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): November 9, 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 November 9, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended September 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 November 9, 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: November 9, 2026

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Third Quarter 2026 Financial Results and Operational Highlights

Third quarter TONMYA® net sales of approximately $15 million, up 37% from the second quarter

Approximately $163 million in cash and cash equivalents as of September 30, 2026

Strategic focus on supporting TONMYA growth and advancing core clinical programs

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

Berkeley Heights, N.J., Nov. 9, 2026 (GlobeNewswire) — 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 September 30, 2026, and provided an overview of recent operational highlights.

"We delivered another strong quarter for TONMYA, with net sales up 37% over the second quarter," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "Total prescriptions, new prescriptions, and refills also increased. Payer access expanded to include two commercial group purchasing organization (GPO) agreements, two managed Medicare agreements, and Medicaid access in almost every state. This expanded access contributed to third quarter sales growth. We have seen promising growth in our key performance indicators since adding 50 sales representatives on September 1, bringing our total sales force to approximately 150."

"In addition to TONMYA's growth, we are focused on our core clinical priorities," Dr. Lederman continued. "Our priorities include advancing TNX-102 SL in major depressive disorder (MDD), TNX-4800 for Lyme disease prevention, and the investigator-initiated study of TNX-1500 (mosdaprubart)[1] to prevent kidney transplant rejection."

TONMYA Updates

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

Performance

- Third quarter 2026 key performance metrics included:
    - Total prescriptions increased 28% quarter-over-quarter to 16,375, including bridge prescriptions 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 prescriptions increased 17% quarter-over-quarter.
    - Refills increased 56% quarter-over-quarter.

Payer Access and Coverage

- TONMYA coverage now totals approximately 166 million covered lives (~53% of the approximately 314 million covered lives in the U.S.). The Company remains engaged with commercial payers, managed Medicare, and Medicaid to increase patient access.
    - In July 2026, Tonix announced a major managed Medicare agreement, adding approximately nine million Medicare lives.
    - In September 2026, Tonix announced a second major managed Medicare agreement, adding approximately 21 million Medicare lives.

Execution

- On September 1, 2026, the Company added 50 representatives to the TONMYA sales force, completing its planned expansion to approximately 150 sales representatives.
- On September 8, 2026, Tonix announced the promotion of Thomas Englese, MBA, to Chief Commercial Officer. Mr. Englese served as Executive Vice President, Commercial Operations, since September 2024.
- On October 2, 2026, the Company disclosed it had received notice from Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) that DRL had filed an Abbreviated New Drug Application (ANDA) containing a Paragraph IV patent certification with the U.S. Food and Drug Administration (FDA) for a generic version of TONMYA. The Company intends to vigorously enforce its intellectual property rights relating to TONMYA against infringement but cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Prioritized R&D Pipeline Updates

Central Nervous System (CNS)

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): MDD

- Enrollment is ongoing for HORIZON, a potentially pivotal, six-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.

Infectious Disease

TNX-4800 (anti-OspA monoclonal antibody (mAb): long-acting human mAb in development for the seasonal prevention of Lyme disease in the U.S.

- On August 3, 2026, Tonix announced receipt of positive official minutes from its Type C meeting with the FDA. The FDA is reviewing the final study protocol.
- The adaptive Phase 2 TRAIL field study is expected to begin in the first quarter of 2027 pending final FDA agreement on the study protocol.
- The Company is on track to deliver investigational product to the Phase 2 clinical study sites in the first quarter of 2027.

Immunology

TNX-1500 (mosdaprubart) (dimeric Fc-modified humanized anti-CD40L mAb): Phase 2-ready third-generation anti-CD40L mAb in development to prevent kidney transplant rejection and treat autoimmune diseases

- A Phase 2, open-label, investigator-initiated study at Massachusetts General Hospital (MGH) is expected to initiate in the first quarter of 2027 and enroll five adult kidney transplant recipients.

Recent Financial Highlights

Tonix had approximately $163 million of cash and cash equivalents as of September 30, 2026, compared to approximately $207.6 million as of December 31, 2025. Net cash used in operating activities was approximately $125.6 million for the nine months ended September 30, 2026, compared to approximately $60.2 million for the same period in 2025.

The Company believes that its cash resources as of September 30, 2026, together with the net proceeds of approximately $1.5 million raised from equity offerings subsequent to September 30, 2026, will meet its operating and capital expenditure requirements into the early third quarter of 2027.

As of November 6, 2026, the Company had 19,431,516 shares of common stock outstanding.

