

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, 2024

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) 799-9155

(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 Global 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 12, 2024, there were 186,894,225 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)**

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 28,233	\$ 24,948
Accounts receivable, net	4,013	—
Inventory	7,931	13,639
Prepaid expenses and other current assets	10,366	9,181
Total current assets	50,543	47,768
Property and equipment, net	42,747	94,028
Intangible assets, net	120	9,743
Goodwill	—	965
Operating lease right-to-use assets	628	824
Other non-current assets	951	1,129
Total assets	\$ 94,989	\$ 154,457
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,935	\$ 3,782
Accrued expenses and other current liabilities	8,151	12,482
Term loan payable, short term	2,820	2,350
Lease liability, short term	275	270
Total current liabilities	15,181	18,884
Term loan payable, long term	5,172	6,561
Series C warrant liabilities	—	14,595
Series D warrant liabilities	—	8,260
Lease liability, long term	425	632
Total liabilities	20,778	48,932
Commitments (See Note 18)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, 0 shares designated as of both September 30, 2024, and December 31, 2023; 0 shares issued and outstanding - as of both September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 1,000,000,000 shares authorized; 155,631,049 and 2,077,088 shares issued and outstanding as of September 30, 2024, and December 31, 2023, respectively and 2,074 shares to be issued as of December 31, 2023	156	3
Additional paid in capital	782,891	706,412
Accumulated deficit	(708,586)	(600,658)
Accumulated other comprehensive loss	(250)	(232)
Total stockholders' equity	74,211	105,525
Total liabilities and stockholders' equity	\$ 94,989	\$ 154,457

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,	
	2024	2023	2024	2023
REVENUE:				
Product revenue, net	\$ 2,822	\$ 3,989	\$ 7,512	\$ 3,989
COSTS AND EXPENSES:				
Cost of revenue	1,555	2,374	6,582	2,374
Research and development	9,114	21,050	31,675	69,535
Selling, general and administrative	7,707	8,712	24,519	23,131
Asset impairment charges	—	—	58,957	—
	<u>18,376</u>	<u>32,136</u>	<u>121,733</u>	<u>95,040</u>
Operating loss	(15,554)	(28,147)	(114,221)	(91,051)
Grant income	1,668	—	1,668	—
Gain on change in fair value of warrant liabilities	—	—	6,150	—
Other (expense) income, net	(327)	172	(1,525)	1,715
Net loss available to common stockholders	<u>\$ (14,213)</u>	<u>\$ (27,975)</u>	<u>\$ (107,928)</u>	<u>\$ (89,336)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (38.63)</u>	<u>\$ (4.66)</u>	<u>\$ (143.47)</u>
Weighted average common shares outstanding, basic and diluted	<u>62,122,283</u>	<u>724,190</u>	<u>23,136,172</u>	<u>622,684</u>

See the accompanying notes to the condensed consolidated financial statements

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Net loss	\$ (14,213)	\$ (27,975)	\$ (107,928)	\$ (89,336)
Other comprehensive loss:				
Foreign currency translation loss	(7)	(8)	(18)	(53)
Comprehensive loss	<u>\$ (14,220)</u>	<u>\$ (27,983)</u>	<u>\$ (107,946)</u>	<u>\$ (89,389)</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 Gain (loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2023	2,077,088	\$ 2	\$ 706,413	\$ (232)	\$ (600,658)	\$ 105,525
Issuance of common stock upon exercise of prefunded common warrants	470,102	1	(1)	—	—	—
Fair value of warrants reclassified from liabilities to equity	—	—	15,850	—	—	15,850
Employee stock purchase plan	2,074	—	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	2,549,264	3	723,977	(240)	(615,597)	108,143
Issuance of common stock, net of transactional expenses of \$1,704	4,369,807	4	10,726	—	—	10,730
Issuance of common stock upon exercise of prefunded common warrants	2,913,516	3	(3)	—	—	—
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	9,832,587	10	736,709	(243)	(694,373)	42,103
Issuance of common stock, net of transactional expenses of \$557	3,393,600	3	3,481	—	—	3,484
Issuance of common stock upon exercise of prefunded common warrants	7,931,298	8	(8)	—	—	—
Issuance of common stock under the At-the- Market agreement, net of transactional expenses of \$1,681	134,466,637	135	41,667	—	—	41,802
Employee stock purchase plan	6,927	—	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	155,631,049	\$ 156	\$ 782,891	\$ (250)	\$ (708,586)	\$ 74,211

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 Gain (loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2022	631,704	\$ 1	\$ 677,386	\$ (167)	\$ (470,038)	\$ 207,182
Repurchase of common stock under share repurchase program, including transactional expenses of \$334	(83,502)	—	(3)	—	(13,962)	(13,965)
Issuance of common stock under 2022 Purchase agreement with Lincoln Park	3,000	—	441	—	—	441
Issuance of common stock net of transactional expenses of \$101	16,089	—	1,995	—	—	1,995
Employee stock purchase plan	469	—	29	—	—	29
Stock-based compensation	—	—	2,794	—	—	2,794
Foreign currency transaction loss	—	—	—	(44)	—	(44)
Net loss	—	—	—	—	(33,005)	(33,005)
Balance, March 31, 2023	567,760	1	682,642	(211)	(517,005)	165,427
Issuance of common stock net of transactional expenses of \$36	13,766	—	1,029	—	—	1,029
Stock-based compensation	—	—	2,364	—	—	2,364
Foreign currency transaction loss	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(28,356)	(28,356)
Balance, June 30, 2023	581,526	1	686,035	(212)	(545,361)	140,463
Issuance of common stock under AGP Financing, net of transactional expenses of \$726	79,063	—	6,274	—	—	6,274
Issuance of common stock upon exercise of prefunded warrants under AGP Financing	139,689	—	—	—	—	—
Stock-based compensation	—	—	2,079	—	—	2,079
Foreign currency transaction loss	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(27,975)	(27,975)
Balance, September 30, 2023	800,278	1	694,388	(220)	(573,336)	120,833

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,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (107,928)	\$ (89,336)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,925	3,030
Asset impairment charges	58,957	—
Gain on disposal of property and equipment	—	(196)
Change in fair value of warrant liabilities	(6,150)	—
Inventory write-off	2,018	—
Amortization of debt discount	640	—
Stock-based compensation	3,884	7,237
Changes in operating assets and liabilities:		
Accounts receivable	(4,982)	(1,562)
Inventory	3,691	—
Prepaid expenses and other	670	3,334
Accounts payable	346	446
Lease liabilities and ROU asset, net	(8)	24
Accrued expenses and other current liabilities	(358)	(2,640)
Net cash used in operating activities	<u>(46,295)</u>	<u>(79,663)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of a business	—	(22,174)
Disposal of property and equipment	—	992
Purchase of property and equipment	(117)	(7,457)
Net cash used in investing activities	<u>(117)</u>	<u>(28,639)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Deferred payment related to purchase a business	(3,000)	—
Repurchase of common stock	—	(13,965)
Proceeds from ESPP	27	29
Payment of term loan	(1,645)	—
Proceeds, net of \$3,942 and \$863 expenses, from sale of common stock and warrants	54,336	9,739
Net cash provided by (used in) financing activities	<u>49,718</u>	<u>(4,197)</u>
Effect of currency rate change on cash	<u>(20)</u>	<u>(55)</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	3,286	(112,554)
Cash, cash equivalents and restricted cash beginning of the period	<u>25,850</u>	<u>120,470</u>
Cash, cash equivalents and restricted cash end of period	<u>\$ 29,136</u>	<u>\$ 7,916</u>
Supplemental disclosures of cash flow information:		
Interest expense paid	\$ 954	\$ —
Non-cash financing and investing activities:		
At-the-market agreement receivable	\$ 1,680	—
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ —	\$ 275

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2024 AND 2023 (UNAUDITED)

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp. (“Tonix” or the “Company”), through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. (“Tonix Sub”), is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges.

Tonix’s priority is to advance its TNX-102 SL product candidate for the management of fibromyalgia, for which a New Drug Application (“NDA”) was submitted to the U.S. Food and Drug Administration (“FDA”) based on two statistically significant Phase 3 studies. The FDA granted Fast Track designation to TNX-102 SL for the management of fibromyalgia in the third quarter 2024. The Company expects an FDA decision on the acceptance of the NDA for review and PDUFA date in December and if accepted, a decision on NDA approval in 2025. Fibromyalgia is a common chronic pain condition that affects mostly women. Fibromyalgia is now recognized as the prototypic nociplastic pain syndrome. TNX-102 SL is a non-opioid, centrally acting analgesic developed for long-term use in fibromyalgia. If approved, TNX-102 SL would be the first new drug therapy for fibromyalgia in more than 15 years. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated Investigational New Drug application (“IND”) at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (“DoD”). We expect to initiate enrollment in the OASIS study in the fourth quarter. Tonix’s CNS portfolio includes TNX-1300 (cocaine esterase), a biologic drug candidate in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the U.S. National Institute of Drug Abuse. Tonix’s immunology development portfolio includes TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) in Phase 1 development for the prevention of allograft rejection and for the treatment of autoimmune diseases. TNX-1700 is a fusion protein of TFF2 and albumin and is in the pre-IND stage of development to treat gastric and pancreatic cancer. Tonix also has pre-clinical product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including TNX-801, a potential vaccine to prevent mpox and smallpox. Tonix recently announced a contract with the U.S. DoD’s Defense Threat Reduction Agency (“DTRA”) for up to \$34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents 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 infectious disease research facility in Frederick, MD. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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, Inc., 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.

Going Concern

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, 2024, the Company had working capital of approximately \$35.4 million. At September 30, 2024, the Company had an accumulated deficit of approximately \$708.6 million. The Company held unrestricted cash and cash equivalents of approximately \$28.2 million as of September 30, 2024. During the fourth quarter of 2023, the Company engaged CBRE, an international real estate brokerage firm, to potentially find a strategic partner for, or buyer of, its Advanced Development Center in North Dartmouth, Massachusetts (“ADC”), to align with the Company’s current business objectives and priorities. As of September 30, 2024, the Company does not have a commitment in place to sell the ADC.

