other Infection Associated
Chronic Illness (IACI)*



Addressing the Lyme Disease Spectrum



Introducing TNX-4800

TNX-4800^{1,2} is a human anti-OspA monoclonal antibody (HuMAb) with engineered Fc domain for extended half-life, licensed from UMass Chan Medical School in 2025 (Formerly 2217LS)

Expected Mechanism of Action



TNX-4800 provides passive immunity by directly supplying neutralizing antibodies, bypassing the need for a patient's immune system to generate its own antibodies

1. TNX-4800 is an investigational biologic and is not approved for any indication.
2. TNX-4800 is protected by [Issued US Patent US 10,457,721](#), which is licensed from UMass Chan with expiry in January 2036 (with PTA), excluding any possible patent term extension.

Clinical and Market Acceptance of Monoclonal Antibody Preventive Treatments

Monoclonal antibody prophylaxis has been approved for respiratory syncytial virus (RSV) and COVID-19, including ENFLONIA™ (clesrovimab),¹ BEYFORTUS® (nirsevimab)² and PEMGARDA™ (pemivibart)³



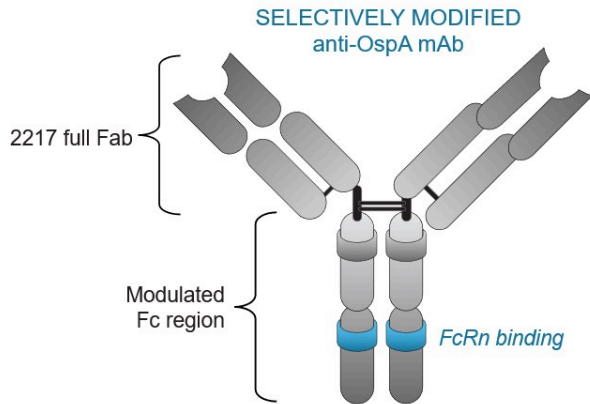
1. Enflonia. Prescribing information. Merck Sharp & Dohme LLC; 2025.
2. Beyfortus. Prescribing information. Sanofi; 2024.
3. Pemgarda. Prescribing information. Invivyd, Inc.; 2025.

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TNX-4800 Long-acting anti-OspA Monoclonal Antibody Design



Engineered Fc domain (LS) binding to FcRn for an extended half-life that targets OspA of *Borrelia burgdorferi*^{1,2}

LS substitutions maintain C1q binding and function and augment FcRn binding for extended half-life

1. Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.
2. Wang Y, et al. *J Infect Dis*. 2016;214(2):205-211.

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TNX-4800 is Not a Vaccine

Limitations of OspA vaccines

- Protection depends on titer of OspA at the moment the deer tick sucks blood
- High-titer vaccine responses require onerous immunization schedule
- Little or no “memory” response on *Borrelia* exposure
 - OspA-expressing *Borrelia* is sequestered in the tick midgut
- Protection depends on patient’s immune status
- Results in heterogeneous polyclonal antibody response to vaccine
- “Titer” of polyclonal response has uncertain correlation with individual protection
- Associated with typical side-effects of vaccination



Prophylactic Monoclonal Antibody (mAb) Characteristics

Potential attributes of anti-OspA mAb TNX-4800

- Nearly-immediate protection (within 2 days)
- Not reliant on patient's immune status
- Replaces heterogeneous polyclonal response of vaccine with homogeneous monoclonal agent with defined properties
- Replaces "titer" of polyclonal response with quantifiable serum levels
- Potential for quantifying serum mAb levels as immune correlate of protection
- Avoids side-effects of vaccination

Analysis of Minimum Effective Concentration (MEC) – Method # 1 – *in vivo* Primate Challenge Model

A screenshot of a web page from The Journal of Clinical Investigation (JCI). The page features a dark blue header with the JCI logo and the journal's name. Below the header is a navigation bar with links for 'About', 'Editors', 'Consulting Editors', 'For authors', 'Alerts', 'Advertising/recruitment', and 'Subscribe'. A secondary navigation bar includes 'Current Issue', 'Past Issues', 'By specialty', 'Videos', 'Reviews', 'Viewpoint', and 'Collections'. The main content area displays the title of an article: 'Blocking Borrelia burgdorferi transmission from infected ticks to non-human primates with a human monoclonal antibody'. Below the title, the authors 'Zachary A. Schiller, ... , Mark S. Klempner, Yang Wang' are listed, along with the publication date 'Published April 29, 2021' and citation information: 'Citation Information: J Clin Invest. 2021. https://doi.org/10.1172/JCI144843.' At the bottom of the article preview, there are links for 'View: Text | PDF'.

