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, 2023

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	**26-1434750**
(State or other jurisdiction of incorporation or organization)	(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	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	□

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13 (a) of the Exchange Act. □

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

As of November 9, 2023, there were 23,849,341 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)

	September 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,914	$ 120,229
Inventory	13,317	—
Receivables, net	1,562	—
Prepaid expenses and other	9,544	10,548
Total current assets	31,337	130,777
Property and equipment, net	94,866	93,814
Intangible assets, net	9,982	120
Goodwill	965	—
Operating lease right-to-use assets	1,081	715
Other non-current assets	1,051	264
Total assets	$ 139,282	$ 225,690
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,799	$ 8,068
Accrued expenses and other current liabilities	9,500	9,680
Lease liability, short term	434	432
Total current liabilities	17,733	18,180
Lease liability, long term	716	328
Total liabilities	18,449	18,508
Commitments (See Note 19)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized		
Series B Convertible Preferred stock, 0 shares designated as of both September 30, 2023 and December 31, 2022; issued and outstanding - none	—	—
Series A Convertible Preferred stock, 0 shares designated as of both September 30, 2023 and December 31, 2022; issued and outstanding - none	—	—
Common stock, $0.001 par value; 160,000,000 shares authorized; 17,762,341 and 12,368,620 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively and 14,999 shares to be issued as of December 31, 2022	18	12
Additional paid in capital	694,371	677,375
Accumulated deficit	(573,336)	(470,038)
Accumulated other comprehensive loss	(220)	(167)
Total stockholders' equity	120,833	207,182
Total liabilities and stockholders' equity	$ 139,282	$ 225,690

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,	
	2023	**2022**	**2023**	**2022**
REVENUE:				
Product revenue, net	$ 3,989	$ —	$ 3,989	$ —
COSTS AND EXPENSES:				
Cost of revenue	$ 2,374	$ —	$ 2,374	$ —
Research and development	21,050	22,201	69,535	57,202
Selling, general and administrative	8,712	7,390	23,131	22,161
	32,136	29,591	95,040	79,363
Operating loss	(28,147)	(29,591)	(91,051)	(79,363)
Interest income, net	172	610	1,715	825
Net loss	(27,975)	(28,981)	(89,336)	(78,538)
Preferred stock deemed dividend	—	—	—	4,255
Net loss available to common stockholders	$ (27,975)	$ (28,981)	$ (89,336)	$ (82,793)
Net loss per common share, basic and diluted	$ (1.83)	$ (4.24)	$ (7.40)	$ (18.58)
Weighted average common shares outstanding, basic and diluted	15,327,558	6,843,099	12,079,583	4,455,943

See the accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (27,975)	$ (28,981)	$ (89,336)	$ (78,538)
Other comprehensive loss:				
Foreign currency translation loss	(8)	(17)	(53)	(68)
Comprehensive loss	$ (27,983)	$ (28,998)	$ (89,389)	$ (78,606)

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
NINE MONTHS ENDED SEPTEMBER 30, 2023
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance, December 31, 2022	12,368,620	$ 12	$ 677,375	$ (167)	$ (470,038)	$ 207,182
Repurchase of common stock under Share Repurchase Program	(2,672,044)	(3)	—	—	(13,962)	(13,965)
Issuance of common stock under 2022 Purchase agreement	96,000	—	441	—	—	441
Issuance of common stock under At-the-market offering, net of transactional expenses of $101	514,502	1	1,994	—	—	1,995
Employee stock purchase plan	14,999	—	29	—	—	29
Stock-based compensation	—	—	2,794	—	—	2,794
Foreign currency transaction gain	—	—	—	(44)	—	(44)
Net loss	—	—	—	—	(33,005)	(33,005)
Balance, March 31, 2023	10,322,077	$ 10	$ 682,633	$ (211)	$ (517,005)	$ 165,427
Issuance of common stock under At-the-market offering, net of transactional expenses of $36	440,264	1	1,028	—	—	1,029
Stock-based compensation	—	—	2,364	—	—	2,364
Foreign currency transaction gain	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(28,356)	(28,356)
Balance, June 30, 2023	10,762,341	$ 11	$ 686,025	$ (212)	$ (545,361)	$ 140,463
Issuance of common stock under AGP Financing, net of transactional expenses of $726	2,530,000	3	6,271	—	—	6,274
Issuance of common stock upon exercise of prefunded warrants under AGP Financing	4,470,000	4	(4)	—	—	—
Stock-based compensation	—	—	2,079	—	—	2,079
Foreign currency transaction gain	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(27,975)	(27,975)
Balance, September 30, 2023	17,762,341	$ 18	$ 694,371	$ (220)	$ (573,336)	$ 120,833

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
NINE MONTHS ENDED SEPTEMBER 30, 2022
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance, December 31, 2021	2,634,110	$ 3	$ 578,626	$ (92)	$ (359,820)	$ 218,717
Issuance of common stock in January and March 2022 under At-the-market offering, net of transactional expenses of $507	172,276	—	8,488	—	—	8,488
Issuance of common stock under 2021 Purchase agreement	110,000	—	4,535	—	—	4,535
Employee stock purchase plan	646	—	40	—	—	40
Stock-based compensation	—	—	2,620	—	—	2,620
Foreign currency transaction gain	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	(26,417)	(26,417)
Balance, March 31, 2022	2,917,032	3	594,309	(118)	(386,237)	207,957
Issuance of common stock in April, May and June 2022 under At-the-market offering, net of transaction expenses of $1,426	2,220,699	2	42,966	—	—	42,968
Issuance of common stock under 2021 Purchase agreement	65,000	—	1,964	—	—	1,964
Preferred stock dividend	—	—	(4,255)	—	—	(4,255)
Stock-based compensation	—	—	2,813	—	—	2,813
Foreign currency transaction gain	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	(23,140)	(23,140)
Balance, June 30, 2022	5,202,731	5	637,797	(143)	(409,377)	228,282
Issuance of common stock in July, August and September 2022 under At-the-market offering, net of transactional expenses of $805	3,079,176	3	24,689	—	—	24,692
Issuance of common stock under the 2021 Purchase agreement	281,557	1	2,182	—	—	2,183
Issuance of commitment shares under 2022 Purchase Agreement	100,000	—	—	—	—	—
Stock-based compensation	—	—	2,765	—	—	2,765
Foreign currency transaction gain	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(28,981)	(28,981)
Balance, September 30, 2022	8,663,464	$ 9	$ 667,433	$ (160)	$ (438,358)	$ 228,924

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,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (89,336)	$ (78,538)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,030	417
Gain on disposal of property and equipment	(196)	—
Stock-based compensation	7,237	8,198
Changes in operating assets and liabilities:		
Receivables, net	(1,562)	—
Prepaid expenses and other	3,334	(753)
Accounts payable	446	(4,079)
Operating lease liabilities and ROU asset, net	24	5
Accrued expenses and other current liabilities	(2,640)	(1,002)
Net cash used in operating activities	(79,663)	(75,752)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of a business	(22,174)	—
Disposal of property and equipment	992	—
Purchase of property and equipment	(7,457)	(43,476)
Net cash used in investing activities	(28,639)	(43,476)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from ESPP	29	40
Proceeds, net of $0 and $4,255 expenses, from sale of convertible redeemable preferred stock	—	27,245
Redemption of convertible redeemable preferred stock	—	(31,500)
Repurchase of common stock	(13,965)	—
Proceeds, net of $863 and $2,738 expenses, from sale of common stock	9,739	84,830
Net cash (used in) provided by financing activities	(4,197)	80,615
Effect of currency rate change on cash	(55)	(69)
Net decrease in cash, cash equivalents and restricted cash	(112,554)	(38,682)
Cash, cash equivalents and restricted cash beginning of the period	120,470	178,900
Cash, cash equivalents and restricted cash end of period	$ 7,916	$ 140,218
Supplemental disclosures of cash flow information:		
Non-cash financing and investing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 275	$ (3,310)
Preferred stock deemed dividend	$ —	$ 4,255

See the accompanying notes to the condensed consolidated financial statements

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. ("Tonix Sub"), is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. The therapeutics under development include both small molecules and biologics. Tonix, through its recent acquisition, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg. Zembrace® SymTouch® and Tosymra®, which were acquired as of June 30, 2023 (See Note 10), are each indicated for the treatment of acute migraine with or without aura in adults. All other drug product and vaccine candidates are still in development, and are not approved or marketed.

