

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2025

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____

Commission file number: 001-36019

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation or organization)

26-1434750
(I.R.S. Employer Identification No.)

26 Main Street, Suite 101
Chatham, New Jersey
(Address of Principal Executive Offices)

07928
(Zip Code)

(862) 799-8599
(Registrant's telephone number, including area code)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 10, 2025, there were 11,776,542 shares of registrant's common stock outstanding.

TONIX PHARMACEUTICALS HOLDING CORP.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

**TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands, Except Par Value and Share Amounts)
(unaudited)**

	<u>September 30, 2025</u>	<u>December 31, 2024</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 190,055	\$ 98,776
Accounts receivable, net	3,481	3,683
Inventory	5,729	8,408
Prepaid expenses and other current assets	8,806	8,135
Total current assets	<u>208,071</u>	<u>119,002</u>
Property and equipment, net	42,574	42,252
Intangible assets, net	120	120
Operating lease right-to-use assets	376	565
Other non-current assets	<u>1,299</u>	<u>951</u>
Total assets	<u>\$ 252,440</u>	<u>\$ 162,890</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,540	\$ 4,546
Accrued expenses and other current liabilities	12,332	10,667
Term loan payable, short term	—	2,820
Lease liability, short term	159	274
Total current liabilities	<u>21,031</u>	<u>18,307</u>
Term loan payable, long term	—	4,667
Lease liability, long term	<u>266</u>	<u>358</u>
Total liabilities	21,297	23,332
Commitments (See Note 17)	—	
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, 0 shares designated as of both September 30, 2025, and December 31, 2024; 0 shares issued and outstanding as of both September 30, 2025 and December 31, 2024	—	—
Common stock, \$0.001 par value; 1,000,000,000 shares authorized; 10,168,204 and 4,385,929 shares issued and outstanding as of September 30, 2025, and December 31, 2024, respectively	10	4
Additional paid in capital	1,039,212	870,503
Accumulated deficit	(807,805)	(730,694)
Accumulated other comprehensive loss	<u>(274)</u>	<u>(255)</u>
Total stockholders' equity	<u>231,143</u>	<u>139,558</u>
Total liabilities and stockholders' equity	<u>\$ 252,440</u>	<u>\$ 162,890</u>

See the accompanying notes to the condensed consolidated financial statements

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,	
	2025	2024	2025	2024
REVENUE:				
Product revenue, net	\$ 3,290	\$ 2,822	\$ 7,717	\$ 7,512
COSTS AND EXPENSES:				
Cost of revenue	1,367	1,555	5,582	6,582
Research and development	9,289	9,114	27,545	31,675
Selling, general and administrative	25,701	7,707	52,007	24,519
Asset impairment charges	—	—	—	58,957
	<u>36,357</u>	<u>18,376</u>	<u>85,134</u>	<u>121,733</u>
Operating loss	(33,067)	(15,554)	(77,417)	(114,221)
Grant income	982	1,668	2,941	1,668
Gain on change in fair value of warrant liabilities	—	—	—	6,150
Loss on extinguishment of debt	—	—	(2,092)	—
Interest income	1,231	18	2,802	21
Interest expense	—	(301)	(89)	(954)
Other expense, net	<u>(1,156)</u>	<u>(44)</u>	<u>(3,256)</u>	<u>(592)</u>
Net loss available to common stockholders	\$ <u>(32,010)</u>	\$ <u>(14,213)</u>	\$ <u>(77,111)</u>	\$ <u>(107,928)</u>
Net loss per common share, basic and diluted	\$ <u>(3.59)</u>	\$ <u>(22.68)</u>	\$ <u>(10.42)</u>	\$ <u>(466.17)</u>
Weighted average common shares outstanding, basic and diluted	<u>8,922,792</u>	<u>626,669</u>	<u>7,403,400</u>	<u>231,523</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In Thousands)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
Net loss	\$ (32,010)	\$ (14,213)	\$ (77,111)	\$ (107,928)
Other comprehensive loss:				
Foreign currency translation loss	(4)	(7)	(19)	(18)
Comprehensive loss	<u>\$ (32,014)</u>	<u>\$ (14,220)</u>	<u>\$ (77,130)</u>	<u>\$ (107,946)</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Common stock			Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount					
Balance, December 31, 2024	4,385,929	\$ 4		\$ 870,503	\$ (255)	\$ (730,694)	\$ 139,558
Issuance of common stock under the At-the-Market agreement, net of transactional expenses of \$2,182	2,741,887		3	59,840	—	—	59,843
Repurchase of common stock under share repurchase program, including transactional expenses of \$8	(250,000)	—		(3,047)	—	—	(3,047)
Stock-based compensation	—	—		882	—	—	882
Foreign currency transaction loss	—	—		—	(11)	—	(11)
Net loss	—	—		—	—	(16,829)	(16,829)
Balance, March 31, 2025	6,877,816		7	928,178	(266)	(747,523)	180,396
Issuance of common stock, under the At-the-Market agreement, net of transactional expenses of \$487	769,752		1	15,522	—	—	15,523
Repurchase of common stock under share repurchase program, including transactional expenses of \$5	(150,000)	—		(2,902)	—	—	(2,902)
Issuance of commitment shares	48,708	—		1,837	—	—	1,837
Stock-based compensation	—	—		1,423	—	—	1,423
Foreign currency transaction loss	—	—		—	(4)	—	(4)
Net loss	—	—		—	—	(28,272)	(28,272)
Balance, June 30, 2025	7,546,276		8	944,058	(270)	(775,795)	168,001
Issuance of common stock under the At-the-Market agreement, net of transactional expenses of \$2,993	2,621,928		2	93,231	—	—	93,233
Stock-based compensation	—	—		1,923	—	—	1,923
Foreign currency transaction loss	—	—		—	(4)	—	(4)
Net loss	—	—		—	—	(32,010)	(32,010)
Balance, September 30, 2025	10,168,204	\$ 10		\$ 1,039,212	\$ (274)	\$ (807,805)	\$ 231,143

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2023	20,926	\$ —	\$ 706,415	\$ (232)	\$ (600,658)	\$ 105,525
Issuance of common stock upon exercise of prefunded common warrants	4,701	—	—	—	—	—
Fair value of warrants reclassified from liabilities to equity	—	—	15,850	—	—	15,850
Employee stock purchase plan	21	—	23	—	—	23
Stock-based compensation	—	—	1,692	—	—	1,692
Foreign currency transaction loss	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(14,939)	(14,939)
Balance, March 31, 2024	25,648	—	723,980	(240)	(615,597)	108,143
Issuance of common stock, net of transactional expenses of \$1,704	43,699	—	10,730	—	—	10,730
Issuance of common stock upon exercise of prefunded common warrants	29,140	—	—	—	—	—
Fair value of warrants reclassified from equity to liabilities	—	—	(9,977)	—	—	(9,977)
Fair value of warrants reclassified from liabilities to equity	—	—	10,832	—	—	10,832
Stock-based compensation	—	—	1,154	—	—	1,154
Foreign currency transaction loss	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(78,776)	(78,776)
Balance, June 30, 2024	98,487	—	736,719	(243)	(694,373)	42,103
Issuance of common stock, net of transactional expenses of \$557	33,936	—	3,484	—	—	3,484
Issuance of common stock upon exercise of prefunded common warrants	79,314	—	—	—	—	—
Issuance of common stock under the At-the- Market agreement, net of transactional expenses of \$1,681	1,344,674	2	41,800	—	—	41,802
Employee stock purchase plan	70	—	4	—	—	4
Stock-based compensation	—	—	1,038	—	—	1,038
Foreign currency transaction loss	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(14,213)	(14,213)
Balance, September 30, 2024	<u>1,556,481</u>	<u>\$ 2</u>	<u>\$ 783,045</u>	<u>\$ (250)</u>	<u>\$ (708,586)</u>	<u>\$ 74,211</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)
(unaudited)

	Nine Months Ended September 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (77,111)	\$ (107,928)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,437	2,925
Asset impairment charges	—	58,957
Loss on note	1,159	—
Loss on extinguishment of debt	2,092	—
Bad debt	31	—
Issuance costs of derivative instruments	1,837	—
Change in fair value of warrant liabilities	—	(6,150)
Inventory write-off	1,318	2,018
Amortization of debt discount	65	640
Stock-based compensation	4,228	3,884
Changes in operating assets and liabilities:		
Accounts receivable	170	(4,982)
Inventory	1,362	3,691
Prepaid expenses and other	(2,159)	670
Accounts payable	3,732	346
Lease liabilities and ROU asset, net	(18)	(8)
Accrued expenses and other current liabilities	1,663	(358)
Net cash used in operating activities	<u>(60,194)</u>	<u>(46,295)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Issuance of note	(2,012)	—
Purchase of property and equipment	(1,495)	(117)
Net cash used in investing activities	<u>(3,507)</u>	<u>(117)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Deferred payment related to purchase a business	—	(3,000)
Repurchase of common stock	(5,949)	—
Proceeds from ESPP	—	27
Payment of term loan	(9,650)	(1,645)
Proceeds, net of \$5,750 and \$3,942 expenses, from sale of common stock and warrants	170,986	54,336
Net cash provided by financing activities	<u>155,387</u>	<u>49,718</u>
Effect of currency rate change on cash	<u>(17)</u>	<u>(20)</u>
Net increase in cash, cash equivalents and restricted cash	91,669	3,286
Cash, cash equivalents and restricted cash beginning of the period	<u>99,680</u>	<u>25,850</u>
Cash, cash equivalents and restricted cash end of period	<u>\$ 191,349</u>	<u>\$ 29,136</u>
Supplemental disclosures of cash flow information:		
Interest expense paid	\$ 89	\$ 954
Non-cash financing and investing activities:		
At-the-market agreement receivable	\$ —	\$ 1,680
Issuance costs from derivative instruments	\$ 1,837	\$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 263	\$ —

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2025 AND 2024 (UNAUDITED)

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp. (“Tonix” or the “Company”), through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. (“Tonix Sub”), and its wholly owned commercial subsidiary, Tonix Medicines, Inc. (“Tonix Medicines”), is a fully-integrated, commercial-stage biotechnology company with marketed products and a pipeline of development candidates.

Tonix’s marketed products include TonmyaTM (cyclobenzaprine HCl sublingual tablets), a first-in-class, non-opioid analgesic medicine for the treatment of fibromyalgia, for which the Company received approval in August 2025 by the U.S. Food and Drug Administration (“FDA”). Fibromyalgia is a chronic pain condition that affects millions of adults, the majority of whom are women. Tonmya is the first new prescription medicine for fibromyalgia approved by the FDA in more than 15 years. Tonix expects to launch Tonmya in the U.S. before the end of November 2025. Tonix also markets two treatments for acute migraine in adults, Zembrace® SymTouch® (sumatriptan injection) and Tosymra® (sumatriptan nasal spray).

Tonix’s development pipeline is focused on central nervous system (“CNS”) disorders, immunology, immuno-oncology, rare disease and infectious disease. Within CNS, TNX-102 SL is being studied to treat acute stress reaction and acute stress disorder under an Investigator -Initiated Investigational New Drug Application (“IND”) at the University of North Carolina in the OASIS Phase 2 study funded by the U.S. Department of Defense (“DoD”). TNX-102 SL is also in development for major depressive disorder, with the Company expecting to initiate a potential pivotal Phase 2 study by mid-year 2026, contingent on IND clearance by the FDA. Tonix’s immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a dimeric Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of kidney transplant rejection and the treatment of autoimmune diseases. In collaboration with Massachusetts General Hospital (“MGH”), an open-label Phase 2 study of TNX-1500 is planned to initiate in the first half of 2026 to evaluate safety and activity in five kidney transplant recipients, contingent on FDA clearance of an investigator-initiated IND and approval by the institutional review board (“IRB”). Tonix’s rare disease portfolio includes TNX-2900, intranasal oxytocin potentiated with magnesium, in development for Prader-Willi syndrome and for which the Company plans to initiate a Phase 2 study in the second half of 2026. Tonix’s infectious disease portfolio includes TNX-801 (recombinant horsepox, live virus vaccine), a vaccine in development for prevention of mpox and smallpox. Tonix is also developing TNX-4800 (anti-OspA mAb), a long-acting monoclonal antibody for the seasonal prevention of Lyme Disease, and expects to initiate an adaptive Phase 2/3 study in 2027. TNX-4800 was licensed from the University of Massachusetts Chan Medical School in 2025. Finally, 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, 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 research and development facility in Frederick, Maryland.

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its wholly owned subsidiaries, Tonix Sub, Krele LLC, Tonix Pharmaceuticals (Canada), Inc., Tonix Medicines, Jenner Institute LLC, Tonix R&D Center LLC, Tonix Pharma Holdings Limited and Tonix Pharma Limited (collectively, the “Company” or “Tonix”). All intercompany balances and transactions have been eliminated in consolidation.