JCI The Journal of Clinical Investigation

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Blocking *Borrelia burgdorferi* transmission from infected ticks to non-human primates with a human monoclonal antibody

Zachary A. Schiller, ... , Mark S. Klempner, Yang Wang

Published April 29, 2021

Citation Information: *J Clin Invest.* 2021. <https://doi.org/10.1172/JCI144843>.

View: Text | PDF

Three Models for MEC determination used:

- *in vitro* borreliacidal activity
- *in vitro* tick feeding assays
- *in vivo* NHP challenge

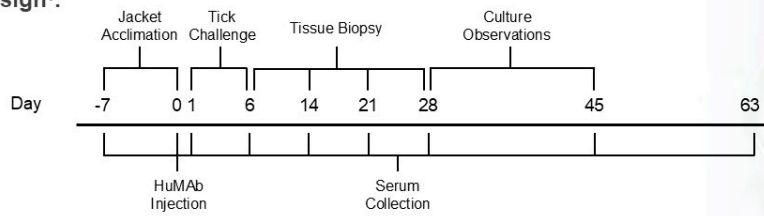
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Nonhuman Primate Challenge Model: Protocol and Protection by Dosage Level

Study Design¹:



- Dose escalation study: 4 cohorts, 1 irrelevant IgG control
- 4 to 6 animals per cohort; challenged with 20 infected ticks
- Seroconversion for IgG antibodies against *B. burgdorferi* was measured as an indicator of efficacy

Results:

Cohort	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Irrelevant IgG
Dose (mg/kg)	3	10	30	90	10
Protection (%)	100	83	100	100	0
P value	<0.001	<0.001	<0.001	<0.001	N/A

¹ Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e1144843.
HuMAb=human monoclonal antibody; IgG=immunoglobulin G.

Analysis of Minimum Effective Concentration (MEC) –Three Methods

- **Serum ~5 µg/mL – *in vitro* bactericidal activity (not shown)**
 - TNX-4800 showed $EC_{50} \approx 0.56 \mu\text{g/mL}$ *in vitro*¹
 - MEC ~ 10X EC_{50} ²
- **Serum <10 µg/mL – *in vitro* tick feeding experiment (not shown)**
 - TNX-4800 showed killing $\geq 10 \mu\text{g/ml}$ ³
- **Serum <21 µg/mL – *in vivo* primate challenge model**
 - TNX-4800 serum levels $>21 \mu\text{g/ml}$ were 95% protective^{1,3}

1. Wang Y, et al. *J Infect Dis.* 2016; 214(2):205-11.
2. Rogers RR et al. *Antimicrobial Agents and Chemotherapy*, Oct. 2004, p. 3670–3676.
3. Schiller ZA, et al. *J Clin Invest.* 2021;131(11):e144843.



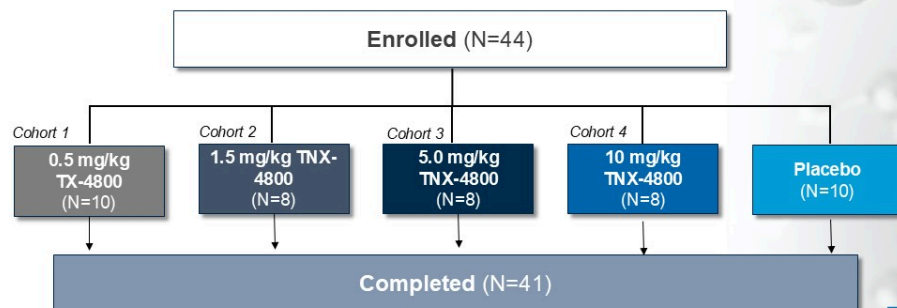
PHASE 1 CLINICAL TRIAL

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Human Phase 1 Study: Safety, Tolerability and Immunogenicity: Design

