

**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, 2022

or

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

For the Transition Period from _____ to _____

Commission file number: 001-36019

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

26-1434750

(I.R.S. Employer Identification No.)

26 Main Street, Suite 101
Chatham, New Jersey

(Address of Principal Executive Offices)

07928

(Zip Code)

(862) 799-9155

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TNXP	The NASDAQ Global Market

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

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

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

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

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

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

As of November 4, 2022, there were 57,536,293 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, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 139,978	\$ 178,660
Prepaid expenses and other	11,161	10,389
Total current assets	151,139	189,049
Property and equipment, net	90,307	50,558
Operating lease right-to-use assets	840	914
Other non-current assets	360	379
Total assets	<u>\$ 242,646</u>	<u>\$ 240,900</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,556	\$ 13,282
Accrued expenses and other current liabilities	8,280	7,945
Lease liability, short term	504	489
Total current liabilities	13,340	21,716
Lease liability, long term	382	467
Total liabilities	13,722	22,183
Commitments (See Note 18)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized 0 shares designated as of September 30, 2022 and December 31, 2021, 0 issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 150,000,000 and 25,000,000 shares authorized as of September 30, 2022 and December 31, 2021, respectively; 53,321,511 and 15,638,274 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	53	16
Additional paid in capital	667,389	578,613
Accumulated deficit	(438,358)	(359,820)
Accumulated other comprehensive loss	(160)	(92)
Total stockholders' equity	228,924	218,717
Total liabilities and stockholders' equity	<u>\$ 242,646</u>	<u>\$ 240,900</u>

See the accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
COSTS AND EXPENSES:				
Research and development	\$ 22,201	\$ 13,082	\$ 57,202	\$ 46,542
General and administrative	7,390	5,453	22,161	16,291
	<u>29,591</u>	<u>18,535</u>	<u>79,363</u>	<u>62,833</u>
Operating loss	(29,591)	(18,535)	(79,363)	(62,833)
Interest income, net	610	7	825	99
Net loss	(28,981)	(18,528)	(78,538)	(62,734)
Preferred stock deemed dividend	—	—	4,255	—
Net loss available to common stockholders	<u>\$ (28,981)</u>	<u>\$ (18,528)</u>	<u>\$ (82,793)</u>	<u>\$ (62,734)</u>
Net loss per common share, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (1.60)</u>	<u>\$ (3.06)</u>	<u>\$ (6.02)</u>
Weighted average common shares outstanding, basic and diluted	<u>41,944,289</u>	<u>11,581,367</u>	<u>27,066,489</u>	<u>10,429,028</u>

See the accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	\$ (28,981)	\$ (18,528)	\$ (78,538)	\$ (62,734)
Other comprehensive loss:				
Foreign currency translation loss	(17)	(10)	(68)	(19)
Comprehensive loss	<u>\$ (28,998)</u>	<u>\$ (18,538)</u>	<u>\$ (78,606)</u>	<u>\$ (62,753)</u>

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	Accumulated	Other	Accumulated	
	Shares	Amount	Paid in	Comprehensive	Gain (loss)	Deficit	Total
			Capital				
Balance, December 31, 2021	15,638,274	\$ 16	\$ 578,613	\$ (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	1,076,661	1	8,487	—	—	8,488	
Issuance of common stock under 2021 Purchase agreement	687,500	1	4,534	—	—	4,535	
Employee stock purchase plan	4,033	—	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	17,406,468	18	594,294	(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	13,879,306	14	42,954	—	—	42,968	
Issuance of common stock under 2021 Purchase agreement	406,250	—	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	31,692,024	32	637,770	(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	19,244,757	19	24,673	—	—	24,692	
Issuance of common stock under the 2021 Purchase agreement	1,759,730	2	2,181	—	—	2,183	
Issuance of commitment shares under 2022 Purchase Agreement	625,000	—	—	—	—	—	
Stock-based compensation	—	—	2,765	—	—	2,765	
Foreign currency transaction gain	—	—	—	(17)	—	(17)	
Net loss	—	—	—	—	(28,981)	(28,981)	
Balance, September 30, 2022	53,321,511	\$ 53	\$ 667,389	\$ (160)	\$ (438,358)	\$ 228,924	

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, 2021
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Common stock		Additional	Accumulated	Other	Accumulated	
	Shares	Amount	Paid in	Comprehensive	Gain (loss)	Deficit	Total
			Capital				
Balance, December 31, 2020	6,568,335	\$ 6	\$ 355,237	\$	(62)	\$ (267,533)	\$ 87,648
Issuance of common stock in exchange for exercise of warrants in March 2021 (\$18.24 per share)	107	—	2		—	—	2
Issuance of common stock in January 2021 (\$25.60 per share), net of transactional expenses of \$3,096	1,562,500	2	36,902		—	—	36,904
Issuance of common stock in February 2021 (\$38.40 per share), net of transactional expenses of \$5,002	1,822,917	2	64,995		—	—	64,997
Issuance of common stock in January 2021 under At-the-market offering, net of transactional expenses of \$230	297,437	—	6,779		—	—	6,779
Employee stock purchase plan	1,703	—	28		—	—	28
Stock-based compensation	—	—	1,212		—	—	1,212
Foreign currency transaction gain	—	—	—		(1)	—	(1)
Net loss	—	—	—		—	(20,653)	(20,653)
Balance, March 31, 2021	10,252,999	10	465,155		(63)	(288,186)	176,916
Issuance of common stock in April and June 2021 under At-the-market offering, net of transactional expenses of \$612	489,332	1	18,701		—	—	18,702
Issuance of commitment shares under 2021 Purchase Agreement	40,000	—	—		—	—	—
Issuance of common stock under 2021 Purchase Agreement	85,938	—	3,347		—	—	3,347
Issuance of common stock in the acquisition of the OyaGen license	86,010	—	3,000		—	—	3,000
Stock-based compensation	—	—	2,089		—	—	2,089
Foreign currency transaction gain	—	—	—		(8)	—	(8)
Net loss	—	—	—		—	(23,553)	(23,553)
Balance, June 30, 2021	10,954,279	11	492,292		(71)	(311,739)	180,493
Issuance of common stock in July, August and September 2021 under At-the-market offering, net of transactional expenses of \$389	537,450	1	11,727		—	—	11,728
Issuance of common stock under 2021 Purchase Agreement	1,250,000	1	26,164		—	—	26,165
Employee stock purchase plan	3,641	—	68		—	—	68
Stock-based compensation	—	—	2,302		—	—	2,302
Foreign currency transaction gain	—	—	—		(10)	—	(10)
Net loss	—	—	—		—	(18,528)	(18,528)
Balance, September 30, 2021	12,745,370	\$ 13	\$ 532,553	\$	(81)	\$ (330,267)	\$ 202,218

