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): August 3, 2026

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.)**

200 Connell Drive, Suite 3100, 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 August 3, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced receipt of official minutes from a Type C meeting held with the U.S. Food and Drug Administration ("FDA") to discuss the Company's plans for Phase 2 field study of its TNX-4800 (human anti-outer-surface protein A monoclonal antibody) for seasonal prevention of Lyme disease in adults. A copy of the press release that discusses this matter 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 August 3, 2026, the Company announced receipt of official minutes from the Type C meeting with the FDA to discuss the Company's plans for an adaptive Phase 2 field study of TNX-4800 to prevent Lyme disease in adults in the U.S. The official FDA minutes indicate alignment between the Company and the FDA on a randomized, placebo-controlled adaptive field study design enrolling 3,300 adult participants from Lyme-endemic areas over two seasons, with a primary efficacy endpoint of Lyme disease prevention at six months after the first dose, and a key secondary efficacy endpoint of Lyme disease prevention at three months. The primary safety objective will be to evaluate the safety and tolerability of TNX-4800 over a 52-week period after dosing. The Company expects the majority of participants will be enrolled in the 2028 season. If the attack rate is lower than expected, enrollment of participants may extend to 2029.

Participants in the planned adaptive Phase 2 field study will be randomized 1:1 to receive either TNX-4800 450 mg subcutaneously or a placebo, in a two dose regimen with the first dose in early Spring and a second dose or placebo approximately three months later. The Company plans to enroll adults aged 18 and older who live in Lyme-endemic areas in the U.S. and engage in activities that increase their risk of deer tick bites.

The Company has been focused on manufacturing investigational product for TNX-4800, which is on track for delivery to study sites in the first quarter of 2027.

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	Press Release of the Company, dated August 3, 2026
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: August 3, 2026

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

Exhibit 99.01

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Tonix Pharmaceuticals Announces Positive Minutes from Type C FDA Meeting to Discuss Adaptive Phase 2 Field Study of TNX-4800, a Human, anti-OspA Monoclonal Antibody, to Prevent Lyme Disease in the U.S.

Alignment with FDA on key elements of the study design support planned start of the Phase 2 study in the first quarter of 2027

Long-acting monoclonal antibody TNX-4800 is a rapidly acting alternative to vaccination against Lyme disease with potential advantages in efficacy and tolerability over vaccines in development

BERKELEY HEIGHTS, N.J., August 3, 2026 (GLOBE NEWSWIRE) — Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial-stage biotechnology company, today announced the receipt of official minutes from the Type C meeting with the U.S. Food and Drug Administration (FDA) to discuss the Company's plans for an adaptive Phase 2 field study of TNX-4800 (human anti-outer-surface protein A [OspA] monoclonal antibody [mAb]) to prevent Lyme disease in adults in the U.S. OspA on immature *Borrelia* bacteria in the midgut of infected deer ticks is a validated target for Lyme disease prevention previously targeted by vaccines.[1-3] TNX-4800 is a potential seasonal immunopreventative alternative to vaccination and is Fc-modified for extended half-life and duration of protection.

"We appreciate the constructive feedback from the FDA on the design of the planned adaptive Phase 2 field study of TNX-4800, Tonix's long-acting mAb to prevent Lyme disease in the U.S.," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-4800 has the potential to fill a major unmet need given there are no FDA approved Lyme disease vaccines or prophylactics and the passive immunity from this long-acting mAb is a novel approach with potential advantages in efficacy and tolerability over vaccines in development that require onerous immunization schedules.[4] Lyme disease is the most common vector borne illness in the U.S. and presents a significant and growing public health threat for millions of Americans, particularly since 10-20% of individuals develop long-term consequences from Lyme disease.[5,6]"

Dr. Lederman continued, "The annual two dose regimen of TNX-4800, with a first dose in the early Spring and a second dose three months later, is expected to provide protection for at least six months, to cover the entire U.S. Lyme disease season. The protection is expected to begin within two days of the first dose. Pending FDA review and approval of the final protocol, we plan to test TNX-4800 as two subcutaneous (SC) injections three months apart. While this will be a Phase 2 study, it has the potential to demonstrate efficacy."