Liquidity

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At September 30, 2025, the Company had working capital of approximately \$187.0 million. At September 30, 2025, the Company had an accumulated deficit of approximately \$807.8 million. The Company held unrestricted cash and cash equivalents of approximately \$190.1 million as of September 30, 2025.

The Company believes that its cash resources at September 30, 2025, and the net proceeds of \$34.7 million that it received from the sale of equity in the fourth quarter of 2025 (See Note 18), will meet its planned operating and capital expenditure requirements into the first quarter of 2027.

The Company continues to face significant challenges and uncertainties and must successfully launch Tonmya and obtain additional funding through public and private financing and collaborative arrangements with strategic partners to increase the funds available to fund operations. However, the Company may not be able to raise capital on terms acceptable to the Company, or at all. Without the successful product launch of Tonmya and obtaining additional funds, the Company may be forced to delay, scale back or eliminate some or all of its research and development activities or other operations, and potentially delay product development in an effort to maintain sufficient funds to continue operations. If any of these events occurs, the Company’s ability to achieve development and commercialization goals will be adversely affected and the Company may be forced to cease operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2025 AND 2024 (UNAUDITED)

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Interim financial statements

The unaudited condensed consolidated interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included.

The condensed consolidated balance sheet as of December 31, 2024, contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2025 are not necessarily indicative of results that may be expected for the year ending December 31, 2025. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2024, included in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 18, 2025.

On February 5, 2025, the Company effected a 1-for-100 reverse stock split of its issued and outstanding shares of common stock. On June 10, 2024, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock. The Company accounted for both reverse stock splits on a retrospective basis pursuant to ASC 260, Earnings Per Share. All issued and outstanding common stock, common stock warrants, stock option awards, exercise prices and per share data have been adjusted in these consolidated financial statements, on a retrospective basis, to reflect the reverse stock splits for all periods presented. Authorized common and preferred stock were not adjusted because of the reverse stock splits.

Risks and uncertainties

The Company’s primary efforts are devoted to commercializing its approved products and conducting research and development of innovative pharmaceutical and biological products to address public health challenges. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. Further, the Company currently generates revenue from the sale of its commercial products, Zembrace SymTouch and Tosymra. There is no assurance that the Company will be able to generate sufficient cash flow to fund operations from the sale of its commercial products or products in development, if and when approved. In addition, there can be no assurance that the Company’s research and development will be successfully completed or that any product in development will be approved or commercially viable.

Use of estimates

The preparation of financial statements in accordance with Generally Accepted Accounting Principles (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include, but are not limited to, impairments, provisions for product returns, coupons, rebates, chargebacks, discounts, allowances, inventory realization, the assumptions used in the fair value of stock-based compensation and other equity instruments, and the percent of completion of research and development contracts.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2025 AND 2024 (UNAUDITED)

Segment Information and Concentrations

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker (“CODM”), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company considers its chief executive officer to be the Company’s CODM. The CODM manages its operations and allocates resources based on the Company’s consolidated results and therefore operates as one segment.

Segment revenue, profit or loss, significant segment expenses and other segment items - The accounting policies of the Company’s single operating and reportable segment are the same as those described in the summary of significant accounting policies. The Company’s method for measuring segment profitability includes net income (loss), which the CODM uses to assess performance and make decisions for resource allocation, consistent with the measurement principals for net income (loss) as reported on the Company’s consolidated statements of operations. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company’s consolidated statements of operations, and expenses are not regularly reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources.

The Company has two products that each accounted for more than 10% of total revenues during the three and nine months ended September 30, 2025, and 2024. These products collectively accounted for 100% of revenues during the three and nine months ended September 30, 2025, and 2024.

As of September 30, 2025, accounts receivable from four customers accounted for 37%, 33%, 16%, and 10% of total accounts receivable. For the three months ended September 30, 2025, revenues from five customers accounted for 25%, 24%, 22%, 19% and 11% of net product revenues, respectively. For the nine months ended September 30, 2025, revenues from five customers accounted for 23%, 22%, 21%, 20% and 13% of net product revenues, respectively. For the three months ended September 30, 2024, revenues from five customers accounted for 26%, 23%, 22%, 16% and 10% of net product revenues, respectively. For the nine months ended September 30, 2024, revenues from five customers accounted for 24%, 24%, 22%, 16% and 12% of net product revenues, respectively.

Cash, Cash Equivalents and Restricted Cash

The Company considers cash equivalents to be those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased. At September 30, 2025, and September 30, 2024, cash equivalents, which consisted of money market funds and other cash equivalents, amounted to approximately \$97.6 million and \$24,000, respectively. Restricted cash, which is included in Other non-current assets on the condensed consolidated balance sheets, at September 30, 2025, of approximately \$1.3 million collateralizes a letter of credit issued in connection with the lease of office space in Berkley Heights, New Jersey and Chatham, New Jersey (see Note 17) and restricted cash held by vendors in escrow accounts for patient support services. Restricted cash at September 30, 2024, of approximately \$0.9 million, collateralizes a letter of credit issued in connection with the lease of office space in Chatham, New Jersey and New York, New York, and restricted cash held by vendors in escrow accounts for patient support services.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statement of cash flows:

	September 30, 2025	September 30, 2024
	(in thousands)	
Cash and cash equivalents	\$ 190,055	\$ 28,233
Restricted cash	1,294	903
Total	<u>\$ 191,349</u>	<u>\$ 29,136</u>

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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Accounts Receivable, net

Accounts receivable consists of amounts due from our wholesale and other third-party distributors and pharmacies and have standard payment terms that generally require payment within 30 to 90 days. For certain customers, the accounts receivable for the customer is net of cash discounts, chargebacks and customer rebates. We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale. We provide reserves against accounts receivable for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve.

As of September 30, 2025 and December 31, 2024, the Company had \$30,000 and \$0, respectively, as an allowance for credit losses. An allowance for credit losses is determined based on the financial condition and creditworthiness of customers and the Company considers economic factors and events or trends expected to affect future collections experience. Any allowance would reduce the net receivables to the amount that is expected to be collected. The payment history of the Company's customers will be considered in future assessments of collectability as these patterns are established over a longer period.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk include cash and cash equivalents, and receivables. We attempt to minimize the risks related to cash and cash equivalents by investing in money market accounts, and we have established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Concentrations of credit risk with respect to receivables, which are typically unsecured, are somewhat mitigated due to the variety of customers using our products, as well as their dispersion across different geographic areas.

We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions and assess their possible impact on our business.

Inventories

Inventories are recorded at the lower of cost or net realizable value, with cost determined by the weighted average cost method. Acquired inventory was valued at estimated selling price less a reasonable margin. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise non-saleable items taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. If non-saleable items are observed and there are no alternate uses for the inventory, the Company records a write-down to net realizable value in the period that the decline in value is first recognized. During the three months ended September 30, 2025 and 2024, the Company recorded write-downs related to Tosymra and Zembrace finished goods inventory of approximately (\$0.1) million and \$0.3 million, respectively. During the nine months ended September 30, 2025 and 2024, the Company recorded write-downs related to Tosymra and Zembrace finished goods inventory of approximately \$1.3 million and \$2.0 million, respectively, based on an assessment of inventory on hand and projected sales. Although the Company makes every effort to ensure the accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of inventories and reported operating results.

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation and amortization is calculated using the straight-line method over the asset's estimated useful life, which ranges from 20 to 40 years for buildings, 15 years for land improvements and laboratory equipment, three years for computer assets, five years for furniture and all other equipment and the shorter of the useful life or term of lease for leasehold improvements. Depreciation and amortization on assets begin when the asset is placed in service. Depreciation and amortization expense for the three months ended September 30, 2025, and 2024 was \$0.4 million and \$0.5 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2025, and 2024 was \$1.4 million and \$2.4 million, respectively. The Company's property and equipment is located in the United States.

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Intangible assets, net

Intangible assets deemed to have finite lives are carried at acquisition-date fair value less accumulated amortization and impairment, if any. Finite-lived intangible assets consisted of developed technology intangible assets acquired in connection with the acquisition of certain products from Upsher Smith Laboratories, LLC ("Upsher Smith") consummated on June 30, 2023 (See Note 5). The acquired intangible assets were amortized using the straight-line method over the estimated useful lives of the respective assets. Amortization expense for the three and nine months ended September 30, 2024, was \$0 million and \$0.5 million, respectively. The Company recorded a full impairment of its developed technology assets during the second quarter of 2024, therefore there is no amortization for the three and nine months ended September 30, 2025.

Impairment testing of long-lived assets

The Company evaluates long-lived assets for impairment, including property and equipment, finite-lived intangibles assets and operating lease right-to-use assets whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, the Company compares the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amount. Impairment, if any, is based on the excess of the carrying amount over the fair value, based on market value when available, or discounted expected cash flows, of those assets and is recorded in the period in which the determination is made. For the three and nine months ended September 30, 2025, the Company concluded that no impairment existed.

During the three months ended June 30, 2024, the Company identified certain triggering events related to its decommissioned Advance Development Center in Dartmouth, Massachusetts ("ADC"). The Company determined that the carrying value of the ADC was not recoverable and that the carrying value exceeded its fair value. As such, the Company recorded a non-cash impairment charge of \$48.8 million, which is reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024.

Additionally, due to a sustained decline in revenues and continued delays in building out the sales team for its commercialized products, the Company also tested its commercialized products asset group for recoverability as of June 30, 2024. The Company determined that the carrying value was not recoverable and therefore estimated the fair value of the asset group using a discounted cash flow analysis. As the carrying value of the asset group significantly exceeded its fair value, the Company recorded a full non-cash impairment charge of \$9.2 million, consisting of \$6.2 million and \$3.0 million for the Zembrace and Tosymra developed technology intangible assets, respectively, which is reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024.

Goodwill

Goodwill represents the excess of the aggregate purchase price over the fair value of the net tangible and intangible assets acquired in a business combination. Goodwill is reviewed for impairment on an annual basis, or more frequently if events or changes in circumstances indicate that the carrying amount of goodwill may be impaired. The Company previously recognized goodwill in connection with the USL Acquisition consummated on June 30, 2023. The Company completed the required annual impairment test for goodwill as of June 30, 2024, which resulted in full non-cash impairment of the Company's \$965,000 of goodwill, which is reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024.

Leases

The Company determines if an arrangement is, or contains, a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, operating lease liabilities, current and operating lease liabilities, noncurrent in the Company's consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the transition date and subsequent lease commencement dates in determining the present value of lease payments. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The operating lease ROU asset excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments made under operating leases is recognized on a straight-line basis over the lease term.

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Deferred financing costs

Deferred financing costs represent the cost of obtaining financing arrangements and are amortized over the term of the related debt agreement using the effective interest method. Deferred financing costs related to term debt arrangements are reflected as a direct reduction of the related debt liability on the condensed consolidated balance sheet. Amortization of deferred financing costs are included in interest expense on the consolidated statements of operations.

Revenue Recognition

The Company records and recognizes revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company's revenues primarily result from contracts with customers, which are generally short-term and have a single performance obligation - the delivery of product. The Company's performance obligation to deliver products is satisfied at the point in time that the goods are received by the customer, which is when the customer obtains title to and has the risks and rewards of ownership of the products, which is generally upon shipment or delivery to the customer as stipulated by the terms of the sale agreements. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Our contractual payment terms are typically 30 to 90 days.

Revenues from product sales, net of gross-to-net deductions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring and when the uncertainty associated with gross-to-net deductions is subsequently resolved. Taxes assessed by governmental authorities and collected from customers are excluded from product sales. Shipping and handling activities are considered to be fulfillment activities and not a separate performance obligation.

Many of the Company's products sold are subject to a variety of deductions. Revenues are recognized net of estimated rebates and chargebacks, cash discounts, distributor fees, sales return provisions and other related deductions. Deductions to product sales are referred to as gross-to-net deductions and are estimated and recorded in the period in which the related product sales occur. Accruals for these provisions are presented in the consolidated financial statements as reductions to gross sales in determining net sales, and as a contra asset within accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). Amounts recorded for revenue deductions can result from a complex series of judgements about future events and uncertainties and can rely heavily on estimates and assumptions. The following section briefly describes the nature of the Company's provisions for variable consideration and how such provisions are estimated:

Chargebacks - The Company sells a portion of its products indirectly through wholesaler distributors, and enters into specific agreements with these indirect customers to establish pricing for the Company's products, and in-turn, the indirect customers and entities independently purchase these products. Because the price paid by the indirect customers and/or entities is lower than the price paid by the wholesaler, the Company provides a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and the wholesale customer's purchase price. The Company's provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to the indirect customers and estimated wholesaler inventory levels as well as historical chargeback rates. The Company continually monitors its reserve for chargebacks and adjusts the reserve accordingly when expected chargebacks differ from actual experience.