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,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (78,538)	\$ (62,734)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	417	23
Common stock issued to acquire in-process research and development	—	3,000
Stock-based compensation	8,198	5,603
Changes in operating assets and liabilities:		
Prepaid expenses and other	(753)	(1,217)
Accounts payable	(4,079)	3,370
Operating lease liabilities and ROU asset, net	5	(10)
Accrued expenses and other current liabilities	(1,002)	(1,147)
Net cash used in operating activities	<u>(75,752)</u>	<u>(53,112)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(43,476)	(9,685)
Net cash used in investing activities	<u>(43,476)</u>	<u>(9,685)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	—	2
Proceeds from ESPP	40	96
Proceeds, net of \$4,255 expenses, from sale of convertible redeemable preferred stock	27,245	—
Redemption of convertible redeemable preferred stock	(31,500)	—
Proceeds, net of \$2,738 and \$9,329 expenses, from sale of common stock	84,830	168,622
Net cash provided by financing activities	<u>80,615</u>	<u>168,720</u>
Effect of currency rate change on cash	(69)	(21)
Net (decrease) increase in cash, cash equivalents and restricted cash	(38,682)	105,902
Cash, cash equivalents and restricted cash beginning of the period	<u>178,900</u>	<u>77,308</u>
Cash, cash equivalents and restricted cash end of period	<u>\$ 140,218</u>	<u>\$ 183,210</u>
Supplemental disclosures of cash flow information:		
Non-cash financing and investing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ (3,310)	\$ —
Preferred stock deemed dividend	<u>\$ 4,255</u>	<u>\$ —</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. (“Tonix Sub”), is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and vaccines to treat and prevent human disease and alleviate suffering. The therapeutics include both small molecules and biologics. All drug product and vaccine candidates are still in development and none are 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, 2022, the Company had working capital of approximately \$137.8 million. At September 30, 2022, the Company had an accumulated deficit of approximately \$438.4 million. The Company held cash and cash equivalents of approximately \$140.0 million as of September 30, 2022.

The Company believes that its cash resources at September 30, 2022, and the gross proceeds of approximately \$2.1 million, that it raised from equity offerings subsequent to the end of the third quarter of 2022 (See Note 19), will allow the Company to meet its operating and capital expenditure requirements into the third quarter of 2023, but not beyond.

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, as a result, its available capital resources may be consumed more rapidly than currently expected due to changes it may make in its research and development spending plans. The Company believes that it has the ability to 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. 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, the Company’s ability to achieve its development and commercialization goals would be adversely affected. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Reverse Stock Split

On May 16, 2022, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 17, 2022. Pursuant to the Certificate of Change, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock. The Company accounted for the reverse stock split on a retrospective basis pursuant to ASC 260, Earnings Per Share. All 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 retroactive basis, to reflect the reverse stock split for all periods presented. Authorized preferred stock was not adjusted because of the reverse stock split.

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, 2021 contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of results that may be expected for the year ending December 31, 2022. 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, 2021 included in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 14, 2022.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

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 does not have any commercial products available for sale and has not generated revenues, and there is no assurance that if its products are approved for sale, that the Company will be able to generate cash flow to fund operations. 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. Moreover, the extent to which COVID-19 impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time.

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 the assumptions used in the fair value of stock-based compensation and other equity instruments, and the percent of completion of research and development contracts.

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, 2022 and December 31, 2021, cash equivalents, which consisted of money market funds, amounted to \$121.2 million and \$120.4 million, respectively. Restricted cash, which is included in Other non-current assets on the condensed consolidated balance sheet, at both September 30, 2022, and December 31, 2021 of approximately \$240,000 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 17).

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, 2022	September 30, 2021
	(in thousands)	
Cash and cash equivalents	\$ 139,978	\$ 182,970
Restricted cash	240	240
Total	<u>\$ 140,218</u>	<u>\$ 183,210</u>

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 30 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 term of lease for leasehold improvements. Depreciation on assets begin when the asset is available for its intended use. Depreciation and amortization expense for the three and nine months ended September 30, 2022 was \$252,000 and \$417,000, respectively, and \$10,000 and \$23,000, respectively, for the three and nine months ended September 30, 2021. All property and equipment is located in the United States.

Intangible assets with indefinite lives

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 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, 2022, the Company believed that no impairment existed.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

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.

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. No funding was received as of September 30, 2022.

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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

Foreign Currency Translation

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

Comprehensive Income (Loss)

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

Income Taxes

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

The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the 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, 2022, 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, 2022 and 2021 excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

All warrants issued participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing EPS, these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the three and nine months ended September 30, 2022, and 2021, 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, 2022 and 2021, are as follows:

	2022	2021
Warrants to purchase common stock	19,970	20,156
Options to purchase common stock	2,455,280	805,742
Totals	<u>2,475,250</u>	<u>825,898</u>

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NOTE 3 – PROPERTY AND EQUIPMENT, NET

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

	September 30 2022	December 31 2021
	(in thousands)	
Land	\$ 8,011	\$ 7,911
Land improvements	43	—
Buildings	15,030	—
Construction in progress	58,723	41,921
Office furniture and equipment	970	756
Laboratory equipment	8,313	347
Leasehold improvements	34	23
	91,124	50,958
Less: Accumulated depreciation and amortization	(817)	(400)
	\$ 90,307	\$ 50,558

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 has been allocated to buildings, and approximately \$1.5 million was allocated to Office furniture and equipment and Laboratory equipment. During the quarter ended September 30, 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 \$32.6 million of costs during the nine months ended September 30, 2022, bringing total costs incurred-to-date to \$55.4 million, of which the majority relates to the build-out of the facility. Subsequent to the quarter ended September 30, 2022, the assets were 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, 2022, the asset was not ready for its intended use.

NOTE 4 – 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, 2022, and December 31, 2021, the Company used Level 1 quoted prices in active markets to value cash equivalents of \$121.2 million and \$120.4 million, respectively. The Company did not have any Level 2 or Level 3 assets or liabilities as of both September 30, 2022 and December 31, 2021.

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NOTE 5 – STOCKHOLDERS' EQUITY

On May 16, 2022, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 17, 2022. Pursuant to the Certificate of Change, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock, whereby 599,679,596 outstanding shares of the Company's common stock were exchanged for 18,740,141 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 130,462 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 800 million to 50 million. All per share amounts and number of shares in the condensed consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split. As a result of the reverse-stock-split, on June 1, 2022, the Company's stock regained compliance with the minimum bid price requirement of \$1.00 per share for continued listing on the NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(a)(2). On August 5, 2022, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 50,000,000 to 150,000,000.

NOTE 6 – TEMPORARY EQUITY

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% original issue discount ("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 \$4.00 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 50,000,000 to 150,000,000, 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 \$4.00 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.