The condensed 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 LLC, Tonix R&D Center LLC, Tonix Pharma Holdings Limited and Tonix Pharma Limited (collectively hereafter referred to as 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, 2023, the Company had working capital of approximately $13.6 million. At September 30, 2023, the Company had an accumulated deficit of approximately $573.3 million. The Company held cash and cash equivalents of approximately $6.9 million as of September 30, 2023.

The Company believes that its cash resources at September 30, 2023 and the proceeds that it raised from equity offerings in the fourth quarter of 2023 (See Note 20), will not meet its operating and capital expenditure requirements through the fourth quarter of 2023.

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 of its research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue operations. If any of these events occurs, its ability to achieve our development and commercialization goals would be adversely affected and the Company may be forced to cease operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, 2022 contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of results that may be expected for the year ending December 31, 2023. 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, 2022 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on March 13, 2023.

Reverse Stock Split

On May 9, 2023, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 10, 2023. Pursuant to the Certificate of Change, the Company effected a 1-for-6.25 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 authorized, 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 preferred stock was 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.

Use of estimates

The preparation of financial statements in accordance with Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include, but are not limited to, 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, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in 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, 2023. These products collectively accounted for 100% of revenues during the three and nine months ended September 30, 2023.

As of September 30, 2023, accounts receivable from four customers accounted for 25%, 23%, 19% and 15% of total accounts receivable. 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. As of September 30, 2022, and for the three and nine months ended September 30, 2022, the Company had no commercialized products and therefore had no accounts receivables or revenues.

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, 2023 and December 31, 2022, cash equivalents, which consisted of money market funds, amounted to $3.7 million and $116.3 million, respectively. Restricted cash, which is included in Other non-current assets on the condensed consolidated balance sheet, at both September 30, 2023, and December 31, 2022, of approximately $244,000 and $241,000, respectively, collateralizes a letter of credit issued in connection with the lease of office space in Chatham, New Jersey and New York, New York (see Note 18). In addition, the Company has $758,000 of restricted cash held by vendors in escrow accounts for patient support services as of September 30, 2023.

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, 2023	September 30, 2022
	(in thousands)	
Cash and cash equivalents	$ 6,914	$ 139,978
Restricted cash	1,002	240
Total	$ 7,916	$ 140,218

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 prompt payment or specialty pharmacy discounts. 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. However, during the period covered by the Transition Services Agreement, the Seller has agreed to collect the accounts receivable on behalf of the Company and net settle within 45 days from each month-end. See note 10 for further details. The Company had no accounts receivable as of any prior period presented other than as of September 30, 2023.

As of September 30, 2023, the Company did not have an allowance for doubtful accounts. An allowance for doubtful accounts 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 wide 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. 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. 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. The Company's reserves were approximately $21,000 as of September 30, 2023. 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 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 on assets begins when the asset is placed in service. Depreciation and amortization expense for the three and nine months ended September 30, 2023, was $978,000 and $2.8 million, respectively, and $252,000 and $417,000, respectively, for the three and nine months ended September 30, 2022. All property and equipment are 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, LLS ("USL Acquisition") consummated on June 30, 2023 (See Note 8). 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 months ended September 30, 2023, was $238,000. The annual impairment assessment date will be June 30. No triggering events were identified during the nine months ended September 30, 2023.

During the year ended December 31, 2015, the Company purchased certain internet domain rights, which were determined to have an indefinite life. Identifiable intangibles with indefinite lives, which are included in Intangible assets, net on the condensed consolidated balance sheet, are not amortized but are tested for impairment annually or whenever events or changes in circumstances indicate that their carrying amount may be less than fair value. As of September 30, 2023, the Company believed that no impairment existed.

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. As of September 30, 2023, the Company has recognized goodwill in connection with the USL Acquisition consummated on June 30, 2023 (See Note 8).

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 condensed 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.

Convertible Preferred Stock

Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

Revenue Recognition

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

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

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

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

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

- Managed Care Rebates are processed in the quarter following the quarter in which they are earned. The managed care reporting entity submits utilization data after the end of the quarter and the Company processes the payment in accordance with contract terms. All rebates earned but not paid are estimated by the Company according to historical payments trended for market growth assumptions.
- Medicaid and State Agency rebates are based upon historical experience of claims submitted by various states. The Company monitors Medicaid legislative changes to determine what impact such legislation may have on the provision for Medicaid rebates. The accrual of State Agency reserves is based on historical payment rates. There is an approximate three-month lag from the time of product sale until the rebate is paid.
- Tri-Care represents a regionally managed health care program for active duty and retired members, dependents and survivors of the US military. The Tri-Care program supplements health care resources of the US military with civilian health care professionals for greater access and quality healthcare coverage. Through the Tri-Care program, the Company provides pharmaceuticals on a direct customer basis. Prices of pharmaceuticals sold under the Tri-Care program are pre-negotiated and a reserve amount is established to represent the proportionate rebate amount associated with product sales.
- Coverage Gap refers to the Medicare prescription drug program and represents specifically the period between the initial Medicare Part D prescription drug program coverage limit and the catastrophic coverage threshold. Applicable pharmaceutical products sold during this coverage gap timeframe are discounted by the Company. Since the nature of the program is that coverage limits are reset at the beginning of the calendar year; the payments escalate each quarter as the participants reach the coverage limit before reaching the catastrophic coverage threshold. The Company has determined that the cost of this reserve will be viewed as an annual cost. Therefore, the accrual will be incurred evenly during the year with quarterly review of the liability based on payment trends and any revision to the projected annual cost.

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

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

Research and Development Costs

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

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

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

Government Grants

From time to time, the Company may enter into arrangements with governmental entities for the purpose of obtaining funding for research and development activities. The Company is reimbursed for costs incurred that are associated with specified research and development activities included in the grant application approved by the government authority. The Company classifies government grants received under these arrangements as a reduction to the related research and development expense in the same period as the relevant expenses are incurred. In August 2022, the Company announced that it received a Cooperative Agreement grant from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health, to support the development of its TNX-1300 product candidate for the treatment of cocaine intoxication. During the three and nine months ended September 30, 2023, we received $0.4 and $2.3 million, respectively, for the three and nine months ended September 30, 2023, in funding as a reduction of related research and development expense.

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 condensed consolidated statements of operations as compensation or other expense over the requisite service period. The Company accounts for share-based awards in accordance with the provisions of the Accounting Standards Codification ("ASC") 718, Compensation – Stock Compensation.