Rebates - The Company participates in certain government and specific sales rebate programs which provides discounted prescription drugs to qualified recipients, and primarily relate to Medicaid and managed care rebates in the U.S., pharmacy rebates, Tri-Care rebates and discounts, specialty pharmacy program fees and other governmental rebates or applicable allowances.

- Managed Care Rebates are processed in the quarter following the quarter in which they are earned. The managed care reporting entity submits utilization data after the end of the quarter and the Company processes the payment in accordance with contract terms. All rebates earned but not paid are estimated by the Company according to historical payments trended for market growth assumptions.
- Medicaid and State Agency rebates are based upon historical experience of claims submitted by various states. The Company monitors Medicaid legislative changes to determine what impact such legislation may have on the provision for Medicaid rebates. The accrual of State Agency reserves is based on historical payment rates. There is an approximate three-month lag from the time of product sale until the rebate is paid.
- Tri-Care represents a regionally managed health care program for active duty and retired members, dependents and survivors of the US military. The Tri-Care program supplements health care resources of the US military with civilian health care professionals for greater access and quality healthcare coverage. Through the Tri-Care program, the Company provides pharmaceuticals on a direct customer basis. Prices of pharmaceuticals sold under the Tri-Care program are pre-negotiated and a reserve amount is established to represent the proportionate rebate amount associated with product sales.

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- Coverage Gap refers to the Medicare prescription drug program and represents specifically the period between the initial Medicare Part D prescription drug program coverage limit and the catastrophic coverage threshold. Applicable pharmaceutical products sold during this coverage gap timeframe are discounted by the Company. Since the nature of the program is that coverage limits are reset at the beginning of the calendar year; the payments escalate each quarter as the participants reach the coverage limit before reaching the catastrophic coverage threshold. The Company has determined that the cost of this reserve will be viewed as an annual cost. Therefore, the accrual will be incurred evenly during the year with quarterly review of the liability based on payment trends and any revision to the projected annual cost.

Prompt-Pay and other Sales Discounts - The Company provides for prompt pay discounts, which early payments are recorded as a reduction of revenue and as a reduction in the accounts receivable at the time of sale based on the customer's contracted discount rate. Consumer sales discounts represent programs the Company has in place to reduce costs to the patient. This includes copay buy down and eVoucher programs.

Product Returns - Consistent with industry practice, the Company offers customers a right to return any unused product. The customer's right of return commences typically six months prior to product expiration date and ends one year after product expiration date. Products returned for expiration are reimbursed at current wholesale acquisition cost or indirect contract price. The Company estimates the amount of its product sales that may be returned by the Company's customers and accrues this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company estimates products returns as a percentage of sales to its customers. The rate is estimated by using historical sales information, including its visibility and estimates into the inventory remaining in the distribution channel. Adjustments are made to the current provision for returns when data suggests product returns may differ from original estimates.

Research and Development Costs

The Company outsources certain of its research and development efforts and expenses these costs as incurred, including the cost of manufacturing products for testing, as well as licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired has been expensed as research and development costs, as such property is related to particular research and development projects and had no alternative future uses.

The Company estimates its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials.

The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company accounts for trial expenses according to the timing of various aspects of the trial. The Company determines accrual estimates taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed.

During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Government Grants

From time to time, the Company may enter into arrangements with governmental entities for the purpose of obtaining funding for research and development activities. The Company is reimbursed for costs incurred that are associated with specified research and development activities included in the grant application approved by the government authority and, in certain arrangements, U.S. GAAP does not have specific accounting standards covering government grants to business entities. The Company applies International Accounting Standards 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance by analogy when accounting for government grants.

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Under IAS 20, government grants are initially recognized when there is reasonable assurance the conditions of the grant will be met and the grant will be received. After initial recognition, government grants received are recognized in earnings in the same period the underlying costs for which the grant is intended to compensate are incurred. The Company classifies government grants received under these arrangements as either a reduction to the related research and development expense or as grant income in the consolidated statements of operations, depending on the fee structure of the arrangement. The Company also applies the disclosure requirements of ASC 832, Government Assistance.

In August 2022, the Company received a Cooperative Agreement grant from the National Institute on Drug Abuse (“NIDA”), part of the National Institutes of Health, to support the development of its TNX-1300 product candidate for the treatment of cocaine intoxication. During the three and nine months ended September 30, 2025, the Company recorded \$0 and \$0.6 million in funding as a reduction of related research and development expense. During the three and nine months ended September 30, 2024, the Company received \$0.6 million and \$1.1 million, respectively, in funding as a reduction of related research and development expense.

In June 2024, the Company was awarded a prototype Other Transaction Agreement from the Defense Threat Reduction Agency (“DTRA”), an agency within the U.S. Department of Defense, to fund the Company’s TNX-4200 program for the development of a small molecule broad-spectrum antiviral for the prevention or treatment of viral infections to improve the medical readiness of military personnel in biological threat environments. The DTRA grant provides for payments totaling up to \$34.1 million over five years, which is subject to adjustment based on costs, scope, budget, and other factors as the program advances. Funding under the DTRA grant is earned and recognized under a cost-plus-fixed-fee arrangement in which the Company is reimbursed for all direct costs incurred plus allowable indirect costs and a fixed fee. During the three and nine months ended September 30, 2025, \$1.0 million and \$2.9 million, respectively, was recognized in grant income related to the DTRA grant. As of September 30, 2025, \$1.0 million of the grant income, included above, was earned but not yet received and is presented in Prepaid expenses and other current assets. During the three and nine months ended September 30, 2024, \$1.7 million was recognized in grant income related to the DTRA grant.

Stock-based Compensation

All stock-based payments to employees and to nonemployees for their services, including grants of restricted stock units (“RSUs”), and stock options, are measured at fair value on the grant date and recognized in the consolidated statements of operations as compensation expense over the requisite service period. The Company accounts for share-based awards in accordance with the provisions of the Accounting Standards Codification (“ASC”) 718, Compensation – Stock Compensation.

Foreign Currency Translation

Operations of the Company’s Canadian subsidiary, Tonix Pharmaceuticals (Canada), Inc., are conducted in local currency, which represents its functional currency. The U.S. dollar is the functional currency of the other foreign subsidiaries. Balance sheet accounts of the Canadian subsidiary were translated from foreign currency into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated at the average rate of exchange prevailing during the period. Translation adjustments resulting from this process were included in accumulated other comprehensive loss on the consolidated balance sheets.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business during a period from transactions and other events and circumstances from non-owners sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. Other comprehensive income (loss) represents foreign currency translation adjustments.

Income Taxes

Deferred income tax assets and liabilities are determined based on the estimated future tax effects of net operating loss and credit carryforwards and temporary differences between the tax basis of assets and liabilities and their respective financial reporting amounts measured at the current enacted tax rates. The Company records a valuation allowance on its deferred income tax assets if it is not more likely than not that these deferred income tax assets will be realized.

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The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. As of September 30, 2025, the Company has not recorded any unrecognized tax benefits. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the United States. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company assessed the changes and concluded that they were not material.

Derivative Instruments and Warrant Liabilities

The Company evaluates all of its financial instruments, including issued warrants to purchase common stock under ASC 815 – Derivatives and Hedging, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives (See Note 13). For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The Company uses the Black-Scholes option pricing model to value the derivative instruments at inception and subsequent valuation dates, which is adjusted for instrument-specific terms as applicable.

From time to time, certain equity-linked instruments may be classified as derivative liabilities due to the variable exercise price of the shares to fully settle the equity-linked financial instruments in shares. In such case, the Company has adopted a sequencing approach under ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity to determine the classification of its contracts at issuance and at each subsequent reporting date.

In the event that reclassification of contracts between equity and assets or liabilities is necessary, the Company first allocates remaining authorized shares to equity on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest issuance date receiving the first allocation of shares. In the event of identical issuance dates, shares are then allocated to equity beginning with instruments with the latest maturity date first.

The classification of derivative instruments is reassessed at each reporting date. If the classification changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified. During the three and nine months ended September 30, 2025, the Company recorded \$0 and \$2.0 million, respectively, in issuance costs related to the equity line of credit with Lincoln Park Capital Fund, LLC ("Lincoln Park"). These costs were expensed, and are included in other expense, net on the condensed consolidated statement of operations, as the equity line qualified as a derivative instrument.

The Company evaluated the contract that includes the right to require Lincoln Park to purchase shares of Common Stock in the future ("purchased put right") considering the guidance in ASC 815-40, and concluded that it is an equity-linked contract that does not qualify for equity classification, and therefore requires fair value accounting as a derivative asset (liability). The Company has analyzed the terms of the purchased put right and has concluded that it had insignificant value as of September 30, 2025.

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Per Share Data

The computation of basic and diluted loss per share for the quarters ended September 30, 2025 and 2024 excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

All warrants issued participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing EPS, these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. Prefunded warrants are assumed exercised on date of issuance and are included in the basic EPS calculation. No income was allocated to the warrants for the three and nine months ended September 30, 2025, and 2024, as results of operations were a loss for the periods.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share, as of September 30, 2025 and 2024, are as follows:

	2025	2024
Warrants to purchase common stock	26,239	63,072
Options to purchase common stock	1,139,202	3,895
Totals	<u>1,165,441</u>	<u>66,967</u>

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which requires entities to disclose disaggregated information about their effective tax rate reconciliations as well as expanded information on income taxes by jurisdiction. The standard is effective for fiscal years beginning after December 15, 2024 on a prospective basis. The Company discloses its income tax rate reconciliation in its annual consolidated financial statements only and does not expect the adoption to have a material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

In March 2024, the SEC adopted new rules relating to the disclosure of a range of climate-change-related physical and transition risks, data, and opportunities. The adopted rule contains several new disclosure obligations, including, (i) disclosure on how the board of directors and management oversee climate-related risks and certain climate-related governance items, (ii) disclosure of information related to a registrant's climate-related targets, goals, and/or transition plans, and (iii) disclosure on whether and how climate-related events and transition activities impact line items above a threshold amount on a registrant's consolidated financial statements, including the impact of the financial estimates and the assumptions used. This new rule will first be effective in the Company's disclosures for the year ending December 31, 2027. The Company is in the process of assessing the impact on our consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, to improve transparency in financial reporting by requiring entities to present more detailed information about the nature of expenses included within the Income Statement. The guidance will first be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2024-03 on our financial statements.

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NOTE 3 – INVENTORY

The components of inventory consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
	(in thousands)	
Raw Materials	\$ 2,482	\$ 3,071
Work-in-process	1,486	213
Finished Goods	1,761	5,124
Total Inventory	<u>\$ 5,729</u>	<u>\$ 8,408</u>

NOTE 4 – PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
	(in thousands)	
Property and equipment, net:		
Land	\$ 8,011	\$ 8,011
Land improvements	305	305
Buildings	24,504	24,504
Office furniture and equipment	1,567	1,371
Laboratory equipment	13,687	12,124
Leasehold improvements	34	34
Property and equipment gross	<u>48,108</u>	<u>46,349</u>
Less: Accumulated depreciation and amortization	<u>(5,534)</u>	<u>(4,097)</u>
Property and equipment, net	<u>\$ 42,574</u>	<u>\$ 42,252</u>

NOTE 5 – GOODWILL AND INTANGIBLE ASSETS

The following table provides the gross carrying amount and accumulated amortization for each major class of intangible asset:

	September 30, 2025	December 31, 2024
	(in thousands)	
Intangible assets subject to amortization		
Developed technology	\$ —	\$ 10,100
Less: Impairment charge	—	9,147
Less: Accumulated amortization	—	953
Total	<u>\$ —</u>	<u>\$ —</u>
Intangible assets not subject to amortization Internet domain rights	<u>\$ 120</u>	<u>\$ 120</u>
Total intangible assets, net	<u>\$ 120</u>	<u>\$ 120</u>

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NOTE 6 – FAIR VALUE MEASUREMENTS

Fair value measurements affect the Company’s accounting for certain of its financial assets. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured according to a hierarchy that includes:

- Level 1: Observable inputs, such as quoted prices in active markets.
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly. Level 2 assets and liabilities include debt securities with quoted market prices that are traded less frequently than exchange-traded instruments. This category includes U.S. government agency-backed debt securities and corporate-debt securities.
- Level 3: Unobservable inputs in which there is little or no market data.

As of September 30, 2025, and December 31, 2024, the Company used Level 1 quoted prices in active markets to value cash equivalents of \$97.6 million and \$24,000, respectively. The Company did not have any Level 2 or Level 3 assets or liabilities as of September 30, 2025. The Company received stockholder approval to increase the number of authorized shares on January 25, 2024, at which time previous liability classified Series D Warrants and the Series C Warrants met all requirements for equity classification, and, as a result, the Company reclassified them to equity as of January 25, 2024.