The Company believes that its cash resources at September 30, 2024 and the net proceeds of \$5.1 million that it raised from an equity offering in the fourth quarter of 2024 (See Note 19), will not meet its operating and capital expenditure requirements through the first quarter of 2025.

These factors raise substantial doubt about the Company’s ability to continue as a going concern. The Company continues to face significant challenges and uncertainties and must 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 additional funds, it 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. Moreover, the Company may default under the terms of its existing indebtedness. 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, 2024 AND 2023 (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, 2023, contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of results that may be expected for the year ending December 31, 2024. 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, 2023, included in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on April 1, 2024.

Reverse Stock Split

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 the reverse stock split 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 condensed consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. Authorized common and preferred stock were not adjusted because of the reverse stock split.

Risks and uncertainties

The Company’s primary efforts are devoted to 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 now has commercial products available for sale, and generates revenue from the sale of its Zembrace SymTouch and Tosymra products, with no assurance that the Company will be able to generate sufficient cash flow to fund operations from 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 will be approved or commercially viable.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2024 AND 2023 (UNAUDITED)

Use of estimates

The preparation of financial statements in accordance with 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 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, the percent of completion of research and development contracts, fair value estimates for assets acquired in business combinations, and assessment of useful lives of acquired intangible assets.

Business Combinations

The Company accounts for business combinations in accordance with the provisions of ASC 805, Business Combinations and ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. Business combinations are accounted for using the acquisition method, whereby the consideration transferred is allocated to the net assets acquired based on their respective fair values measured on the acquisition date. The difference between the fair value of these assets and the purchase price is recorded as goodwill. Transaction costs other than those associated with the issue of debt or equity securities, and other direct costs of a business combination are not considered part of the business acquisition transaction and are expensed as incurred.

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.

The Company has two products that each accounted for more than 10% of total revenues during the three and nine months ended September 30, 2024 and 2023. These products collectively accounted for 100% of revenues during the three and nine months ended September 30, 2024 and 2023.

As of September 30, 2024, accounts receivable from four customers accounted for 29%, 27%, 27%, and 11% of accounts receivable. 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. For the three and nine months ended September 30, 2023, revenues from four customers accounted for 25%, 21%, 18% and 14% 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, 2024 and September 30, 2023, cash equivalents, which consisted of money market funds, amounted to \$24,000 and \$3.7 million, respectively. Restricted cash, which is included in Other non-current assets on the condensed consolidated balance sheet, 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 (see Note 17) and restricted cash held by vendors in escrow accounts for patient support services. Restricted cash at September 30, 2023, of approximately \$1.0 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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2024 AND 2023 (UNAUDITED)

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, 2024	September 30, 2023
	(in thousands)	
Cash and cash equivalents	\$ 28,233	\$ 6,914
Restricted cash	903	1,002
Total	\$ 29,136	\$ 7,916

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, 2024, the Company did not have an allowance for credit losses, as the Company's exposure to credit losses is *de minimis*. 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 accounts receivable. We attempt to minimize the risks related to cash and cash equivalents by investing in a broad and diverse range of financial instruments, 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 and nine months ended September 30, 2024, the Company recorded write-downs related to Tosymra and Zembrace finished goods inventory of approximately \$0.3 million and \$2.0 million, respectively, based on an assessment of inventory on hand and projected sales prior to the respective expiration dates. 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.

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The Company did not have inventory on hand prior to the acquisition of Zembrace and Tosymra on June 30, 2023.

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, 2024, and 2023 was \$0.5 million and \$1.0 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2024, and 2023 was \$2.4 million and \$2.8 million, respectively. The Company's property and equipment is located in the United States.

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 consist 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 6). The acquired intangible assets are 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 and \$0.5 million, respectively. The Company recorded a full impairment of its developed technology assets during the second quarter of 2024, discussed further below. Amortization expense for the three months ended September 30, 2023, was \$0.2 million.

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.

During the second quarter of 2024, the Company identified certain triggering events related to and the decommissioning of the 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. No new triggering events were identified during the third quarter ended September 30, 2024.

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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 during the second quarter of 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. The Company recorded a non-cash impairment charge for the amount of \$9.2 million, representing the excess carrying value over the fair value, 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. As the carrying value of these intangibles is \$0, there were no further impairment considerations during the third quarter 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 (See Note 6). The Company completed the required annual impairment test for goodwill during the second quarter of 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.

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 consolidated balance sheet. Amortization of deferred financing costs are included in interest expense on the consolidated statements of operations.

Original issue discount

Certain term debt issued by the Company provides the debt holder with an original issue discount. Original issue discounts are reflected as a direct reduction of the related debt liability on the consolidated balance sheets and are amortized over the term of the related debt agreement using the effective interest method. Amortization of original issue discounts are included in interest expense on the consolidated statements of operations.

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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.

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- 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.
- 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.

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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. 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 nine months ended September 30, 2024, we received \$1.1 million in funding as a reduction of related research and development expense. Included in prepaid expenses and other current assets is an additional \$0.3 million which was received in October 2024 and resulted in a further reduction of research and development expense during the nine months ended September 30, 2024. During the nine months ended September 30, 2023, we received \$2.3 million 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 nine months ended September 30, 2024, \$1.7 million was recognized in grant income related to the DTRA grant (\$0 for the nine months ended September 30, 2023). As of September 30, 2024, \$1.2 million of grant income, included above, was earned but not yet received and is presented in prepaid expenses and other current assets.

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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 condensed 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.

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, 2024, 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.

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 14). 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.

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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.

Per Share Data

The computation of basic and diluted loss per share for the quarters ended September 30, 2024 and 2023 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. Prefunded warrants are assumed exercised on date of issuance and are included in the basic earnings per share (“EPS”) calculation.

All warrants (See Note 16) 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. No income was allocated to the warrants for the three and nine months ended September 30, 2024, and 2023, 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, 2024 and 2023, are as follows:

	2024	2023
Warrants to purchase common stock	6,307,205	218,781
Options to purchase common stock	356,173	43,260
Totals	6,663,378	262,041

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, *Segment Reporting--Improvements to Reportable Segment Disclosures*, which requires incremental disclosures about a public entity’s reportable segments but does not change the definition of a segment or the guidance for determining reportable segments. The new guidance requires disclosure of significant segment expenses that are (1) regularly provided to (or easily computed from information regularly provided to) the chief operating decision maker and (2) included in the reported measure of segment profit or loss. The new standard also allows companies to disclose multiple measures of segment profit or loss if those measures are used to assess performance and allocate resources. The guidance will first be effective in our annual disclosures for the year ending December 31, 2024, and will be adopted retrospectively unless impracticable. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2023-07 on our disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which requires disaggregated information about our effective tax rate reconciliation as well as information on income taxes paid. The guidance will first be effective in our annual disclosures for the year ending December 31, 2025, and should be applied on a prospective basis with the option to apply retrospectively. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2023-09 on our disclosures.

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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.

NOTE 3 – INVENTORY

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

	September 30, 2024	December 31, 2023
	(in thousands)	
Raw Materials	\$ 3,346	\$ 3,611
Work-in-process	1,953	2,539
Finished Goods	2,632	7,489
Total Inventory	<u>\$ 7,931</u>	<u>\$ 13,639</u>

During the nine months ended September 30, 2024, the Company recorded write-downs related to Tosymra and Zembrace finished goods inventory of approximately \$2.0 million based on an assessment of inventory on hand and projected sales prior to the respective expiration dates.

NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
	(in thousands)	
Contract-related	\$ 1,629	\$ 4,590
Government grants	1,595	199
At-the-market receivable	1,680	—
Non-trade receivables	2,135	—
Debt interest and fees	523	1,513
Inventory	339	508
Insurance	340	143
Other	2,125	2,228
	<u>\$ 10,366</u>	<u>\$ 9,181</u>

NOTE 5 – PROPERTY AND EQUIPMENT, NET

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

	September 30, 2024	December 31, 2023
	(in thousands)	
Property and equipment, net:		
Land	\$ 8,011	\$ 8,011
Land improvements	305	326
Buildings	24,504	66,749
Office furniture and equipment	1,369	2,366
Laboratory equipment	12,124	21,904
Leasehold improvements	34	34
	<u>46,347</u>	<u>99,390</u>
Less: Accumulated depreciation and amortization	(3,600)	(5,362)
	<u>\$ 42,747</u>	<u>\$ 94,028</u>

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During the second quarter of 2024, primarily as a result of the Company's decision to decommission its ADC facility in Dartmouth, Massachusetts, the Company recognized 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. The 45,000 square foot facility was purchased on September 28, 2020, for \$4.0 million and incurred approximately \$61.6 million to the build-out of the facility.

On October 1, 2021, the Company completed the acquisition of its approximately 45,000 square foot research and development facility in Frederick, Maryland totaling \$17.5 million, to process development activities. Of the total purchase price, \$2.1 million was allocated to the value of land acquired, and \$13.9 million was allocated to buildings, and approximately \$1.5 million was allocated to office furniture and equipment and laboratory equipment. As of August 1, 2022, the assets became ready for the intended use and were placed in service.

On December 23, 2020, the Company completed the purchase of its approximately 44-acre site in Hamilton, Montana for \$4.5 million, for the construction of a vaccine development and commercial scale manufacturing facility. As of September 30, 2024, the asset was not ready for its intended use.

NOTE 6 – GOODWILL AND INTANGIBLE ASSETS

The following table provides the gross carrying value of goodwill as follows:

	Amounts
	(in thousands)
Balance at December 31, 2023	\$ 965
Impairment of goodwill	(965)
Balance at September 30, 2024	\$ —

The Company completed its annual impairment test for goodwill during the second quarter of 2024, which resulted in full 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.