Foreign Currency Translation

Operations of the Company's Canadian subsidiary, Tonix Pharmaceuticals (Canada), Inc., are conducted in local currency, which represents its functional currency. The U.S. dollar is the functional currency of the other foreign subsidiaries. Balance sheet accounts of the Canadian subsidiary were translated from foreign currency into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated at the average rate of exchange prevailing during the period. Translation adjustments resulting from this process were included in accumulated other comprehensive loss on the consolidated condensed 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 condensed 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, 2023, 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.

Per Share Data

The computation of basic and diluted loss per share for the quarters ended September 30, 2023 and 2022 excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

All warrants and preferred stock 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 and preferred stock 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 and preferred stock for the three and nine months ended September 30, 2023, and 2022, 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, 2023 and 2022, are as follows:

	2023	2022
Warrants to purchase common stock	7,003,196	3,196
Options to purchase common stock	1,384,264	392,643
Totals	8,387,460	395,839

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. The Company adopted ASU 2020-06 on January 1, 2023, under the modified retrospective method of transition. The adoption of ASU 2020-06 did not impact the Company's financial position, results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Instruments. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. ASU 2016-13 will be effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption is permitted. The Company adopted ASU 2016-13 and related updates as of January 1, 2023. The adoption of ASU 2016-13 did not impact the Company's financial position, results of operations or cash flows.

NOTE 3 – INVENTORY

The components of inventory consisted of the following as of September 30, 2023:

	September 30, 2023	December 31, 2022
	(in thousands)	
Raw Materials	$ 3,064	$ —
Work-in-process	1,565	—
Finished Goods	8,709	—
	13,338	$ —
Less: Inventory reserves	(21)	—
Total Inventory	$ 13,317	$ —

NOTE 4 – PROPERTY AND EQUIPMENT, NET

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

	September 30, 2023	December 31, 2022
	(in thousands)	
Property and equipment, net:		
Land	$ 8,011	$ 8,011
Land improvements	326	79
Buildings	65,825	65,644
Office furniture and equipment	2,355	1,893
Laboratory equipment	21,506	18,440
Leasehold improvements	34	34
Construction in progress	1,204	1,366
	99,261	95,467
Less: Accumulated depreciation and amortization	(4,395)	(1,653)
	$ 94,866	$ 93,814

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. During 2022, the assets became ready for the intended use and were placed in service.

On September 28, 2020, the Company completed the purchase of its approximately 45,000 square foot facility in Dartmouth, Massachusetts for $4.0 million, to house its new Advanced Development Center for the development and manufacturing of vaccines. Of the total purchase price, $1.2 million was allocated to the value of land acquired, and $2.8 million was allocated to buildings. Additionally, the Company incurred approximately $38.8 million of costs during the year ended December 31, 2022, bringing total costs incurred-to-date to $61.6 million, of which the majority related to the build-out of the facility. During 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, 2023, the asset was not ready for its intended use.

During the quarter ended September 30, 2023, property and equipment with a net book value of approximately $0.8 million were sold for net proceeds of approximately $1.0 million.

NOTE 5 – GOODWILL AND INTANGIBLE ASSETS

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

	Amounts (in thousands)
Balance at December 31, 2022	$ —
Acquired during the period (see Note 8)	965
Balance at September 30, 2023	$ 965

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

	September 30, 2023	December 31, 2022
	(in thousands)	
Intangible assets subject to amortization		
Developed technology	$ 10,100	$ —
Less: Accumulated amortization	238	—
Total	$ 9,862	$ —
Intangible assets not subject to amortization		
Internet domain rights	$ 120	$ 120
Total intangible assets, net	$ 9,982	$ 120

During the three months ended September 30, 2023, the Company recorded amortization of $238,000.

At September 30, 2023, the related amortization for each of the next five years ended December 31 is as follows (in thousands):

Year Ending December 31,	
Remainder of 2023	$ 238
2024	953
2025	953
2026	953
2027 and beyond	6,765
	$ 9,862

NOTE 6 – FAIR VALUE MEASUREMENTS

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

Level 1: Observable inputs, such as quoted prices in active markets.

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly. Level 2 assets and liabilities include debt securities with quoted market prices that are traded less frequently than exchange-traded instruments. This category includes U.S. government agency-backed debt securities and corporate-debt securities.

Level 3: Unobservable inputs in which there is little or no market data.

As of September 30, 2023, and December 31, 2022, the Company used Level 1 quoted prices in active markets to value cash equivalents of $3.7 million and $116.3 million, respectively. The Company did not have any Level 2 or Level 3 assets or liabilities as of both September 30, 2023 and December 31, 2022.

NOTE 7 – STOCKHOLDERS' EQUITY

On May 9, 2023, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 10, 2023. Pursuant to the Certificate of Change, the Company effected a 1-for-6.25 reverse stock split of its issued and outstanding shares of common stock, whereby 64,627,246 outstanding shares of the Company's common stock were exchanged for 10,340,506 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 131,902 shares of the Company's common stock due to fractional shares. Furthermore, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 1,000,000,000 to 160,000,000. 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.

On October 17, 2023, the Company received a letter from the Listing Qualifications staff of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company no longer meets the requirement to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 55450(a)(1) (the "Minimum Bid Price Requirement").

The Company was initially provided with a 180 calendar day period, or until April 15, 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, with the exception of the Minimum Bid Price Requirement, and provides written notice to Nasdaq of its intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary.

NOTE 8 – TEMPORARY EQUITY

On October 26, 2022, the Company closed on an offering ("the October offering") with certain institutional investors (the "Investors"), pursuant to which the Company issued and sold, in a private placement, 1,400,000 shares of the Company's Series A Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 100,000 shares of the Company's Series B Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock," and together with the Series A Preferred Stock, the "Preferred Stock"), at an offering price of $9.50 per share, representing a 5% original issue discount ("OID) to the stated value of $10.00 per share, for gross proceeds of $14.3 million in the aggregate for the October offering, before the deduction of fees and offering expenses. The shares of Preferred Stock were convertible, at a conversion price of $6.25 per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, at the option of the holders and, in certain circumstances, by the Company.

On December 13, 2022, an amendment (the "December Amendment") to the Company's Articles of Incorporation, as amended, to increase the Company's authorized shares of common stock from 24,000,000 to 160,000,000, as adjusted for the reverse split, was approved at a special meeting of shareholders. The Series A Preferred Stock had the right to vote on such December Amendment on an as-converted to common stock basis. The shares of the Series B Preferred Stock were automatically voted in a manner that "mirrored" the proportions on which the shares of common stock (excluding any shares of common stock that were not voted) and Series A Preferred Stock were voted to increase the Authorized Shares. The December Amendment required the approval of the majority of the votes associated with the Company's outstanding stock entitled to vote on the proposal. Because the Series B Preferred Stock were automatically and without further action of the purchaser voted in a manner that "mirrored" the proportions on which the shares of common stock (excluding any shares of common stock that were not voted) and Series A Preferred Stock were voted on the December Amendment, abstentions by common stockholders did not have any effect on the votes cast by the holders of the Series B Preferred Stock. The Certificates of Designation for the Preferred Stock provides that the Preferred Stock have no voting rights other than the right to vote on the December Amendment and as a class on certain other specified matters, and, with respect to the Series B Certificate of Designation, the right to cast 2,500 votes per share of Series B Preferred Stock on the December Amendment.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of common stock. The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of common stock at a conversion price of $6.25 per share. The holders of the Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares through January 23, 2023. The Company had the option to redeem the Preferred Stock for cash at 105% of the stated value, subject to the holders' rights to convert the shares prior to such redemption.

