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): June 29, 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 June 29, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the first participant was enrolled in HORIZON, a potentially pivotal Phase 2 study evaluating the Company's TNX-102 SL 5.6 mg product candidate as a first-line monotherapy in adults with major depressive disorder (the "HORIZON Study"). 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 June 29, 2026, the Company announced that the first participant was enrolled in the HORIZON Study.

Item 9.01 Financial Statements and Exhibits.

(d)	**Exhibit No.**	**Description.**
	99.01	Press Release of the Company, June 29, 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: June 29, 2026

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

Exhibit 99.01

Tonix Pharmaceuticals Announces First Patient Enrolled in Phase 2 HORIZON Study of TNX-102 SL for the Treatment of Major Depressive Disorder (MDD)

HORIZON is a potentially pivotal, randomized, double-blind, placebo-controlled Phase 2 study evaluating TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg as a first-line monotherapy in adults with MDD

Primary endpoint is change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6

TNX-102-SL was approved by the U.S. Food and Drug Administration (FDA) in August 2025 and launched commercially as TONMYA® for the treatment of fibromyalgia in adults

BERKELEY HEIGHTS, N.J., June 29, 2026 (GLOBE NEWSWIRE) — Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial-stage biotechnology company, today announced that the first patient has been enrolled in HORIZON, a potentially pivotal Phase 2 study evaluating TNX-102 SL 5.6 mg as a first-line monotherapy in adults with major depressive disorder (MDD).

"We are committed to extending the science of TNX-102 SL into other conditions in which disturbed sleep quality plays important roles, including MDD," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-102 SL for MDD is designed to target poor sleep quality. Bedtime TNX-102 SL showed signals for improving depressive symptoms and subjective sleep quality in both a prior Phase 2 posttraumatic stress disorder study and two Phase 3 fibromyalgia studies. We look forward to evaluating TNX-102 SL in the Phase 2 HORIZON trial to learn if these promising signals will translate into benefits in MDD."

Dr. Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals added, "More than 21 million U.S. adults[1] experience a major depressive episode each year, and many current therapies are associated with tolerability and adherence challenges. TNX-102 SL for MDD is designed to target disturbed sleep through potent antagonism at four neuronal receptors that influence sleep quality. The quality of sleep, particularly deep slow wave sleep, is a critical factor in the nightly homeostatic neuro-restoration critical for recovery from stress-associated conditions such as MDD."

HORIZON is a 6-week, randomized, double-blind, placebo-controlled Phase 2 study evaluating TNX-102 SL 5.6 mg as a first-line monotherapy in adults with MDD. Approximately 360 patients are expected to enroll at approximately 30 sites across the United States. Eligible participants are 18 years of age or older and currently experiencing a moderate to severe major depressive episode. Participants will receive TNX-102 SL 5.6 mg taken sublingually at bedtime or matching placebo. The primary endpoint of the study is the change from baseline in MADRS total score at Week 6. Secondary endpoints include global impression scores, anxiety ratings, and measures of sleep quality and disturbance.

About Major Depressive Disorder (MDD)

MDD is a prevalent and serious psychiatric illness that affects adults of all ages, races, and backgrounds. It is characterized by persistent feelings of sadness or loss of interest, along with symptoms such as sleep and appetite disturbances, fatigue, difficulty concentrating, and thoughts of worthlessness or suicide. These symptoms must last at least two weeks and significantly impair daily functioning. In the United States, more than 21 million adults experience a major depressive episode each year. While several antidepressant medications are available, many individuals do not achieve adequate relief or discontinue treatment due to side effects such as weight gain, sleep disruption, cognitive impairment, and sexual dysfunction. MDD is associated with an increased risk of suicide and substantial impairment in quality of life, underscoring the urgent need for new, first-line therapies that are demonstrated to be both effective and well tolerated.

About TNX-102 SL

TNX-102 SL is a novel sublingual tablet formulation of cyclobenzaprine hydrochloride that enables rapid transmucosal absorption and reduces production of the persistent active metabolite, norcyclobenzaprine, by bypassing first-pass hepatic metabolism. TNX-102 SL is a tertiary amine tricyclic (TAT) and multifunctional agent with potent binding and antagonist activities at the 5-HT_{2A} serotonergic, α_1-adrenergic, H_1-histaminergic, and M_1-muscarinic receptors. It is currently FDA approved in the U.S. as a once-daily bedtime treatment for fibromyalgia in adults under the brand name TONMYA® (cyclobenzaprine HCl sublingual tablets). TNX-102 SL is also in development as a daily bedtime treatment for acute stress disorder (ASD)/acute stress reaction (ASR) under an investigator-initiated IND. In addition to MDD, Tonix also holds active INDs for the following indications for TNX-102 SL: Long COVID (post-acute sequelae of COVID-19), PTSD, alcohol use disorder, and agitation in Alzheimer's disease. The United States Patent and Trademark Office issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10357465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patents are important elements of Tonix's proprietary composition. These patents are expected to provide TNX-102 SL U.S. market exclusivity until 2034. Pending patent applications related to method of use could extend exclusivity until 2044. The potential use of TNX-102 SL in MDD, ASD/ASR, and other unapproved indications is currently under clinical development, and the safety and efficacy have not been evaluated by any regulatory authority.

Citations

[1]Substance Abuse and Mental Health Services Administration (SAMHSA). 2024. Key Substance Use and Mental Health Indicators in the United States: Results from the 2024 National Survey on Drug Use and Health.

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 new 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 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, including TONMYA for unapproved indications, are investigational new drugs or biologics. Their efficacy and safety have not been established and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. TONMYA is a registered trademark of Tonix Pharma Limited. All other marks are property of their respective owners.

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 completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering 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 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. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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.