"Our focus in 2026 has been on manufacturing investigational product for TNX-4800, which is on track for delivery to study sites in the first quarter of 2027," said Zeil Rosenberg, M.D., Executive Vice President, Medical at Tonix. "The official FDA minutes indicate alignment on a randomized, placebo-controlled adaptive field study design enrolling approximately 3,300 adult participants over two seasons with a primary efficacy endpoint of Lyme disease prevention through six months after the first dose, and a key secondary efficacy endpoint of prevention through three months. The primary safety objective will be to evaluate the safety and tolerability of TNX-4800 over a 52-week period after dosing. We expect the majority of participants will be enrolled in the 2028 season. If the attack rate is lower than expected, enrollment could potentially extend into 2029."

Participants in the planned adaptive Phase 2 field study will be randomized 1:1 to receive either TNX-4800 450 mg SC or a placebo, and another dose of TNX-4800 or placebo approximately three months later. The Company plans to enroll adult volunteers aged 18 and older who live in Lyme-endemic areas in the U.S. and engage in activities that increase their risk of deer tick bites.

About TNX-4800

TNX-4800 is a long-acting bactericidal, human monoclonal antibody with an engineered extended half-life that targets the outer-surface protein A (OspA) on *Borrelia* bacteria. When TNX-4800-containing blood is ingested by the tick, TNX-4800 either kills or blocks the maturation of *Borrelia burgdorferi* in the mid-gut of infected deer ticks. The Company in-licensed TNX-4800 from UMass Chan Medical School in 2025. Published work in animals showed that TNX-4800 serum levels of at least 21 μg/ml, were approximately 95% effective at preventing infection of non-human primates after six days of exposure to ticks infected with *Borrelia burgdorferi*.[7,8] TNX-4800 contains amino acid substitutions in its Fc domain, which serve to prolong the serum half-life. As a monoclonal antibody, TNX-4800 is designed to provide passive immunity against Lyme disease within two days without relying on the recipient's immune system to generate antibodies. TNX-4800 also avoids the complex immunization schedules required for an alum-based combination multi-OspA subunit vaccine in development[4] and the FDA-approved alum-based OspA subunit vaccine that was withdrawn from the market.[2,9] TNX-4800 is protected by Issued US Patent US 10,457,721, which is licensed from UMass Chan with expiry in January 2036, excluding any possible Patent Term Extension based on the duration of the clinical trials and the FDA approval process. The Biologics Price Competition and Innovation Act (BPCIA), enacted as part of the Affordable Care Act in 2010, establishes a 12-year exclusivity period for original biologic products. This means that once a biologic product is licensed, no biosimilar application can be approved by the FDA during this time.

About Lyme Disease

In the U.S., Lyme disease is caused by the spirochete bacteria *Borrelia burgdorferi*. Lyme disease remains the most common vector-borne infection in the United States, and its incidence is climbing each year, due to the expanding the habitat range for *Ixodes scapularis* ("deer ticks") ticks.[6] Approximately 87 million people in the United States live, work, or vacation in a tick-endemic area placing them at risk of contracting the disease. It occurs most commonly in the Northeast, mid-Atlantic, and upper-Midwest regions. Lyme disease bacteria are transmitted through the bite of infected *Ixodes* ticks. Typical symptoms include fever, headache, fatigue, and a characteristic skin rash called erythema migrans. If left untreated, infection can spread to joints, heart, and nervous system. Laboratory testing is helpful if used correctly and performed with FDA-cleared tests. Although many cases of Lyme disease can be treated successfully with antibiotics, diagnosis and treatment are often delayed or missed. Up to 20% of acute Lyme Disease cases may progress to a Post-Treatment Lyme Disease Syndrome (PTLDS) or Chronic Lyme (also known as "Long Lyme"). Chronic Lyme is considered an Infection Associated Chronic Illness (IACI), and is a chronic, debilitating disease state characterized by joint and muscle pain, fatigue, and other symptoms.[6]