The $14.3 million in gross proceeds of the October offering was held in an escrow account, along with an additional $1.5 million deposited by the Company to cover the aggregate OID as well as the additional amount that would be necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock, as applicable, subject to the earlier payment to redeeming holders. Upon expiration of the redemption period, any proceeds remaining in the escrow account would be disbursed to the Company.

Since the Preferred Stock had a redemption feature at the option of the holder, it was classified as temporary equity. The Series A Preferred Stock and Series B Preferred Stock was recorded at redemption value of approximately $14.7 million and $1.1 million, respectively, as calculated in the following table (in thousands):

	Series A Preferred Stock	Series B Preferred Stock
Gross Proceeds	$ 13,300	$ 950
Less:		
Preferred stock issuance costs	(844)	(60)
Plus:		
Accretion of carrying value to redemption value	2,244	160
Preferred stock subject to possible redemption	$ 14,700	$ 1,050

During December 2022, the Company received redemption notices for all outstanding shares of Preferred Stock. The Preferred Stock was redeemed during December 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $15.8 million in the aggregate.

On June 24, 2022, the Company closed on an offering ("the Offering") with certain institutional investors (the "Investors"), pursuant to which the Company issued and sold, in a private placement, 2,500,000 shares of the Company's Series A Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 500,000 shares of the Company's Series B Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock," and together with the Series A Preferred Stock, the "Preferred Stock"), at an offering price of $9.50 per share, representing a 5% OID to the stated value of $10.00 per share, for gross proceeds of $28.5 million in the aggregate for the Offering, before the deduction of fees and offering expenses. The shares of Preferred Stock were convertible, at a conversion price of $25.00 per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, at the option of the holders and, in certain circumstances, by the Company.

On August 5, 2022, an amendment (the "Amendment") to the Company's Articles of Incorporation, as amended, to increase the Company's authorized shares of common stock from 8,000,000 to 24,000,000, as adjusted for the reverse split, was approved at a special meeting of shareholders. The Series A Preferred Stock had the right to vote on such Amendment on an as-converted to common stock basis. The shares of the Series B Preferred Stock were automatically voted in a manner that "mirrored" the proportions on which the shares of common stock (excluding any shares of common stock that were not voted) and Series A Preferred Stock were voted to increase the Authorized Shares. The Amendment required the approval of the majority of the votes associated with the Company's outstanding stock entitled to vote on the proposal. Because the Series B Preferred Stock were automatically and without further action of the purchaser voted in a manner that "mirrored" the proportions on which the shares of common stock (excluding any shares of common stock that were not voted) and Series A Preferred Stock were voted on the Amendment, abstentions by common stockholders did not have any effect on the votes cast by the holders of the Series B Preferred Stock. The Certificates of Designation for the Preferred Stock provides that the Preferred Stock have no voting rights other than the right to vote on the Amendment and as a class on certain other specified matters, and, with respect to the Series B Certificate of Designation, the right to cast 2,500 votes per share of Series B Preferred Stock on the Amendment.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of common stock. The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of common stock at a conversion price of $25.00 per share. The holders of the Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares through September 22, 2022. The Company had the option to redeem the Preferred Stock for cash at 105% of the stated value, subject to the holders' rights to convert the shares prior to such redemption.

The $28.5 million in gross proceeds of the Offering was held in an escrow account, along with an additional $3.0 million deposited by the Company to cover the aggregate OID as well as the additional amount that would be necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock, as applicable, subject to the earlier payment to redeeming holders. Upon expiration of the redemption period, any proceeds remaining in the escrow account would be disbursed to the Company.

Since the Preferred Stock had a redemption feature at the option of the holder, it was classified as temporary equity. The Series A Preferred Stock and Series B Preferred Stock was recorded at redemption value of approximately $26.3 million and $5.2 million, respectively, as calculated in the following table (in thousands):

	Series A Preferred Stock	Series B Preferred Stock
Gross Proceeds	$ 23,750	$ 4,750
Less:		
Preferred stock issuance costs	(1,046)	(209)
Plus:		
Accretion of carrying value to redemption value	3,546	709
Preferred stock subject to possible redemption	$ 26,250	$ 5,250

During August 2022, the Company received redemption notices for all outstanding shares of Preferred Stock. The Preferred Stock was redeemed during August 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $31.5 million in the aggregate.

NOTE 9 – REVENUES

Disaggregation of Net Revenues

The Company's net product revenues are summarized below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Zembrace® Symtouch®	$ 3,292	$ —	$ 3,292	$ —
Tosymra®	697	$ —	$ 697	$ —
Total product revenues	$ 3,989	$ —	$ 3,989	$ —

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 $2.5 million at September 30, 2023, $0.7 million of which was recorded as a reduction to accounts receivable and $1.8 million recorded as a component of accrued expenses.

NOTE 10 – ASSET PURCHASE AGREEMENT WITH UPSHER-SMITH

On June 30, 2023, the Company completed the acquisition of certain assets from Upsher-Smith Laboratories LLC ("USL") 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 USL entered into a Transition Services Agreement (the "Transition Services Agreement"), pursuant to which USL will provide 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 assumed certain obligations of Seller, including the payment of quarterly earn-out 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. Earn-out 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, earn-out 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 earn-out payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable earn-out 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 earn-out 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 earn-out payment rates and annual net sales tiers described above will apply.

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. On the earlier of March 2024 and the completion of the transition services to be provided by USL, as described above, the Company agreed to pay an additional deferred payment of $3.0 million in cash, which is included in Accrued expenses and other current liabilities on the accompanying balance sheet. The following table summarizes the components of the purchase consideration (in thousands):

Preliminary purchase consideration	Amount
Closing cash consideration	$ 22,174
Inventory adjustment payment liability	1,348
Deferred payment liability	3,000
Purchase price to be allocated	$ 26,522

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 acquisition-date fair value analyses will be finalized as soon as practicable, but in no event later than one year after the acquisition date.

The following table represents the preliminary 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):

Preliminary 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	$ 26,522

The acquired inventory consists of USL'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.

The $1.0 million of goodwill arising from the USL Acquisition represents expected synergies from combining operations, intangible assets that do not qualify for separate recognition, and other factors, of which all is expected to be deductible for tax purposes, subject to any limitations.

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	9
Developed technology - Zembrace	6,700	14
Total	$ 10,100	

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.

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 and 2022 as if the USL Acquisition had occurred as of January 1, 2022 and gives effect to transactions that are directly attributable to the acquisition. 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net Product Sales	$ 3,989	$ 3,635	$ 11,610	$ 7,612
Net Loss	$ (27,072)	$ (33,698)	$ (91,252)	$ (95,073)

The pro forma information for all periods presented include additional amortization expense related to the fair value of the acquired intangible assets as if such assets were acquired on January 1, 2022. The pro forma financial information for the three and nine months ended September 30, 2022 also reflects an increase in Cost of Sales related to the preliminary acquisition-date fair value adjustment to inventory. This adjustment is not reflected in the three and nine months ended September 30, 2023 as the acquired inventory is expected to be sold within one year from the acquisition date.

As described above, in connection with the USL Acquisition, the Company and USL entered into a Transition Services Agreement with the Seller 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. The Seller 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 Buyer.