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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 on the balance sheet 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	<u>\$ 26,250</u>	<u>\$ 5,250</u>

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 7 – ASSET PURCHASE AGREEMENT WITH KATANA

On December 22, 2020, the Company entered into an asset purchase agreement (the “Katana Asset Purchase Agreement”) with Katana Pharmaceuticals, Inc. (“Katana”) pursuant to which Tonix acquired Katana assets related to insulin resistance and related syndromes, including obesity (the “Katana Assets”). In connection with the acquisition of the Katana Assets, Tonix assumed Katana’s rights and obligations under that certain Exclusive License Agreement by and between Katana and The University of Geneva (“Geneva”) (the “Geneva License Agreement”) pursuant to an Assignment and Assumption Agreement with Geneva (“Geneva Assignment and Assumption Agreement”), dated December 22, 2020. As consideration for entering into the Katana Asset Purchase Agreement, Tonix paid \$0.7 million to Katana. The costs associated with the cash payments were recorded to research and development expenses in the statement of operations for the year ended December 31, 2020. Because the Katana intellectual property was acquired prior to U.S. Food and Drug Administration (FDA) approval, the cash consideration totaling \$0.7 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.

Pursuant to the terms of the Geneva Assignment and Assumption Agreement, Geneva has granted to Tonix an exclusive license, with the right to sublicense, certain patents related to the Katana Assets. Tonix is obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Geneva License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to Geneva.

As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 8 – ASSET PURCHASE AGREEMENT WITH TRIGEMINA

On June 11, 2020, the Company entered into an asset purchase agreement (the “Trigemina Asset Purchase Agreement”) with Trigemina, Inc. (“Trigemina”) and certain shareholders named therein (the “Executive Shareholders”) pursuant to which Tonix acquired Trigemina assets related to migraine and pain treatment technologies (the “Trigemina Assets”). In connection with the acquisition of the Trigemina Assets, Tonix assumed Trigemina’s rights and obligations under that certain Amended and Restated Exclusive License Agreement, dated November 30, 2007, as amended, by and between Trigemina and The Board of Trustees of the Leland Stanford Junior University (“Stanford”) (the “Stanford License Agreement”) pursuant to an Assignment and Assumption Agreement with Stanford (“Assignment and Assumption Agreement”), dated June 11, 2020. As consideration for entering into the Asset Purchase Agreement, Tonix paid \$824,759 to Trigemina and issued to Trigemina 62,500 shares of the Company’s common stock, valued at \$21.76 per share, based on the closing stock price on June 11, 2020, and paid Stanford \$250,241 pursuant to the terms of the Assignment and Assumption Agreement. The common stock is unregistered and subject to a 12-month lock-up and a Shareholder Voting Agreement, dated June 11, 2020, pursuant to which Trigemina and the Executive Shareholders have agreed to vote the common stock on any matter put to a vote of the shareholders of the Company in accordance with management’s recommendations. Both the costs associated with the cash payments and share issuance, totaling \$2.4 million, were recorded to research and development expenses in the statement of operations for the year ended December 31, 2020. Because the Trigemina intellectual property was acquired prior to FDA approval, the cash and stock consideration, was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

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Pursuant to the terms of the Assignment and Assumption Agreement, Stanford has granted to Tonix an exclusive license, with the right to sublicense, certain patents related to the Trigemina Assets. Stanford has reserved for itself the right to practice under the patents for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Trigemina License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to Stanford.

As of September 30, 2022, other than the annual maintenance fee, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 9 – ASSET PURCHASE AGREEMENT WITH TRIMARAN

On August 19, 2019, the Company entered into an asset purchase agreement (the “Asset Purchase Agreement”) with TRImaran Pharma, Inc. (“TRImaran”) and the selling shareholders named therein (the “Selling Shareholders”) pursuant to which Tonix acquired TRImaran’s assets related to certain pyran-based compounds (the “Assets”). In connection with the acquisition of the Assets, Tonix entered into a First Amended and Restated Exclusive License Agreement (the “WSU License Agreement”) with Wayne State University (“WSU”) on August 19, 2019. As consideration for entering into the Asset Purchase Agreement, Tonix paid \$100,000 to TRImaran and has assumed certain liabilities of TRImaran totaling \$68,500. The \$168,500 was previously recorded to research and development expenses in the statement of operations. Upon the achievement of specified development, regulatory and sales milestones, Tonix also agreed to pay TRImaran and the Selling Shareholders, in restricted stock or cash, at Tonix’s option, a total of approximately \$3.4 million. Pursuant to the terms of the Asset Purchase Agreement, TRImaran and the Selling Shareholders are prohibited from disclosing confidential information related to the Assets and are restricted from engaging, for a period of three years, in the development or commercialization of any therapeutic containing any pyran-based drug compound for the treatment of post-traumatic stress disorder, attention deficit hyperactivity disorder or major depressive disorder. Also for a period of three years, if TRImaran or any Selling Shareholder engage in the research or development of any potential therapeutic compound for the treatment of any central nervous system disorder, TRImaran or such Selling Shareholder is obliged to provide notice and opportunity to Tonix to make an offer to acquire or license rights with respect to such product candidate.

Pursuant to the terms of the WSU License Agreement, WSU has granted to Tonix an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the “Technology”) related to the Assets. WSU has reserved for itself the right to practice the Technology for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to obtain regulatory approval for one or more products utilizing the Technology (“WSU Products”) and to use commercially reasonable marketing efforts throughout the term of the WSU License Agreement. The WSU License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to WSU. Tonix is obligated to substantially manufacture WSU Products in the United States if WSU Products will be sold in the United States.

Pursuant to the WSU License Agreement, Tonix paid \$75,000 to WSU as reimbursement of certain patent expenses, and, upon the achievement of specified development, regulatory and sales milestones, the Company also agreed to pay WSU, milestone payments totaling approximately \$3.4 million. Tonix has also agreed to pay WSU single-digit royalties on net sales of WSU Products sold by Tonix or a sublicensee on a tiered basis based on net sales, and additional sublicense fees on certain consideration received from sublicensees. Royalties on each particular WSU Product are payable on a country-by-country and Product-by-Product basis until the date of expiration of the last valid claim in the last to expire of the issued patents covered by the WSU License Agreement. Royalties payable on net sales of WSU Products may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the WSU License Agreement, provided that the royalty payable on a WSU Product may not be reduced by more than 50%. Each party also has the right to terminate the agreement for customary reasons such as material breach and bankruptcy. The WSU License Agreement contains provisions relating to termination, indemnification, confidentiality and other customary matters for an agreement of this kind. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

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NOTE 10 – 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, 2022, other than the upfront fee, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 11 – LICENSE AGREEMENT WITH OYAGEN

On April 14, 2021, the Company and OyaGen, Inc. (“OyaGen”) entered into an exclusive License Agreement (the “OyaGen License Agreement”) pursuant to which OyaGen granted to Tonix an exclusive license to certain patents and technical information related to an antiviral inhibitor of SARS-CoV-2, sangivamycin, and to develop and commercialize products thereunder, and to acquire rights to any technology based thereon for the prevention or treatment of COVID-19 developed by OyaGen during the term of the License Agreement.

