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 11, 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, 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 May 11, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended March 31, 2026. A copy of the press release that discusses these matters 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 May 11, 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: May 11, 2026

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

Exhibit 99.01

Tonix Pharmaceuticals Reports First Quarter 2026 Financial Results and Operational Highlights

In the first full quarter since launch, 2,145 healthcare providers prescribed TONMYA®, 3,588 patients initiated treatment, and ~5,400 prescriptions were filled

Agreement signed in May with leading group purchasing organization (GPO) that provides access to TONMYA for approximately 35 million U.S. commercial lives

Expect to initiate adaptive Phase 2 field study for the prevention of Lyme disease in the U.S. in the first half of 2027 for TNX-4800, pending FDA agreement

Approximately $185.5 million in cash and cash equivalents as of March 31, 2026

BERKELEY HEIGHTS, N.J., May 11, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial biotechnology company, today announced financial results for the quarter ended March 31, 2026, and provided an overview of recent operational highlights.

“TONMYA is the first new fibromyalgia medicine in 15 years," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “TONMYA is a non-opioid analgesic designed for bedtime administration and long-term use by adults. Since launch in November 2025, TONMYA has shown growth in prescriptions, new writers, refills, and patient access. Our first managed care partnership was announced in May, providing access to approximately 35 million U.S. commercial lives. We will continue engagement with commercial and government payers to expand patient access. Our focus remains on operational excellence across sales, marketing, medical affairs, and market access to educate and deliver on TONMYA’s differentiated potential.”

Dr. Lederman continued, “We also continue to meaningfully advance our mid-stage clinical programs and our earlier-stage pipeline. For TNX-4800, our investigational long-acting borreliacidal, human monoclonal antibody targeting OspA on *Borrelia burgdorferi*, which causes the majority of Lyme disease in the U.S., we announced positive Phase 1 data and plans for an adaptive Phase 2 field study in 2027, pending FDA agreement. We look forward to our scheduled Type C meeting with the FDA early in the third quarter of 2026 to discuss the study. We believe TNX-4800 offers several advantages over vaccines in development, including onset of protection within two days and a simpler two-dose regimen with a second booster dose two months after the first. We also expect to begin our Phase 2 study of TONMYA for the treatment of Major Depressive Disorder (MDD) mid-year. Our other programs across CNS, infectious disease, immunology, and rare disease remain well positioned for near-term milestones.”

Commercial Updates

TONMYA (cyclobenzaprine HCl sublingual tablets): a centrally acting, non-opioid analgesic for the treatment of fibromyalgia in adults

- On November 17, 2025, TONMYA became commercially available, following U.S. FDA approval in August 2025 for the treatment of fibromyalgia in adults. TONMYA is the first new prescription medicine approved for fibromyalgia in more than 15 years. The approval was based on two double-blind, randomized, placebo-controlled Phase 3 clinical studies of nearly 1,000 patients that demonstrated durable and statistically significant reduction in daily pain scores compared to placebo. There are now approximately 100 TONMYA sales reps in the field.
- In the first quarter of 2026, the first full quarter since launch, key metrics include:
  - 2,145 unique healthcare providers prescribed TONMYA to patients.
  - 3,588 unique patients initiated treatment with TONMYA.
  - Approximately 5,400 prescriptions were filled. This includes bridge prescriptions that are facilitated through the Company's specialty pharmacy channel. Bridge prescriptions represent initial patient fills provided while coverage determinations are pending and do not immediately generate net product revenue.
- For the period beginning November 17, 2025, through April 24, 2026, cumulative key metrics include:
  - More than 2,700 unique healthcare providers have prescribed TONMYA to patients.
  - Approximately 5,618 unique patients have initiated treatment with TONMYA.
- For the period beginning November 17, 2025, through May 1, 2026, cumulative key metrics include:
  - Approximately 11,016 prescriptions were filled. This includes bridge prescriptions that are facilitated through the Company's specialty pharmacy channel.
- Repeat prescriber and patient refill trends are encouraging.
- The Company is prioritizing engagement with commercial payers, Medicare, and Medicaid to increase access:
  - In May 2026, Tonix secured commercial payer coverage with its first managed care partnership agreement with a leading GPO, which will provide access for approximately 35 million U.S. patients (20% of ~177 million commercial lives in the U.S.)
  - To date, TONMYA is covered under Medicaid in 38 states, for approximately 55 million lives, representing 73% of the roughly 75 million Medicaid lives.
- Tonix has a robust patient access program and support services in place, including a TONMYA savings card, copay assistance, and prior authorization support, intended to reduce access barriers during early commercialization.
- To educate healthcare providers (HCPs), the Company held a multidisciplinary dialogue about TONMYA via a national webcast. Tonix also launched a national speaker training program with approximately 100 HCPs to maximize peer-to-peer speaker programs expected to occur across target specialties and regions this year.
- As part of a commitment to continued clinical evidence generation and education, Tonix presented clinical data on TONMYA at the 8th International Congress on Controversies in Fibromyalgia, 2026 American Academy of Pain Medicine (AAPM) PainConnect Annual Meeting, and 2026 Non-Opioid Pain Therapeutics Summit. The Company also published two articles 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; remains on track to initiate mid-year 2026