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

	September 30,	December 31,
	2024	2023
	(in thousands)	
Intangible assets subject to amortization		
Developed technology	\$ 10,100	\$ 10,100
Less: Impairment charge	9,147	—
Less: Accumulated amortization	953	477
Total	\$ —	\$ 9,623
Intangible assets not subject to amortization		
Internet domain rights	\$ 120	\$ 120
Total intangible assets, net	\$ 120	\$ 9,743

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During the three and nine months ended September 30, 2024, the Company recorded amortization of \$0 and \$476,000, respectively. During the three and nine months ended September 30, 2023, the Company recorded amortization of \$238,000.

As a result of certain triggering events identified impacting the Company's commercialized products asset group during the second quarter of 2024, the Company tested the asset group for impairment as of June 30, 2024, resulting in a full impairment of its Zembrace and Tosymra developed technology intangible assets, of \$6.2 million and \$3.0 million, respectively, which is reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024.

NOTE 7 – 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, 2024, and December 31, 2023, the Company used Level 1 quoted prices in active markets to value cash equivalents which were *de minimis* for both periods presented. The Company did not have any Level 2 or Level 3 assets or liabilities as of September 30, 2024. As of December 31, 2023, Level 3 liabilities included a portion of the Company's outstanding Series D Warrants and all of the Company's outstanding Series C Warrants issued in December 2023, which did not meet the criteria for equity classification due to insufficient authorized shares to settle the instruments and were therefore accounted for as liabilities at fair value. After the Company received stockholder approval to increase the number of authorized shares on January 25, 2024, the 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 as of December 31, 2023 and on the respective reclassification dates for the nine months ended September 30, 2024:

	Nine months ended September 30, 2024	As of December 31, 2023
Common stock price	\$ 6.080 - 9.888	\$ 12.896
Risk-free rate	4.01% - 5.37%	3.84% - 4.23%
Expected term (in years)	0.86 - 5.00	1.78 - 5.15
Expected volatility	105.00% - 120.00%	108.00%
Discount for lack of marketability	N/A	5.00%

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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 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	\$ —

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, 2023. Changes in the fair value of the liability-classified warrants are recognized as a separate component of income and expense in the consolidated statement of operations.

NOTE 8 – DEBT FINANCING

Long-term debt consists of the following:

	September 30, 2024	December 31, 2023
Term Loan	\$ 9,355	\$ 11,000
Less: current portion	(2,820)	(2,350)
Total long-term debt	6,535	8,650
Less: unamortized debt discount and deferred financing costs	(1,363)	(2,089)
Total long-term debt, net	\$ 5,172	\$ 6,561

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 is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

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Borrowings under the Term Loan bear 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 is 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 September 30, 2024 totals \$0.5 million, which is 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 is 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 must pay 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 is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

The Loan Agreement provides for voluntary prepayments of the Term Loan, in whole or in part, subject to a prepayment premium. The Loan Agreement contains customary affirmative and negative covenants by the Company, which among other things, will require the Borrowers to provide certain financial reports to the lenders, to maintain a deposit account to fund interest payments, and limit the ability of the Company to incur or guarantee additional indebtedness, pay dividends or make other equity distributions, sell assets, engage in certain transactions, and effect a consolidation or merger. The obligations of the Company under the Loan Agreement may be accelerated upon customary events of default, including non-payment of principal, interest, fees and other amounts, covenant default, insolvency, material judgements, inaccuracy of representations and warranties, invalidity of guarantees. The Term Loan is 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.

Annual future principal payments due on the Term Loan as of September 30, 2024 are as follows (in thousands):

Fiscal years ending	
Remainder of 2024	\$ 705
2025	2,820
2026	5,830
	<u>\$ 9,355</u>

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NOTE 9 – STOCKHOLDERS’ EQUITY

On June 10, 2024, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock, whereby 95,543,805 outstanding shares of the Company’s common stock were exchanged for 2,985,924 shares of the Company’s common stock. In connection with the reverse stock split, the Company issued an additional 245,205 shares of the Company’s common stock due to fractional shares. All per share amounts and number of shares in the condensed 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 June 26, 2024, 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).

On January 25, 2024, the Company filed a Certificate of Amendment to its Articles of Incorporation, as amended, with the Secretary of State of the State of Nevada to increase the number of authorized shares of the Company’s common stock from 160,000,000 to 1,000,000,000 shares (the “Charter Amendment”). The Charter Amendment was approved by the Company’s shareholders at a special meeting of shareholders held on January 25, 2024.

On August 9, 2024, the Company received notice from the Listing Qualifications staff of The Nasdaq Stock Market LLC (“Nasdaq”) that the Company no longer met the requirement to maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 5545(a)(1) (the “Minimum Bid Price Requirement”). The Company was initially provided with a 180 calendar day period, or until February 5, 2024, in which to regain compliance. In the event that the Company does not regain compliance within this 180-day period, the Company may be eligible to seek an additional 180 day compliance period if it meets the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market.

NOTE 10 – REVENUES

Disaggregation of Net Revenues

The Company’s net product revenues are summarized below:

	Three months ended	
	September 30,	
	2024	2023
Zembrace Symtouch	\$ 2,485	\$ 3,292
Tosymra	337	697
Total product revenues	\$ 2,822	\$ 3,989

	Nine months ended	
	September 30,	
	2024	2023
Zembrace Symtouch	\$ 6,059	\$ 3,292
Tosymra	1,453	697
Total product revenues	\$ 7,512	\$ 3,989

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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 \$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 and subject to customary adjustments (such transaction, the “USL Acquisition”).

On June 30, 2023, in connection with the USL Acquisition, the Company and Upsher Smith entered into a Transition Services Agreement (the “Transition Services Agreement”), pursuant to which Upsher Smith provided certain transition services to the Company for base fees equal to \$100,000 per month for the first six months, and \$150,000 per months for the seventh through ninth months, plus additional monthly fees for each service category totaling up to \$150,000 per month. The Company has amended the transitional services agreement with Upsher Smith so that Upsher Smith can continue to provide for the management of certain government rebates. Upsher Smith will be reimbursed by the Company at cost for any rebates they pay on the Company’s behalf.

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 are 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.

As consideration for acquisition of the Business and certain product-related inventories, the Company paid approximately \$23.5 million in cash upfront. In April 2024, the Company paid the additional deferred payment of \$3.0 million in cash.

The following table summarizes the components of the purchase consideration (in thousands):

Purchase consideration	Amount
Closing cash consideration	\$ 22,174
Inventory adjustment payment liability	1,348
Deferred payment liability	3,000
Purchase price to be allocated	<u>\$ 26,522</u>

The USL Acquisition was accounted for as a business combination using the acquisition method, in accordance with the provisions of ASC 805, *Business Combinations* and ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The tangible and intangible assets acquired were recorded at their estimated fair values on the acquisition date, and the difference between the fair value of these assets and the purchase price has been recorded as goodwill. The purchase price allocation is based upon preliminary valuations and estimates and assumptions which are subject to change. As the Company receives additional information about facts and circumstances that existed at the acquisition date, the fair values of the acquired inventory and intangible assets may be adjusted, with the offset recorded to goodwill.

The following table represents the allocation of the purchase price to the assets acquired by the Company in the USL Acquisition recognized in the Company's consolidated balance sheets (in thousands):

Purchase price allocation	Amount
Inventory	\$ 13,700
Prepaid expenses and other	1,757
Intangible assets, net	10,100
Goodwill	965
Fair value of assets acquired	<u>\$ 26,522</u>

The acquired inventory consists of Upsher Smith's raw materials, semi-finished goods, and finished goods inventory as of the Closing date. The fair value was determined based on the estimated selling price of the inventory, less the estimated total costs to complete, disposal effort and holding costs.

Intangible assets eligible for recognition separate from goodwill were those that satisfied either the contractual or legal criterion or the separability criterion in the accounting guidance. The identifiable intangible assets acquired and their estimated useful lives for amortization are as follows (in thousands):

	Fair Value	Useful Life (years)
Developed technology - Tosymra	\$ 3,400	8
Developed technology - Zembrace	6,700	13
Total	<u>\$ 10,100</u>	

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The developed technology intangible assets related to Zembrace and Tosymra includes the value associated with the acquired patents, customer relationships, and trademarks and trade names associated with the technology. The developed technology intangible assets were valued as composite assets under the premise that each asset is reliant on one another to generate cash flow, is not considered separable from the technology, and are assumed to have similar useful lives. The composite intangible assets were valued using a multi-period excess earnings method and are being amortized over their estimated useful lives using the straight-line method of amortization. The key assumptions used in estimating the fair values of intangible assets include forecasted financial information, the weighted average cost of capital, customer retention rates, and certain other assumptions.

The fair values assigned to the assets acquired are based on reasonable assumptions and estimates that market participants would use. Actual results may differ from these estimates and assumptions.

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 during the second quarter of 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. The Company recorded a non-cash impairment charge in the amount of \$9.2 million, representing the excess carrying value over the fair value, 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. As the carrying value of these intangibles is \$0, there were no further impairment considerations during the third quarter ended September 30, 2024.

Supplemental Pro Forma Information

The following unaudited pro forma consolidated financial information reflects the results of operations of the Company for the three and nine months ended September 30, 2023 as if the USL Acquisition had occurred as of January 1, 2023, and gives effect to transactions that are directly attributable to the acquisition, including additional amortization expense related to the fair value of intangible assets acquired and an increase in Cost of Sales related to the acquisition-date fair value adjustment to inventory. On an unaudited pro forma basis, consolidated Net Product Sales and Net Loss for the nine months ended September 30, 2023, would have been \$11.6 million and \$91.3 million, respectively. These amounts are based on financial information of the acquired business and are not necessarily indicative of what the Company's operating results would have been had the acquisition taken place on the date presented, nor is it indicative of the Company's future operating results. The net loss of USL Acquisition business is included in the Company's consolidated results since the date of acquisition. The revenue and net loss of the USL Acquisition business reflected in the condensed consolidated statements for the three and nine months ended September 30, 2024, is \$2.8 million and \$1.0 million, and \$7.5 million and \$15.8 million, respectively.

