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): September 17, 2025

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 Capital Market

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

Emerging growth company ☐

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

Item 7.01 Regulation FD Disclosure.

On September 17, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the in-licensing of worldwide rights to its TNX-4800 (formerly known as mAb 2217LS) product candidate. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

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 September 17, 2025, the Company announced the in-licensing of worldwide rights to TNX-4800, a long-acting human monoclonal antibody that targets the outer surface protein A ("OspA") of Borrelia burgdorferi, the causative agent of Lyme disease in humans. TNX-4800 was developed by researchers at UMass Chan Medical School. TNX-4800 is a fully human monoclonal antibody with an engineered extended half-life that targets the OspA on Lyme-causing *Borrelia* bacteria. By binding OspA, TNX-4800 blocks the maturation of *Borrelia burgdorferi* in the mid-gut of infected deer ticks. The mAb 2217LS was derived from mAb 2217 by amino acid substitutions that crystallizable fragment domain to prolong the serum half-life. A single subcutaneous springtime administration is designed to maintain protective antibody titers through the Fall, or the entire U.S. tick season, providing pre-exposure prophylaxis against Lyme disease without relying on the recipient's immune system to generate antibodies. By delivering a well-characterized antibody directly, TNX-4800 has been shown to block transmission of the major *Borrelia* genospecies from ticks to animals. TNX-4800 sidesteps the multidose schedules required for OspA vaccines in development and FDA-approved vaccines that have been withdrawn from the market due to concerns about increased risk of autoimmunity. The Company intends to advance TNX-4800 through additional clinical trials with the goal of submitting a Biologics Licensing Application to the U.S. Food and Drug and Administration.

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, September 17, 2025
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: September 17, 2025

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

Exhibit 99.01

Tonix Pharmaceuticals Announces In-licensing Phase 2/3-Ready
Monoclonal Antibody Designed for Seasonal Prevention of Lyme Disease (TNX-4800)

Positive Phase 1 study showed safety, tolerability and a linear pharmacokinetic: pharmacodynamic: efficacy relationship (1: 1: 1)

Planning adaptive Phase 2/3 study

Approximately 70 million people that are eligible for treatment live in areas of the U.S. in which Lyme Disease is endemic

*C*HATHAM, N.J., September 17, 2025 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the in-licensing of worldwide rights to TNX-4800 (formerly known as mAb 2217LS)[1], which is a long-acting human monoclonal antibody that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the causative agent of Lyme disease in humans. TNX-4800 is being developed for annual seasonal use, as one subcutaneous dose administered in the Spring to protect against Lyme disease through Fall, or the entire tick season in the U.S. TNX-4800 was developed by researchers at UMass Chan Medical School, which is licensing the technology to Tonix. There are currently no FDA-approved vaccines or prophylactics to protect against Lyme Disease.

"Lyme disease remains the most common vector-borne infection in the United States and its incidence is climbing each year,"[2] said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Licensing TNX-4800 expands our infectious disease pipeline with a potentially differentiated, single-dose approach that can be given each Spring to provide protection within two days and protect through Fall, which is the entire tick season in the U.S. We believe TNX-4800's long-acting monoclonal antibody prophylaxis could play an important role for preventing Lyme for millions of people who live, work, and vacation in regions endemic for Lyme disease. TNX-4800's novel mechanism of blocking the maturation of *Borrelia* in the midgut of infected ticks is consistent with Tonix's focus on innovation. We look forward to advancing the TNX-4800 program."

"Preventing Lyme disease is an urgent public health priority, and more than thirty years of clinical experience confirm that monoclonal antibodies can be delivered safely and can be effective in preventing infections," said Mark Klempner, M.D., Professor of Medicine at UMass Chan Medical School and leader of the research team that discovered and developed mAb 2217LS. "We are delighted to be collaborating with Tonix on the development of this program. TNX-4800 is a single dose and provides immediate immunity to the bacteria that causes Lyme disease, which is very different from Lyme disease vaccine programs currently in development."

Terence R. Flotte, MD, Provost, Dean and Executive Deputy Vice Chancellor of UMass Chan Medical School, said, “We are proud to partner with Tonix Pharmaceuticals to advance the development of our novel monoclonal antibody as a prophylactic for Lyme disease, which is an urgent and growing public health challenge in the United States and around the world. This collaboration reflects UMass Chan’s enduring commitment to translational research that addresses unmet medical needs, and we are excited to work with Tonix to bring forward science-driven solutions that have the potential to prevent infection and protect vulnerable populations.”