The Company used the Black-Scholes option pricing model to estimate the fair value of the Series D Warrants and the Series C Warrants using significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. For periods prior to the receipt of stockholder approval, the fair value was then adjusted by applying a discount for lack of marketability (“DLOM”) based on the expected timing of receipt of stockholder approval to increase the number of authorized shares and to allow the Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635. Additionally, between April 1, 2024 and May 22, 2024, Level 3 liabilities included a portion of the Company’s outstanding August 2023 Warrants, Series A Warrants, Series B Warrants, Series C Warrants, and Series D Warrants (collectively, the “Existing Warrants”), as a result of certain Warrant Amendments entered into upon the closing of an equity financing on April 1, 2024, which provided for adjustments to the exercise prices of the Existing Warrants, contingent on approval by the Company’s stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635. The Company determined that the exercise price adjustment provision that is contingent on stockholder approval precluded the Existing Warrants from being indexed to the Company’s own stock, and therefore were reclassified to liabilities at post-modification fair value on April 1, 2024. After the Company received stockholder approval on May 22, 2024, thereby reducing the exercise prices of each of the Existing Warrants to \$10.56 per share, the Existing Warrants met all requirements for equity classification and the Company reclassified them to equity as of May 22, 2024. To estimate the fair value of the Existing Warrants on the reclassification dates, the Company used a Black-Scholes option pricing model, probability weighted for different scenarios as applicable.

The following table summarizes the range of significant assumptions used in determining the fair value of liability-classified warrants on the respective reclassification dates for the nine months ended September 30, 2024:

	Nine months ended September 30, 2024
Common stock price	\$ 6.080 - 9.888
Risk-free rate	4.01% - 5.37%
Expected term (in years)	0.86 - 5.00
Expected volatility	105.00% - 120.00%
Discount for lack of marketability	N/A

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A reconciliation of the beginning and ending balances for the liability-classified warrants measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the three and nine months ended September 30, 2024:

	Warrant liabilities
Balance at December 31, 2023	\$ 22,855
Fair value - mark to market adjustment	(7,005)
Warrants reclassified from liabilities to equity	(15,850)
Balance at March 31, 2024	\$ —
Warrants reclassified from equity to liabilities	9,977
Fair value - mark to market adjustment	855
Warrants reclassified from liabilities to equity	(10,832)
Balance at June 30, 2024	\$ —
Warrants reclassified from equity to liabilities	—
Fair value - mark to market adjustment	—
Warrants reclassified from liabilities to equity	—
Balance at September 30, 2024	\$ —

For the three and nine months ended September 30, 2024, the Company recognized a change in fair value resulting in a loss of \$0 million and gain of \$6.2 million, respectively, related to the liability-classified warrants prior to meeting the criteria for equity classification.

There were no liability-classified warrants measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three or nine months ended September 30, 2025. Changes in the fair value of the liability-classified warrants are recognized as a separate component in the consolidated statement of operations.

NOTE 7 – OTHER BALANCE SHEET INFORMATION

Components of selected captions in the consolidated balance sheets consist of:

	September 30, 2025	December 31, 2024
	(in thousands)	
Prepaid expenses and other current assets:		
Contract-related	\$ 1,668	\$ 881
Government grants	982	793
At-the-market receivable	—	2,387
Non-trade receivables	908	953
Debt interest and fees	—	180
Insurance	302	1,392
Prefunded launch costs	1,702	—
PDUFA fees	884	606
Taxes	611	565
Professional fees and other	1,749	378
	<u>\$ 8,806</u>	<u>\$ 8,135</u>
Accrued expenses and other current liabilities:		
Contract-related	\$ 2,670	\$ 1,816
Compensation and compensation-related	1,348	4,496
Gross-to-net deductions	6,289	3,658
Professional fees and other	2,025	697
	<u>\$ 12,332</u>	<u>\$ 10,667</u>

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NOTE 8 – DEBT FINANCING

Long-term debt consists of the following:

	September 30, 2025	December 31, 2024
Term Loan	\$ —	\$ 8,650
Less: current portion	—	(2,820)
Total long-term debt	—	5,830
Less: unamortized debt discount and deferred financing costs	—	(1,163)
Total long-term debt, net	\$ —	\$ 4,667

On December 8, 2023, the Company entered into a Loan and Guaranty Agreement (the “Loan Agreement”) by and among the Company, Krele LLC, Tonix Pharmaceuticals, Inc., Jenner and Tonix R&D Center (collectively, the “Loan Parties”), with JGB Capital, LP, JGB Partners, LP, JGB (Cayman) Port Ellen Ltd., and any other lender from time to time party hereto (collectively, the “Lenders”), and JGB Collateral LLC, as administrative agent and collateral agent for the Lenders (in such capacity, “JGB Agent”) for a 36-month term loan (the “Term Loan”) in the aggregate principal amount of \$11.0 million, with a maturity date of December 8, 2026 (the “Maturity Date”). The Term Loan was funded with an original issue discount of 9% of the principal amount of the Term Loan, or \$1.0 million, which was amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

Borrowings under the Term Loan carried interest at a fluctuating rate equal to the greater of (i) the prime rate as defined in the Loan Agreement plus 3.5% and (ii) 12%. Interest was payable monthly in arrears commencing in December 2023. In connection with the Term Loan, the Company deposited into a reserve account \$1.8 million to be used exclusively to fund interest payments related to the Term Loan. The remaining deposit as of December 31, 2024 totaled \$0.2 million, which was reflected in Prepaid expenses and other current assets on the consolidated balance sheet.

Commencing on March 8, 2024 and continuing monthly through the Maturity Date, the outstanding principal was due and payable in monthly installments of \$0.2 million, with the final remaining balance of unpaid principal and interest due and payable on the Maturity Date. In addition, the Company paid a monthly collateral monitoring charge equal to 0.23% of the outstanding principal amount of the term loan as of the date of payment. The Company incurred \$1.1 million in issuance costs, which was amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

The Loan Agreement provided for voluntary prepayments of the Term Loan, in whole or in part, subject to a prepayment premium. The Term Loan was secured by first priority security interests in the Company’s R&D Center in Frederick, Maryland, the Advanced Development Center in North Dartmouth, Massachusetts, and substantially all of the relevant deposit accounts.

During the first quarter of 2025, the Company paid \$9.6 million as a result of a pay-off of the above-mentioned loan. The pay-off amount paid by the Company in connection with the termination of the Loan Agreement was pursuant to a pay-off letter and includes a prepayment fee of \$1.0 million in accordance with the terms and provisions of the Loan Agreement. In connection with the pay-off of the loan, the Company incurred a loss on extinguishment of the debt amounting to \$0 and \$2.1 million, respectively, during the three and nine months ended September 30, 2025.

NOTE 9 – STOCKHOLDERS’ EQUITY

On February 5, 2025, the Company effected a 1-for-100 reverse stock split of its issued and outstanding shares of common stock, whereby 559,044,486 outstanding shares of the Company’s common stock were exchanged for 5,590,667 shares of the Company’s common stock. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split. As a result of the reverse-stock-split, on February 20, 2025, the Company’s stock regained compliance with the minimum bid price requirement of \$1.00 per share for continued listing on the NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(a)(2).

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NOTE 10 – REVENUES

Disaggregation of Net Revenues

The Company's net product revenues are summarized below:

Three months ended September 30,			
	2025		2024
Zembrace Symtouch	\$ 2,582	\$	2,485
Tosymra	708		337
Total product revenues	\$ 3,290	\$	2,822

Nine months ended September 30,			
	2025		2024
Zembrace Symtouch	\$ 6,178	\$	6,059
Tosymra	1,539		1,453
Total product revenues	\$ 7,717	\$	7,512

Gross-to-Net Sales Accruals

We record gross-to-net sales accruals for chargebacks, rebates, sales and other discounts, and product returns, which are all customary to the pharmaceutical industry.

Our provision for gross-to-net allowances was \$7.0 million at September 30, 2025, of which \$0.7 million was recorded as a reduction to accounts receivable and \$6.3 million was recorded as a component of accrued expenses. Our provision for gross-to-net allowances was \$4.8 million at September 30, 2024, of which \$1.0 million was recorded as a reduction to accounts receivable and \$3.8 million was recorded as a component of accrued expenses.

NOTE 11 – ASSET PURCHASE AGREEMENT WITH UPSHER-SMITH

On June 30, 2023, the Company completed the acquisition of certain assets from Upsher Smith related to Zembrace SymTouch (sumatriptan injection) 3 mg (“Zembrace”) and Tosymra (sumatriptan nasal spray) 10 mg (“Tosymra”) products (such businesses collectively, the “Business”) and certain inventory related to the Business for an aggregate purchase price of approximately \$26.5 million, including certain deferred payments (such transaction, the “USL Acquisition”). The Company paid the \$3.0 million deferred payment to Upsher Smith in April 2024.

The Company has assumed certain obligations of Upsher Smith, including the payment of quarterly royalty payments on annual net sales from the Business in the U.S. as follows: for Tosymra, 4% for net sales of \$0 to \$30 million, 7% of net sales of \$30 to \$75 million; 9% for net sales of \$75 to \$100 million; 12% for net sales of \$100 to \$150 million; and 15% for net sales greater than \$150 million. Royalty payments with respect to Tosymra are payable until the expiration or termination of the product's Orange Book listed patent(s) with respect to the United States or, outside the United States, the expiration of the last valid claim covering the product in the relevant country of the territory.

For Zembrace, royalty payments on annual net sales in the U.S. are 3% for net sales of \$0 to \$30 million, 6% of net sales of \$30 to \$75 million; 12% for net sales of \$75 to \$100 million; 16% for net sales of greater than \$100 million. Such royalty payments were payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable royalty rates shall be reduced by 90% percent with respect to Zembrace, and by 66.7% percent for Tosymra. Prior to Purchaser or a licensee filing an application for marketing authorization for either of the products in a permitted country outside the U.S., the parties will negotiate in good faith the royalty payment rates annual net sales tiers that will apply for such country, based on the market opportunity for the product in such country. If the parties fail to agree, then the royalty payment rates and annual net sales tiers described above will apply.

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In addition, the Company has assumed the obligation to pay an additional 3% royalty on net sales of Tosymra, plus an additional 3% if a patent containing certain claims related to Tosymra issues in the U.S., for 15 years from the first commercial sale of Tosymra in the applicable country or for as long as the manufacture, use or sale of Tosymra in such country is covered by a valid claim of a licensed patent, and up to \$15 million per Tosymra product on the achievement of sales milestones.

NOTE 12 – LICENSE AGREEMENTS WITH UMASS

On June 26, 2025, Tonix obtained an exclusive worldwide license from UMass Chan Medical School for the development of TNX-4800 (formerly known as mAb 2217LS). As of September 30, 2025, other than the upfront fee of \$1.3 million, no payments have been accrued or paid in relation to this agreement.

NOTE 13 – SALE AND PURCHASE OF COMMON STOCK

2025 Lincoln Park Transaction

On June 11, 2025, the Company entered into a purchase agreement (the “2025 Purchase Agreement”) and a registration rights agreement (the “2025 Registration Rights Agreement”) with Lincoln Park. Pursuant to the terms of the 2025 Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to \$75,000,000 of the Company’s common stock (subject to certain limitations) from time to time during the term of the 2025 Purchase Agreement. Pursuant to the terms of the 2025 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2025 Purchase Agreement.

Pursuant to the terms of the 2025 Purchase Agreement, at the time the Company signed the 2025 Purchase Agreement and the 2025 Registration Rights Agreement, the Company issued 48,708 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company’s common stock under the 2025 Purchase Agreement. The commitment shares were valued at \$1.8 million and recorded as an addition to equity for the issuance of the common stock and treated as other expense, net on the condensed consolidated statement of operations under the 2025 Purchase Agreement. No shares were sold during the three and nine months ended September 30, 2025, under the 2025 Purchase Agreement.

The Company evaluated the 2025 Purchase Agreement under ASC 815-40 *Derivatives and Hedging-Contracts on an Entity’s Own Equity* as it represents the right to require Lincoln Park to purchase shares of common stock in the future, similar to a put option. The Company concluded that the 2025 Purchase Agreement represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. The Company analyzed the terms of the contract and concluded that the derivative instrument had insignificant value as of September 30, 2025.

2025 At-the-Market Offerings

On June 11, 2025, the Company entered into a Sales Agreement (the “2025 Sales Agreement”), with A.G.P./Alliance Global Partners (“AGP”) pursuant to which the Company may issue and sell, from time to time, shares of common stock having an aggregate offering price of up to \$150.0 million in sales. AGP is sales agent under the ATM and paid a 3% commission on each sale under the 2025 Sales Agreement. The Company’s common stock is sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During both the three and nine months ended September 30, 2025, the Company sold 1.7 million shares of common stock under the 2025 Sales Agreement, for net proceeds of approximately \$55.7 million. Subsequent to September 30, 2025, the Company sold 1.6 million shares of common stock under the 2025 Sales Agreement, for net proceeds of approximately \$34.7 million.