Third Quarter 2026 Financial Results

Net product revenue for the third quarter 2026 was approximately $17.2 million, compared to $3.3 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 third quarter was approximately $15.0 million. Net revenue from sales of Zembrace SymTouch and Tosymra was approximately $2.2 million, compared to $3.3 million for the same quarter in 2025. Cost of sales for the third quarter 2026 was approximately $1.3 million, compared to $1.4 million for the same period in 2025. The decrease in cost of sales is driven by a change in product mix.

Research and development expenses for the third quarter 2026 were approximately $25.8 million, compared to $9.3 million for the same period in 2025. The increase of $16.5 million was primarily attributable to higher manufacturing expenses of $9.8 million, clinical expenses of $3.6 million and non-clinical expenses of $1.1 million as the Company advanced its prioritized pipeline, as well as higher employee-related costs of $1.5 million due to increased headcount.

Selling, general, and administrative expenses for the third quarter 2026 were approximately $45.6 million, compared to $25.7 million for the same period in 2025. The increase of $19.9 million was primarily attributable to higher sales and marketing expenses of $13.5 million, employee-related expenses of $4.1 million, and professional expenses of $1.5 million. These increases primarily reflect commercialization activities following the launch of TONMYA in November 2025.

Net loss available to common stockholders was $53.3 million, or $2.89 per basic and diluted share, for the third quarter 2026, compared to net loss available to common stockholders of $32.0 million, or $3.59 per basic and diluted share, for the same period in 2025. The basic and diluted weighted average common shares outstanding for the third quarter 2026 was 18,440,773 compared to 8,922,792 shares for the same period in 2025.

Conference Call and Webcast Information

The Company will host a conference call and webcast to report third quarter 2026 financial results and operational highlights on Monday, November 9, 2026, at 8:30 a.m. ET. To listen to the conference call, register at this link. To view the webcast, register at this link. A replay will be available under "IR Events" in the Investors section of the Company's website at https://ir.tonixpharma.com/news-events/ir-events.

Citations

[1]Mosdaprubart is the proposed International Nonproprietary Name (INN); final designation pending confirmation from the World Health Organization (WHO).

Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully integrated, commercial-stage biopharmaceutical company focused on central nervous system (CNS) disorders, infectious diseases, and immunology conditions with high unmet medical needs. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8 mg), the Company's flagship internally conceived and developed medicine, is the first FDA-approved 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 (Tonix-led study) and acute stress disorder/acute stress reaction (investigator-initiated study). Tonix is also advancing monoclonal antibody TNX-4800 (anti-OspA mAb) for Lyme disease prevention in the U.S. Within immunology, Tonix is developing TNX-1500 (anti-CD40L mAb), a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection (investigator-initiated study). 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 for the indications being investigated have not been established, and they have not been approved for those indications.*

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 preclinical programs, expected enrollment in the Company's clinical trials, expected adoption by the medical community and patients of the Company's products, and the expected outcome of litigation. 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; uncertainties of patent protection and litigation; 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 government or third-party payer 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. Investors should read the risk factors set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. 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 hereof.

Investor Contacts

Deborah Elson
Tonix Pharmaceuticals
deborah.elson@tonixpharma.com
investor.relations@tonixpharma.com

Brian Korb
astr partners
(917) 653-5122
brian.korb@astrpartners.com

Media Contacts

Andrea Cohen
Sam Brown Inc.
(917) 209-7163
andreacohen@sambrown.com

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
REVENUE:				
Product revenue, net	$ 17,234	$ 3,290	$ 37,656	$ 7,717
COSTS AND EXPENSES:				
Cost of sales	1,252	1,367	3,533	5,582
Research and development	25,824	9,289	63,454	27,545
Selling, general and administrative	45,590	25,701	110,173	52,007
	72,666	36,357	177,160	85,134
Operating loss	(55,432)	(33,067)	(139,504)	(77,417)
Contract income	666	982	1,266	2,941
Loss on extinguishment of debt	—	—	—	(2,092)
Interest income, net	1,362	1,231	4,140	2,713
Other income (expense), net	75	(1,156)	23	(3,256)
Net loss available to common stockholders	$ (53,329)	$ (32,010)	$ (134,075)	$ (77,111)
Net loss per common share, basic and diluted	$ (2.89)	$ (3.59)	$ (8.24)	$ (10.42)
Weighted average common shares outstanding, basic and diluted	18,440,773	8,922,792	16,278,383	7,403,400

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

	September 30, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 162,793	$ 207,637
Accounts receivable, net	14,599	6,271
Inventory	4,478	6,013
Prepaid expenses and other	10,265	8,955
Total current assets	192,135	228,876
Other non-current assets	50,291	48,295
Total assets	$ 242,426	$ 277,171
Liabilities and stockholders' equity		
Total liabilities	$ 42,941	$ 32,021
Stockholders' equity	199,485	245,150
Total liabilities and stockholders' equity	$ 242,426	$ 277,171

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