TNX-4800 is a fully human monoclonal antibody with an engineered extended half-life that targets the outer-surface protein A (OspA) on Lyme-causing *Borrelia* bacteria. By binding OspA, TNX-4800 blocks the maturation of *Borrelia burgdorferi* in the mid-gut of infected deer ticks. The mAb 2217LS[1] was derived from mAb 2217 by amino acid substitutions that crystallizable fragment (Fc) domain to prolong the serum half-life. A single administration in the Spring is designed to maintain protective antibody titers for the entire tick season, providing pre-exposure prophylaxis against Lyme disease without relying on the recipient’s immune system to generate antibodies. By delivering a well-characterized antibody directly, TNX-4800 has been shown to block transmission of the major *Borrelia* genospecies from ticks to animals. TNX-4800 sidesteps the multidose schedules required for OspA vaccines in development[3] and FDA-approved vaccines that have been withdrawn from the market due to concerns about increased risk of autoimmunity. [4] Tonix intends to advance TNX-4800 through additional clinical trials with the goal of submitting a Biologics Licensing Application (BLA).

About Lyme Disease

In the United States, Lyme disease is caused by the bacterium *Borrelia burgdorferi*. 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, the heart, and the 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, and even with treatment, up to 20% of cases may progress to a Post-Treatment Lyme Disease Syndrome (PTLDS) called “Chronic Lyme” or “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.[5]

About *Borrelia Burgdorferi*

In infected deer ticks, *Borrelia's* OspA binds to tick-gut receptor TROSPA and helps it adhere to the midgut lining. During a tick bite *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 salivary glands and invasion of human host tissues. The mAb 2217LS blocks the metamorphic-like transformation of *Borrelia* in the tick's midgut preventing transmission of the bacteria. Lyme-causing *Borrelia* exposed or infected individuals, rarely make antibodies against OspA which allows for people to be reinfected despite having immunity to OspC. Consequently we expect that protection against *Borrelia* would require annual prophylaxis.

About Monoclonal Antibody Prophylaxis

Two long-acting monoclonal antibody products[6,7] have won FDA approval for prophylaxis against respiratory syncytial virus (RSV). AstraZeneca (in partnership with Sanofi) markets Beyfortus™ (nirsevimab) and Merck markets Enflonsia™ (clesrovimab).

Tonix Pharmaceuticals Holding Corp.*

Tonix Pharmaceuticals is a fully-integrated biotechnology company with marketed products and a pipeline of development candidates. Tonix recently received FDA approval for Tonmya™, a first-in-class, non-opioid analgesic medicine for the treatment of fibromyalgia, a chronic pain condition that affects millions of adults. This marks the first approval for a new prescription medicine for fibromyalgia in more than 15 years. Tonix also markets two treatments for acute migraine in adults. Tonix's development portfolio is focused on central nervous system (CNS) disorders, immunology, immuno-oncology and infectious diseases. TNX-102 SL is being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix's infectious disease portfolio includes TNX-801, a vaccine in development for mpox and smallpox, as well as TNX-4200 for which Tonix has a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years. TNX-4200 is a small molecule broad-spectrum antiviral agent targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, Md.

* 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.

This press release and further information about Tonix can be found at www.tonixpharma.com.

UMass Chan Medical School

UMass Chan Medical School, one of five campuses of the University of Massachusetts system, comprises the T.H. Chan School of Medicine, the Morningside Graduate School of Biomedical Sciences, the Tan Chingfen Graduate School of Nursing, ForHealth Consulting at UMass Chan Medical School, MassBiologics, and a thriving Nobel-Prize-winning biomedical research enterprise. UMass Chan is advancing together to improve the health and wellness of our diverse communities throughout Massachusetts and across the world by leading and innovating in education, research, health care delivery and public service. It is ranked among the best medical schools in the nation for primary care education and biomedical research by *U.S. News & World Report*. Learn more at www.umassmed.edu.

[1] Schiller ZA, et al. *J Clin Invest.* 2021 131(11):e144843. doi: 10.1172/JCI144843. PMID: 33914704; PMCID: PMC8159683.

[2] Gomes-Solecki M, et. al.. *Clin Infect Dis.* 2020 70(8):1768-1773. doi: 10.1093/cid/ciz872. PMID: 31620776; PMCID: PMC7155782.

[3] Connaught's (ImuLyme™) and SmithKline Beecham's (LYMErix™) Lyme disease vaccines were withdrawn over concerns about an increased risk of autoimmune arthritis triggered by molecular mimicry, particularly in HLADRB1*0401 ("DR4+") individuals. Nigrovic LE, et al. *Epidemiol Infect.* 2007 135(1):1-8. doi: 10.1017/S0950268806007096. Epub 2006 Aug 8. PMID: 16893489; PMCID: PMC2870557.