As consideration for entering into the License Agreement, Tonix paid a low-seven digit license fee to OyaGen, and issued to OyaGen and an affiliated entity an aggregate of 86,010 shares of the Company’s common stock, which are unregistered and subject to a six-month lock-up and a voting agreement, pursuant to which OyaGen and the affiliated entity have agreed to vote the common stock on any matter put to a vote of the shareholders of the Company in accordance with management’s recommendations. The shares were valued at \$3.0 million, which was recorded as research and development expense. The OyaGen License also provides for single-digit royalties and contingent milestone payments.

As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

In July 2022, the Company notified OyaGen of its intent to terminate the OyaGen License Agreement, and the agreement was terminated effective September 20, 2022.

NOTE 12 – LICENSE AGREEMENT WITH INSERM

On February 11, 2021, the Company entered into a license agreement (the “Inserm License Agreement”) pursuant to which it licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from Inserm (the French National Institute of Health and Medical Research), Aix-Marseille Université and Centre Hospitalier Universitaire de Toulouse. The Inserm License Agreement provides for the payment of annual fees and milestone payments upon the occurrence of specified sales milestones totaling approximately \$0.4 million, as well royalties on net sales of products based on the licensed technology, and assignment/transfer and sublicense royalties.

As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement

NOTE 13 – LICENSE AGREEMENTS WITH COLUMBIA UNIVERSITY

On September 16, 2019, the Company entered into an exclusive License Agreement (the “Columbia License Agreement”) with the Trustees of Columbia University in the City of New York (“Columbia”) pursuant to which Columbia granted to Tonix an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the “TFF2 Technology”) related to a recombinant Trefoil Family Factor 2 (TFF2), and to develop and commercialize products thereunder (each, a “TFF2 Product”). Pursuant to the terms of the Columbia License Agreement, Columbia reserved for itself the right to practice the TFF2 Technology for academic research and educational purposes.

The Company paid a five-digit license fee to Columbia as consideration for entering into the Columbia License Agreement, which was recorded to research and development expenses in the statement of operations for the year ended December 31, 2019. The Company is obligated to use Commercially Reasonable Efforts, as defined in the Columbia License Agreement, to develop and commercialize the TFF2 Product, and to achieve specified developmental milestones.

The Company is obligated to pay Columbia single-digit royalties on net sales of (i) TFF2 Products sold by Tonix or a sublicensee and (ii) any other products that involve material or technical information related to the TFF2 Product and transferred to Tonix pursuant to the Columbia License Agreement (“Other Products”) sold by Tonix or a sublicensee. Royalties on each particular TFF2 Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the Columbia License Agreement, and (ii) a specified period of time after the first commercial sale of a TFF2 Product in the country in question. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until a specified period of time after the first commercial sale of such particular Other Product in such country. Royalties payable on net sales of the TFF2 Product and Other Products may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the Columbia License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

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The Company is also obligated to make contingent milestone payments to Columbia totaling \$4.1 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a TFF2 Product. In addition, the Company shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to the Company by a sublicensee.

As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

On May 20, 2019, the Company entered into an exclusive License Agreement (the “License Agreement”) with Columbia pursuant to which Columbia, for itself and on behalf of the University of Kentucky and the University of Michigan (collectively, the “Institutions”) granted to the Company an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the “Technology”) related to a double-mutant cocaine esterase, and to develop and commercialize products thereunder (each, a “Product”). Pursuant to the terms of the License Agreement, Columbia has reserved for itself and the Institutions the right to practice the Technology for academic research and educational purposes.

The Company paid a six-digit license fee to Columbia as consideration for entering into the License Agreement. The Company is obligated to use Commercially Reasonable Efforts, as defined in the License Agreement, to develop and commercialize the Product, and to achieve specified developmental milestones.

The Company agreed to pay Columbia single-digit royalties on net sales of (i) Products sold by the Company or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to the Company pursuant to the License Agreement (“Other Products”) sold by the Company or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the License Agreement, (ii) a specified period of time after the first commercial sale of a Product in the country in question, or (iii) expiration of any market exclusivity period granted by a regulatory agency. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until the later of (i) a specified period of time after the first commercial sale of such particular Other Product in such country or (ii) expiration of any market exclusivity period granted by a regulatory agency. Royalties payable on net sales of the Product and Other Products may be reduced by 50% of the royalties payable by the Company to any third party for intellectual property rights which are necessary for the practice of the rights licensed to the Company under the License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

The Company is also obligated to make contingent milestone payments to Columbia totaling \$3 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a Product. In addition, the Company shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to the Company by a sublicensee.

As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 14 – SALE OF COMMON STOCK

2022 Lincoln Park Transaction

On August 16, 2022, the Company entered into a purchase agreement (the “2022 Purchase Agreement”) and a registration rights agreement (the “2022 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2022 Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to \$50,000,000 of the Company’s common stock (subject to certain limitations) from time to time during the term of the 2022 Purchase Agreement. Pursuant to the terms of the 2022 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2022 Purchase Agreement.

Pursuant to the terms of the 2022 Purchase Agreement, at the time the Company signed the 2022 Purchase Agreement and the 2022 Registration Rights Agreement, the Company issued 625,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company’s common stock under the 2022 Purchase Agreement. The commitment shares were valued at \$1,000,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2022 Purchase Agreement.

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During the nine months ended September 30, 2022, no shares of common stock were sold under the 2022 Purchase Agreement. Subsequent to September 30, 2022, the Company sold 1.0 million shares of common stock under the 2022 Purchase Agreement, for net proceeds of approximately \$0.5 million.

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 90,910 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 2.9 million shares of common stock under the Purchase Agreement with Lincoln Park, for net proceeds of approximately \$8.7 million.

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 2.9 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 2.9 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.

2021 Lincoln Park Transaction

On May 14, 2021, the Company entered into a purchase agreement (the “2021 Purchase Agreement”) and a registration rights agreement (the “2021 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2021 Purchase Agreement, 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 2021 Purchase Agreement. Pursuant to the terms of the 2021 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 2021 Purchase Agreement.

Pursuant to the terms of the 2021 Purchase Agreement, at the time the Company signed the 2021 Purchase Agreement and the 2021 Registration Rights Agreement, the Company issued 40,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2021 Purchase Agreement. 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 2021 Purchase Agreement.

During the nine months ended September 30, 2021, the Company sold an aggregate of approximately 1.3 million shares of common stock under the 2021 Purchase Agreement, for gross proceeds of approximately \$29.5 million.

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 2021 Purchase Agreement (approximately 2.0 million shares) to Lincoln Park under the 2021 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 2021 Purchase Agreement equals or exceeds a threshold amount. As the Company has issued approximately 2.0 million shares to Lincoln Park under the 2021 Purchase Agreement, at less than the threshold amount, the Company will not sell any additional shares under the 2021 Purchase Agreement without shareholder approval.

