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 10, 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 2.02 Results of Operations and Financial Condition.

On August 10, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended June 30, 2026. A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description.**
99.01	Press Release of the Company, dated August 10, 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 10, 2026

By: */s/ Bradley Saenger*

Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Reports Second Quarter 2026 Financial Results and Operational Highlights

TONMYA® net sales totaled approximately $11 million, an increase of 197% quarter-over-quarter

Commercial and government payer coverage for TONMYA meaningfully expanded, now reaching approximately 136 million covered lives (43% of total U.S. lives)

First patient enrolled in Phase 2 HORIZON study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the treatment of major depressive disorder (MDD)

Phase 2 adaptive field study of TNX-4800 for the prevention of Lyme disease in the U.S. on track to start in the first quarter of 2027 pending final FDA review and agreement on study protocol

Approximately $176.2 million in cash and cash equivalents as of June 30, 2026

Conference call today at 8:30 a.m. ET

BERKELEY HEIGHTS, N.J., August 10, 2026 (GLOBE NEWSWIRE) — Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial-stage biopharmaceutical company, today announced financial results for the quarter ended June 30, 2026, and provided an overview of recent operational highlights.

"We are pleased with the execution of TONMYA's launch, including nearly tripling net sales and achieving growth across our key metrics in the second quarter," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "We are seeing TONMYA's value resonate among healthcare providers and patients as the first FDA-approved treatment for fibromyalgia in 15 years. It is a first-in-class, non-opioid analgesic designed for daily bedtime administration and long-term use. We are now beginning to see coverage translate into broader patient access following the execution of agreements with commercial payers, managed Medicare, and Medicaid. Our newly expanded sales force is expected to deploy in the field by September. We believe we are well positioned to reach more of our target prescribers and support the treatment of more patients with TONMYA."

Dr. Lederman continued, "We are also progressing our clinical development pipeline priorities. We enrolled the first patient in HORIZON, our potentially pivotal Phase 2 study of TNX-102 SL in MDD. For Lyme prevention, we expect to start enrollment in the first quarter of 2027 in a Phase 2 adaptive field study after we reached alignment with FDA on the development path for TNX-4800, an investigational long-acting borreliacidal human monoclonal antibody targeting OspA on *Borrelia burgdorferi*."

Commercial Updates

TONMYA (cyclobenzaprine HCl sublingual tablets): a centrally acting, non-opioid analgesic for the treatment of fibromyalgia in adults; commercially launched on November 17, 2025

Performance Across Key Metrics

- In the second quarter of 2026, key metrics include:
    - 12,592 total prescriptions, increasing 100% quarter-over-quarter. This includes bridge prescriptions that are facilitated through the Company's digital pharmacy channel. Bridge prescriptions represent initial patient fills provided while coverage determinations are pending and do not immediately generate net product revenue.
    - New patient prescriptions increased 36% quarter-over-quarter.
    - Refills increased 207% quarter-over-quarter.

Payer Access and Coverage

- The Company is prioritizing ongoing engagement with commercial payers, managed Medicare, and Medicaid to increase access:
    - Tonix announced commercial payer agreements with two leading GPOs in May and June 2026, providing access to a combined approximate 52 million lives (29% of the total commercial lives in the U.S.).
    - Currently, total coverage for TONMYA across commercial, managed Medicare, and Medicaid channels represents approximately 136 million covered lives (~43% of the approximately 314 million covered lives in the U.S.).
    - When the managed Medicare payer coverage agreement goes into effect on January 1, 2027, it will add approximately nine million Medicare lives (16% of the approximately 55 million Medicare lives in the U.S.). Total coverage will then reach approximately 145 million covered lives (~46% of the 314 million covered lives in the U.S.).
    - TONMYA is covered under Medicaid in most states, representing approximately 75 million lives.

Commercial Execution

- Following these coverage milestones and encouraging trends across launch key performance indicators, Tonix is implementing its strategy to expand the TONMYA sales force. The Company expects to deploy 50 new sales representatives in the field by September 2026, bringing the full sales force to approximately 150 people.
- In parallel, the Company is advancing marketing activities to enhance understanding of fibromyalgia and product awareness among patients and healthcare providers, as well as non-commercial medical affairs initiatives.
- In the second quarter of 2026, Tonix presented data highlighting TONMYA at the European Alliance of Associations for Rheumatology (EULAR) 2026, 2026 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, and Professional Society for Health and Outcomes Research (ISPOR 2026) Annual Meeting, as well as published a manuscript in the peer-reviewed journal, *Clinical Pharmacology in Drug Development.*

Key Product Pipeline Candidates: Recent Highlights

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): in Phase 2 development for MDD

- In June 2026, Tonix enrolled the first patient in HORIZON, a potentially pivotal, 6-week, randomized, double-blind, placebo-controlled Phase 2 study of 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 U.S. sites, with the primary endpoint of change from baseline in MADRS (Montgomery-Asberg Depression Rating Scale) total score at Week 6. TNX-102 SL targets disturbed sleep through antagonism at four neuronal receptors, an approach mechanistically distinct from currently available antidepressants.