The amount due to USL for reimbursement of services performed under the transition services agreement was $498,000 as of September 30, 2023. The transition service fees were netted against the receivables collected of $4,784,000 and liabilities paid of $2,724,000 on behalf of the Company with the net amount due to the Company of $1,562,000 recorded within receivables, net on the condensed consolidated balance sheet as of September 30, 2023.

NOTE 11 – 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.

NOTE 12 – LICENSE AGREEMENT WITH CURIA

On December 12, 2022, the Company entered into an exclusive license agreement with Curia for the development of three humanized murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection. We believe that the licensing of these mAbs strengthens our pipeline of next-generation therapeutics to treat COVID-19, which is caused by SARS-CoV-2. As consideration for entering into the License Agreement, we paid a license fee of approximately $0.4 million to Curia. The License Agreement also provides for single-digit royalties and contingent milestone payments. As of September 30, 2023, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

NOTE 13 – LICENSE AGREEMENT WITH UNIVERSITY OF ALBERTA

On May 18, 2022, the Company entered into an exclusive License Agreement with the University of Alberta focused on identifying and testing broad-spectrum antiviral drugs against future variants of SARS-CoV-2 and other emerging viruses. As consideration for entering into the License Agreement, Tonix paid a low-five digit license fee to University of Alberta. The License Agreement also provides for single-digit royalties and contingent milestone payments. As of September 30, 2023, other than the upfront fee, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 14 – LICENSE AGREEMENTS WITH COLUMBIA UNIVERSITY

On February 13, 2023, Tonix exercised an option to obtain an exclusive license from 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.

NOTE 15 – SALE OF COMMON STOCK

July 2023 Financing

On July 27, 2023, the Company sold 2,530,000 shares of common stock; pre-funded warrants to purchase up to 4,470,000 shares of common stock, and accompanying common warrants to purchase up to 7,000,000 shares of common stock with an exercise price of $1.00 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 $1.00, and the offering price per share of pre-funded warrant and accompanying common warrant was $0.9999.

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 an equity line of credit with Lincoln Park Capital Fund, LLC (“Lincoln Park”), pursuant to which Lincoln Park agreed to purchase up to $50,000,000 of the Company’s common stock (subject to certain limitations) from time to time. 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. The Company issued 100,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company’s common stock. 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 equity line of credit.

During the three and nine months ended September 30, 2023, the Company sold 0 and 0.1 million shares, respectively, of common stock under the equity line of credit with Lincoln Park, for net proceeds of approximately $0 and $0.4 million, respectively.

During the nine months ended September 30, 2022, no shares of common stock were sold under the equity line of credit.

Purchase Agreement with Lincoln Park

On December 3, 2021, the Company entered into a purchase agreement (the "Purchase Agreement with Lincoln Park") and a registration rights agreement (the "Lincoln Park Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the Purchase Agreement with Lincoln Park, Lincoln Park agreed to purchase from the Company up to $80,000,000 of the Company's common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement with Lincoln Park. Pursuant to the terms of the Lincoln Park 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 Purchase Agreement with Lincoln Park.

Pursuant to the terms of the Purchase Agreement with Lincoln Park, at the time the Company signed the Purchase Agreement with Lincoln Park and the Lincoln Park Registration Rights Agreement, the Company issued 14,546 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement with Lincoln Park. The commitment shares were valued at $1.6 million 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 Purchase Agreement with Lincoln Park.

During the nine months ended September 30, 2022, the Company sold 0.5 million shares of common stock under the Purchase Agreement with Lincoln Park, for net proceeds of approximately $8.7 million. No sales occurred in 2023.

Under applicable rules of the NASDAQ Global Market, the Company could not issue or sell more than 19.99% of the shares of its common stock outstanding immediately prior to the execution of the Purchase Agreement with Lincoln Park (approximately 0.5 million shares) to Lincoln Park under the Purchase Agreement with Lincoln Park without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the Purchase Agreement with Lincoln Park equals or exceeds a threshold amount. As the Company has issued approximately 0.4 million shares to Lincoln Park, by September 30, 2022, under the Purchase Agreement with Lincoln Park at less than the threshold amount, the Company will not sell any additional shares under the Purchase Agreement with Lincoln Park without shareholder approval.

At-the-Market Offerings

On April 8, 2020, the Company entered into a sales agreement with AGP pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $320.0 million in at-the-market offerings ("ATM") sales at prevailing market prices at the time of the sale, and, as a result, prices will vary. AGP receives a 3% commission on each ATM sale under the Sales Agreement.

During the three and nine months ended September 30, 2023, the Company sold approximately 0 and 1.0 million shares, respectively, of common stock under the Sales Agreement, for net proceeds of approximately $0 million and $3.0 million, respectively. During the nine months ended September 30, 2022, the Company sold approximately 5.5 million shares of common stock under the Sales Agreement, for net proceeds of approximately $76.2 million.

Stock Repurchases

During the first quarter of 2023, the Company has repurchased 2,512,044 of its shares of common stock outstanding under the 2022 share repurchase program for up to $12.5 million at prices ranging from $2.75 to $8.61 per share for a gross aggregate cost of approximately $12.5 million. In addition, the Company incurred expenses of $0.3 million.

In January 2023, the Board of Directors approved a new 2023 share repurchase program pursuant to which the Company may repurchase up to an additional $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 first quarter of 2023, the Company has repurchased 160,000 of our shares of common stock outstanding under the new 2023 share repurchase program at $7.12 per share for a gross aggregate cost of $1.1 million. No additional repurchases have occurred since the first quarter of 2023.

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 16 – STOCK-BASED COMPENSATION

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

Under the terms of the Amended and Restated 2020 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights ("SARs"), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 50,000 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). 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, 2023, 1,062,874 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, 2023 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2022	392,643	$ 334.08	8.70	$ —
Grants	1,019,130	4.64		
Exercised	—	—		
Forfeitures or expirations	(27,509)	453.81		
Outstanding at September 30, 2023	1,384,264	$ 89.09	9.01	$ —
Exercisable at September 30, 2023	248,656	$ 392.48	7.78	$

The weighted average fair value of options granted during the three and nine months ended September 2023 was $0.84 per share and $3.99 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 2022 was $0 per share and $32.81 per share, respectively.

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

The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2023 and 2022 were as follows:

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Risk-free interest rate	3.42% to 4.35%	1.67% to 3.05%
Expected term of option	5.0 to 10 years	5.5 to 10 years
Expected stock price volatility	122.19% - 142.72%	120.32% - 133.22%
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' historical stock price volatility.

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 $2.7 million, of which $2.0 million and $0.7 million, related to General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2022.

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. Stock-based compensation expense relating to options granted of $8.1 million, of which $5.9 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, 2022.

As of September 30, 2023, the Company had approximately $8.2 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 1.74 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 800,000 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, 2023, 800,000 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 three months ended September 30, 2023 and 2022, $34,000 and $46,000, respectively, was expensed. For the nine months ended September 30, 2023 and 2022, $34,000 and $46,000, respectively were expensed. In January 2022, 646 shares that were purchased as of December 31, 2021, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2022, approximately $40,000 of employee payroll deductions accumulated at December 31, 2021, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $30,000 was returned to the employees. In January 2023, 14,999 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 September 30, 2023, approximately $32,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses.