About *Borrelia Burgdorferi*

In infected deer ticks, *Borrelia's* OspA lipoprotein binds to tick-gut receptor TROSPA and helps it adhere to the midgut lining. During a tick bite blood meal, *Borrelia* downregulates OspA, upregulates OspC, and activates motility genes. *Borrelia* undergoes a metamorphic-like transformation, becoming highly flagellated and mobile, which facilitates migration to the tick salivary glands and invasion of human host tissues. During a tick bite of an animal pre-treated with TNX-4800, the tick is expected to ingest host blood containing TNX-4800, which prevents transmission of the bacteria by killing pre-infectious *Borrelia* in the tick's midgut, blocking *Borrelia's* metamorphic-like transformation and preventing their migration from the tick's midgut to its salivary glands. *Borrelia*-exposed or -infected individuals, rarely make antibodies against OspA which allows for people to be reinfected despite having immunity to OspC. The Company expects that protection against *Borrelia* would require annual prophylaxis with TNX-4800.

About Monoclonal Antibody Prophylaxis

Two long-acting monoclonal antibody products[10,11] have earned FDA approval for prophylaxis against respiratory syncytial virus (RSV). AstraZeneca (in partnership with Sanofi) markets Beyfortus® (nirsevimab) and Merck markets Enflonsia™ (clesrovimab).

Citations

1. Dattwyler RJ and Gomes-Solecki M. 2022. *NPJ Vaccines*. 7(1):10.
2. Steere AC, et al. 1998. *N Engl J Med*. 339(4):209-15.
3. Sigal LH, et al. 1998. *N Engl J Med*. 23;339(4):216-22.
4. March 23, 2026. Pfizer Press Release. "Pfizer and Valneva announce Lyme disease candidate demonstrates strong efficacy in Phase 3 VALOR Trial." URL: www.pfizer.com/news/press-release/press-release-detail/pfizer-and-valneva-announce-lyme-disease-vaccine-candidate.
5. Melia M.T. *N Engl J Med*. 2016;374:1277–1278.
6. National Academies of Sciences, Engineering, and Medicine. 2025. *Charting a Path Toward New Treatments for Lyme Infection-Associated Chronic Illnesses*. Washington, DC: The National Academies Press. https://doi.org/10.17226/28578.
7. Schiller ZA, et al. *J Clin Invest.* 2021 131(11):e144843.
8. Wang Y, et al. *J Infect Dis*. 2016. 214(2):205-11.
9. SmithKline Beecham's Lyme disease vaccine (LYMErix™) was voluntarily withdrawn. Nigrovic LE, et al. *Epidemiol Infect.* 2007 135(1):1-8.
10. May 29, 2025. Sanofi Press Release. "Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs." https://bit.ly/40DeJGf.
11. June 9, 2025. Merck Press Release. "U.S. FDA Approves Merck's ENFLONSIA™ (clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Born During or Entering Their First RSV Season." https://bit.ly/4kkXDE8.

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Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully integrated, commercial-stage biotechnology company focused on central nervous system (CNS) disorders, infectious diseases, immunology conditions, and rare diseases where there exists high unmet medical need. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8mg), the Company's flagship internally conceived and developed medicine, is the first treatment for fibromyalgia in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® SymTouch® (sumatriptan injection 3 mg) and Tosymra® (sumatriptan nasal spray 10 mg). Tonix is extending the science behind TONMYA in Phase 2 clinical studies to evaluate its potential in major depressive disorder and acute stress disorder/acute stress reaction. Tonix is also advancing a pipeline of infectious disease programs, including monoclonal antibody, Phase 2 ready TNX-4800 (anti-OspA mAb) for Lyme disease prevention in the U.S. and TNX-801 (horsepox, live virus vaccine), a vaccine in development for the prevention of mpox and smallpox. Within immunology, Tonix is developing TNX-1500 (anti-CD40L mAb), a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. Finally, the Company's rare disease portfolio includes TNX-2900, which is Phase 2 ready for the treatment of Prader-Willi syndrome. To learn more, visit www.tonixpharma.com.

*Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the clinical development plans, regulatory pathway, and timing of TNX-4800, and other statements that are predictive in nature. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. 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 Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with 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.

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