TNX-102 SL: in Phase 2 development for acute stress disorder (ASD) and acute stress reaction (ASR)

- The U.S. Department of Defense-funded Optimizing Acute Stress Reaction Interventions (OASIS) study is being conducted by the University of North Carolina under an investigator-initiated IND. Topline data is expected to be reported mid-2027.

TNX-1300 (double-mutant cocaine esterase) for cocaine intoxication; Phase 2 program has Breakthrough Therapy designation from the FDA, with no products on the market for this indication

- The Company plans to meet with the FDA in 2026 to inform the clinical design of the next Phase 2 study (a Phase 2 study has been completed).

Infectious Disease Pipeline

TNX-4800 (anti-OspA mAb): Phase 2-ready long-acting human monoclonal antibody in development for the seasonal prevention of Lyme disease in the U.S., for which no FDA-approved vaccines or prophylactics are available

- The Company received final minutes from a Type C meeting held with the FDA in early third quarter of 2026. The adaptive Phase 2 field study is expected to start in the first quarter of 2027 pending final FDA review and agreement on the study protocol.
- The study will be a randomized, double-blind, placebo-controlled field study, with the primary efficacy endpoint of protection through six months, and a key secondary efficacy endpoint of protection through three months. Adults aged 18 and older from U.S. Lyme-endemic areas who engage in activities that increase their risk of deer tick bites will be randomized to receive placebo or two doses of TNX-4800: 450 mg subcutaneous (SC) dose at Day 1, and a second dose of 450 mg SC dose three months later at Day 85.
- In April 2026, Tonix presented Phase 1 data and announced plans for an adaptive Phase 2 field study of TNX-4800 at the 4th Annual Ticks and Tickborne Diseases Symposium at Johns Hopkins University.
- The Company expects to deliver investigational product to the Phase 2 clinical study sites in the first quarter of 2027.

TNX-801 (recombinant horsepox virus): an attenuated, minimally replicative, live virus vaccine candidate in pre-clinical development for the prevention of smallpox and mpox

- In July 2026, Tonix announced a new paper in the *Journal of Virology* describing new murine models for investigating mpox pathogenesis. TNX-801 is expected to enter a Phase 1 study in mid-2027 pending FDA clearance of the Investigational New Drug (IND) application.

TNX-4200 (broad-spectrum antiviral targeting CD45) for the prevention or treatment of high-lethality infections to improve the medical readiness of military personnel in biological threat environments

- The ongoing TNX-4200 program is supported by an up to $34 million contract over five years from the Department of Defense's Defense Threat Reduction Agency (DTRA). In the second quarter, the project began its next project phase.

Immunology Pipeline

TNX-1500 (dimeric Fc-modified anti-CD40L, humanized mAb): Phase 2-ready third-generation anti-CD40L for prophylaxis of kidney transplant rejection and treatment of autoimmune diseases

- In July 2026, the World Health Organization (WHO) included mosdaprubart as the proposed International Nonproprietary Name (pINN) for TNX-1500, pending publication as a recommended INN.
- In May 2026, Tonix announced the publication of Phase 1 clinical data for TNX-1500 in the *Journal of Clinical Immunology* that support TNX-1500 as a potentially first-in-class, best-in-class, third-generation anti-CD40L monoclonal antibody for the prevention of kidney transplant rejection.
- A Phase 2, open-label, investigator-initiated study in adult kidney transplant patients at Massachusetts General Hospital (MGH) is expected to initiate in the second half of 2026 pending FDA clearance of MGH's IND application. The study is expected to enroll five adult kidney transplant recipients.

Rare Disease Pipeline

TNX-2900 (intranasal potentiated oxytocin): in development for Prader-Willi syndrome, with Orphan Drug and Rare Pediatric Disease designation that could potentially make Tonix eligible for a Priority Review Voucher upon approval

- Tonix plans to initiate a Phase 2, randomized, double-blind, placebo-controlled study in children and adolescents with Prader-Willi syndrome in the second half of 2027.

Immuno-oncology Pipeline

TNX-1700 (TFF2-albumin fusion protein): in preclinical development for gastric and colorectal cancer

- In June 2026, Tonix presented preclinical data at the Ninth JCA-AACR Special Joint Conference on Novel Therapies and Diagnostics in Upper Digestive and Head and Neck Cancers demonstrating TNX-1700 normalizes myelopoiesis and enhances anti-PD-1 therapy in gastric cancer.

Financial: Recent Highlights

Tonix had approximately $176.2 million of cash and cash equivalents as of June 30, 2026, compared to approximately $207.6 million as of December 31, 2025. Net cash used in operating activities was approximately $84.6 million for the six months ended June 30, 2026, compared to $31.4 million for the same period in 2025.