2024 At-the-Market Offerings

On July 30, 2024, the Company entered into a Sales Agreement (the “2024 Sales Agreement”), with AGP pursuant to which the Company may issue and sell, from time to time, shares of common stock having an aggregate offering price of up to \$250.0 million in sales. AGP is sales agent under the ATM and paid a 3% commission on each sale under the 2024 Sales Agreement. The Company’s common stock is sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the three and nine months ended September 30, 2025, the Company sold approximately 0.9 million and 4.5 million shares, respectively, of common stock under the Sales Agreement for net proceeds of approximately \$37.5 million and \$112.9 million, respectively. The Company can no longer sell shares under the 2024 Sales Agreement as the Company has reached the aggregate \$250 million in sales.

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July 2024 Financing

On July 9, 2024, the Company entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which the Company sold 33,936 shares of common stock and pre-funded warrants to purchase up to 37,032 shares of common stock. The offering price per share of common stock was \$57.00, and the offering price per share of pre-funded warrant was \$56.99.

The offering closed on July 10, 2024. The Company incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. The Company received net proceeds of approximately \$3.5 million, after deducting the underwriting discount and other offering expenses.

June 2024 Financings

On June 12, 2024, the Company entered into a securities purchase agreement with certain investors, pursuant to which the Company sold 11,995 shares of common stock and pre-funded warrants to purchase up to 25,682 shares of common stock. The offering price per share of common stock was \$106.50, and the offering price per share of pre-funded warrant was \$106.40.

The offering closed on June 13, 2024. The Company incurred offering expenses of approximately \$0.6 million, including placement agent fees of approximately \$0.3 million. The Company received net proceeds of approximately \$3.4 million, after deducting the underwriting discount and other offering expenses.

On June 27, 2024, the Company entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which the Company sold 28,339 shares of common stock and pre-funded warrants to purchase up to 42,282 shares of common stock. The offering price per share of common stock was \$57.00, and the offering price per share of pre-funded warrant was \$56.99.

The offering closed on June 28, 2024. The Company incurred offering expenses of approximately \$0.6 million, including placement agent fees of approximately \$0.3 million. The Company received net proceeds of approximately \$3.4 million, after deducting the underwriting discount and other offering expenses.

March 2024 Financing

On March 28, 2024, the Company entered into an agreement to sell 3,365 shares of common stock, pre-funded warrants to purchase up to 1,219 shares of common stock, and accompanying Series E warrants to purchase up to 4,584 shares of common stock with an exercise price of \$1,056.00 per share and expiring five and a half years from date of issuance in a public offering, which closed on April 1, 2024. The offering price per share of common stock was \$960.00, and the offering price per share of pre-funded warrants was \$959.68.

The Company incurred expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. The Company received net proceeds of approximately \$3.9 million, after deducting the underwriting discount and other offering expenses.

Additionally, with the closing of the financing on April 1, 2024, the Company entered into warrant amendments (collectively, the “Warrant Amendments”) with certain holders of its common warrants (referred to herein as the “Existing Warrants”). The Company agreed to amend the exercise price of each Existing Warrant to \$1,056.00 upon approval by the Company’s stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 or, if stockholder approval is not obtained by October 1, 2024, the Company agreed to automatically amend the exercise price of the Existing Warrants to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of the Company’s common stock on October 1, 2024, if and only if the Minimum Price is below the then current exercise price. Upon stockholder approval, the termination date for the warrants issued August 2023 (the “August Warrants”) to purchase up to an aggregate of 2,172 shares was amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2025; the termination date for Series C Warrants to purchase up to an aggregate of approximately 10,884 shares is the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by the Company to the Series C Warrant holders of the Company’s public announcement of the FDA’s acknowledgement and acceptance of the Company’s NDA relating to TNX-102 SL in patients with Fibromyalgia; the termination date for Series D Warrants to purchase up to an aggregate of approximately 10,884 shares is April 1, 2029. The other terms of the Existing Warrants remained unchanged.

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The Company evaluated the Warrant Amendments as of April 1, 2024, and determined that the potential adjustment to the exercise price that is contingent on stockholder approval precluded the Existing Warrants from being indexed to the Company's own stock, and as a result, did not meet the criteria for equity classification under ASC 815-40. The Company accounted for the incremental fair value of the Warrant Amendments of \$3.0 million as a direct and incremental cost of the March 2024 financing as an offset to the proceeds received. As all of the Existing Warrants were equity-classified prior to the Warrant Amendments, the net impact to the consolidated statement of stockholders' equity was zero. The Company then reclassified the Existing Warrants from equity to liabilities at post-modification fair value on April 1, 2024. On May 22, 2024, the date the Company's stockholders approved the proposal to fix the exercise prices at \$1,056.00 per share, the Existing Warrants were adjusted to fair value and reclassified back to equity.

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The liability-classified Series D Warrants and all of the Series C Warrants were presented within non-current liabilities on the consolidated balance sheets as of December 31, 2023, and were adjusted to fair value through January 25, 2024, when the warrants were reclassified to equity. Changes in the fair value of the liability-classified warrants were recognized as a separate component in the consolidated statement of operations.

Stock repurchases

In September 2024, the Board of Directors approved a 2024 share repurchase program pursuant to which the Company may repurchase up to \$10.0 million in value of its outstanding common stock from time to time on the open market and in privately negotiated transactions subject to market conditions, share price and other factors. No repurchases occurred during the three months ended September 30, 2025.

During the nine months ended September 30, 2025, the Company repurchased 400,000 shares of its common stock outstanding under the 2024 share repurchase at prices ranging from \$9.98 to \$20.47 per share for a gross aggregate cost of approximately \$5.9 million. The repurchased shares were immediately retired.

The Company repurchased the following capital stock:

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Total cost of repurchased shares (in thousands)	\$ 5,949	\$ —
Shares repurchased	400,000	—
Weighted average price per share	\$ 14.84	\$ —

The timing and amount of any shares repurchased will be determined based on the Company's evaluation of market conditions and other factors and the New Share Repurchase Program may be discontinued or suspended at any time. Repurchases will be made in accordance with the rules and regulations promulgated by the Securities and Exchange Commission and certain other legal requirements to which the Company may be subject. Repurchases may be made, in part, under a Rule 10b5-1 plan, which allows stock repurchases when the Company might otherwise be precluded from doing so.

NOTE 14 – STOCK-BASED COMPENSATION

On May 1, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan ("Amended and Restated 2020 Plan").

Under the terms of the Amended and Restated 2020 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights ("SARs"), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 50,000 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). On May 8, 2025, the Company's stockholders approved the addition of 1,000,000 shares to the Company's Amended and Restated 2020 Plan.

The Board of Directors determines the exercise price, vesting and expiration period of the grants under the Amended and Restated 2020 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the expiration period of grants under the Amended and Restated 2020 Plan may not be more than ten years. As of September 30, 2025, there were 737,782 options available for future grants under the Amended and Restated 2020 Plan.

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General

A summary of the stock option activity and related information for the Plans for the nine months ended September 30, 2025, is as follows:

	Shares	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2024	3,865	\$ 27,540,609	8.74	\$ —
Grants	1,157,841	13.79		12,121,775
Exercised	—	—		
Forfeitures or expirations	(22,504)	1,895,690		
Outstanding at September 30, 2025	1,139,202	\$ 54,931	9.49	\$ 12,125,600
Exercisable at September 30, 2025	2,686	\$ 19,116,393	7.97	\$ 1,278

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price at the respective dates.

The weighted average fair value of options granted during the three and nine months ended September 30, 2025 was \$31.62 per share and \$12.72 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 30, 2024 was \$15.24 per share and \$867.96 per share, respectively.

The Company measures the fair value of stock options on the date of grant, based on the Black Scholes option pricing model using certain assumptions discussed below, and the closing market price of the Company's common stock on the date of the grant. The fair value of the award is measured on the grant date. One-third of most stock options granted pursuant to the Plans vest 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, the Company issues options to directors which vest over a one-year period. The Company also issues premium options to executive officers which have an exercise price greater than the grant date fair value and has issued performance-based options which vest when target parameters are met or probable of being met, subject in each case to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable service period using the straight-line method.

The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2025, and 2024 were as follows:

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Risk-free interest rate	3.81% to 4.30%	3.58% to 5.33%
Expected term of option	5.50 to 6.08 years	5.25 to 10.00 years
Expected stock price volatility	149.34% to 153.44%	111.89% - 140.42%
Expected dividend yield	0.0	0.0

The risk-free interest rate is based on the yield of Daily U.S. Treasury Yield Curve Rates with terms equal to the expected term of the options as of the grant date. The expected term of options is determined using the simplified method, as provided in an SEC Staff Accounting Bulletin, and the expected stock price volatility is based on the Company's historical stock price volatility.

Stock-based compensation expense relating to options granted of \$1.8 million, of which \$1.2 million and \$0.6 million, related to Selling, General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2025. Stock-based compensation expense relating to options granted of \$1.0 million, of which \$0.7 million and \$0.3 million, related to Selling, General and Administration and Research and Development, respectively, was recognized for the quarter ended September 30, 2024.

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Stock-based compensation expense relating to options granted of \$4.1 million, of which \$2.8 million and \$1.3 million, related to Selling, General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2025. Stock-based compensation expense relating to options granted of \$3.9 million, of which \$2.8 million and \$1.1 million, related to Selling, General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2024. As of September 30, 2025, the Company had approximately \$13.6 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 2.89 years.

Employee Stock Purchase Plans

On May 5, 2023, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2023 Employee Stock Purchase Plan. (the "2023 ESPP"), which was replaced by the Tonix Pharmaceuticals Holdings Corp. 2025 Employee Stock Purchase Plan (the "2025 ESPP", and together with the 2023 ESPP, the "ESPP Plans"), which was approved by the Company's stockholders on May 8, 2025.

The 2025 ESPP allows eligible employees to purchase up to an aggregate of 2,000,000 shares of the Company's common stock. Under the 2025 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of the Company's common stock at the end of the offering period. Each offering period under the 2025 ESPP is for six months, which can be modified from time to time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee's accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2025 ESPP, subject to the statutory limit under the Code.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 250 shares of the Company's common stock. Under the 2023 ESPP, on the first day of each offering period, each employee eligible for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of the Company's common stock at the end of the offering period. Each offering period under the 2023 ESPP is for six months, which can be modified from time-to-time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee's accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2023 ESPP, subject to the statutory limit under the Code. As of September 30, 2025, 159 shares were available for future sales under the 2023 ESPP and 2,000,000 shares were available under the 2025 ESPP.

The ESPP Plans are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the nine months ended September 30, 2025, and 2024, \$84,000 and \$27,000, respectively, was expensed. In January 2024, 21 shares that were purchased as of December 31, 2023, under the 2022 ESPP, were issued. As of June 30, 2024, approximately \$33,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In July 2024, 70 shares that were purchased as of June 30, 2024, under the 2022 ESPP, were issued. As of September 30, 2025, approximately \$57,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses.

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NOTE 15 – WARRANTS TO PURCHASE COMMON STOCK

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at September 30, 2025:

Exercise Price	Number Outstanding	Expiration Date
\$ 1,056.00	4,585	April 2029
\$ 1,056.00	2,782	April 2029
\$ 1,056.00	2,172	April 2029
\$ 1,056.00	10,884	April 2029
\$ 1,600.00	36	October 2028
\$ 2,720.00	5,758	December 2028
\$ 3,200.00	22	August 2028
	26,239	

During the nine months ended September 30, 2025, 13,666; 5,758 (as the Company received FDA acceptance of our NDA filing), and 1 warrants with an exercise price of \$1,056, \$1,776 and \$364,800, respectively, expired.

During the nine months ended September 30, 2024, 113,155 prefunded common warrants were exercised.

NOTE 16 – LEASES

The Company has various operating lease agreements, which are primarily for office space. These agreements frequently include one or more renewal options and require the Company to pay for utilities, taxes, insurance and maintenance expense. No lease agreement imposes a restriction on the Company's ability to engage in financing transactions or enter into further lease agreements. At September 30, 2025, the Company has right-of-use assets of \$0.4 million and a total lease liability for operating leases of \$0.5 million of which \$0.3 million is included in long-term lease liabilities and \$0.2 million is included in current lease liabilities.

At September 30, 2025, future minimum lease payments for operating leases with non-cancelable terms of more than one year were as follows (in thousands):

Year Ending December 31,	
Remainder of 2025	\$ 72
2026	142
2027	139
2028	100
2029	7
	460
Included interest	(35)
	\$ 425

During the nine months ended September 30, 2025, the Company entered into a new operating lease and lease amendments. The lease commencement is expected during the fourth quarter of 2025, at which time the Company expects to recognize an additional operating lease liability of approximately \$1.3 million based on the present value of the minimum rental payments. The above table does not include future lease payments as the Company has not commenced the lease. The Company also expects to recognize a corresponding increase to ROU assets of approximately \$1.3 million, which will represent a non-cash investing and financing activity. No new leases or amendments were entered into during the nine months ended September 30, 2024.