NOTE 17 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at September 30, 2023:

Exercise Price	Number Outstanding	Expiration Date
$ 1.00	7,000,000	August 2028
$ 100.00	125	November 2024
$ 114.00	618	February 2025
$ 7,000.00	2,453	December 2023
	7,003,196	

In connection with the July 2023 Financing, the Company issued 4,470,000 prefunded warrants with an exercise price of $0.0001. All prefunded warrants were exercised during the quarter ended September 30, 2023. Additionally, the Company issued warrants to purchase up to an aggregate of 7,000,000 shares of the Company's common stock. The warrants are exercisable at $1.00 per share, expire five years from the date of issuance.

No warrants were exercised during either of the nine months ended September 30, 2023, and 2022.

NOTE 18 – 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, 2023, the Company has right-of-use assets of $1.1 million and a total lease liability for operating leases of $1.1 million of which $0.7 million is included in long-term lease liabilities and $0.4 million is included in current lease liabilities.

At September 30, 2023, 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,	
2023	$ 107
2024	460
2025	299
2026	142
2027 and beyond	246
	1,254
Included interest	(104)
	$ 1,150

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 operating activity.

During the nine months ended September 30, 2022, the Company entered into new operating leases and lease amendments, resulting in the Company recognizing an additional operating lease liability of approximately $386,000 based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately $386,000, which represents a non-cash operating activity.

Other information related to leases is as follows:

Operating lease expense was $0.1 million for both three months ended September 30, 2023 and 2022.

Operating lease expense was $0.4 million for both the nine-months ended September 30, 2023 and 2022.

Other information related to leases is as follows:

Cash paid for amounts included in the measurement of lease liabilities:	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Operating cash flow from operating leases (in thousands)	$ 434	$ 447
Weighted Average Remaining Lease Term		
Operating leases	3.50 years	2.33 years
Weighted Average Discount Rate		

Operating leases	4.63%	2.26%

NOTE 19 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $33.4 million at September 30, 2023 for future work to be performed.

Defined contribution plan

The Company has 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 $200,000 and $700,000 for the three and nine months ended September 30, 2023, respectively, and $122,000 and $428,000 for the three and nine months ended September 30, 2022, respectively, for contributions under the 401(k) Plan.

NOTE 20 – SUBSEQUENT EVENTS

On September 28, 2023, the Company sold 4,050,000 shares of common stock; pre-funded warrants to purchase up to 4,950,000 shares of common stock, and accompanying Series A warrants to purchase up to 9,000,000 shares of common stock with an exercise price of $0.50 per share and expiring five years from date of issuance, and Series B warrants to purchase up to 9,000,000 shares of common stock with an exercise price of $0.50 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 $0.50, and the offering price per share of pre-funded warrant and accompanying warrants was $0.4999.

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.

On October 17, 2023, the Company received a letter from the Listing Qualifications staff of The Nasdaq Stock Market LLC ("Nasdaq") indicating 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 5550(a)(2) (the "Minimum Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided a period of 180 calendar days, or until April 14, 2024, in which to regain compliance with the Minimum Bid Price Requirement. In the event that the Company does not regain compliance within this 180-day period, the Company may be eligible to seek an additional compliance period of 180 calendar days if it meets the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Global Market, with the exception of the Minimum Bid Price Requirement, and provides written notice to Nasdaq of its intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice to the Company that its common stock will be subject to delisting.

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" "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: risks related to our ability to successfully commercialize our products, failure to obtain clearances or approvals from the United States Food and Drug Administration, or FDA, and noncompliance with FDA regulations; our need for additional financing; substantial competition; 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 those discussed in the section titled "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in our other SEC filings, as may be amended, supplemented or superseded from time to time by other reports we file with the SEC.

Business Overview

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix's development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, having completed enrollment of a potentially confirmatory Phase 3 study in the third quarter of 2023, with topline data expected in late December 2023. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition, and topline results were reported in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), is in development as a preventive treatment in chronic migraine, and the clinical phase of a Phase 2 proof-of-concept study is now completed with topline data expected in early December 2023. TNX-1900 is also being studied in binge eating disorder, pediatric obesity and social anxiety disorder by academic collaborators under investigator-initiated INDs. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the fourth quarter of 2023. Tonix's rare disease development portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology development portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases, including TNX-1800, in development as a vaccine to protect against COVID-19. In the fourth quarter of 2023, TNX-1800 was selected by the U.S. National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) Project NextGen for inclusion in Phase 1 clinical trials. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as 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, 2023 Compared to Three Months Ended September 30, 2022

Revenues. The Company recognized revenue from customers beginning in the three months period ended September 30, 2023 as a result of the Upsher Smith acquisition. See discussion at Note 10 to our interim condensed financial statements appearing in this Quarterly Report on Form 10-Q. Revenue recognized for the three months ended September 30, 2023 was $4.0 million.

The Company's net product revenues are summarized below:

	Three Months Ended September 30,	
	2023	2022
Zembrace® Symtouch®	$ 3,292	$ —
Tosymra®	697	$ —
Total product revenues	$ 3,989	$ —

Cost of Sales. The Company recognized cost of sales beginning in the three months period ended September 30, 2023 as a result of the Upsher Smith acquisition. See discussion at Note 10 to our interim condensed financial statements appearing in this Quarterly Report on Form 10-Q. Cost of sales recognized for the three months ended September 30, 2023 was $2.4 million.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2023 were $21.1 million, a decrease of $1.1 million, or 5%, from $22.2 million for the three months ended September 30, 2022. This decrease is predominately due to decreased non-clinical expenses of $1.6 million, manufacturing expenses of $2.9 million, offset by an increase in clinical expenses of $1.5 million, an increase in employee-related expenses and professional fees of $1.0 million, office-related expenses of $0.7 million and lab supplies of $0.2 million.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the three months ended September 30, 2023, and 2022.

	Three months ended September 30, (in thousands)		
	2023	2022	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	$ 3,365	$ 4,258	$ (893)
Direct expenses – TNX - 601 ER	2,901	207	2,694
Direct expenses – TNX - 801	551	1,281	(730)
Direct expenses – TNX - 1500	2,420	4,219	(1,799)
Direct expenses – TNX - 1900	627	1,116	(489)
Direct expenses – Other programs	6,127	3,279	2,848
Internal staffing, overhead and other	5,059	7,841	(2,782)
Total research & development	$ 21,050	$ 22,201	$ (1,151)

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 three months ended September 30, 2023 were $8.7 million, an increase of $1.3 million, or 18%, from $7.4 million incurred in the three months ended September 30, 2022. The increase is primarily due to sales and marketing of $1.3 million, transition services agreement fees payable to Upsher-Smith Laboratories, LLC ("USL") of $0.7 million, an increase in amortization expenses of $0.2 million, offset by a decrease in financial reporting expenses of $0.6 million and payroll-related expenses of $0.4 million.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2023 was $28.0 million, compared to a net loss of $29.0 million for the three months ended September 30, 2022.

Nine Months Ended September 30, 2023 Compared to Nine Months Ended September 30, 2022

Revenues. The Company recognized revenue from Customers beginning in the nine months period ended September 30, 2023 as a result of the Upsher Smith acquisition. See discussion at Note 10 to our interim condensed financial statements appearing in this Quarterly Report on Form 10-Q. Revenue recognized for the nine months ended September 30, 2023 was $4.0 million.