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February 2021 Financing

On February 8, 2021, the Company entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.8 million shares of its common stock, in a registered direct public offering (the “February 2021 Financing”), with A.G.P./Alliance Global Partners (“AGP”), acting as placement agent. The public offering price for each share of common stock was \$38.40. The February 2021 Financing closed on February 9, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate amount of \$4.9 million. The Company incurred other offering expenses of approximately \$0.1 million. The Company received net proceeds of approximately \$65.0 million, after deducting the fees and other offering expenses.

January 2021 Financing

On January 11, 2021, the Company entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.6 million shares of its common stock in a registered direct public offering (the “January 2021 Financing”), with AGP as placement agent. The public offering price for each share of common stock was \$25.60. The January 2021 Financing closed on January 13, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate of \$2.8 million. The Company incurred other offering expenses of approximately \$0.3 million. The Company received net proceeds of approximately \$36.9 million, after deducting the fees and other offering expenses.

At-the-Market Offerings

On April 8, 2020, the Company entered into a sales agreement (the “Sales Agreement”) with AGP pursuant to which the Company may issue and sell, from time to time, shares of the Company’s common stock having an aggregate offering price of up to \$320.0 million in at-the-market offerings (“ATM”) sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. The Company’s common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the nine months ended September 30, 2022, the Company sold approximately 34.2 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$76.2 million. During the nine months ended September 30, 2021, the Company sold approximately 1.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$37.2 million. Subsequent to September 30, 2022, the Company has sold 3.2 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$1.6 million.

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NOTE 15 – STOCK-BASED COMPENSATION

Stock Incentive Plans

On May 3, 2019, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the "2019 Plan"). The 2019 Plan provided for the issuance of up to 4,375 shares of common stock. With the adoption of the 2020 Plan (as defined below), no further grants may be made under the 2019 Plan. On January 16, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan (the "2020 Plan"). The 2020 Plan provided for the issuance of up to 18,750 shares of common stock. With the adoption of the Amended and Restated 2020 Plan (as defined below), no further grants may be made under the 2020 Plan.

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"), and together with the 2020 Plan and the 2019 Plan, the "Plans").

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 312,500 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, 2022, 625,496 shares 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, 2022 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2021	805,762	\$ 78.02	8.83	\$ —
Grants	1,695,608	\$ 12.06		
Exercised	—	—		
Forfeitures or expirations	(46,090)	267.12		
Outstanding at September 30, 2022	2,455,280	\$ 28.92	8.95	\$ —
Exercisable at September 30, 2022	532,615	\$ 74.66	7.78	\$ —

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

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The weighted average fair value of options granted during the three and nine months ended September 2022 was \$0 per share and \$5.25 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 2021 was \$21.46 per share and \$33.78 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, 2022 and 2021 were as follows:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Risk-free interest rate	1.67% to 3.05%	0.79% to 1.63%
Expected term of option	5.5 to 10 years	5.5 to 6 years
Expected stock price volatility	120.32% - 133.22%	124.37% - 137.73%
Expected dividend yield	0.0	0.0

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

Stock-based compensation expense relating to options granted of \$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 \$2.3 million, of which \$1.6 million and \$0.7 million, related to General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2021.

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. Stock-based compensation expense relating to options granted of \$5.6 million, of which \$3.9 million and \$1.7 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2021.

As of September 30, 2022, the Company had approximately \$14.3 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.9 years.

Employee Stock Purchase Plans

On May 3, 2019, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2019 Employee Stock Purchase Plan (the "2019 ESPP"). As a result of adoption of the 2020 ESPP, as defined below, by the stockholders, no further grants may be made under the 2019 ESPP Plan. On May 1, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2020 Employee Stock Purchase Plan (the "2020 ESPP"). As a result of the adoption of the 2022 ESPP, as defined below, by the stockholders, no further grants may be made under the 2020 ESPP Plan. On May 6, 2022, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan (the "2022 ESPP", and together with the 2019 ESPP and the 2020 ESPP, the "ESPP Plans").

The 2022 ESPP allows eligible employees to purchase up to an aggregate of 93,750 shares of the Company's common stock. Under the 2022 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 2022 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 2022 ESPP, subject to the statutory limit under the Code. As of September 30, 2022, 1 share was available for future sales under the 2020 ESPP and 93,750 shares were available for future sales under the 2022 ESPP.

The 2022 and 2020 ESPP are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the three months ended September 30, 2022 and 2021, \$46,000 and \$42,000, respectively, was expensed. For the nine months ended September 30, 2022 and 2021, \$46,000 and \$89,000, respectively were expensed. In January 2021, 1,703 shares that were purchased as of December 31, 2020, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2021, approximately \$28,000 of employee payroll deductions accumulated at December 31, 2020, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$4,000 was returned to the employees. In January 2022, 4,033 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. As of September 30, 2022, approximately \$40,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses.

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NOTE 16 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at September 30, 2022:

Exercise Price	Number Outstanding	Expiration Date
\$ 16.00	779	November 2024
\$ 18.24	3,860	February 2025
\$ 1,120.00	15,331	December 2023
	<u>19,970</u>	

No warrants were exercised during the nine months ended September 30, 2022.

During the nine months September 30, 2021, 107 warrants from the February 2020 Financing, with an exercise price of \$18.24, were exercised for proceeds of approximately \$2,000.

NOTE 17 – LEASES

The Company has various operating lease agreements, which are primarily for office space. These agreements frequently include one or more renewal options and require the Company to pay for utilities, taxes, insurance and maintenance expense. No lease agreement imposes a restriction on the Company's ability to engage in financing transactions or enter into further lease agreements. At September 30, 2022, the Company has right-of-use assets of \$0.8 million and a total lease liability for operating leases of \$0.9 million of which \$0.4 million is included in long-term lease liabilities and \$0.5 million is included in current lease liabilities.

At September 30, 2022, 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,	
2022	135
2023	438
2024	163
2025	159
2026 and beyond	11
	<u>906</u>
Included interest	(20)
	<u>\$ 886</u>

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 investing and financing activity.

During the nine months ended September 30, 2021, the Company entered into lease amendments, resulting in the Company recognizing an operating lease liability of approximately \$467,000 based on the present value of the future minimum rental payments. The Company also recognized corresponding ROU assets of approximately \$467,000, which represents a non-cash investing and financing activity.

Other information related to leases is as follows:

Operating lease expense was \$0.1 million and \$0.2 million for the three months ended September 30, 2022 and 2021, respectively.

Operating lease expense was \$0.4 and \$0.5 million for the nine-months ended September 30, 2022 and 2021, respectively.