Operating lease expenses were \$0.1 million for each of the three months ended September 30, 2025, and September 30, 2024.

Operating lease expenses were \$0.2 million for each of the nine months ended September 30, 2025, and September 30, 2024.

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Other information related to leases is as follows:

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow from operating leases (in thousands)	\$ 208	\$ 222
Weighted Average Remaining Lease Term		
Operating leases	2.80 years	3.26 years
Weighted Average Discount Rate		
Operating leases	5.53%	4.81%

NOTE 17 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$22.7 million at September 30, 2025 for future work to be performed.

The Company has entered into various exclusive license agreements with various institutions with the right to sublicense, certain patents, technical information and material, and to develop and commercialize products thereunder. In addition to any upfront payments already paid, the Company may be obligated to pay milestone fees ranging from \$0.4 million to \$5.0 million based on the potential achievement of certain development milestones, as well as milestone fees ranging from \$1.0 million to \$20.0 million based on certain potential commercial achievements, as specified in the respective license agreement. Additionally, for licensed products sold during the applicable royalty term, the Company must pay royalties in the low-to-mid single digits, beginning in the year after the Company completes its first commercial sale of a licensed product. Finally, the Company has the right to grant sublicenses to third parties under each license agreement and is required to pay a sublicense income share based on the stage of development of the licensed product at the time the sublicense is granted.

The Company established a qualified defined contribution plan (the “401(k) Plan”) pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) Plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 100 percent of each participant’s pretax contributions of up to six percent of his or her eligible compensation. The Company charged operations \$0.1 million and \$0.5 million for the three and nine months ended September 30, 2025, respectively, and \$0.1 million and \$0.6 million for the three and nine months ended September 30, 2024, respectively, for contributions under the 401(k) Plan.

NOTE 18 – SUBSEQUENT EVENTS

Subsequent to September 30, 2025, the Company sold 1.6 million shares of common stock under the 2025 Sales Agreement, for net proceeds of approximately \$34.7 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a number of forward-looking statements that reflect Management's current views with respect to future events and financial performance. You can identify these statements by forward-looking words such as "may" "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. Those statements include statements regarding the intent, belief or current expectations of us and members of its management team as well as the assumptions on which such statements are based. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risk and uncertainties, and that actual results may differ materially from those contemplated by such forward-looking statements.

Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission. Important factors known to us could cause actual results to differ materially from those in forward-looking statements. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes in the future operating results over time. We believe that its assumptions are based upon reasonable data derived from and known about our business and operations. No assurances are made that actual results of operations or the results of our future activities will not differ materially from its assumptions. Factors that could cause differences include, but are not limited to: the ability to commercialize our approved products; substantial competition; 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 risks related to failure to obtain clearances or approvals from the United States Food and Drug Administration, or FDA, and noncompliance with FDA regulations.

Business Overview

We are a fully-integrated, commercial-stage biotechnology company with marketed products and a pipeline of development candidates.

Our marketed products include TonmyaTM (cyclobenzaprine HCl sublingual tablets), a first-in-class, non-opioid analgesic medicine for the treatment of fibromyalgia, for which we received approval in August 2025 by the U.S. Food and Drug Administration (FDA). Fibromyalgia is a chronic pain condition that affects millions of adults, the majority of whom are women. Tonmya is the first new prescription medicine for fibromyalgia approved by the FDA in more than 15 years. We expect to launch Tonmya in the U.S. before the end of November 2025. We also market two treatments for acute migraine in adults, Zembrace® SymTouch® (sumatriptan injection) and Tosymra® (sumatriptan nasal spray).

Our development pipeline is focused on central nervous system (CNS) disorders, immunology, immuno-oncology, rare disease and infectious disease. Within CNS, TNX-102 SL is being studied to treat acute stress reaction and acute stress disorder under an Investigator-Initiated Investigational New Drug Application ("IND") at the University of North Carolina in the OASIS Phase 2 study funded by the U.S. Department of Defense ("DoD"). TNX-102 SL is also in development for major depressive disorder, with us expecting to initiate a potential pivotal Phase 2 study by mid-year 2026, contingent on IND clearance by the FDA. Our immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a dimeric Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of kidney transplant rejection and the treatment of autoimmune diseases. In collaboration with Massachusetts General Hospital ("MGH"), an open-label Phase 2 study of TNX-1500 is planned to initiate in the first half of 2026 to evaluate safety and activity in five kidney transplant recipients, contingent on FDA clearance of an investigator-initiated IND and approval by the institutional review board ("IRB"). Our rare disease portfolio includes TNX-2900, intranasal oxytocin potentiated with magnesium, in development for Prader-Willi syndrome and for which we plan to initiate a Phase 2 study in the second half of 2026. Our infectious disease portfolio includes TNX-801 (recombinant horsepox, live vaccine), a vaccine in development for prevention of mpox and smallpox. We are also developing TNX-4800 (anti-OspA mAb), a long-acting monoclonal antibody for the seasonal prevention of Lyme Disease, and expects to initiate an adaptive Phase2/3 study in 2027. TNX-4800 was licensed from the University of Massachusetts Chan Medical School in 2025. Finally, TNX-4200 for which we have a contract with the U.S. DoD's Defense Threat Reduction Agency ("DTRA") for up to \$34 million over five years, 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. We own and operate a state-of-the art research and development facility in Frederick, Maryland.

Our product development candidates are investigational new drugs or biologics and have not been approved for any indication.

TonmyaTM, Zembrace® SymTouch® and Tosymra® are registered trademarks of Tonix Medicines, Inc. All other marks are the property of their respective owners.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as the sales of Zembrace and Tosymra and ultimately Tonmyra, following launch in November 2025, the progress of our research and development efforts and the timing and outcome of regulatory submissions. Due to these uncertainties, accurate predictions of future operations are difficult or impossible to make.

Three Months Ended September 30, 2025 Compared to Three Months Ended September 30, 2024

The following table sets forth our operating expenses for the quarter ended September 30, 2025 and 2024 (in thousands):

	Three months ended September 30,	
	2025	2024
REVENUE		
Product revenue, net	\$ 3,290	\$ 2,822
COSTS AND EXPENSES:		
Cost of sales	\$ 1,367	\$ 1,555
Research and development	9,289	9,114
Selling, general and administrative	25,701	7,707
Total operating expenses	36,357	18,376
Operating loss	(33,067)	(15,554)
Grant income	982	1,668
Interest income	1,231	18
Interest expense	—	(301)
Other expense, net	(1,156)	(44)
Net loss	\$ (32,010)	\$ (14,213)

Revenues. Revenue recognized for the quarter ended September 30, 2025 and 2024, was \$3.3 million and \$2.8 million, respectively. The increase is predominantly due to increased demand for our marketed migraine products and additional sales representatives.

The Company's net product revenues are summarized below:

	Three months ended September 30,	
	2025	2024
Zembrace Symtouch	\$ 2,582	\$ 2,485
Tosymra	708	337
Total product revenues	\$ 3,290	\$ 2,822

Cost of Sales. Cost of sales recognized for the quarter ended September 30, 2025 and 2024, was \$1.4 million and \$1.6 million, respectively. The decrease is predominantly due to decreased inventory write-offs quarter over quarter.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2025 were \$9.3 million, an increase of \$0.2 million, or 2%, from \$9.1 million for the three months ended September 30, 2024. This increase is predominately due to increased manufacturing expenses of \$2.3 million, non-clinical expenses of \$0.4 million and employee-related expenses of \$0.6 million, as a result of pipeline prioritization period over period, offset by a reduction in clinical expenses of \$2.1 million, regulatory expenses of \$0.3 million and professional fees of \$0.6 million due to a reduction in expenditures.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the three months ended September 30, 2025, and 2024.

	Three months ended September 30, (in thousands)		
	2025	2024	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 33	\$ 525	\$ (492)
Direct expenses – TNX - 801	636	104	532
Direct expenses – TNX - 1500	1,887	743	1,144
Direct expenses – TNX - 1700	285	134	151
Direct expenses – TNX - 1900	405	667	(262)
Direct expenses – Other programs	234	703	(469)
Internal staffing, overhead and other	5,809	6,238	(429)
Total research & development	\$ 9,289	\$ 9,114	\$ 175

Our direct research and development expenses consist principally of external costs for clinical, nonclinical and manufacturing, such as fees paid to contractors, consultants and CROs in connection with our development work. Included in “Internal Staffing, Overhead and Other” is overhead, supplies, research and development employee costs (including stock option expenses), travel, regulatory and legal.

Selling, general and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2025, were \$25.7 million, an increase of \$18.0 million, or 234%, from \$7.7 million incurred in the three months ended September 30, 2024. The increase is primarily due to an increase in sales and marketing of \$13.3 million, employee-related expenses of \$2.5 million, professional expenses of \$1.6 million, and legal expenses of \$0.4 million. All increases are related to our marketed migraine products as well as preparation for the launch of Tonmya in November 2025.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2025 was \$32.0 million, an increase of \$17.8 million, or 125%, compared to a net loss of \$14.2 million for the three months ended September 30, 2024.

Nine Months Ended September 30, 2025 Compared to Nine Months Ended September 30, 2024

The following table sets forth our operating expenses for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine months ended September 30,	
	2025	2024
REVENUE		
Product revenue, net	\$ 7,717	\$ 7,512
COSTS AND EXPENSES:		
Cost of sales	\$ 5,582	\$ 6,582
Research and development	27,545	31,675
Selling, general and administrative	52,007	24,519
Asset impairment charges	—	58,957
Total operating expenses	85,134	121,733
Operating loss	(77,417)	(114,221)
Grant income	2,941	1,668
Gain on change in fair value of warrant liabilities	—	6,150
Loss on extinguishment of debt	(2,092)	—
Interest income	2,802	21
Interest expense	(89)	(954)
Other expense, net	(3,256)	(592)
Net loss	\$ (77,111)	\$ (107,928)

Revenues. Revenue recognized for the nine months ended September 30, 2025 and 2024, was \$7.7 million and \$7.5 million, respectively. The increase is predominantly due to increased demand for our marketed migraine products and additional sales representatives.

The Company's net product revenues are summarized below:

	Nine months ended September 30,	
	2025	2024
Zembrace Symtouch	\$ 6,178	\$ 6,059
Tosymra	1,539	1,453
Total product revenues	<u>\$ 7,717</u>	<u>\$ 7,512</u>

Cost of Sales. Cost of sales recognized for the nine months ended September 30, 2025 and 2024, was \$5.6 million and \$6.6 million, respectively. The decrease is predominantly due to decreased write-offs period over period.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2025 were \$27.5 million, a decrease of \$4.2 million, or 13%, from \$31.7 million for the nine months ended September 30, 2024. This decrease is predominately due to decreased clinical expenses of \$2.9 million, as a result of fewer trials in the clinic and pipeline prioritization period over period, employee-related expenses of \$1.5 million, regulatory expenses of \$1.6 million and office-related expenses of \$2.6 million due to a reduction in expenditures offset by an increase in non-clinical expenses of \$1.5 million and manufacturing expenses of \$2.9 million due to pipeline prioritization.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the nine months ended September 30, 2025, and 2024.

	Nine months ended September 30, (in thousands)		
	2025	2024	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 2,530	\$ 3,513	\$ (983)
Direct expenses – TNX - 801	1,049	723	326
Direct expenses – TNX - 1500	3,271	1,966	1,305
Direct expenses – TNX - 1700	483	388	95
Direct expenses – TNX - 1900	741	1,326	(585)
Direct expenses – TNX - 4800	1,295	—	1,295
Direct expenses – Other programs	2,070	2,083	(13)
Internal staffing, overhead and other	16,106	21,676	(5,570)
Total research & development	<u>\$ 27,545</u>	<u>\$ 31,675</u>	<u>\$ (4,130)</u>

Our direct research and development expenses consist principally of external costs for clinical, nonclinical and manufacturing, such as fees paid to contractors, consultants and contract research organizations in connection with our development work. Included in "Internal Staffing, Overhead and Other" is overhead, supplies, research and development employee costs (including stock option expenses), travel, regulatory and legal.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2025 were \$52.0 million, an increase of \$27.5 million, or 112%, from \$24.5 million incurred in the nine months ended September 30, 2024. The increase is primarily due to an increase in sales and marketing of \$19.9 million, employee-related expenses of \$3.6 million, professional expenses of \$2.6 million, and legal expenses of \$1.1 million. All increases are related to our marketed migraine products as well as preparation for the launch of Tonmya in November 2025.