As described above, in connection with the USL Acquisition, the Company and Upsher Smith entered into a Transition Services Agreement with Upsher Smith related to providing ongoing services associated with the assets acquired, such as procuring and selling migraine therapy products, providing accounting, and billing services and collecting accounts receivable and paying trade payables. Upsher Smith collected and will continue to collect cash on behalf of Tonix for revenue generated by sales of the assets acquired from June 30, 2023, through the transition period and the Seller is obligated to transfer cash generated by such sales to the Company. On April 1, 2024, the Company amended the transitional services agreement with Upsher Smith so that Upsher Smith will only provide for the management of certain government rebates. Upsher Smith will be reimbursed by the Company at cost for any rebates they pay on the Company's behalf.

NOTE 12 – ASSET PURCHASE AGREEMENT WITH HEALION

On February 2, 2023, the Company entered into an asset purchase agreement (the "Healion Asset Purchase Agreement") with Healion Bio Inc., ("Healion") pursuant to which the Company acquired all the pre-clinical infectious disease assets of Healion, including its portfolio of next-generation antiviral technology assets. Healion's drug portfolio includes a class of broad-spectrum small molecule oral antiviral drug candidates with a novel host-directed mechanism of action, including TNX-3900, formerly known as HB-121. As consideration for entering into the Healion Asset Purchase Agreement, the Company paid \$1.2 million to Healion. Because the Healion intellectual property was acquired prior to U.S. Food and Drug Administration (FDA) approval, the cash consideration totaling \$1.2 million, was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

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NOTE 13 – LICENSE AGREEMENTS WITH COLUMBIA UNIVERSITY

On February 13, 2023, Tonix exercised an option to obtain an exclusive license from Columbia University (“Columbia”) for the development of a portfolio of both fully human and murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection, including our TNX-3600 and TNX-4100 product candidates, respectively. The licensed mAbs were developed as part of a research collaboration and option agreement between Tonix and Columbia. As of September 30, 2024, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

NOTE 14 – SALE AND PURCHASE OF COMMON STOCK

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 3,393,600 shares of common stock and pre-funded warrants to purchase up to 3,703,140 shares of common stock. The offering price per share of common stock was \$0.57, and the offering price per share of pre-funded warrant was \$0.5699.

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 1,199,448 shares of common stock and pre-funded warrants to purchase up to 2,568,110 shares of common stock. The offering price per share of common stock was \$1.065, and the offering price per share of pre-funded warrant was \$1.064.

The offering closed on June 13, 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.

On June 27, 2024, the Company entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which the Company sold 2,833,900 shares of common stock and pre-funded warrants to purchase up to 4,228,158 shares of common stock. The offering price per share of common stock was \$0.57, and the offering price per share of pre-funded warrant was \$0.5699.

The offering closed on June 28, 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.

March 2024 Financing

On March 28, 2024, the Company entered into an agreement to sell 336,459 shares of common stock, pre-funded warrants to purchase up to 121,875 shares of common stock, and accompanying Series E warrants to purchase up to 458,334 shares of common stock with an exercise price of \$10.56 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 \$9.60, and the offering price per share of pre-funded warrants was \$9.5968.

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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 \$3.9 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 \$10.56 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 217,188 shares was amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 278,125 shares is April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 278,125 shares is April 1, 2025; the termination date for Series C Warrants to purchase up to an aggregate of approximately 1,088,248 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 1,088,248 shares is April 1, 2029. The other terms of the Existing Warrants remained unchanged.

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 Warrant Amendments as a direct and incremental cost of the March 2024 financing and recognized the incremental fair value resulting from the modified terms of approximately \$3.0 million 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 condensed 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.

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On May 22, 2024, at the annual meeting of the Company's stockholders, the Company's stockholders approved the proposal to amend the exercise prices of the Existing Warrants to \$10.56 per share and extend the expiration dates. The Company determined the Existing Warrants met all of the criteria for equity classification as of the approval date. The Existing Warrants were adjusted to fair value through May 22, 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.

December 2023 Financing

On December 20, 2023, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain institutional investors, pursuant to which the Company sold and issued (i) 791,977 shares of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 897,213 shares of common stock and (iii) Series C warrants to purchase up to 2,533,784 shares of common stock (the "Series C Warrants"), and (iv) Series D warrants to purchase up to 2,533,784 shares of common stock (the "Series D Warrants" and, together with the Series C Warrants, the "Common Warrants"). The securities sold in the offering were sold in fixed combinations as units. The offering price per share of common stock and accompanying Common Warrants was \$17.76, and the offering price per Pre-Funded Warrant and accompanying Common Warrants was \$17.7568. The offering closed on December 22, 2023, generating gross proceeds of approximately \$30.0 million, before deducting offering expenses of \$2.3 million payable by the Company. At the closing of the offering, 203,407 Pre-Funded Warrants were immediately exercised into shares of common stock for nominal proceeds.

The Pre-Funded Warrants have an exercise price of \$0.0001 per share, are immediately exercisable subject to certain ownership limitations, and can be exercised at any time until exercised in full. The Series C Warrants have an exercise price of \$17.76 per share, and are exercisable on the later of approval by the Company's stockholders of (i) a proposal to approve the filing of an amendment to the Company's Articles of Incorporation, increasing the number of authorized shares of common stock from 160,000,000 to 1,000,000,000 and (ii) a proposal to allow the Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 (the later of such events, the "Approval Date") and will expire on the later of (a) 10 trading days following the Approval Date and (b) the earlier of (x) the two year anniversary of the Approval Date and (y) 10 trading days following the public announcement of the U.S. Food and Drug Administration's ("FDA") acknowledgement and acceptance of the New Drug Application ("NDA") relating to the Company's TNX-102 SL product candidate in patients with fibromyalgia. The Series D Warrants have an exercise price of \$27.20 per share and are exercisable beginning on the Approval Date through the five-year anniversary of the Approval Date.

Upon the closing of the offering, the Company determined that certain of the Common Warrants did not meet the criteria for equity classification due to the lack of sufficient authorized and unissued shares to settle the instruments. 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, whereby shares are allocated based on 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 beginning with instruments with the latest maturity date first. Pursuant to this sequencing approach, the Company's authorized and unissued shares were applied to the Pre-Funded Warrants and the Common Warrants in the following order: (i) the Pre-Funded Warrants, (ii) the Series D Warrants, and (iii) the Series C Warrants. Based on this analysis, the Company determined that the authorized shares are sufficient to settle the remaining Pre-Funded Warrants and 1,591,665 Series D Warrants and were therefore classified in equity. The remaining 942,120 Series D Warrants and the Series C Warrants associated with the deficit shares were classified as liabilities and are accounted for at fair value.

The \$30.0 million in gross proceeds received by the Company were first allocated to the Series C Warrants and the liability-classified Series D Warrants at their respective fair values of approximately \$14.4 million and \$8.1 million, respectively. The residual proceeds of approximately \$7.5 million were allocated to the shares of common stock, the Pre-Funded Warrants, and the equity-classified Series D Warrants on a relative fair value basis. The issuance costs totaling \$2.3 million were allocated between the equity and liability-classified instruments on a relative fair value basis. Issuance costs of \$1.4 million allocated to the shares, the Pre-Funded Warrants, and the equity-classified Series D Warrants were recognized as a discount to the proceeds allocated to the equity-classified instruments. Issuance costs of \$0.9 million were allocated to the liability-classified Series D Warrants and the Series C Warrants and expensed within Selling, general and administrative expense on the consolidated statements of operations.

On January 25, 2024, the Company's stockholders approved the proposal to file an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 160,000,000 to 1,000,000,000.

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.

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September 2023 Financing

On September 28, 2023, the Company sold 126,563 shares of common stock; pre-funded warrants to purchase up to 154,687 shares of common stock, and accompanying Series A warrants to purchase up to 281,250 shares of common stock with an exercise price of \$16.00 per share and expiring five years from date of issuance, and Series B warrants to purchase up to 281,250 shares of common stock with an exercise price of \$16.00 per share and expiring one year from date of issuance in a public offering, which closed on October 3, 2023. The offering price per share of common stock and accompanying warrants was \$16.00, and the offering price per share of pre-funded warrant and accompanying warrants was \$15.99.

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 \$4.0 million, after deducting the underwriting discount and other offering expenses.

July 2023 Financing

On July 27, 2023, the Company sold 79,062 shares of common stock; pre-funded warrants to purchase up to 139,688 shares of common stock and accompanying common warrants to purchase up to 218,750 shares of common stock with an exercise price of \$32.00 per share in a public offering that closed on August 1, 2023. The offering price per share of common stock and accompanying common warrant was \$32.00, and the offering price per share of pre-funded warrant and accompanying common warrant was \$31.99.

The Company incurred offering expenses of approximately \$0.7 million, including placement agent fees of approximately \$0.5 million. The Company received net proceeds of approximately \$6.3 million, after deducting the underwriting discount and other offering expenses.

2022 Lincoln Park Transaction

On August 16, 2022, the Company entered into a purchase agreement (the “2022 Purchase Agreement”) and a registration rights agreement (the “2022 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2022 Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to \$50,000,000 of the Company’s common stock (subject to certain limitations) from time to time during the term of the 2022 Purchase Agreement. Pursuant to the terms of the 2022 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 2022 Purchase Agreement.

Pursuant to the terms of the 2022 Purchase Agreement, at the time the Company signed the 2022 Purchase Agreement and the 2022 Registration Rights Agreement, the Company issued 3,125 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company’s common stock under the 2022 Purchase Agreement. The commitment shares were valued at \$1,000,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2022 Purchase Agreement.

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During the three and nine months ended September 30, 2023, the Company sold 0 and 3,000 shares, respectively, of common stock under the 2022 Purchase Agreement, for net proceeds of approximately \$0 and \$0.4 million, respectively. No shares were sold during 2024 under the 2022 Purchase Agreement.