- First-in-human, randomized, double-blind, sequential dose-escalation study (N=44)
- Healthy male and female volunteers aged 19 to 65 years, serum negative for anti-*B. burgdorferi* antibodies, by an FDA-approved modified 2-tier ELISA test, were recruited
- Safety was assessed via clinical and lab evaluations. Dose delivered SC.
- Serum TNX-4800 concentrations were measured by ELISA, with pharmacokinetic analysis
- Antidrug antibodies were detected using an electrochemiluminescence immunoassay



TNX-4800 Phase 1 Study objectives and population

Primary Objective:

- Evaluate safety and tolerability of a SC injection of TNX-4800 when administered to healthy volunteers

Secondary Objective:

- Evaluate pharmacokinetics of a SC dose of TNX-4800 when administered to healthy volunteers

Study Population:

- Healthy male and female volunteers, age 19 to 65 years, inclusive
- Median age of 39 years
- 52% male and 48% female
- White 77%, 16% African–American, non-Hispanic/Latino 91%
- Seronegative to *B. burgdorferi* } limit existing Lyme immunity
- Nebraska site to minimize prior }

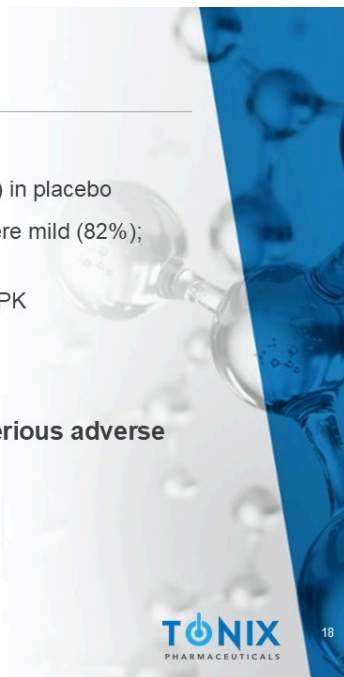


Phase 1 Safety Summary

- 1 serious adverse event (SAE); in placebo group¹
- Total of 61 TEAEs reported by 21/34 (62%) participants compares to 3/10 (30%) in placebo
- Large majority of drug related Treatment-Emergent Adverse Events (TEAEs) were mild (82%); remainder moderate (18%)
- Transient ADAs were detected in 3/34 (9%) treated subjects, with no impact on PK
- No safety signal or clustering of events observed

TNX-4800 was safe and well tolerated with no treatment-related serious adverse events and predominately mild adverse events

¹ Celerion CSR CA29655 Table 14.3.2.1 (SAE Safety population)



Related TEAE Summary¹

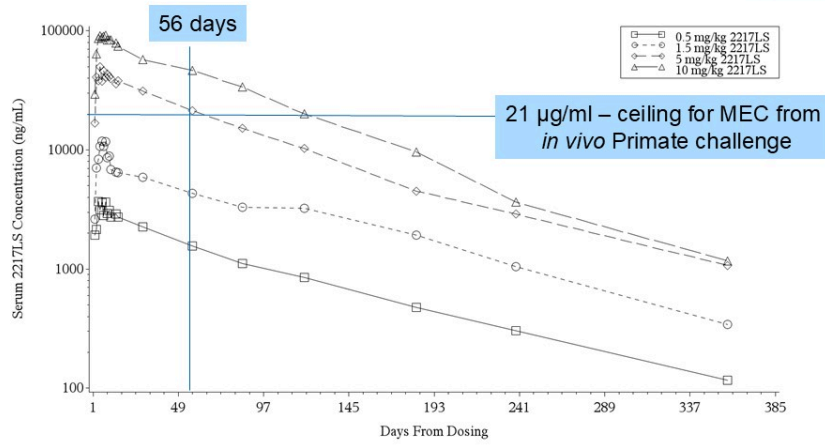
<u>Adverse Event</u>	<u>Severity Grade</u>	<u># Subjects</u>
Dysgeusia	1	1
Feeling hot/ flush	1	2
Injection site reaction*	1	7
Injection site reaction	2	1
Palpitations	1	1
Paresthesia	1	1