Asset impairment charges. Reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024, is a non-cash impairment charge of \$48.8 million related to property and equipment, a non-cash impairment of \$1.0 million related to goodwill, and a non-cash impairment charge of \$9.2 million related to intangible assets.

The impairment of the Tosymra and Zembrace inventory, intangibles and goodwill was driven by our delayed investment in the sales personnel required to drive growth in the business as we are focusing our cash resources to further our efforts to bring TNX-102 SL through the approval process and to market. However, we believe that the benefits and long-term value proposition of the 2023 acquisition of Tosymra and Zembrace remain, in that we now have the infrastructure to be ready to manufacture and sell TNX-102 SL under an expedited timeline following FDA approval in August 2025.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2025 was \$77.1 million, a decrease of \$30.8 million, or 29%, compared to a net loss of \$107.9 million for the nine months ended September 30, 2024.

License Agreement

On June 26, 2025, we obtained an exclusive worldwide license from UMass Chan Medical School for the development of TNX-4800 (formerly known as mAb 2217LS). As of September 30, 2025, other than an upfront fee of \$1.3 million, no payments have been accrued or paid in relation to this agreement.

Asset Purchase Agreements

On June 23, 2023, we entered into an asset purchase agreement with Upsher Smith for the acquisition of certain assets related to Zembrace and Tosymra (such businesses collectively, the “Business”) and certain inventory related to the Business for an aggregate purchase price of approximately \$26.5 million, including certain deferred payments (such transaction, the “USL Acquisition”). The transaction closed on June 30, 2023.

We have assumed certain obligations of Upsher Smith, including the payment of quarterly royalty payments on annual net sales from the Business in the U.S. as follows: for Tosymra, 4% for net sales of \$0 to \$30 million, 7% of net sales of \$30 to \$75 million; 9% for net sales of \$75 to \$100 million; 12% for net sales of \$100 to \$150 million; and 15% for net sales greater than \$150 million. Royalty payments with respect to Tosymra are payable until the expiration or termination of the product’s Orange Book listed patent(s) with respect to the United States or, outside the United States, the expiration of the last valid claim covering the product in the relevant country of the territory. For Zembrace, royalty payments on annual net sales in the U.S. are 3% for net sales of \$0 to \$30 million, 6% of net sales of \$30 to \$75 million; 12% for net sales of \$75 to \$100 million; 16% for net sales of greater than \$100 million. Such royalty payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable royalty rates will be reduced by 90% percent for Zembrace, and by 66.7% percent for Tosymra.

In addition, we have assumed the obligation to pay an additional 3% royalty on net sales of Tosymra, plus an additional 3% if a patent containing certain claims related to Tosymra issues in the U.S., for 15 years from the first commercial sale of Tosymra in the applicable country or for as long as the manufacture, use or sale of Tosymra in such country is covered by a valid claim of a licensed patent, and up to \$15 million per Tosymra product on the achievement of sales milestones.

Liquidity and Capital Resources

As of September 30, 2025, we had working capital of \$187.0 million, comprised primarily of cash and cash equivalents of \$190.1 million, accounts receivable, net of \$3.5 million, inventory of \$5.7 million and prepaid expenses and other of \$8.8 million, offset by \$8.5 million of accounts payable, \$12.3 million of accrued expenses, and current lease liabilities of \$0.2 million. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical programs, accruals for gross to net deductions related to our commercial products and product launch of TNX-102 SL.

The following table provides a summary of operating, investing and financing cash flows for the nine months ended September 30, 2025, and 2024, respectively (in thousands):

	September 30,	
	2025	2024
Net cash used in operating activities	\$ (60,194)	\$ (46,295)
Net cash used in investing activities	(3,507)	(117)
Net cash provided by financing activities	155,387	49,718

For the nine months ended September, 2025 and 2024, we used approximately \$60.2 million and \$46.3 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The increase in cash outlays principally resulted from an increase in general and administrative expenses as a result of the potential product launch of TNX-102 SL. For the nine months ended September 30, 2025, net cash provided from financing activities was \$155.4 million and \$49.7 million, respectively predominately from the issuance of common stock. Cash used in investing activities for the nine months ended September 30, 2025, was \$3.5 million related to the issuance of a note and purchase of property and equipment. Cash used in investing activities for the nine months ended September 30, 2024, was \$0.1 million related to the purchase of property and equipment.

We believe that our cash resources at September 30, 2025, and the proceeds that we received from the sales of equity during the fourth quarter of 2025, will meet our operating and capital expenditure requirements into the first quarter of 2027.

We continue to face significant challenges and uncertainties and must successfully launch Tonmya and obtain additional funding through public and private financing and collaborative arrangements with strategic partners to increase the funds available to fund operations. However, we may not be able to raise capital on terms acceptable to us, or at all. Without the successful product launch of Tonmya and obtaining additional funds, we may be forced to delay, scale back or eliminate some or all of our research and development activities or other operations, and potentially delay product development in an effort to maintain sufficient funds to continue operations. If any of these events occurs, our ability to achieve development and commercialization goals will be adversely affected and we may be forced to cease operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Future Liquidity Requirements

We expect to incur losses from operations for the near future. We expect to increase our operating costs to align the Company's capital and human resources with its previously announced strategic prioritization of the commercial launch of Tonmya for the treatment of fibromyalgia.

Our future capital requirements will depend on a number of factors, including the successful product launch of Tonmya, the progress of our research and development of product candidates, the timing and outcome of regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing and our success in developing markets for our product candidates.

We will need to successfully launch Tonmya and obtain additional capital in order to fund future research and development activities and future capital expenditures. Future financing may include the issuance of equity or debt securities, obtaining credit facilities, or other financing mechanisms. Even if we are able to raise the funds required, it is possible that we could incur unexpected costs and expenses, fail to collect significant amounts owed to us, or experience unexpected cash requirements that would force us to seek alternative financing. Furthermore, if we issue additional equity or debt securities, shareholders may experience additional dilution or the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock.

If the product launch of Tonmya is unsuccessful and additional financing is not available or is not available on acceptable terms, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

2025 Lincoln Park Transaction

On June 11, 2025, we entered into a purchase agreement (the "2025 Purchase Agreement") and a registration rights agreement (the "2025 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2025 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$75,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2025 Purchase Agreement. Pursuant to the terms of the 2025 Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2025 Purchase Agreement.

Pursuant to the terms of the 2025 Purchase Agreement, at the time we signed the 2025 Purchase Agreement and the 2025 Registration Rights Agreement, we issued 48,708 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2025 Purchase Agreement. The commitment shares were valued at \$1.8 million and recorded as an addition to equity for the issuance of the common stock and treated as other expense, net on the condensed consolidated statement of operations under the 2025 Purchase Agreement. No shares were sold during 2025 under the 2025 Purchase Agreement.

We evaluated the 2025 Purchase Agreement under ASC 815-40 *Derivatives and Hedging-Contracts on an Entity's Own Equity* as it represents the right to require Lincoln Park to purchase shares of common stock in the future, similar to a put option. We concluded that the 2025 Purchase Agreement represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. We analyzed the terms of the contract and concluded that the derivative instrument had insignificant value as of September 30, 2025.

2025 At-the-Market Offerings

On June 11, 2025, we entered into a Sales Agreement (the "2025 Sales Agreement"), with A.G.P./Alliance Global Partners ("AGP") pursuant to which we may issue and sell, from time to time, shares of common stock having an aggregate offering price of up to \$150.0 million in sales. AGP is the sales agent under the ATM and paid a 3% commission on each sale under the 2025 Sales Agreement. Our common stock is sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During each of the three and nine months ended September 30, 2025, we sold approximately 1.7 million shares of common stock under the 2025 Sales Agreement for net proceeds of approximately \$55.7 million. Subsequent to September 30, 2025, we sold 1.6 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$34.7 million.

2024 At-the-Market Offerings

On July 30, 2024, we entered into a Sales Agreement (the “2024 Sales Agreement”), with AGP pursuant to which we may issue and sell, from time to time, shares of common stock having an aggregate offering price of up to \$250.0 million in sales. AGP is the sales agent under the ATM and paid a 3% commission on each sale under the 2024 Sales Agreement. Our common stock is sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the three and nine months ended September 30, 2025, we sold approximately 0.9 million and 4.5 million shares, respectively, of common stock under the Sales Agreement for net proceeds of approximately \$37.5 million and \$112.9 million, respectively. We can no longer sell shares under the 2024 Sales Agreement as we have reached the aggregate \$250 million in sales.

July 2024 Financings

On July 9, 2024, we entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which we sold 33,936 shares of common stock and pre-funded warrants to purchase up to 37,032 shares of common stock. The offering price per share of common stock was \$57.00, and the offering price per share of pre-funded warrant was \$56.99.

The offering closed on July 10, 2024. We incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$3.5 million, after deducting the underwriting discount and other offering expenses.

June 2024 Financings

On June 12, 2024, we entered into a securities purchase agreement with certain investors, pursuant to which we sold 11,995 shares of common stock and pre-funded warrants to purchase up to 25,682 shares of common stock. The offering price per share of common stock was \$106.50, and the offering price per share of pre-funded warrant was \$106.40.

The offering closed on June 13, 2024. We incurred offering expenses of approximately \$0.6 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$3.4 million, after deducting the underwriting discount and other offering expenses.

On June 27, 2024, we entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which we sold 28,339 shares of common stock and pre-funded warrants to purchase up to 42,282 shares of common stock. The offering price per share of common stock was \$57.00, and the offering price per share of pre-funded warrant was \$56.99.

The offering closed on June 28, 2024. We incurred offering expenses of approximately \$0.6 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$3.4 million, after deducting the underwriting discount and other offering expenses.

March 2024 Financing

On March 28, 2024, we entered into an agreement to sell 3,365 shares of common stock, pre-funded warrants to purchase up to 1,219 shares of common stock, and accompanying Series E warrants to purchase up to 4,584 shares of common stock with an exercise price of \$1,056.00 per share and expiring five and a half years from date of issuance in a public offering, which closed on April 1, 2024. The offering price per share of common stock was \$960.00, and the offering price per share of pre-funded warrants was \$959.68.

We incurred expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$3.9 million, after deducting the underwriting discount and other offering expenses.

Additionally, with the closing of the financing on April 1, 2024, we entered into warrant amendments (collectively, the “Warrant Amendments”) with certain holders of our common warrants (referred to herein as the “Existing Warrants”). We agreed to amend the exercise price of each Existing Warrant to \$1,056.00 upon approval by our stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 or, if stockholder approval is not obtained by October 1, 2024, we agreed to automatically amend the exercise price of the Existing Warrants to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of our common stock on October 1, 2024, if and only if the Minimum Price is below the then current exercise price. Upon stockholder approval, the termination date for the warrants issued August 2023 (the “August Warrants”) to purchase up to an aggregate of 2,172 shares was amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2025; the termination date for Series C Warrants to purchase up to an aggregate of approximately 10,884 shares is the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by the Company to the Series C Warrant holders of the Company’s public announcement of the FDA’s acknowledgement and acceptance of the Company’s NDA relating to TNX-102 SL in patients with Fibromyalgia; the termination date for Series D Warrants to purchase up to an aggregate of approximately 10,884 shares is April 1, 2029. The other terms of the Existing Warrants remained unchanged.

We evaluated the Warrant Amendments as of April 1, 2024, and determined that the potential adjustment to the exercise price that is contingent on stockholder approval precluded the Existing Warrants from being indexed to our own stock, and as a result, did not meet the criteria for equity classification under ASC 815-40. We accounted for the incremental fair value of the Warrant Amendments of \$3.0 million as a direct and incremental cost of the March 2024 financing as an offset to the proceeds received. As all of the Existing Warrants were equity-classified prior to the Warrant Amendments, the net impact to the consolidated statement of stockholders' equity was zero. We then reclassified the Existing Warrants from equity to liabilities at post-modification fair value on April 1, 2024. On May 22, 2024, the date our stockholders approved the proposal to fix the exercise prices at \$1,056.00 per share, the Existing Warrants were adjusted to fair value and reclassified back to equity.

Stock repurchases

In September 2024, the Board of Directors approved a 2024 share repurchase program pursuant to which we may repurchase up to \$10.0 million in value of its outstanding common stock from time to time on the open market and in privately negotiated transactions subject to market conditions, share price and other factors.

During the nine months ended September 30, 2025, we repurchased 400,000 of shares of common stock outstanding under the 2024 share repurchase at prices ranging from \$9.98 to \$20.47 per share for a gross aggregate cost of approximately \$5.9 million. The repurchased shares were immediately retired.

We repurchased the following capital stock:

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Total cost of repurchased shares (in thousands)	\$ 5,949	\$ —
Shares repurchased	400,000	—
Weighted average price per share	\$ 14.84	\$ —

The timing and amount of any shares repurchased will be determined based on our evaluation of market conditions and other factors and the New Share Repurchase Program may be discontinued or suspended at any time. Repurchases will be made in accordance with the rules and regulations promulgated by the Securities and Exchange Commission and certain other legal requirements to which the Company may be subject. Repurchases may be made, in part, under a Rule 10b5-1 plan, which allows stock repurchases when the Company might otherwise be precluded from doing so.