- In November 2025, the FDA cleared the IND for TNX-102 SL 5.6 mg for the treatment of MDD in adults. The IND clearance enables Tonix to proceed with the HORIZON study, a potentially pivotal Phase 2, 6-week, randomized, double-blind, placebo-controlled study of TNX-102 SL as a first-line monotherapy in adults with MDD. About 360 patients will be enrolled at approximately 30 U.S. sites, with the primary endpoint being the MADRS total score change from baseline at Week 6. Tonix plans to initiate enrollment in mid-2026.

TNX-102 SL in Phase 2 development for the treatment of 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. The OASIS study examines the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients in the emergency department after a motor vehicle collision. Topline data is expected to be reported in the second half of 2026.

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 2a study has been completed).

TNX-1900 (intranasal potentiated oxytocin): in development for several CNS disorders

- TNX-1900 is currently being studied in four Phase 2 and one Phase 1 investigator-initiated studies. The Phase 2 investigator-initiated studies include binge-eating disorder (Massachusetts General Hospital, “MGH”), adolescent obesity (MGH), bone health in autism (MGH and University of Virgina), and arginine vasopressin deficiency (MGH).
- In March 2026, Tonix announced the dosing of the first participant in a Phase 1 investigator-initiated pharmacodynamic study with Erasmus University of TNX-1900 in healthy female volunteers, using capsaicin and electrical stimulation to model trigeminal neurovascular reactivity.

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., which has no FDA-approved vaccines or prophylactics

- In March 2026, Tonix presented Phase 1 data at the World Vaccine Congress Washington 2026 and announced plans to initiate an adaptive Phase 2 field study in the first half of 2027, pending FDA agreement. The Company also presented Phase 1 data in April 2026 at the 4th Annual Ticks and Tickborne Diseases Symposium at Johns Hopkins University.
    - TNX-4800 demonstrated encouraging safety, tolerability, pharmacokinetics, and immunogenicity, with serum TNX-4800 measurable at the earlier sampling time of 48 hours and no significant clinical or laboratory safety signals. The Phase 1 study was conducted by a team at UMass Chan Medical School led by Mark S. Klempner, MD, Professor of Medicine at UMass Chan and an inventor of TNX-4800.
- In April 2026, the Company announced it expects to lead a randomized, double-blind, placebo-controlled, adaptive Phase 2 field study to evaluate the efficacy of a two-dose regimen of TNX-4800 subcutaneous (SC) in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period (Day 3 through Month 6 following administration). Each fixed dose is expected to provide exposures comparable to the 5 mg/kg dose evaluated in Phase 1. The first dose will be administered in the Spring and the second booster dose will be administered two months later. Participants will include adolescents and adults 16 years of age and older in Lyme-endemic areas in the U.S. The primary endpoint will be the prevention of Lyme disease for six months (comparison of TNX-4800 group and placebo group) following the initial dose.
- In April 2026, the Company announced it has scheduled a Type C meeting with the FDA early in the third quarter of 2026 to discuss the planned adaptive Phase 2 field study design.
- The Company expects to have GMP investigational product available for clinical testing in early 2027.

TNX-801 (recombinant horsepox virus): attenuated, pre-clinical live orthopoxvirus vaccine candidate for the prevention of smallpox and mpox

- In March 2026, Tonix presented animal and in vitro data on TNX-801 at the World Vaccine Congress Washington 2026. TNX-801 is expected to enter a Phase 1 study in 2027 pending FDA clearance of the Investigational New Drug (IND) application.

TNX-4200 (small molecule): broad spectrum anti-viral to protect against viral diseases

- TNX-4200 is a small molecule broad-spectrum antiviral agent targeting CD45 for the prevention or treatment of high lethality infections to improve the medical readiness of military personnel in biological threat environments.
- The 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 first quarter of 2026, the Company received confirmation that the project was cleared to enter the next budgetary and developmental 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 disorders

- In November 2025, Tonix announced a collaboration with MGH to advance a Phase 2, open-label, investigator-initiated clinical study of TNX-1500 in kidney transplant recipients, planned for initiation mid-year 2026, pending FDA clearance of the IND. 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 designation as well as Rare Pediatric Disease designation that could make Tonix eligible for a Priority Review Voucher upon approval

- In September 2025, Tonix announced plans to initiate a Phase 2, randomized, double-blind, placebo-controlled study in children and adolescents with Prader-Willi syndrome. The study is expected to initiate in the first quarter of 2027.