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Other information related to leases is as follows:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow from operating leases (in thousands)	\$ 447	\$ 479
Weighted Average Remaining Lease Term		
Operating leases	2.33 years	2.79 years
Weighted Average Discount Rate		
Operating leases	2.26%	1.34%

NOTE 18 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$61.4 million at September 30, 2022 for future work to be performed.

The Company entered into a construction contract with outstanding commitments aggregating approximately \$3.3 million at September 30, 2022 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 \$122,000 and \$428,000 for the three and nine months ended September 30, 2022, respectively, and \$38,000 and \$149,000 for the three and nine months ended September 30, 2021, respectively, for contributions under the 401(k) Plan.

NOTE 19 – SUBSEQUENT EVENTS

Subsequent to September 30, 2022, the Company sold 3.2 million shares of common stock under the ATM Sales Agreement, for net proceeds of approximately \$1.6 million.

Subsequent to September 30, 2022, the Company sold 1.0 million shares of common stock under the 2022 Purchase Agreement, for net proceeds of approximately \$0.5 million.

On October 25, 2022, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company agreed to issue and sell, in a private placement, 1,400,000 shares of the Company’s Series A Convertible Redeemable Preferred Stock, par value \$0.01 per share, and 100,000 shares of the Company’s Series B Convertible Redeemable Preferred Stock, par value \$0.001 per share, at an offering price of \$9.50 per share, representing a 5% original issue discount to the stated value of \$10.00 per share, for gross proceeds of \$14.3 million in the aggregate for the Offering, before the deduction of fees and offering expenses. The shares of Preferred Stock will be convertible, at a conversion price of \$1.00 per share, into shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), at the option of the holders and, in certain circumstances, by the Company. The Offering closed on October 26, 2022. The \$14.3 million in gross proceeds from the sale of the Preferred Stock is being held in escrow and is expected to be used to fund the redemption of the Preferred Stock, which is expected to occur in 2022.

On October 25, 2022, the Company received a letter (the “Notice”) 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 5545(a)(1) (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 24, 2023, in which to regain compliance. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of the Company’s common stock must be at least \$1 per share for a minimum of ten consecutive business days during this 180-day period. 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" and "continue," or similar words. Those statements include statements regarding the intent, belief or current expectations of us and members of its management team as well as the assumptions on which such statements are based. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risk and uncertainties, and that actual results may differ materially from those contemplated by such forward-looking statements.

Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission. Important factors known to us could cause actual results to differ materially from those in forward-looking statements. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes in the future operating results over time. We believe that its assumptions are based upon reasonable data derived from and known about our business and operations. No assurances are made that actual results of operations or the results of our future activities will not differ materially from its assumptions. Factors that could cause differences include, but are not limited to: risks related to failure to obtain clearances or approvals from the United States Food and Drug Administration, or FDA, and noncompliance with FDA regulations; our possible 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 the COVID-19 pandemic, including its impact on the Company.

Business Overview

We are a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and vaccines to treat and prevent human disease and alleviate suffering. Our portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates.

Our CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Our lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, a chronic pain condition. We are enrolling patients into a Phase 3 study that was launched in the second quarter of 2022 and for which interim data are expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. We initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expect interim data in the second quarter of 2023. Finally, TNX-102 SL is being developed to treat posttraumatic stress disorder (PTSD), a serious psychiatric disorder. We expect to begin enrolling a Phase 2 study in Kenya in the fourth quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. We have been awarded a grant from the National Institute of Drug Abuse to support clinical development of TNX-1300. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the fourth quarter of 2022. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023.

Our rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome, a rare genetic disorder. TNX-2900 has been granted Orphan Drug designation by the FDA.

Our immunology 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 is expected to be initiated in the first half of 2023. We are also developing TNX-1700 which is a recombinant fusion protein including Trefoil Family Factor 2 (TFF2)-related peptides as an immune-oncology treatment for certain cancers, particularly colorectal and gastric cancer.

Our infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, our vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. Our lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform. We have collaborated with scientists at Columbia University to make fully human monoclonal antibodies with the potential to treat COVID-19. We own and operate an infectious disease research and development facility in Frederick, MD and a live virus vaccine process development and manufacturing facility in the New Bedford Business Park in Dartmouth, MA.

All of Tonix's product 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, 2022 Compared to Three Months Ended September 30, 2021

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2022 were \$22.2 million, an increase of \$9.1 million, or 69%, from \$13.1 million for the three months ended September 30, 2021. This increase is predominately due to increased clinical expenses of \$2.4 million, manufacturing expenses of \$1.0 million, non-clinical expenses of \$1.4 million, employee-related expenses of \$2.5 million and laboratory expenses of \$0.9 million. We expect research and development expenses to increase during 2022 as we move our clinical development programs forward and continue to invest in our development pipeline.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the three months ended September 30, 2022, and 2021.

	Three months ended September 30, (in thousands)		
	2022	2021	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 4,258	\$ 2,066	\$ 2,192
Direct expenses – TNX - 601 ER	207	593	(386)
Direct expenses – TNX - 801	1,281	—	1,281
Direct expenses – TNX - 1300	935	376	559
Direct expenses – TNX - 1500	4,219	802	3,417
Direct expenses – TNX - 1800	41	2,624	(2,583)
Direct expenses – TNX - 1900	1,116	655	461
Direct expenses – TNX - 2100	168	1,120	(952)
Direct expenses – TNX - 3500	237	132	105
Direct expenses – Other programs	1,898	1,301	597
Internal staffing, overhead and other	7,841	3,413	4,428
Total research & development	\$ 22,201	\$ 13,082	\$ 9,119

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 three months ended September 30, 2022 were \$7.4 million, an increase of \$1.9 million, or 35%, from \$5.5 million incurred in the three months ended September 30, 2021. The increase is primarily due to employee-related expenses of \$0.9 million, an increase in legal fees of \$0.3 million due to increased patent prosecution costs, and an increase in financial reporting expenses of \$0.7 million.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2022 was \$29.0 million, compared to a net loss of \$18.5 million for the three months ended September 30, 2021.

Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2022 were \$57.2 million, an increase of \$10.7 million, or 23%, from \$46.5 million for the nine months ended September 30, 2021. This increase is predominately due to increased clinical expenses of \$1.0 million, employee-related expenses of \$6.7 million, rent and office expenses of \$1.0 million and lab supplies of \$1.9 million. We expect research and development expenses to increase during 2022 as we move our clinical development programs forward and continue to invest in our development pipeline.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the nine months ended September 30, 2022, and 2021.