Severity Grading:
Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life Threatening

*Injection site reaction includes erythema, hemorrhage, edema, pain, pruritus

¹ Celerion CSR CA29655 Table 14.3.1.3 (TEAE Safety Population) © 2026 Tonix Pharmaceuticals Holding Corp.

Observed Phase 1 Pharmacokinetics

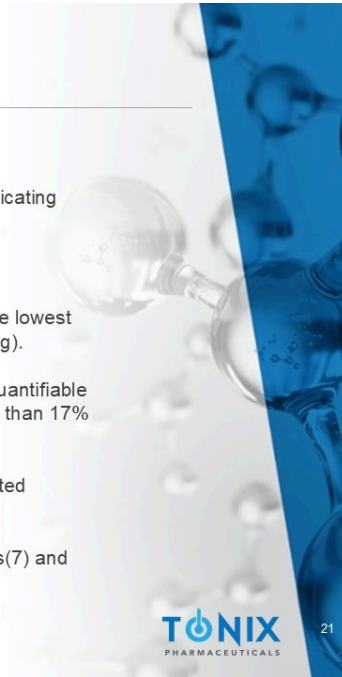


Each point represents a mean for the cohort at the specified timepoint and dose.

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Phase 1 Summary

- No significant clinical or laboratory signals were identified at any dose level.
- Drug exposure increased by approximately 25 times for a 20-times increase in dose, indicating dose proportional PK.
- Serum TNX-4800 was measurable at two days, indicating rapid systemic absorption.
- TNX-4800 concentrations remained quantifiable for >200 days in 80% of volunteers at the lowest dose and for up to 350 days in the majority of volunteers at higher doses (i.e., ≥ 1.5 mg/kg).
- Mean half-life ranged from 62-69 days across groups. Serum concentrations remained quantifiable for up to 12 months in most volunteers. Mean exposure for the 10 mg/kg cohort was less than 17% of the highest exposures in a rat toxicology study, indicating a wide safety margin.
- Transient low levels of anti-drug antibodies were detected in 3 participants (<10% of treated volunteers) with no impact on PK.
- Adverse events associated with the active were mild or moderate : injection site reactions(7) and feeling hot/flushed (2) were the most frequent
- TNX-4800 was safe and well tolerated

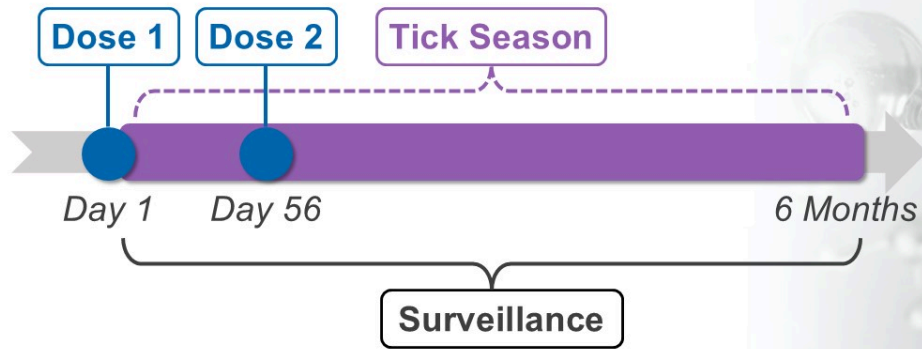


FUTURE PLANS

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Design of Planned Adaptive Phase 2 Field Study* in 2027



Study participants randomized 1:1 to receive TNX-4800 or placebo

*Pending FDA agreement.