The Company's net product revenues are summarized below:

	Nine Months Ended September 30,	
	2023	2022
Zembrace® Symtouch®	$ 3,292	$ —
Tosymra®	697	$ —
Total product revenues	$ 3,989	$ —

Cost of Sales. The Company recognized cost of sales beginning in the nine months period ended September 30, 2023 as a result of the Upsher Smith acquisition. See discussion at Note 10 to our interim condensed financial statements appearing in this Quarterly Report on Form 10-Q. 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, 2023 were $69.5 million, an increase of $12.3 million, or 22%, from $57.2 million for the nine months ended September 30, 2022. This increase is predominately due to increased clinical expenses of $6.9 million, employee-related expenses of $3.7 million, office-related expenses of $3.5 million and lab supplies of $2.7 million, offset by a decrease in manufacturing costs of $6.1 million and non-clinical expenses of $0.2 million.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the nine months ended September 30, 2023, and 2022.

	Nine months ended September 30, (in thousands)		
	2023	2022	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	$ 10,342	$ 10,388	$ (46)
Direct expenses – TNX - 601 ER	7,431	854	6,577
Direct expenses – TNX - 801	2,261	1,478	783
Direct expenses – TNX - 1800	1,576	3,503	(1,927)
Direct expenses – TNX - 1500	6,010	7,731	(1,721)
Direct expenses – TNX - 1900	4,168	2,669	1,499
Direct expenses – Other programs	10,696	10,650	46
Internal staffing, overhead and other	27,051	19,929	7,122
Total research & development	$ 69,535	$ 57,202	$ 12,333

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.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2023 were $23.1 million, an increase of $0.9 million, or 4%, from $22.2 million incurred in the nine months ended September 30, 2022. The increase is primarily due to sales and marketing of $1.3 million, and transition services agreement fees payable to USL of $0.7 million, depreciation expenses of $0.3 million and accounting-related expenses of $0.3 million, offset by a decrease in financial reporting expenses of $1.8 million and compensation-related expenses of $0.2 million.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2023 was $89.3 million, compared to a net loss of $78.5 million for the nine months ended September 30, 2022.

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.

On December 12, 2022, we entered into an exclusive license agreement with Curia for the development of three humanized murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection. As consideration for entering into the License Agreement, we paid a license fee of approximately $0.4 million to Curia. The license agreement also provides for single-digit royalties and contingent milestone payments. As of September 30, 2023, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

On May 18, 2022, we entered into an exclusive license agreement with the University of Alberta focused on identifying and testing broad-spectrum antiviral drugs against future variants of SARS-CoV-2 and other emerging viruses. As consideration for entering into the license agreement, we paid a low-five digit license fee to University of Alberta. The license agreement also provides for single-digit royalties and contingent milestone payments. As of September 30, 2023, 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 USL for the acquisition of certain assets related to Zembrace® SymTouch® (sumatriptan injection) 3 mg ("Zembrace") and Tosymra® (sumatriptan nasal spray) 10 mg ("Tosymra") products (such businesses collectively, the "Business") and certain inventory related to the Business for an aggregate purchase price of approximately $26.5 million, including certain deferred payments (such transaction, the "USL Acquisition"). The transaction closed on June 30, 2023.

Additionally, in connection with the USL Acquisition, we and USL entered into a transition services agreement pursuant to which USL will 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.

As the assets acquired 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 USL, including the payment of quarterly earn-out 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. Earn-out 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, earn-out 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 earn-out payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable earn-out rates shall be reduced by 90% percent with respect to 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 (the "Healion Purchase Agreement") with Healion Bio Inc., pursuant to which we acquired all the pre-clinical infectious disease assets of Healion. As consideration for entering into the Healion Purchase Agreement, we paid $1.2 million to Healion. Because the Healion intellectual property was acquired prior to 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.

Liquidity and Capital Resources

As of September 30, 2023, we had working capital of $13.6 million, comprised primarily of cash and cash equivalents of $6.9 million, inventory of $13.3 million, receivables, net of $1.6 million and prepaid expenses and other of $9.5 million, offset by $7.8 million of accounts payable, $9.5 million of accrued expenses and current lease liabilities of $0.4 million. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical programs, and the USL Acquisition.

The following table provides a summary of operating, investing and financing cash flows for the nine months ended September 30, 2023, and 2022, respectively (in thousands):

	September 30,	
	2023	**2022**
Net cash used in operating activities	$ (79,663)	$ (75,752)
Net cash used in investing activities	(28,639)	(43,476)
Net cash (used in) provided by financing activities	(4,198)	80,615

For the nine months ended September 2023 and 2022, we used approximately $79.7 million and $75.8 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The increase in cash outlays principally resulted from an increase in both research and development and general and administrative activities. For the nine months ended September 30, 2023, net cash used from financing activities was $4.2 million predominately from the repurchase of common stock. For the nine months ended September 30, 2022, net proceeds in financing activities was $80.6 million, predominately from the sale of our common and preferred stock. Cash used in investing activities for the nine months ended September 30, 2023 was $28.6 related to the purchase of the USL assets and property and equipment, and $43.5 million for the nine months ended September 30, 2022 related to the purchase of property and equipment.

We believe that our cash resources at September 30, 2023, and the proceeds that we raised from equity offerings subsequent to the end of the third quarter of 2023 will not meet our operating and capital expenditure requirements through the fourth quarter of 2023.

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 must 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 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 would be adversely affected and we may be forced to cease operations.

Future Liquidity Requirements

We expect to incur losses from operations for the near future. We expect to incur increasing research and development expenses, including expenses related to additional clinical trials and the buildout of our research and development operations and manufacturing. 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.

Share Repurchase Program

During the first quarter of 2023, we repurchased 2,512,044 of our shares of common stock outstanding under the 2022 share repurchase program for up to $12.5 million at prices ranging from $2.75 to $8.61 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 160,000 of our shares of common stock outstanding under the new 2023 share repurchase program at $7.12 per share for a gross aggregate cost of $1.1 million. No share repurchases occurred in the third quarter of 2023.

Convertible Redeemable Preferred stock

On October 26, 2022, we issued 1,400,000 shares of Series A Preferred Stock and 100,000 shares of Series B Preferred Stock to certain institutional investors in a private placement. The Preferred Stock had an aggregate stated value of $15,000,000. Each share of the Preferred Stock had a purchase price of $9.50, representing an OID of 5% of the stated value. The shares of the preferred stock were convertible into shares of our common stock, upon the occurrence of certain events, at a conversion price of $6.25 per share.

All outstanding shares of the Series A Convertible Redeemable Preferred Stock and Series B Convertible Redeemable Preferred Stock were redeemed in December 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $15.8 million in the aggregate.

On June 24, 2022, we issued 2,500,000 shares of Series A Preferred Stock and 500,000 shares of Series B Preferred Stock to certain institutional investors in a private placement. The Preferred Stock had an aggregate stated value of $30,000,000. Each share of the Preferred Stock had a purchase price of $9.50, representing an OID of 5% of the stated value. The shares of the preferred stock were convertible into shares of our common stock, upon the occurrence of certain events, at a conversion price of $25.00 per share.

All outstanding shares of the Series A Convertible Redeemable Preferred Stock and Series B Convertible Redeemable Preferred Stock were redeemed in August 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $31.5 million in the aggregate.

September 2023 Financing

On September 28, 2023, we sold 4,050,000 shares of common stock; pre-funded warrants to purchase up to 4,950,000 shares of common stock, and accompanying common warrants to purchase up to 9,000,000 shares of common stock with an exercise price of $0.50 per share and expiring one year from date of issuance, and common warrants to purchase up to 9,000,000 shares of common stock with an exercise price of $0.50 per share and expiring five years from date of issuance in a public offering which closed on October 3, 2023. The offering price per share of common stock and accompanying common warrant was $0.50, and the offering price per share of pre-funded warrant and accompanying common warrant was $0.4999.