	Nine months ended September 30, (in thousands)		
	2022	2021	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 10,388	\$ 9,520	\$ 868
Direct expenses – TNX - 601 ER	854	2,126	(1,272)
Direct expenses – TNX - 801	1,478	70	1,408
Direct expenses – TNX - 1800	3,503	6,100	(2,597)
Direct expenses – TNX - 1300	2,597	5,116	(2,519)
Direct expenses – TNX - 1500	7,731	2,804	4,927
Direct expenses – TNX - 1900	2,669	1,355	1,314
Direct expenses – TNX - 2100	1,217	2,115	(898)
Direct expenses – TNX - 3500	1,301	5,123	(3,822)
Direct expenses – Other programs	5,535	3,629	1,906
Internal staffing, overhead and other	19,929	8,584	11,345
Total research & development	<u>\$ 57,202</u>	<u>\$ 46,542</u>	<u>\$ 10,660</u>

Our direct research and development expenses consist principally of external costs for clinical, nonclinical and manufacturing, such as fees paid to contractors, consultants and 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, 2022 were \$22.2 million, an increase of \$5.9 million, or 36%, from \$16.3 million incurred in the nine months ended September 30, 2021. The increase is primarily due to employee-related expenses of \$3.8 million, an increase in technology and software expenses of \$0.5 million, an increase in travel and entertainment of \$0.3 million and an increase in financial reporting expenses of \$0.6 million.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2022 was \$78.5 million, compared to a net loss of \$62.7 million for the nine months ended September 30, 2021.

License Agreements

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, 2022, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

On April 14, 2021, we and OyaGen, Inc. (“OyaGen”) entered into an exclusive License Agreement (the “OyaGen License Agreement”) pursuant to which OyaGen granted us an exclusive license to certain patents and technical information related to an antiviral inhibitor of SARS-CoV-2, sangivamycin, and to develop and commercialize products thereunder, and to acquire rights to any technology based thereon for the prevention or treatment of Covid-19 developed by OyaGen during the term of the License Agreement.

As consideration for entering into the License Agreement, we agreed to pay a low-seven digit license fee to OyaGen, and agreed to issue to OyaGen and an affiliated entity an aggregate of 86,010 shares of our common stock, valued at \$3.0 million, which are unregistered and subject to a six-month lock-up and a voting agreement, pursuant to which OyaGen and the affiliated entity have agreed to vote the common stock on any matter put to a vote of the shareholders of the Company in accordance with management’s recommendations. The OyaGen License also provides for single-digit royalties and contingent milestone payments. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement. In July 2022, we notified OyaGen of our intent to terminate the License Agreement, and the agreement was terminated effective September 20, 2022.

On February 11, 2021, we entered into a license agreement (the “Inserm License Agreement”) pursuant to which we licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from Inserm (the French National Institute of Health and Medical Research), Aix-Marseille Université and Centre Hospitalier Universitaire of Toulouse. The Inserm License Agreement provides for the payment of annual fees and milestone payments upon the occurrence of specified sales milestones, totaling approximately \$0.4 million, as well royalties on net sales of products based on the licensed technology, and assignment/transfer and sublicense royalties. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

On September 16, 2019, we entered into an exclusive License Agreement (the “Columbia License Agreement”) with the Trustees of Columbia University in the City of New York (“Columbia”) pursuant to which Columbia granted to us an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the “TFF2 Technology”) related to a recombinant Trefoil Family Factor 2 (TFF2), and to develop and commercialize products thereunder (each, a “TFF2 Product”). Pursuant to the terms of the Columbia License Agreement, Columbia has reserved for itself the right to practice the TFF2 Technology for academic research and educational purposes.

We paid a five-digit license fee to Columbia as consideration for entering into the Columbia License Agreement, which was recorded to research and development expenses in the statement of operations for the year ended December 31, 2019. We are obligated to use Commercially Reasonable Efforts, as defined in the Columbia License Agreement, to develop and commercialize the TFF2 Product, and to achieve specified developmental milestones.

We are obligated to pay Columbia single-digit royalties on net sales of (i) TFF2 Products sold by us or a sublicensee and (ii) any other products that involve material or technical information related to the TFF2 Product and transferred to us pursuant to the License Agreement (“Other Products”) sold by us or a sublicensee. Royalties on each particular TFF2 Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the Columbia License Agreement, and (ii) a specified period of time after the first commercial sale of a TFF2 Product in the country in question. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until a specified period of time after the first commercial sale of such particular Other Product in such country. Royalties payable on net sales of the TFF2 Product and Other Products may be reduced by 50% of the royalties payable by us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us under the Columbia License Agreement, provided that the royalty payable on a TFF2 Product or Other Product may not be reduced by more than 50%.

We are also obligated to make contingent milestone payments to Columbia totaling \$4.1 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a TFF2 Product. In addition, we shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to us by a sublicensee. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

On May 20, 2019, we entered into an exclusive License Agreement (the “License Agreement”) with Columbia pursuant to which Columbia, for itself and on behalf of the University of Kentucky and the University of Michigan (collectively, the “Institutions”) granted to us an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the “Technology”) related to a double-mutant cocaine esterase, and to develop and commercialize products thereunder (each, a “Product”). Pursuant to the terms of the License Agreement, Columbia has reserved for itself and the Institutions the right to practice the Technology for academic research and educational purposes.

We paid a six-digit license fee to Columbia as consideration for entering into the License Agreement. We are obligated to use Commercially Reasonable Efforts, as defined in the License Agreement, to develop and commercialize the Product, and to achieve specified developmental milestones.

We are obligated to pay Columbia single-digit royalties on net sales of (i) Products sold by us or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to us pursuant to the License Agreement (“Other Products”) sold by us or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the License Agreement, (ii) a specified period of time after the first commercial sale of a Product in the country in question, or (iii) expiration of any market exclusivity period granted by a regulatory agency. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until the later of (i) a specified period of time after the first commercial sale of such particular Other Product in such country or (ii) expiration of any market exclusivity period granted by a regulatory agency. Royalties payable on net sales of the Product and Other Products may be reduced by 50% of the royalties payable by us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us under the License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

We are also obligated to make contingent milestone payments to Columbia totaling \$3 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a Product. In addition, we shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to us by a sublicensee. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

Asset Purchase Agreements

On December 22, 2020, we entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Katana Pharmaceuticals, Inc. (“Katana”) pursuant to which we acquired Katana assets related to insulin resistance and related syndromes, including obesity (the “Katana Assets”). In connection with the acquisition of the Assets, we assumed Katana’s rights and obligations under that certain Exclusive License Agreement by and between Katana and The University of Geneva (“Geneva”) (the “Geneva License Agreement”) pursuant to an Assignment and Assumption Agreement with Geneva (“Geneva Assignment and Assumption Agreement”), dated December 22, 2020. As consideration for entering into the Asset Purchase Agreement, we paid \$0.7 million to Katana. Because the Katana intellectual property was acquired prior to FDA approval, the cash consideration totaling \$0.7 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.