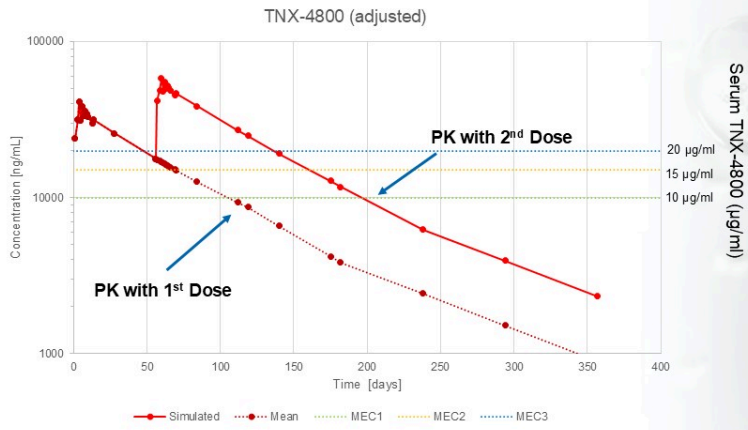
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Mean Predictions: 350mg SC on Day 1 and 56 Days

Preliminary Modeling



Minimum Effective Concentration - 1 (MEC₁)(10 µg/mL): 196 days; MEC₂ (15 µg/mL): 161 days; MEC₃ (20 µg/mL): 136 days and MEC₄ (5 µg/mL): 265 days

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Planned Adaptive Phase 2 Field Trial 2027

Adaptive, randomized, double-blind, placebo-controlled study

- **Objective:**
 - To evaluate the efficacy and safety of TNX-4800 in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period (Day 3 through Month 6 following administration)
- **Inclusion:**
 - Adolescents and adults >16 years of age from Lyme-endemic areas in the U.S.
- **Primary endpoint:**
 - Prevention of Lyme disease at six months (comparison of TNX-4800 group and placebo group)
- **Dose:**
 - Two SC doses of TNX-4800 or placebo at day 1 and day 56

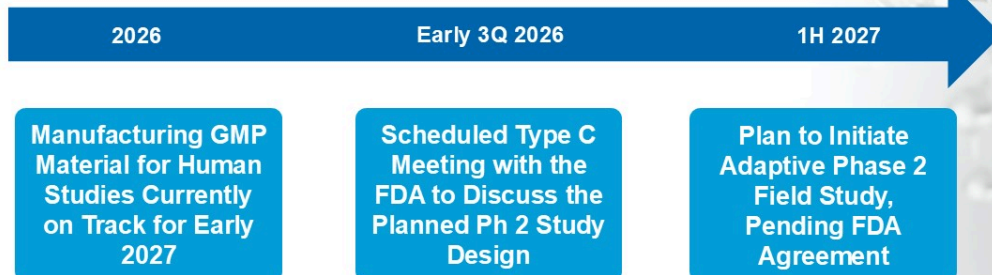
1. Average patient is assumed to be approximately 70kg.
2. Pending FDA agreement



Addressing the Significant Public Health Challenge of Lyme Disease in the U.S.

- ✓ Phase 1 study complete, showing favorable safety, tolerability, immunogenicity, and pharmacokinetics
- ✓ Phase 2 adaptive field study planning and GMP manufacturing underway for 1H 2027

TNX-4800 Upcoming Milestones



GMP = Good Manufacturing Process

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Development of TNX-4800 (formerly 2217 LS)

ACKNOWLEDGEMENTS

Inventors: UMass Chan School of Medicine

- Mark S. Klempner, MD
- Yang Wang MD, PhD
- William D. Thomas MD
- Naomi K. Boatright PhD

Support (to U Mass Chan):

- National Center for Advancing Translational Sciences (NCATS), NIH
- DARPA
- DOD Tick Borne Disease Research Program
- NIAID, NIH

Tonix Acknowledgements

Tonix Pharmaceuticals:

Seth Lederman MD
Greg Sullivan MD
Siobhan Fogarty MS
Sina Bavari PhD
Christopher Cooper PhD
Hadi Falahatpisheh PhD
Nita Patel PhD
Agnes Meade PhD
Jean Heilman MS
Misha Chittoda

Advisors/Consultants:

Mark Klempner, MD
Yang Wang, MD PhD
Grace Chen-Phillips MD
Phil Krause MD
Cathy Panozzo PhD
Bernd Meibohm, PhD
Martha Nason PhD



THANK YOU

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TONMYA Important Safety Information (ISI)

Indication

- Tonmya is indicated for the treatment of fibromyalgia in adults.