[4] Pfizer and Valneva's VLA15 vaccine candidate has been specifically engineered and clinically evaluated to mitigate the autoimmune concerns that contributed to the withdrawal of earlier OspA-based vaccines. Comstedt P, et al. *Vaccine*. 2015 33(44):5982-8. doi: 10.1016/j.vaccine.2015.07.095. Epub 2015 Aug 13. PMID: 26277070.

[5] 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.

[6] Sanofi Press Release. "May 29, 2025. Press Release: Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs." https://bit.ly/40DeJGf

[7] 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.

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 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, 2024, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2025, 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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INDICATION

TONMYA is indicated for the treatment of fibromyalgia in adults.

CONTRAINDICATIONS

TONMYA is contraindicated:

In patients with hypersensitivity to cyclobenzaprine or any inactive ingredient in TONMYA. Hypersensitivity reactions may manifest as an anaphylactic reaction, urticaria, facial and/or tongue swelling, or pruritus. Discontinue TONMYA if a hypersensitivity reaction is suspected.

With concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after discontinuation of an MAO inhibitor. Hyperpyretic crisis seizures and deaths have occurred in patients who received cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitors drugs.

During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure.

In patients with hyperthyroidism.

WARNINGS AND PRECAUTIONS

Embryofetal toxicity: Based on animal data, TONMYA may cause neural tube defects when used two weeks prior to conception and during the first trimester of pregnancy. Advise females of reproductive potential of the potential risk and to use effective contraception during treatment and for two weeks after the final dose. Perform a pregnancy test prior to initiation of treatment with TONMYA to exclude use of TONMYA during the first trimester of pregnancy.

Serotonin syndrome: Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome, a potentially life-threatening condition. Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Treatment with TONMYA and any concomitant serotonergic agent should be discontinued immediately if serotonin syndrome symptoms occur and supportive **symptomatic treatment should be initiated.** If concomitant treatment with TONMYA and other serotonergic drugs is clinically warranted, careful observation is advised, particularly during treatment initiation or dosage increases.

Tricyclic antidepressant-like adverse reactions: Cyclobenzaprine is structurally related to TCAs. TCAs have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke. If clinically significant central nervous system (CNS) symptoms develop, consider discontinuation of TONMYA. Caution should be used when TCAs are given to patients with a history of seizure disorder, because TCAs may lower the seizure threshold. Patients with a history of seizures should be monitored during TCA use to identify recurrence of seizures or an increase in the frequency of seizures.

Atropine-like effects: Use with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic drugs.

CNS depression and risk of operating a motor vehicle or hazardous machinery: TONMYA monotherapy may cause CNS depression. Concomitant use of TONMYA with alcohol, barbiturates, or other CNS depressants may increase the risk of CNS depression. Advise patients not to operate a motor vehicle or dangerous machinery until they are reasonably certain that TONMYA therapy will not adversely affect their ability to engage in such activities.

Oral mucosal adverse reactions: In clinical studies with TONMYA, oral mucosal adverse reactions occurred more frequently in patients treated with TONMYA compared to placebo. Advise patients to moisten the mouth with sips of water before administration of TONMYA to reduce the risk of oral sensory changes (hypoesthesia). Consider discontinuation of TONMYA if severe reactions occur.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer.

DRUG INTERACTIONS

MAO 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, TONMYA may cause fetal harm when administered to a pregnant woman. The limited amount of available observational data on oral cyclobenzaprine use in pregnancy is of insufficient quality to inform a TONMYA-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women about the potential risk to the fetus with maternal exposure to TONMYA and to avoid use of TONMYA two weeks prior to conception and through the first trimester of pregnancy. Report pregnancies to the Tonix Medicines, Inc., adverse-event reporting line at 1-888-869-7633 (1-888-TNXPMED).

Lactation: A small number of published cases report the transfer of cyclobenzaprine into human milk in low amounts, but these data cannot be confirmed. There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TONMYA and any potential adverse effects on the breastfed child from TONMYA or from the underlying maternal condition.

Pediatric use: The safety and effectiveness of TONMYA have not been established.

Geriatric patients: Of the total number of TONMYA-treated patients in the clinical trials in adult patients with fibromyalgia, none were 65 years of age and older. Clinical trials of TONMYA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

Hepatic impairment: The recommended dosage of TONMYA in patients with mild hepatic impairment (HI) (Child Pugh A) is 2.8 mg once daily at bedtime, lower than the recommended dosage in patients with normal hepatic function. The use of TONMYA is not recommended in patients with moderate HI (Child Pugh B) or severe HI (Child Pugh C). Cyclobenzaprine exposure (AUC) was increased in patients with mild HI and moderate HI compared to subjects with normal hepatic function, which may increase the risk of TONMYA-associated adverse reactions.

Please see additional safety information in the full Prescribing Information.

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.