We incurred other offering expenses of approximately $0.5 million, which included a placement agent discount. 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 securities consisting of 2,530,000 shares of common stock; pre-funded warrants to purchase up to 4,470,000 shares of common stock and common warrants to purchase up to 7,000,000 shares of common stock in a public offering that closed on August 1, 2023. The offering price per Share and accompanying Common Warrant is $1.00, and the offering price per Pre-Funded Warrant and accompanying Common Warrant is $0.9999.

We incurred other offering expenses of approximately $0.7 million, which included a placement agent discount. 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 with Lincoln Park, pursuant to which Lincoln Park agreed to purchase from us up to $50,000,000 of our common stock (subject to certain limitations) from time to time. We filed a registration statement to register for resale the shares that have been or may be issued to Lincoln Park under the 2022 Purchase Agreement.

We issued 100,000 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 0.1 million shares, respectively, of common stock under the 2022 Purchase Agreement, for net proceeds of approximately $0 and $0.4 million, respectively. During the nine months ended September 30, 2022, no shares of common stock were sold under the 2022 Purchase Agreement.

2021 Lincoln Park Transaction

On December 3, 2021, we entered into a purchase agreement (the "2021 Purchase Agreement") and a registration rights agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to $80,000,000 of our common stock (subject to certain limitations) from time to time. We filed a registration statement to register for resale the shares that have been or may be issued to Lincoln Park under the 2021 Purchase Agreement.

We issued 14,546 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2021 Purchase Agreement with Lincoln Park. The commitment shares were valued at $1.6 million 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 Purchase Agreement with Lincoln Park.

During the nine months ended September 30, 2022, we sold 0.5 million shares of common stock under the 2021 Purchase Agreement with Lincoln Park, for net proceeds of approximately $8.7 million. No sales occurred in 2023, and we may not sell any additional shares under the 2021 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. During the three and nine months ended September 30, 2023, we sold approximately 0 million and 1.0 million shares, respectively, of common stock under the Sales Agreement, for net proceeds of approximately $0 million and $3.0 million, respectively. During the three and nine months ended September 30, 2022, we sold approximately 3.1 million and 5.5 million shares, respectively, of common stock under the Sales Agreement, for net proceeds of approximately $43.0 million and $76.2 million, respectively.

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) restricted stock units, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 50,000 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). 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, 2023, 1,062,874 options were available for future grants under the Amended and Restated 2020 Plan.

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

The 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' historical stock price volatility.

The weighted average fair value of options granted during the three and nine months ended September 30, 2023 was $0.84 per share and $3.99 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 30, 2022 was $0 per share and $32.81 per share, respectively.

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 $2.7 million, of which $2.0 million and $0.7 million, related to General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2022.

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. Stock-based compensation expense relating to options granted of $8.1 million, of which $5.9 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, 2022.

As of September 30, 2023, the Company had approximately $8.2 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 1.74 years.

Employee Stock Purchase Plan

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 the Company's stockholders on May 5, 2023.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 800,000 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, 2023, 800,000 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 three months ended September 30, 2023 and 2022, $34,000 and $46,000, respectively, was expensed. For the nine months ended September 30, 2023 and 2022, $34,000 and $46,000, respectively were expensed. In January 2022, 646 shares that were purchased as of December 31, 2021, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2022, approximately $40,000 of employee payroll deductions accumulated at December 31, 2021, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $30,000 was returned to the employees. In January 2023, 14,999 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 September 30, 2023, approximately $32,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses.

Commitments

Research and Development Contracts

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $33.4 million at September 30, 2023 for future work to be performed.

Operating leases

As of September 30, 2023, future minimum lease payments are as follows (in thousands):

Year Ending December 31,		
2023	$	107
2024		460
2025		299
2026		142
2027 and beyond		246
Included interest		(104)
	$	1,150

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our condensed 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 condensed 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.

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 in the period ended September 30, 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.

Redeemable Convertible Preferred Stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

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

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. We adopted ASU 2020-06 on January 1, 2023, under the modified retrospective method of transition. The adoption of ASU 2020-06 did not impact the Company's financial position, results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, Measurement of Credit Losses on Financial Instruments. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. ASU 2016-13 will be effective for us for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption is permitted. We adopted ASU 2016-13 and related updates as of January 1, 2023. The adoption of ASU 2016-13 did not impact the Company’s financial position, results of operations or cash flows.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

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

Based on our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2023, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting.

The acquisition of marketed products from USL has had a material impact on the Company's internal control over financial reporting as we are now required and have implemented controls related to revenue and inventory management. Management established controls to mitigate the risk over financial reporting as it relates to the services provided by USL under the transition services agreement.

Except as otherwise described above, there was no change in our internal control over financial reporting that occurred during the third quarter of 2023 that has materially affected, or is 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

Except as set forth below, 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, 2022. You should carefully consider the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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, 2022, 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.

We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.

We have had in the past, and may in the future, have difficulty satisfying Nasdaq listing requirements for our common stock. We are currently not in compliance with Nasdaq listing requirements, specifically the minimum bid price requirement, and must regain compliance prior to April 15, 2024. If we are unable to regain such compliance, we will cease to be eligible to trade on Nasdaq. In such event:

- We may have to pursue trading on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets."
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a "penny stock," transactions in our stock would be more difficult and cumbersome.
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

1.01	Placement Agent Agreement, dated September 28, 2023, among Tonix Pharmaceuticals Holding Corp., A.G.P./Alliance Global Partners and Brookline Capital Markets, a division of Arcadia Securities, LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Securities and Exchange Commission (the "Commission") on September 29, 2023 and incorporated herein by reference
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 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 Tonix Pharmaceuticals Holding Corp.'s 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, effective February 10, 2022, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 10, 2022 and incorporated herein by reference.
3.07	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.'s Articles of Incorporation, as amended, May 17, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 16, 2022 and incorporated herein by reference.
3.08	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.'s Articles of Incorporation, effective December 13, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 13, 2022 and incorporated herein by reference.
3.09	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.'s Articles of Incorporation, as amended, filed with the Commission on May 9, 2023 and incorporated herein by reference.
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	Description of Registrant's Securities, filed as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 14, 2022 and incorporated herein by reference.
4.03	Form of Common Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 28, 2023 and incorporated herein by reference.
4.04	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 28, 2023 and incorporated herein by reference.
4.05	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023 and incorporated herein by reference.
4.06	Form of Series A Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023 and incorporated herein by reference.
4.07	Form of Series B Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023 and incorporated herein by reference.
10.01	Form of Securities Purchase Agreement, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 28, 2023 and incorporated herein by reference.
10.02	Form of Securities Purchase Agreement, dated September 28, 2023, among Tonix Pharmaceuticals Holding Corp. and the purchasers named therein, , filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023 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.**
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)*

* Filed herewith.
** Furnished, not filed.

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 9, 2023

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

Date: November 9, 2023

By: /s/ BRADLEY SAENGER
Bradley Saenger
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.01

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 9, 2023

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

Exhibit 31.02

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 9, 2023

/s/ BRADLEY SAENGER
Bradley Saenger
Chief Financial Officer

Exhibit 32.01

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

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, 2023 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 9, 2023

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

I, Bradley Saenger, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended September 30, 2023 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 9, 2023

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