Subsequent to quarter-end, the Company raised $3.7 million in proceeds under its At-the-Market facility.

The Company believes that its cash resources as of June 30, 2026, together with the net proceeds that it raised from equity offerings in the third quarter of 2026 to date, will meet its planned operating and capital expenditure requirements into early second quarter of 2027.

As of August 7, 2026, the Company had 17,151,024 shares of common stock outstanding.

Second Quarter 2026 Financial Results

Net product revenue for the second quarter 2026 was approximately $13.5 million, compared to $2.0 million for the same period in 2025, and consisted of combined net sales of TONMYA, Zembrace® SymTouch®, and Tosymra®. Net revenue from sales of TONMYA for the second quarter was approximately $11.0 million. Net revenue from sales of Zembrace SymTouch and Tosymra was approximately $2.5 million, compared to $2.0 million for the same quarter in 2025. Cost of sales for the second quarter 2026 was approximately $0.7 million, compared to $3.3 million for the same period in 2025. The decrease in the cost of sales is predominantly driven by a change in product mix and a write-off related to the migraine products in 2025.

Research and development expenses for the second quarter 2026 were approximately $19.4 million, compared to $10.8 million for the same period in 2025. The increase of $8.6 million was primarily attributable to higher manufacturing and clinical trial costs associated with advancing the Company's prioritized pipeline programs, as well as increased employee-related costs reflecting expanded headcount.

Selling, general, and administrative expenses for the second quarter 2026 were approximately $36.0 million, compared to $16.2 million for the same period in 2025. The increase of $19.8 million was primarily attributable to sales and marketing investment supporting the commercial launch of TONMYA and the Company's migraine products, together with increased employee-related and professional expenses.

Net loss available to common stockholders was $40.6 million, or $2.44 per basic and diluted share, for the second quarter 2026, compared to net loss available to common stockholders of $28.3 million, or $3.86 per basic and diluted share, for the same period in 2025. The basic and diluted weighted average common shares outstanding for the second quarter 2026 was 16,635,254 compared to 7,327,257 shares for the same period in 2025.

Conference Call and Webcast Information

The Company will host a conference call and webcast to report second quarter 2026 financial results and operational highlights on Monday, August 10, 2026, at 8:30 a.m. ET.

To listen to the conference call, register at thislink. To view the webcast, register at thislink.

A replay will be available under "IR Events" in the Investors section of the Company's website athttps://ir.tonixpharma.com/news-events/ir-events.

Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully integrated, commercial-stage biopharmaceutical company focused on central nervous system (CNS) disorders, infectious diseases, immunology conditions, and rare diseases with high unmet medical needs. 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 the potential of TNX-102 SL 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 TNX-102 SL for new, 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 Company's expected financial performance, the Company's anticipated cash runway, the Company's expected timelines regarding its clinical and pre-clinical programs, expected enrollment in the Company's clinical trials, expected adoption by the medical community and patients of the Company's products and expected timelines regarding the Company's manufacturing processes. 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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TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
REVENUE:				
Product revenue, net	$ 13,544	$ 1,998	$ 20,422	$ 4,427
COSTS AND EXPENSES:				
Cost of revenue	703	3,272	2,281	4,215
Research and development	19,417	10,820	37,630	18,256
Selling, general and administrative	35,959	16,202	64,583	26,306
	56,079	30,294	104,494	48,777
Operating loss	(42,535)	(28,296)	(84,072)	(44,350)
Grant income	600	1,036	600	1,959
Loss on extinguishment of debt	—	—	—	(2,092)
Interest income, net	1,432	943	2,778	1,571
Other expense, net	(49)	(1,955)	(52)	(2,189)
Net loss available to common stockholders	$ (40,552)	$ (28,272)	$ (80,746)	$ (45,101)
Net loss per common share, basic and diluted	$ (2.44)	$ (3.86)	$ (5.32)	$ (6.80)
Weighted average common shares outstanding, basic and diluted	16,635,254	7,327,257	15,179,268	6,631,111

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands)
(Unaudited) [1]

	June 30, 2026	**December 31, 2025**
Assets		
Cash and cash equivalents	$ 176,232	$ 207,637
Accounts Receivable, net	11,805	6,271
Inventory	4,678	6,013
Prepaid expenses and other	10,717	8,955
Total current assets	203,432	228,876
Other non-current assets	50,656	48,295
Total assets	$ 254,088	$ 277,171
Liabilities and stockholders' equity		
Total liabilities	$ 31,807	$ 32,021
Stockholders' equity	222,281	245,150
Total liabilities and stockholders' equity	$ 254,088	$ 277,171

1 The condensed consolidated balance sheet for the year ended December 31, 2025, has been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.