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 the Company’s common stock having an aggregate offering price of up to \$150.0 million in ATM sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the 2024 Sales Agreement. The Company’s common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the three months ended September 30, 2024, the Company sold approximately 134.5 million shares of common stock under the Sales Agreement, as defined below, for net proceeds of approximately \$41.8 million. Subsequent to September 30, 2024, the Company has sold 31.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$5.1 million.

On April 8, 2020, the Company entered into a sales agreement (the “Sales Agreement”) with AGP pursuant to which the Company may issue and sell, from time to time, shares of the Company’s common stock having an aggregate offering price of up to \$320.0 million in at-the-market offerings (“ATM”) sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. The Company’s common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. There were no sales under the Sales Agreement during the three and nine months ended September 30, 2024. During the three and nine months ended September 30, 2023, the Company sold approximately 0 and 29,855 shares, respectively, of common stock under the Sales Agreement, for net proceeds of approximately \$0 million and \$3.0 million, respectively. There will be no more sales under the 2020 ATM.

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 and nine months ended September 30, 2024.

During the quarter ended March 31, 2023, the Company repurchased 78,502 of its shares of common stock outstanding under its 2022 share repurchase program for \$12.5 million at prices ranging from \$88.00 to \$275.52 per share for a gross aggregate cost of approximately \$12.5 million.

In January 2023, the Board of Directors approved a new 2023 share repurchase program pursuant to which the Company may repurchase up to \$12.5 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 quarter ended March 31, 2023, the Company repurchased 5,000 of its shares of common stock outstanding under the new 2023 share repurchase program at \$227.84 per share for a gross aggregate cost of \$1.1 million.

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 15 – 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”).

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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 1,563 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). 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, 2024, 10,168 options were available for future grants under the Amended and Restated 2020 Plan.

General

A summary of the stock option activity and related information for the Plans for the nine months ended September 30, 2024, is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2023	43,235	\$ 50,542.10	8.75	\$ —
Grants	338,934	10.30		
Exercised	—	—		
Forfeitures or expirations	(25,996)	34,586.33		
Outstanding at September 30, 2024	356,173	\$ 3,622.40	9.32	\$ —
Exercisable at September 30, 2024	65,691	\$ 17,687.56	8.68	\$

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 2024 was \$0.15 per share and \$8.68 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 2023 was \$26.88 per share and \$127.68 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.

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The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2024, and 2023 were as follows:

	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Risk-free interest rate	3.58% to 5.33%	3.42% to 4.35%
Expected term of option	5.25 to 10.00 years	5.0 to 10 years
Expected stock price volatility	111.89% to 140.42%	122.19% to 142.72%
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 \$1.0 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 \$2.1 million, of which \$1.4 million and \$0.7 million, related to General and Administration and Research and Development, respectively, was recognized for the quarter ended September 30, 2023.

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. Stock-based compensation expense relating to options granted of \$7.2 million, of which \$5.0 million and \$2.2 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2023.

As of September 30, 2024, the Company had approximately \$4.3 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 1.73 years.

Employee Stock Purchase Plans

On May 6, 2022, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan. (the "2022 ESPP"), which was replaced by the Tonix Pharmaceuticals Holdings Corp. 2023 Employee Stock Purchase Plan (the "2023 ESPP", and together with the 2022 ESPP, the "ESPP Plans"), which was approved by the Company's stockholders on May 5, 2023.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 25,000 shares of the Company's common stock. Under the 2023 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 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, 2024, 22,926 shares were available for future sales under the 2023 ESPP.

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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, 2024 and 2023, \$27,000 and \$34,000, respectively, was expensed. In January 2023, 469 shares that were purchased as of December 31, 2022, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2023, approximately \$29,000 of employee payroll deductions accumulated at December 31, 2022, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$14,000 was returned to the employees. As of December 31, 2023, approximately \$44,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In January 2024, 2,074 shares that were purchased as of December 31, 2023, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2024, approximately \$24,000 of employee payroll deductions accumulated at December 31, 2023, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$20,000 was returned to the employees. As of June 30, 2024, approximately \$33,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In July 2024, 6,927 shares that were purchased as of June 30, 2024, under the 2023 ESPP, were issued. Accordingly, during the third quarter of 2024, approximately \$4,000 of employee payroll deductions accumulated at June 30, 2024, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$29,000 was returned to the employees.

NOTE 16 – 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, 2024:

Exercise Price	Number Outstanding	Expiration Date
\$ 10.56	458,334	April 2029
\$ 10.56	278,125	April 2029
\$ 10.56	278,125	April 2025
\$ 10.56	217,188	April 2029
\$ 10.56	1,088,263	April 2026
\$ 10.56	1,088,263	April 2029
\$ 16.00	3,131	October 2024
\$ 16.00	3,131	October 2028
\$ 17.76	1,445,526	December 2025
\$ 27.20	1,445,526	December 2028
\$ 32.00	1,569	August 2028
\$ 3,200.00	4	November 2024
\$ 3,648.00	20	February 2025
	6,307,205	

During the nine months ended September 30, 2024, 11,315,090 prefunded common warrants were exercised.

No common warrants were exercised during the nine months ended September 30, 2023.

Additionally, with the closing of the financing on April 1, 2024, the Company entered into the Warrant Amendments (as defined in Note 13) with certain holders of its warrants to purchase common stock, agreeing to amend the exercise price of each Existing Warrant to \$10.56 upon approval by the Company's stockholders of a proposal to allow the warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 or, if stockholder approval is not obtained by October 1, 2024, the exercise price would be automatically amended 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. The Company's stockholders approved the proposal to amend the exercise prices of the Existing Warrants to \$10.56 per share and extend the termination dates at the annual meeting of the Company's stockholders held on May 22, 2024. As such, the table above reflects the modified terms of the Existing Warrants in effect as of September 30, 2024. See Note 13 for further details.

NOTE 17 – 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, 2024, the Company has right-of-use assets of \$0.6 million and a total lease liability for operating leases of \$0.7 million of which \$0.3 million is included in long-term lease liabilities and \$0.4 million is included in current lease liabilities.

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At September 30, 2024, 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 2024	\$ 75
2025	299
2026	142
2027	139
2028 and beyond	108
	763
Included interest	(63)
	<u>\$ 700</u>

No new leases or amendments were entered into during the nine months ended September 30, 2024. During the nine months ended September 30, 2023, the Company entered into new operating leases and lease amendments, resulting in the Company recognizing an additional operating lease liability of approximately \$898,000 based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately \$898,000, which represents a non-cash investing and financing activity.

Operating lease expense was \$0.1 million for both the three months ended September 30, 2024, and 2023, respectively.

Operating lease expense was \$0.2 million and \$0.4 million for the nine-months ended September 30, 2024, and 2023, respectively.

Other information related to leases is as follows:

	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow from operating leases (in thousands)	\$ 222	\$ 434
Weighted Average Remaining Lease Term		
Operating leases	3.26 years	3.50 years
Weighted Average Discount Rate		
Operating leases	4.81%	4.63%

NOTE 18 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$15.1 million at September 30, 2024 for future work to be performed.

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Defined contribution plan

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, and the Company is also required to make a contribution equal to three percent of each participant’s salary, on an annual basis, subject to limitations under the Code. The Company charged operations \$100,000 and \$600,000 for the three and nine months ended September 30, 2024, respectively, and \$200,000 and \$700,000 for the three and nine months ended September 30, 2023, respectively, for contributions under the 401(k) Plan.

NOTE 19 – SUBSEQUENT EVENTS

Subsequent to September 30, 2024, the Company sold 31.3 million shares of common stock under the 2024 Sales Agreement, for net proceeds of approximately \$5.1 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: substantial competition; our possible 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 biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges. Our priority is to advance our TNX-102 SL product candidate for the management of fibromyalgia, for which a New Drug Application ("NDA") was submitted to the U.S. Food and Drug Administration ("FDA") in October 2024, based on two statistically significant Phase 3 studies. The FDA granted Fast Track designation to TNX-102 SL for the management of fibromyalgia in the third quarter. We expect an FDA decision on the acceptance of the NDA for review and PDUFA date in December and if accepted, a decision on NDA approval in 2025. Fibromyalgia is a common chronic pain condition that affects mostly women. Fibromyalgia is now recognized as the prototypic nociplastic pain syndrome. TNX-102 SL is a non-opioid, centrally acting analgesic developed for long-term use in fibromyalgia. If approved, TNX-102 SL would be the first new drug therapy for fibromyalgia in more than 15 years. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated Investigational New Drug application ("IND") at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). We expect to initiate enrollment in the OASIS study in the fourth quarter. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic drug candidate in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the U.S. National Institute of Drug Abuse. Our immunology development portfolio includes TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) in Phase 1 development for the prevention of allograft rejection and for the treatment of autoimmune diseases. TNX-1700 is a fusion protein of TFF2 and albumin and is in the pre-IND stage of development to treat gastric and pancreatic cancer. We also have pre-clinical product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including TNX-801 a potential vaccine to prevent mpox and smallpox. We recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency ("DTRA") for up to \$34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents 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 infectious disease research facility in Frederick, MD. Tonix Medicines, our commercial subsidiary, markets Zembrace[®] SymTouch[®] (sumatriptan injection) 3 mg and Tosymra[®] (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. 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[®], 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, 2024 Compared to Three Months Ended September 30, 2023

The following table sets forth our operating expenses for the quarter ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,	
	2024	2023
REVENUE		
Product revenue, net	\$ 2,822	\$ 3,989
COSTS AND EXPENSES:		
Cost of sales	\$ 1,555	\$ 2,374
Research and development	9,114	21,050
Selling, general and administrative	7,707	8,712
Total operating expenses	18,376	32,136
Operating loss	(15,554)	(28,147)
Grant income	1,668	—
Other (expense) income, net	(327)	172
Net loss	\$ (14,213)	\$ (27,975)

Revenues. We recognized revenue beginning in July 2023, as a result of the acquisition of two marketed products. Revenue recognized for the quarter ended September 30, 2024 and 2023, was \$2.8 million and \$4.0 million, respectively.