Stock Compensation

On May 1, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan (“Amended and Restated 2020 Plan”).

Under the terms of the Amended and Restated 2020 Plan, we may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights (“SARs”), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 50,000 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an “evergreen provision” providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). On May 8, 2025, our stockholders approved the addition of 1,000,000 shares to the Company’s Amended and Restated 2020 Plan.

The Board of Directors determines the exercise price, vesting and expiration period of the grants under the Amended and Restated 2020 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the expiration period of grants under the Amended and Restated 2020 Plan may not be more than ten years. As of September 30, 2025, there were 737,782 options available for future grants under the Amended and Restated 2020 Plan.

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on options with an exercise price less than our closing stock price at the respective dates.

The weighted average fair value of options granted during the three and nine months ended September 30, 2025 was \$31.62 per share and \$12.72 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 30, 2024 was \$15.24 per share and \$867.96 per share, respectively.

We measure the fair value of stock options on the date of grant, based on the Black Scholes option pricing model using certain assumptions discussed below, and the closing market price of our common stock on the date of the grant. The fair value of the award is measured on the grant date. One-third of most stock options granted pursuant to the Plans vest 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, we issue options to directors which vest over a one-year period. We also issue premium options to executive officers which have an exercise price greater than the grant date fair value and has issued performance-based options which vest when target parameters are met or probable of being met, subject in each case to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable service period using the straight-line method.

Stock-based compensation expense relating to options granted of \$1.8 million, of which \$1.2 million and \$0.6 million, related to General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2025. Stock-based compensation expense relating to options granted of \$1.0 million, of which \$0.7 million and \$0.3 million, related to General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2024.

Stock-based compensation expense relating to options granted of \$4.1 million, of which \$2.8 million and \$1.3 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2025. Stock-based compensation expense relating to options granted of \$3.9 million, of which \$2.8 million and \$1.1 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2024.

As of September 30, 2025, we had approximately \$13.6 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 2.89 years.

Employee Stock Purchase Plans

On May 5, 2023, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2023 Employee Stock Purchase Plan. (the “2023 ESPP”), which was replaced by the Tonix Pharmaceuticals Holdings Corp. 2025 Employee Stock Purchase Plan (the “2025 ESPP”, and together with the 2023 ESPP, the “ESPP Plans”), which was approved by our stockholders on May 8, 2025.

The 2025 ESPP allows eligible employees to purchase up to an aggregate of 2,000,000 shares of our common stock. Under the 2025 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of our common stock at the end of the offering period. Each offering period under the 2025 ESPP is for six months, which can be modified from time to time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee’s accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2025 ESPP, subject to the statutory limit under the Code.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 250 shares of our common stock. Under the 2023 ESPP, on the first day of each offering period, each employee eligible for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of our common stock at the end of the offering period. Each offering period under the 2023 ESPP is for six months, which can be modified from time-to-time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee’s accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2023 ESPP, subject to the statutory limit under the Code. As of September 30, 2025, 159 shares were available for future sales under the 2023 ESPP and 2,000,000 shares were available under the 2025 ESPP.

The ESPP Plans are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the nine months ended September 30, 2025, and 2024, \$84,000 and \$27,000, respectively, was expensed. In January 2024, 21 shares that were purchased as of December 31, 2023, under the 2022 ESPP, were issued. As of June 30, 2024, approximately \$33,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In July 2024, 70 shares that were purchased as of June 30, 2024, under the 2022 ESPP, were issued. As of September 30, 2025, approximately \$57,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses.

Commitments

Research and Development Contracts

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$22.7 million at September 30, 2025 for future work to be performed.

We have entered into various exclusive license agreements with various institutions with the right to sublicense, certain patents, technical information and material, and to develop and commercialize products thereunder. In addition to any upfront payments already paid, we may be obligated to pay milestone fees ranging from \$0.4 million to \$5.0 million based on the potential achievement of certain development milestones, as well as milestone fees ranging from \$1.0 million to \$20.0 million based on certain potential commercial achievements, as specified in the respective license agreement. Additionally, for licensed products sold during the applicable royalty term, we must pay royalties in the low-to-mid single digits, beginning in the year after we complete our first commercial sale of a licensed product. Finally, we have the right under each license agreement to grant sublicenses to third parties and are required to pay a sublicense income share based on the stage of development of the licensed product at the time the sublicense is granted.

At September 30, 2025, future minimum lease payments for operating leases with non-cancelable terms of more than one year were as follows (in thousands):

Year Ending December 31,	
Remainder of 2025	\$ 72
2026	142
2027	139
2028	100
2029	7
	<u>460</u>
Included interest	(35)
	<u>\$ 425</u>

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition. Our gross product revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration represents chargebacks, rebates, prompt pay and other sales discounts, and product returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on gross sales for a reporting period. We began recognizing revenue following the completion of the USL Acquisition, beginning July 1, 2023, and required variable consideration estimates are currently primarily based on the acquired products historical results. Adjustments to these estimates to reflect actual results or updated expectations will be assessed each period. If any of our ratios, factors, assessments, experiences, or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. The potential of our estimates to vary differs by program, product, type of customer and geographic location. In addition, estimates associated with U.S. Medicare and Medicaid governmental rebate programs are at risk for material adjustment because of the extensive time delay.

Research and Development. We outsource certain of our research and development efforts and expense the related costs as incurred, including the cost of manufacturing product for testing, licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired was expensed as research and development costs, as it related to particular research and development projects and had no alternative future uses.

We estimate our research and development accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants and clinical research organizations and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We account for trial expenses according to the progress of the trial as measured by participant progression and the timing of various aspects of the trial. We determine accrual estimates that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us at that time. Our clinical trial accruals and prepaid assets are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Stock-Based Compensation. All stock-based payments to employees and to nonemployee directors for their services as directors consisted of grants of restricted stock and stock options, which are measured at fair value on the grant date and recognized in the consolidated statements of operations as compensation expense over the relevant vesting period. In addition, for awards that vest immediately and are nonforfeitable, the measurement date is the date the award is issued.

Derivative Instruments and Warrant Liabilities. The Company evaluates all of its financial instruments, including issued warrants to purchase common stock under ASC 815 – Derivatives and Hedging, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The Company uses the Black-Scholes option pricing model to value the derivative instruments at inception and subsequent valuation dates, which is adjusted for instrument-specific terms as applicable.

From time to time, certain equity-linked instruments may be classified as derivative liabilities due to the Company having insufficient authorized shares to fully settle the equity-linked financial instruments in shares. In such a case, the Company has adopted a sequencing approach under ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity to determine the classification of its contracts at issuance and at each subsequent reporting date. If reclassification of contracts between equity and assets or liabilities is necessary, the Company first allocates remaining authorized shares to equity on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest issuance date receiving the first allocation of shares. In the event of identical issuance dates, shares are then allocated to equity beginning with instruments with the latest maturity date first.

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retain or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which requires entities to disclose disaggregated information about their effective tax rate reconciliations as well as expanded information on income taxes by jurisdiction. The standard is effective for fiscal years beginning after December 15, 2024 on a prospective basis. The Company discloses its income tax rate reconciliation in its annual consolidated financial statements only and does not expect the adoption to have a material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

In March 2024, the SEC adopted new rules relating to the disclosure of a range of climate-change-related physical and transition risks, data, and opportunities. The adopted rule contains several new disclosure obligations, including, (i) disclosure on how the board of directors and management oversee climate-related risks and certain climate-related governance items, (ii) disclosure of information related to a registrant's climate-related targets, goals, and/or transition plans, and (iii) disclosure on whether and how climate-related events and transition activities impact line items above a threshold amount on a registrant's consolidated financial statements, including the impact of the financial estimates and the assumptions used. This new rule will first be effective in the Company's disclosures for the year ending December 31, 2027. The Company is in the process of assessing the impact on our consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, to improve transparency in financial reporting by requiring entities to present more detailed information about the nature of expenses included within the Income Statement. The guidance will first be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2024-03 on our disclosures.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934 as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2025, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are currently not a party to any material legal proceedings or claims.

Item 1A. Risk Factors

Other than as set forth below, as well as other reports and statements that we have filed with the SEC, there were no material changes from the risk factors set forth under Part I, Item 1A., “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024. You should carefully consider the risk factors set forth below and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as well as other reports and statements that we file and have filed with the SEC, in addition to the other information set forth in this report which could materially affect our business, financial condition or future results. The risks and uncertainties described in this report and in our Annual Report on Form 10-K for the year ended December 31, 2024, as well as other reports and statements that we file with the SEC, are not the only risks and uncertainties facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also have a material adverse effect on our financial position, results of operations or cash flows.

Our prospects are dependent on the successful commercialization of Tonmya. If Tonmya is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

We may not be able to successfully commercialize Tonmya. Our inability to commercialize Tonmya may be based on, among other things, lack of adequate coverage or reimbursement from third-party payors, including government health administration authorities, pharmacy benefit managers, managed care organizations and other private health insurers; healthcare legislative or regulatory reform measures; lack of market acceptance; serious adverse events or undesirable side effects; existing, or the introduction of new, products targeting the same or similar indication; the failure to adequately maintain the manufacturing, marketing, sales and distribution channels. Any one or combination of these factors would limit our ability to successfully commercialize Tonmya and would harm our business, financial condition, and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 2(c). Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None of the Company’s directors and officers adopted, modified, or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended September 30, 2025 (each as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended).

Item 6. Exhibits**EXHIBIT INDEX**

Exhibit No.	Description
<u>3.01</u>	Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the “Commission”) on April 9, 2008 and incorporated herein by reference.
<u>3.02</u>	Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.
<u>3.03</u>	Third Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 3, 2016 and incorporated herein by reference.
<u>3.04</u>	Certificate of Change of Tonix Pharmaceuticals Holding Corp., dated March 13, 2017 and effective March 17, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 16, 2017 and incorporated herein by reference.
<u>3.05</u>	Certificate of Amendment to Articles of Incorporation, effective June 16, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 16, 2017 and incorporated herein by reference.
<u>3.06</u>	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.’s Articles of Incorporation, as amended, filed with the Secretary of State of the State of Nevada on May 3, 2019.
<u>3.07</u>	Form of Certificate of Designation of Series A Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
<u>3.08</u>	Form of Certificate of Designation of Series B Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
<u>3.09</u>	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.’s Articles of Incorporation, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 16, 2022 and incorporated herein by reference.
<u>3.10</u>	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.’s Articles of Incorporation, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 25, 2024 and incorporated herein by reference
<u>4.01</u>	Specimen Common Stock Certificate of the Registrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 24, 2018 and incorporated herein by reference.
<u>4.07</u>	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 18, 2023 and incorporated herein by reference.
<u>4.08</u>	Form of Common Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 28, 2023 and incorporated herein by reference.
<u>4.09</u>	Form of Pre-Funded Warrant. filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 and incorporated herein by reference.
<u>4.10</u>	Form of Series C Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 and incorporated herein by reference.
<u>4.11</u>	Form of Series D Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 and incorporated herein by reference.
<u>4.12</u>	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 29, 2024, and incorporated herein by reference.
<u>4.13</u>	Form of Series E Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 29, 2024, and incorporated herein by reference.

- [4.14](#) Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 13, 2024, and incorporated herein by reference.
- [4.15](#) Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 28, 2024 and incorporated herein by reference.
- [4.16](#) Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 10, 2024 and incorporated herein by reference.
- [31.01](#) Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
- [31.02](#) Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
- [32.01](#) Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.

† Certain portions of this exhibit, that are not material and would likely cause competitive harm to the registrant if publicly disclosed, have been redacted pursuant to Item 601(b)(10) of Regulation S-K.

SIGNATURES

Pursuant to the requirements 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.

(Registrant)

Date: November 10, 2025

By: /s/ SETH LEDERMAN

Seth Lederman

Chief Executive Officer (Principal Executive Officer)

Date: November 10, 2025

By: /s/ BRADLEY SAENGER

Bradley Saenger

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

CERTIFICATION

I, Seth Lederman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tonix Pharmaceuticals Holding Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2025

/s/ SETH LEDERMAN

Seth Lederman

Chief Executive Officer

CERTIFICATION

I, Bradley Saenger, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tonix Pharmaceuticals Holding Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2025

/s/ BRADLEY SAENGER

Bradley Saenger

Chief Financial Officer

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended September 30, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: November 10, 2025

By: /s/ SETH LEDERMAN
Name: Seth Lederman
Title: *Chief Executive Officer*

I, Bradley Saenger, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended September 30, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: November 10, 2025

By: /s/ BRADLEY SAENGER
Name: Bradley Saenger
Title: *Chief Financial Officer*