Immuno-oncology Pipeline

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

- In March 2026, Tonix presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting 2026. Data presented in an oral presentation showed how TNX-1700 reversed aging-associated gastric inflammation and significantly attenuated tumor progression in an aged gastric microenvironment in preclinical models. Data in a poster presentation demonstrated TNX-1700 exhibited dose-independent, linear pharmacokinetics in animals.

TNX-4700 (human anti-BTLA mAb): in preclinical development for immuno-oncology indications

- In March 2026, Tonix presented preclinical data in a poster presentation at the AACR Annual Meeting 2026 demonstrating TNX-4700 demonstrated potent, high-affinity binding and functional antagonism. The mAb technology was licensed from Curia.

Financial: Recent Highlights

Tonix had approximately $185.5 million of cash and cash equivalents as of March 31, 2026, compared to approximately $207.6 million as of March 31, 2025. Net cash used in operations was approximately $42.3 million for the first quarter ended March 31, 2026, compared to $16.6 million for the same period in 2025.

Subsequent to quarter-end, the Company has raised $22.6 million proceeds using its at-the-market (ATM) facility.

The Company believes that its cash resources as of March 31, 2026, together with the net proceeds that it raised from equity offerings in the second quarter of 2026, will fund its planned operating and capital expenditure requirements into early second quarter of 2027.

As of May 8, 2026, the Company had 15,940,601 shares of common stock outstanding.

First Quarter 2026 Financial Results

Net product revenue for the first quarter 2026 was approximately $6.9 million, compared to $2.4 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 first quarter was approximately $3.7 million. TONMYA was launched in November 2025. Net revenue from sales of TONMYA for the period from November 17, 2025, to December 31, 2025, was approximately $1.4 million. Net revenue from sales of Zembrace® SymTouch® and Tosymra® for the was approximately $3.2 million compared to $2.4 million for the same quarter in 2025. Cost of sales for the first quarter 2026 was approximately $1.6 million, compared to $0.9 million for the same period in 2025.

Research and development expenses for the first quarter 2026 were approximately $18.2 million, compared to $7.4 million for the same period in 2025. This increase is predominately due to pipeline prioritization period over period, and increased headcount.

Selling, general, and administrative expenses for the first quarter 2026 were $28.6 million, compared to $10.1 million for the same period in 2025. The increase is predominately due to spending on sales and marketing related to TONMYA, as well as increased headcount.

Net loss available to common stockholders was $40.2 million, or $2.93 per basic and diluted share, for the first quarter 2026, compared to net loss available to common stockholders of $16.8 million, or $2.84 per basic and diluted share, for the same period in 2025. The basic and diluted weighted average common shares outstanding for the first quarter 2026 was 13,707,104 compared to 5,927,231 shares for the same period in 2025.

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 recently approved flagship 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® and Tosymra®. Tonix is maximizing 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 for Lyme disease prevention in the U.S. and TNX-801, a vaccine in development for the prevention of mpox and smallpox. Within immunology, Tonix is developing TNX-1500, 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 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. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially as a result of a number of factors, including the ability of the Company to satisfy the conditions to the closing of the offering and the timing thereof, as well as those described 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 March 31,	
	2026	**2025**
REVENUES:		
Product revenue, net	$ 6,878	$ 2,429
COSTS AND EXPENSES:		
Cost of sales	1,578	943
Research and development	18,213	7,436
General and administrative	28,624	10,104
Total operating expenses	48,415	18,483
Operating loss	(41,537)	(16,054)
Grant income	—	923
Loss on Extinguishment of Debt	—	(2,092)
Interest income	1,346	394
Other expense, net	(3)	—
Net loss available to common stockholders	$ (40,194)	$ (16,829)
Net loss to common stockholders per common share, basic and diluted	$ (2.93)	$ (2.84)
Weighted average common shares outstanding, basic and diluted	13,707,104	5,927,231

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

	March 31, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 185,470	$ 207,637
Accounts Receivable, net	8,820	6,271
Inventory	3,645	6,013
Prepaid expenses and other	9,233	8,955
Total current assets	207,168	228,876
Other non-current assets	50,744	48,295
Total assets	$ 257,912	$ 277,171
Liabilities and stockholders' equity		
Total liabilities	$ 30,775	$ 32,021
Stockholders' equity	227,137	245,150
Total liabilities and stockholders' equity	$ 257,912	$ 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.