The Company's net product revenues are summarized below:

	Three months ended September 30,	
	2024	2023
Zembrace Symtouch	\$ 2,485	\$ 3,292
Tosymra	337	697
Total product revenues	\$ 2,822	\$ 3,989

Cost of Sales. We recognized cost of sales beginning in July 2023 as a result of the acquisition of Zembrace and Tosymra from Upsher Smith. Cost of sales recognized for the quarter ended September 30, 2024, was \$1.6 million, including write-downs related to Tosymra finished goods inventory of approximately \$0.3 million based on an assessment of inventory on hand and projected sales prior to the respective expiration dates. Cost of sales recognized for the quarter ended September 30, 2023, was \$2.4 million.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2024 were \$9.1 million, a decrease of \$11.9 million, or 57%, from \$21.0 million for the three months ended September 30, 2023. This decrease is predominately due to decreased clinical expenses of \$5.3 million, non-clinical expenses of \$2.8 million, manufacturing expenses of \$0.5 million as a result of fewer trials in the clinic and pipeline prioritization period over period, employee-related expenses of \$2.0 and lab supplies of \$0.7 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, 2024, and 2023.

	Three months ended September 30, (in thousands)		
	2024	2023	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 525	\$ 3,365	\$ (2,840)
Direct expenses – TNX - 601 ER	36	2,901	(2,865)
Direct expenses – TNX - 801	104	551	(447)
Direct expenses – TNX - 1500	743	2,420	(1,677)
Direct expenses – TNX - 1900	667	627	40
Direct expenses – Other programs	801	6,127	(5,326)
Internal staffing, overhead and other	6,238	5,059	1,179
Total research & development	\$ 9,114	\$ 21,050	\$ (11,936)

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, 2024, were \$7.7 million, a decrease of \$1.0 million, or 11%, from \$8.7 million incurred in the three months ended September 30, 2023. The decrease is primarily due to a decrease in employee-related expenses of \$0.3 million, a decrease in the transactional services provided by Upsher Smith of \$0.7 million and a decrease in sales and marketing of \$0.4 million, offset by an increase in professional fees of \$0.4 million.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2024 was \$14.2 million, a decrease of \$13.8 million, or 49%, compared to a net loss of \$28.0 million for the three months ended September 30, 2023.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

The following table sets forth our operating expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine months ended September 30,	
	2024	2023
REVENUE		
Product revenue, net	\$ 7,512	\$ 3,989
COSTS AND EXPENSES:		
Cost of sales	\$ 6,582	\$ 2,374
Research and development	31,675	69,535
Selling, general and administrative	24,519	23,131
Asset impairment charges	58,957	—
Total operating expenses	121,733	95,040
Operating loss	(114,221)	(91,051)
Grant income	1,668	—
Gain on change in fair value of warrant liabilities	6,150	—
Other (expense) income, net	(1,525)	1,715
Net loss	\$ (107,928)	\$ (89,336)

Revenues. We recognized revenue beginning in July 2023, as a result of the acquisition of two marketed products. Revenue recognized for the nine months ended September 30, 2024 and 2023, was \$7.5 million and \$4.0 million, respectively.

The Company's net product revenues are summarized below:

	Nine months ended September 30,	
	2024	2023
Zembrace Symtouch	\$ 6,059	\$ 3,292
Tosymra	1,453	697
Total product revenues	<u>\$ 7,512</u>	<u>\$ 3,989</u>

Cost of Sales. We recognized cost of sales beginning in July 2023 as a result of the acquisition of Zembrace and Tosymra from Upsher Smith. Cost of sales recognized for the nine months ended September 30, 2024, was \$6.6 million, including write-downs related to Tosymra and Zembrace finished goods inventory of approximately \$2.0 million based on an assessment of inventory on hand and projected sales prior to the respective expiration dates. Cost of sales recognized for the nine months ended September 30, 2023, was \$2.4 million

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2024 were \$31.7 million, a decrease of \$37.8 million, or 54%, from \$69.5 million for the nine months ended September 30, 2023. This decrease is predominately due to decreased clinical expenses of \$14.1 million, non-clinical expenses of \$10.9 million, manufacturing expenses of \$2.9 million as a result of fewer trials in the clinic and pipeline prioritization period over period, employee-related expenses of \$4.4 and lab supplies of \$3.8 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 nine months ended September 30, 2024, and 2023.

	Nine months ended September 30, (in thousands)		
	2024	2023	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 3,513	\$ 10,342	\$ (6,829)
Direct expenses – TNX - 601 ER	709	7,431	(6,722)
Direct expenses – TNX - 801	723	2,261	(1,538)
Direct expenses – TNX - 1800	301	1,576	(1,275)
Direct expenses – TNX - 1500	1,966	6,010	(4,044)
Direct expenses – TNX - 1900	1,326	4,168	(2,842)
Direct expenses – Other programs	1,461	10,696	(9,235)
Internal staffing, overhead and other	21,676	27,051	(5,375)
Total research & development	<u>\$ 31,675</u>	<u>\$ 69,535</u>	<u>\$ 37,860</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, 2024 were \$24.5 million, an increase of \$1.4 million, or 6%, from \$23.1 million incurred in the nine months ended September 30, 2023. The increase is primarily due to an increase in financial reporting expenses of \$1.1 million, related to the special shareholder meetings in 2024, an increase in sales and marketing of \$0.5 million, an increase in depreciation of property and equipment of \$0.3 million and an increase in fees and permits of \$0.4 million, related to licenses obtained to sell the migraine products, offset by a decrease in employee-related costs of \$1.0 million, due to less employees.

Asset impairment charges. We recognized 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, which is reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024.

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 pending FDA approval for which we expect an FDA decision in 2025.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2024 was \$107.9 million, an increase of \$18.6 million, or 21%, compared to a net loss of \$89.3 million for the nine months ended September 30, 2023.

License Agreements

On February 13, 2023, we exercised an option to obtain an exclusive license from Columbia for the development of a portfolio of fully human and murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection, including our TNX-3600 and TNX-4100 product candidates, respectively. The licensed mAbs were developed as part of a research collaboration and option agreement between us and Columbia. As of September 30, 2024, other than the upfront fee, 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.

Additionally, in connection with the acquisition from Upsher Smith, we and Upsher Smith entered into a transition services agreement pursuant to which Upsher Smith agreed to provide certain transition services to us for base fees equal to \$100,000 per month for the first six months, and \$150,000 per month for the seventh through ninth months, plus additional monthly fees for each service category totaling up to \$150,000 per month. We have signed an amendment to the transitional services agreement with Upsher Smith so that Upsher Smith will continue to manage certain government rebates, and Upsher Smith will be reimbursed by us at cost for any rebates they pay on our behalf.

As the assets acquired from Upsher Smith met the definition of a business under the current accounting guidance, the total purchase price was allocated to the acquired inventory and other tangible assets, and the developed technology intangible assets related to Zembrace and Tosymra based on their estimated fair values on the acquisition date. The excess of the purchase price over the fair value of the acquired assets was recorded as goodwill.

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.

On February 2, 2023, we entered into an asset purchase agreement with Healion Bio Inc., pursuant to which we acquired all the pre-clinical infectious disease assets of Healion for \$1.2 million. Because the Healion intellectual property was acquired prior to FDA approval, the \$1.2 million cash consideration was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

Liquidity and Capital Resources

As of September 30, 2024, we had working capital of \$35.4 million, comprised primarily of cash and cash equivalents of \$28.2 million, Accounts receivable, net of \$4.0 million, Inventory of \$7.9 million and prepaid expenses and other of \$10.4 million, offset by \$3.9 million of accounts payable, \$8.1 million of accrued expenses, short-term loan payable of \$2.8 million, and current lease liabilities of \$0.3 million. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical programs, and the operations related to Zembrace and Tosymra. During the fourth quarter of 2023, we engaged CBRE, an international real estate brokerage firm, to potentially find a strategic partner for, or buyer of, our Advanced Development Center in North Dartmouth, Massachusetts (“ADC”), to align with our current business objectives and priorities. Currently, we do not have a commitment in place to sell the ADC.

The following table provides a summary of operating, investing and financing cash flows for the nine months ended September 30, 2024, and 2023, respectively (in thousands):

	Nine Months ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (46,295)	\$ (79,663)
Net cash used in investing activities	(117)	(28,639)
Net cash provided by (used in) financing activities	49,718	(4,198)

For the nine months ended September 30, 2024 and 2023, we used approximately \$46.3 million and \$79.7 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The decrease in cash outlays principally resulted from a decrease in research and development activities. For the nine months ended September 30, 2024, net cash provided by financing activities was \$49.7 million predominately from the issuance of common stock offset by the deferred payment to USL. For the nine months ended September 30, 2023, net cash used in financing activities was \$4.2 million, predominately from the repurchase of our common stock. 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, and \$28.6 million for the nine months ended September 30, 2023 related to the purchase of the USL assets and property and equipment.

We believe that our cash resources at September 30, 2024, and the proceeds that we raised from equity offerings subsequent to the end of the third quarter of 2024 will meet our operating and capital expenditure requirements into the first quarter of 2025, but not beyond.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes we may make in our research and development spending plans. These factors raise substantial doubt about our ability to continue as a going concern for the one year period from the date of filing of this Form 10-Q. We have the ability to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. Without 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 provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals will be adversely affected.

Future Liquidity Requirements

We expect to incur losses from operations for the near future. We expect to decrease our operating costs to align the Company’s capital and human resources with its previously announced strategic prioritization of TNX-102 SL product candidate for the management of fibromyalgia. We will not have enough resources to meet our operating requirements for the one-year period from filing date of this report.

Our future capital requirements will depend on a number of factors, including 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 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 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.