Contraindications:

- Hypersensitivity to cyclobenzaprine or any inactive ingredient in cyclobenzaprine HCl sublingual tablets
- Concomitant use of monoamine oxidase inhibitors or within 14 days after their discontinuation
- During acute recovery phase of myocardial infarction and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure
- Hyperthyroidism

Warnings and Precautions:

- Embryofetal toxicity: Cyclobenzaprine HCl sublingual tablets may cause neural tube defects when used 2 weeks prior to conception and during the first trimester of pregnancy (animal data). Advise female patients of reproductive potential of the potential risk and to use effective contraception during treatment and for 2 weeks after the final dose. Perform a pregnancy test prior to initiation of treatment
- Serotonin syndrome: Concomitant use of serotonergic drugs with cyclobenzaprine HCl sublingual tablets increases the risk of serotonin syndrome, which may be life threatening. Treatment with cyclobenzaprine sublingual HCl tablets and serotonergic drugs should be closely monitored, particularly during treatment initiation and dosage increases, and should be immediately discontinued if serotonin syndrome symptoms occur, including mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms
- Tricyclic antidepressant-like adverse reactions: Given the structural similarity of cyclobenzaprine to tricyclic antidepressants (TCAs), discontinuation of cyclobenzaprine HCl sublingual tablets should be considered for patients experiencing clinically significant central nervous system (CNS) symptoms, such as arrhythmia, sinus tachycardia, myocardial infarctions, or stroke, and caution is advised for patients with a history of seizure disorder, as TCAs may lower the seizure threshold
- Atropine-like adverse reactions: Caution is advised for patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and those taking anticholinergic drugs
- CNS depression and risk of operating a motor vehicle or hazardous machinery: Cyclobenzaprine HCl sublingual tablets may cause CNS depression, which may be exacerbated by concomitant use of alcohol, barbiturates, or other CNS depressants. Patients should not operate motor vehicles/heavy machinery until they are reasonably certain that cyclobenzaprine HCl sublingual tablets will not impair their ability to operate them
- Oral mucosal adverse reactions: The risk of oral sensory changes can be reduced by moistening the mouth with sips of water prior to administration of cyclobenzaprine HCl sublingual tablets

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TONMYA ISI (Continued)

Drug Interactions:

- **Monoamine oxidase inhibitors:** Life-threatening interactions may occur
- **Other serotonergic drugs:** Serotonin syndrome has been reported
- **CNS depressants:** CNS depressant effects of alcohol, barbiturates, and other CNS depressants may be enhanced
- **Tramadol:** Seizure risk may be enhanced
- **Guanethidine or other similar acting drugs:** The antihypertensive action of these drugs may be blocked

Use in Specific Populations:

- **Pregnancy:** Based on animal data, cyclobenzaprine HCl sublingual tablets may cause fetal harm when administered to a pregnant patient; pregnant women should be advised of the potential risk to the fetus and avoid use of cyclobenzaprine HCl sublingual tablets two weeks prior to conception and through the first trimester of pregnancy
- **Lactation:** There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production
- **Pediatric use:** The safety and effectiveness of cyclobenzaprine HCl sublingual tablets have not been established
- **Geriatric patients:** Clinical trials of cyclobenzaprine HCl sublingual tablets did not include sufficient numbers of patients ≥ 65 years of age to determine whether they respond differently from younger adult patients
- **Hepatic impairment (HI):** The recommended dose of cyclobenzaprine HCl sublingual tablets in patients with mild HI (Child Pugh A) is 2.8 mg daily. The use of cyclobenzaprine HCl sublingual tablets is not recommended in patients with moderate or severe HI (Child Pugh B and C, respectively) due to increased adverse reaction risk
- **To report suspected adverse reactions, contact Tonix Medicines, Inc. at 1-888-869-7633, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**