2024 At-the-Market Offering

On July 30, 2024, we entered into a Sales Agreement with AGP pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$150.0 million in the ATM. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. Our common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the three months ended September 30, 2024, we sold approximately 134.5 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$41.8 million. Subsequent to September 30, 2024, we sold 31.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$5.1 million.

July 2024 Financing

On July 9, 2024, we entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which we sold 3,393,600 shares of common stock and pre-funded warrants to purchase up to 3,703,140 shares of common stock. The offering price per share of common stock was \$0.57, and the offering price per share of pre-funded warrant was \$0.5699.

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 1,199,448 shares of common stock and pre-funded warrants to purchase up to 2,568,110 shares of common stock. The offering price per share of common stock was \$1.065, and the offering price per share of pre-funded warrant was \$1.064.

The offering closed on June 13, 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.

On June 27, 2024, we entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which we sold 2,833,900 shares of common stock and pre-funded warrants to purchase up to 4,228,158 shares of common stock. The offering price per share of common stock was \$0.57, and the offering price per share of pre-funded warrant was \$0.5699.

The offering closed on June 28, 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.

March 2024 Financing

On March 28, 2024, we entered into an agreement to sell 336,459 shares of common stock, pre-funded warrants to purchase up to 121,875 shares of common stock, and accompanying Series E warrants to purchase up to 458,334 shares of common stock with an exercise price of \$10.56 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 \$9.60 and the offering price per share of pre-funded warrants was \$9.5968.

We incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$3.9 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 \$10.56 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 on May 22, 2024, the termination date for the warrants issued August 2023 (the “August Warrants”) to purchase up to an aggregate of 217,188 shares was amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 278,125 shares is April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 278,125 shares is April 1, 2025; the termination date for Series C Warrants to purchase up to an aggregate of approximately 1,088,248 shares is the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by us to the Series C Warrant holder of our public announcement of the FDA’s acknowledgement and acceptance of our 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 1,088,248 shares is April 1, 2029. The other terms of the Existing Warrants will remain unchanged. On May 22, 2024, at the annual meeting of stockholders, our stockholders approved the proposal to amend the exercise prices of the Existing Warrants to \$10.56 per share and extend the expiration dates.

December 2023 Financing

On December 20, 2023, we entered into a securities purchase agreement (the “Purchase Agreement”) with certain institutional investors, pursuant to which we sold and issued (i) 791,977 shares of our common stock, (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 897,213 shares of common stock and (iii) Series C warrants to purchase up to 2,533,784 shares of common stock (the “Series C Warrants”), and (iv) Series D warrants to purchase up to 2,533,784 shares of common stock (the “Series D Warrants” and, together with the Series C Warrants, the “Common Warrants”). The securities sold in the offering were sold in fixed combinations as units. The offering price per share of common stock and accompanying Common Warrants was \$17.76, and the offering price per Pre-Funded Warrant and accompanying Common Warrants was \$17.7568. The offering closed on December 22, 2023, generating gross proceeds of approximately \$30.0 million, before deducting offering expenses of \$2.3 million payable by us. At the closing of the offering, 203,407 Pre-Funded Warrants were immediately exercised into shares of common stock for nominal proceeds.

The Pre-Funded Warrants have an exercise price of \$0.0001 per share, are immediately exercisable subject to certain ownership limitations, and can be exercised at any time until exercised in full. The Series C Warrants have an exercise price of \$17.76 per share, and are exercisable on the later of approval by our stockholders of (i) a proposal to approve the filing of an amendment to our Articles of Incorporation, increasing the number of authorized shares of common stock from 160,000,000 to 1,000,000,000 and (ii) a proposal to allow the Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 (the later of such events, the “Approval Date”) and will expire on the later of (a) 10 trading days following the Approval Date and (b) the earlier of (x) the two year anniversary of the Approval Date and (y) 10 trading days following the public announcement of the U.S. Food and Drug Administration’s (“FDA”) acknowledgement and acceptance of the New Drug Application (“NDA”) relating to our TNX-102 SL product candidate in patients with fibromyalgia. The Series D Warrants have an exercise price of \$27.20 per share and are exercisable beginning on the Approval Date through the five-year anniversary of the Approval Date.

Upon the closing of the offering, we determined that certain of the Common Warrants did not meet the criteria for equity classification due to the lack of sufficient authorized and unissued shares to settle the instruments. We have 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, whereby shares are allocated based on 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 beginning with instruments with the latest maturity date first. Pursuant to this sequencing approach, our authorized and unissued shares were applied to the Pre-Funded Warrants and the Common Warrants in the following order: (i) the Pre-Funded Warrants, (ii) the Series D Warrants, and (iii) the Series C Warrants. Based on this analysis, we determined that the authorized shares are sufficient to settle the remaining Pre-Funded Warrants and 1,591,665 Series D Warrants and were therefore classified in equity. The remaining 942,120 Series D Warrants and the Series C Warrants associated with the deficit shares were classified as liabilities and are accounted for at fair value.

The \$30.0 million in gross proceeds received by us was first allocated to the Series C Warrants and the liability-classified Series D Warrants at their respective fair values of approximately \$14.4 million and \$8.1 million, respectively. The residual proceeds of approximately \$7.5 million were allocated to the shares of common stock, the Pre-Funded Warrants, and the equity-classified Series D Warrants on a relative fair value basis. The issuance costs totaling \$2.3 million were allocated between the equity and liability-classified instruments on a relative fair value basis. Issuance costs of \$1.4 million allocated to the shares, the Pre-Funded Warrants, and the equity-classified Series D Warrants were recognized as a discount to the proceeds allocated to the equity-classified instruments. Issuance costs of \$0.9 million were allocated to the liability-classified Series D Warrants and the Series C Warrants and expensed within Selling, general and administrative expense on the consolidated statements of operations.

On January 25, 2024, our stockholders approved the proposal to file an amendment to our Articles of Incorporation to increase the number of authorized shares of common stock from 160,000,000 to 1,000,000,000.

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.

September 2023 Financing

On September 28, 2023, we sold 126,563 shares of common stock; pre-funded warrants to purchase up to 154,687 shares of common stock, and accompanying Series A warrants to purchase up to 281,250 shares of common stock with an exercise price of \$16.00 per share and expiring five years from date of issuance, and Series B warrants to purchase up to 281,250 shares of common stock with an exercise price of \$16.00 per share and expiring one year from date of issuance in a public offering, which closed on October 3, 2023. The offering price per share of common stock and accompanying warrants was \$16.00, and the offering price per share of pre-funded warrant and accompanying warrants was \$15.99.

We incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$4.0 million, after deducting the underwriting discount and other offering expenses.

July 2023 Financing

On July 27, 2023, we sold 79,062 shares of common stock; pre-funded warrants to purchase up to 139,688 shares of common stock and accompanying common warrants to purchase up to 218,750 shares of common stock with an exercise price of \$32.00 per share in a public offering that closed on August 1, 2023. The offering price per share of common stock and accompanying common warrant was \$32.00, and the offering price per share of pre-funded warrant and accompanying common warrant was \$31.99.

We incurred offering expenses of approximately \$0.7 million, including placement agent fees of approximately \$0.5 million. We received net proceeds of approximately \$6.3 million, after deducting the underwriting discount and other offering expenses.

2022 Lincoln Park Transaction

On August 16, 2022, we entered into a purchase agreement (the “2022 Purchase Agreement”) and a registration rights agreement (the “2022 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2022 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$50,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2022 Purchase Agreement. Pursuant to the terms of the 2022 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 2022 Purchase Agreement.

Pursuant to the terms of the 2022 Purchase Agreement, at the time we signed the 2022 Purchase Agreement and the 2022 Registration Rights Agreement, we issued 3,125 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2022 Purchase Agreement. The commitment shares were valued at \$1,000,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2022 Purchase Agreement.

During the three and nine months ended September 30, 2023, we sold 0 and 3,000 shares, respectively, of common stock under the 2022 Purchase Agreement, for net proceeds of approximately \$0 and \$0.4 million, respectively. No shares were sold during 2024 under the 2022 Purchase Agreement.

At-the-Market Offerings

On April 8, 2020, we entered into a sales agreement (the “Sales Agreement”) with AGP pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$320.0 million in at-the-market offerings (“ATM”) sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. Our common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. There were no sales under the Sales Agreement during the three and nine months ended September 30, 2024. During the three and nine months ended September 30, 2023, we sold approximately 0 shares and 29,855 shares, respectively, of common stock under the Sales Agreement, for net proceeds of approximately \$0 million and \$3.0 million, respectively. There will be no more sales under the 2020 ATM.

Share Repurchase Program

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 our 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 and nine months ended September 30, 2024.

During the first quarter of 2023, we repurchased 78,502 of our shares of common stock outstanding under the 2022 share repurchase program for \$12.5 million at prices ranging from \$88.00 to \$275.52 per share for a gross aggregate cost of approximately \$12.5 million. In addition, we incurred expenses of \$0.3 million.

In January 2023, the Board of Directors approved a new 2023 share repurchase program pursuant to which we may repurchase up to an additional \$12.5 million in value of our 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 first quarter of 2023, we repurchased 5,000 of our shares of common stock outstanding under the new 2023 share repurchase program at \$227.84 per share for a gross aggregate cost of \$1.1 million.

Debt Financing

On December 8, 2023, we executed a Loan and Guaranty Agreement (the “Loan Agreement”) to issue a 36-month term loan (the “Term Loan”) in the 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 is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

Borrowings under the Term Loan bear 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 is payable monthly in arrears commencing in December 2023. In connection with the Term Loan, we deposited into a reserve account \$1.8 million to be used exclusively to fund interest payments related to the Term Loan. The deposit is reflected as prepaid and other current assets on the consolidated balance sheet.

Commencing on March 8, 2024 and continuing monthly through the Maturity Date, the outstanding principal will be 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, we must pay a monthly collateral monitoring charge equal to 0.23% of the outstanding principal amount of the term loan as of the date of payment. We incurred \$1.1 million in issuance costs, which is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

The Loan Agreement provides for voluntary prepayments of the Term Loan, in whole or in part, subject to a prepayment premium. The Loan Agreement contains customary affirmative and negative covenants by us, which among other things, will require us to provide certain financial reports to the lenders, to maintain a deposit account to fund interest payments, and limit the ability of us to incur or guarantee additional indebtedness, pay dividends or make other equity distributions, sell assets, engage in certain transactions, and effect a consolidation or merger. Our obligations under the Loan Agreement may be accelerated upon customary events of default, including non-payment of principal, interest, fees and other amounts, covenant default, insolvency, material judgements, inaccuracy of representations and warranties, invalidity of guarantees. The Term Loan is secured by first priority security interests in our R&D Center in Frederick, Maryland, the Advanced Development Center in North Dartmouth, Massachusetts, and substantially all of the relevant deposit accounts.

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 1,563 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). 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, 2024, 10,168 options were 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 2024 was \$0.15 per share and \$8.68 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 2023 was \$26.88 per share and \$127.68 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.

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 our historical stock price volatility.

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 \$2.1 million, of which \$1.4 million and \$0.7 million, related to General and Administration and Research and Development, respectively, was recognized for the quarter ended September 30, 2023.

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. Stock-based compensation expense relating to options granted of \$7.2 million, of which \$5.0 million and \$2.2 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2023.

As of September 30, 2024, we had approximately \$4.3 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 1.73 years.

Employee Stock Purchase Plans

On May 6, 2022, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan. (the “2022 ESPP”), which was replaced by the Tonix Pharmaceuticals Holdings Corp. 2023 Employee Stock Purchase Plan (the “2023 ESPP”, and together with the 2022 ESPP, the “ESPP Plans”), which was approved by our stockholders on May 5, 2023.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 25,000 shares of our common stock. Under the 2023 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 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, 2024, 22,926 shares were available for future sales under the 2023 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, 2024 and 2023, \$27,000 and \$34,000, respectively, was expensed. In January 2023, 469 shares that were purchased as of December 31, 2022, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2023, approximately \$29,000 of employee payroll deductions accumulated at December 31, 2022, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$14,000 was returned to the employees. As of December 31, 2023, approximately \$44,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In January 2024, 2,074 shares that were purchased as of December 31, 2023, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2024, approximately \$24,000 of employee payroll deductions accumulated at December 31, 2023, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$20,000 was returned to the employees. As of June 30, 2024, approximately \$33,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In July 2024, 6,927 shares that were purchased as of June 30, 2024, under the 2022 ESPP, were issued. Accordingly, during the third quarter of 2024, approximately \$4,000 of employee payroll deductions accumulated at June 30, 2024, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$29,000 was returned to the employees.

Commitments

Research and Development Contracts

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$15.1 million at September 30, 2024 for future work to be performed.

At September 30, 2024, 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 2024	\$ 75
2025	299
2026	142
2027	139
2028 and beyond	108
	<u>763</u>
Included interest	(63)
	<u>\$ 700</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.

Business Combinations. We apply the acquisition method of accounting for business combinations. Under the acquisition method, the acquiring entity recognizes all of the identifiable assets acquired and liabilities assumed at their acquisition date fair values. We use our best estimates and assumptions to estimate the fair values of these tangible and intangible assets. Any excess of the purchase price over amounts allocated to the assets acquired is recorded as goodwill. The acquired intangible assets are amortized using the straight-line method over the estimated useful lives of the respective assets. 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.

Asset impairment charges. We test certain assets for impairment, including goodwill, indefinite-lived intangibles, long-lived assets and amortizing intangibles. Goodwill is reviewed for impairment by comparing the carrying value of a reporting unit to its fair value on an annual basis as of June 30, or more frequently if events or changes in circumstances indicate that the carrying amount of goodwill may be impaired. We evaluate long-lived assets for impairment, including property and equipment and finite-lived intangibles assets whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, we compare 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.

We completed the required annual impairment test for goodwill as of June 30, 2024, primarily using an income approach or discounted cash flow analysis. Additionally, due to a sustained decline in revenues and continued delays in building out the sales team for our commercialized products, we also tested the commercialized products asset group for recoverability as of June 30, 2024, and determined that the carrying value was not recoverable and therefore estimated the fair value of the asset group using a discounted cash flow analysis. The significant assumptions used in the discounted cash flow model included revenue growth, long-term growth rate, and discounts rate. The impairment assessments resulted in full non-cash impairment of \$965,000 of goodwill and \$9.2 million, consisting of \$6.2 million and \$3.0 million for the Zembrace and Tosymra developed technology, intangible assets, which are reflected in asset impairment charges in the consolidated statements of operations for the nine months ended September 30, 2024.

During the second quarter of 2024, we identified certain triggering events related to the ADC and the decommissioning of the ADC. The Company determined that the carrying value of the ADC was not recoverable and that the carrying value exceeded its fair value. We engaged independent appraisers to value the building and land, using sales comparison and income capitalization approaches, and the related fixed assets using an indirect cost approach and market approach. The assessments resulted in 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.

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 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.

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 consolidated balance sheet. Amortization of deferred financing costs is included in interest expense on the consolidated statements of operations.

Original issue discount. Certain term debt issued by the Company provides the debt holder with an original issue discount. Original issue discounts are reflected as a direct reduction of the related debt liability on the consolidated balance sheets and are amortized over the term of the related debt agreement using the effective interest method. Amortization of original issue discounts are included in interest expense on the consolidated statements of operations.

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.

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.

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.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, *Segment Reporting--Improvements to Reportable Segment Disclosures*, which requires incremental disclosures about a public entity’s reportable segments but does not change the definition of a segment or the guidance for determining reportable segments. The new guidance requires disclosure of significant segment expenses that are (1) regularly provided to (or easily computed from information regularly provided to) the chief operating decision maker and (2) included in the reported measure of segment profit or loss. The new standard also allows companies to disclose multiple measures of segment profit or loss if those measures are used to assess performance and allocate resources. The guidance will first be effective in our annual disclosures for the year ending December 31, 2024, and will be adopted retrospectively unless impracticable. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2023-07 on our disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which requires disaggregated information about our effective tax rate reconciliation as well as information on income taxes paid. The guidance will first be effective in our annual disclosures for the year ending December 31, 2025, and should be applied on a prospective basis with the option to apply retrospectively. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2023-09 on our disclosures.

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.

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our principal executive officer and our principal financial officer, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act, as amended) as of the end of the period covered by this report. 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 that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective as of September 30, 2024, as the material weakness described below has been remediated.

Previously Reported Material Weakness in Internal Control Over Financial Reporting

In the 2024 Form 10-Q, filed with the SEC on August 16, 2024, management concluded that our internal control over financial reporting was not effective as of June 30, 2024. In the evaluation, we did not maintain an effective control environment over the internal control activities to ensure the proper recognition and measurement related to the accounting for complex and non-routine transactions. We did not have adequate supervision and review controls over the complex accounting related to the non-cash impairment of intangibles, non-cash equity transactions and the recoverability of inventory. As a result, management review of asset impairment calculations did not identify errors in the associated cash flow projections which led to an error in the conclusion of the initial impairment assessment. We also did not properly assess the realizability of inventory based upon the projections utilized and our assessment of an amendment to existing warrants that were reclassified into equity in the same period did not include a quantitative evaluation of the potential materiality of revaluation adjustments.

In connection with the material weakness as it relates to the accounting for complex and non-routine transactions related to the non-cash impairment of intangibles, non-cash equity transactions and the recoverability of inventory, management re-evaluated the effectiveness of such controls as of September 30, 2024, and concluded that such controls were operating effectively as of September 30, 2024. The remediation of the material weakness over the complex accounting related to the non-cash impairment of intangibles, non-cash equity transactions was as a result of no material balances related to these financial statement captions as of September 30, 2024, and consequently there was no risk of material misstatements for these financial statement captions. In relation to the realizability of inventory, the remediation of this material weakness constituted expanded review processes including but not limited to the assessment of additional data points for the assessment and additional personnel included to evaluate our ability to realize inventory balances.

Changes in internal control over financial reporting.

Other than as described above, there were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2024 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

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, 2023 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024. You should carefully consider the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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, 2023, 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.

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

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 Company's fiscal quarter ended September 30, 2024 (each as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended).

Item 6. Exhibits

- [2.01](#) 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.
- [3.01](#) 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.
- [3.02](#) 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.
- [3.03](#) 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.
- [3.04](#) 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.
- [3.05](#) Specimen Common Stock Certificate, 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.
- [3.06](#) 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.
- [3.07](#) 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 16, 2022.
- [3.08](#) 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 9, 2023.
- [4.01](#) 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.
- [4.02](#) Form of Pre-Funded Warrant, dated as of July 9, 2024, 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.

10.01	Placement Agency Agreement, dated as of July 9, 2024, between Tonix Pharmaceuticals Holding Corp. and Dawson James Securities Inc., 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.
10.02	Warrant Agent Agreement, dated as of July 10, 2024, between Tonix Pharmaceuticals Holding Corp. and VStock Transfer, 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.
10.03	Form of Securities Purchase Agreement, dated as of July 9, 2024, 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.
10.04	Sales Agreement, dated July 30, 2024, by and between Tonix Pharmaceuticals Holdings Corp. and A.G.P./Alliance Global Partners, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 30, 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.
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.
32.01	Certification 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.
32.02	Certification of Chief Executive Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 INS	XBRL Instance Document
101 SCH	XBRL Taxonomy Extension Schema Document
101 CAL	XBRL Taxonomy Calculation Linkbase Document
101 LAB	XBRL Taxonomy Labels Linkbase Document
101 PRE	XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

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.

Date: November 12, 2024

By: /s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer (Principal Executive Officer)

Date: November 12, 2024

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 12, 2024

/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 12, 2024

/s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE 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, 2024 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 12, 2024

By: /s/ Seth Lederman

Name: Seth Lederman

Title: *Chief Executive Officer*

**CERTIFICATION OF 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, 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, 2024 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 12, 2024

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