Pursuant to the terms of the Geneva Assignment and Assumption Agreement, Geneva granted us an exclusive license, with the right to sublicense, certain patents related to the Katana Assets. We are obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Geneva License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to Geneva. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

On June 11, 2020, we entered into an asset purchase agreement (the “Trigemina Asset Purchase Agreement”) with Trigemina, Inc. (“Trigemina”) and certain shareholders named therein (the “Executive Shareholders”) pursuant to which we acquired Trigemina assets related to migraine and pain treatment technologies (the “Trigemina Assets”). In connection with the acquisition of the Trigemina Assets, we assumed Trigemina’s rights and obligations under that certain Amended and Restated Exclusive License Agreement, dated November 30, 2007, as amended, by and between Trigemina and The Board of Trustees of the Leland Stanford Junior University (“Stanford”) (the “Stanford License Agreement”) pursuant to an Assignment and Assumption Agreement with Stanford (“Assignment and Assumption Agreement”), dated June 11, 2020.

As consideration for entering into the Trigemina Asset Purchase Agreement, we paid \$824,759 to Trigemina and issued to Trigemina 62,500 shares of our common stock and paid Stanford \$250,241 pursuant to the terms of the Assignment and Assumption Agreement. The common stock is unregistered and subject to a 12 month lock-up and a Shareholder Voting Agreement, dated June 11, 2020, pursuant to which Trigemina and the Executive Shareholders have agreed to vote the common stock on any matter put to a vote of our shareholders in accordance with management's recommendations. Both the costs associated with the cash payments and share issuance, totaling \$2.4 million, were recorded to research and development in the statement of operations for the year ended December 31, 2020. Because the Trigemina intellectual property was acquired prior to FDA approval, the cash and stock consideration was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

Pursuant to the terms of the Assignment and Assumption Agreement, Stanford has granted us an exclusive license, with the right to sublicense, certain patents related to the Trigemina Assets. Stanford has reserved for itself the right to practice under the patents for academic research and educational purposes. We are obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Stanford License Agreement specifies developmental milestones and the period of time during which such milestones must be completed, and provides for an annual maintenance fee payable to Stanford. As of September 30, 2022, other than the annual maintenance fee, no milestone payments have been accrued or paid in relation to this agreement.

On August 19, 2019, we entered into an asset purchase agreement (the "TRImaran Asset Purchase Agreement") with TRImaran Pharma, Inc. ("TRImaran") and the selling shareholders named therein (the "Selling Shareholders") pursuant to which we acquired TRImaran's assets related to certain pyran-based compounds (the "TRImaran Assets"). In connection with the acquisition of the TRImaran Assets, we entered into a First Amended and Restated Exclusive License Agreement (the "WSU License Agreement") with Wayne State University ("WSU") on August 19, 2019. As consideration for entering into the TRImaran Asset Purchase Agreement, we paid \$100,000 to TRImaran and have assumed certain liabilities of TRImaran totaling \$68,500. The \$168,500 was recorded to research and development expenses in the statement of operations in 2019. Upon the achievement of specified development, regulatory and sales milestones, we also agreed to pay TRImaran and the Selling Shareholders, in restricted stock or cash, at our option, a total of approximately \$3.4 million. Pursuant to the terms of the TRImaran Asset Purchase Agreement, TRImaran and the Selling Shareholders are prohibited from disclosing confidential information related to the TRImaran Assets and are restricted from engaging, for a period of three years, in the development or commercialization of any therapeutic containing any pyran-based drug compound for the treatment of post-traumatic stress disorder, attention deficit hyperactivity disorder or major depressive disorder. Also for a period of three years, if TRImaran or any Selling Shareholder engage in the research or development of any potential therapeutic compound for the treatment of any central nervous system disorder, TRImaran or such Selling Shareholder is obliged to provide notice and opportunity to Tonix to make an offer to acquire or license rights with respect to such product candidate. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

Pursuant to the terms of the WSU License Agreement, WSU granted us an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the "Technology") related to the TRImaran Assets. WSU has reserved for itself the right to practice the Technology for academic research and educational purposes. We are obligated to use commercially reasonable efforts to obtain regulatory approval for one or more products utilizing the Technology ("WSU Products") and to use commercially reasonable marketing efforts throughout the term of the WSU License Agreement. The WSU License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to WSU. We are obligated to substantially manufacture WSU Products in the United States if WSU Products will be sold in the United States.

Pursuant to the WSU License Agreement, we paid \$75,000 to WSU as reimbursement of certain patent expenses, and, upon the achievement of specified development, regulatory and sales milestones, we also agreed to pay WSU, milestone payments totaling approximately \$3.4 million. We have also agreed to pay WSU single-digit royalties on net sales of WSU Products sold by us or a sublicensee on a tiered basis based on net sales, and additional sublicense fees on certain consideration received from sublicensees. Royalties on each particular WSU Product are payable on a country-by-country and Product-by-Product basis until the date of expiration of the last valid claim in the last to expire of the issued patents covered by the WSU License Agreement. Royalties payable on net sales of WSU Products may be reduced by 50% of the royalties payable by us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us under the WSU License Agreement, provided that the royalty payable on a WSU Product may not be reduced by more than 50%. Each party also has the right to terminate the agreement for customary reasons such as material breach and bankruptcy. The WSU License Agreement contains provisions relating to termination, indemnification, confidentiality and other customary matters for an agreement of this kind. As of September 30, 2022, no milestone payments have been accrued or paid in relation to this agreement.

Liquidity and Capital Resources

As of September 30, 2022, we had working capital of \$137.8 million, comprised primarily of cash and cash equivalents of \$140.0 million and prepaid expenses and other of \$11.2 million, offset by \$4.6 million of accounts payable, \$8.3 million of accrued expenses and current lease liabilities of \$0.5 million. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our Phase 3 clinical trial in FM, our vaccine program and the build-out of our facilities.

The following table provides a summary of operating, investing and financing cash flows for the nine months ended September 30, 2022, and 2021, respectively (in thousands):

	September 30,	
	2022	2021
Net cash used in operating activities	\$ (75,752)	\$ (53,112)
Net cash used in investing activities	(43,476)	(9,685)
Net cash provided by financing activities	80,615	168,720

For the nine months ended September, 2022 and 2021, we used approximately \$75.8 million and \$53.1 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 research and development activities. For the nine months ended September 30, 2022 and 2021, net proceeds from financing activities were \$80.6 million and \$168.7 million, respectively, predominately from the sale of our common stock and warrants.

Cash used in investing activities for the nine months ended September 30, 2022 and 2021, was \$43.5 million and \$9.7 respectively, related to the purchase of property and equipment.

We believe that our cash resources at September 30, 2022, and the proceeds that we raised from equity offerings subsequent to the end of the third quarter of 2022 will allow us to meet our operating and capital expenditure requirements into the third quarter of 2023, but not beyond.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes we may make in our research and development spending plans. These factors raise substantial doubt about our ability to continue as a going concern for the one year period from the date of filing of this Form 10-Q. We believe we have the ability to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. Without additional funds, we may be forced to delay, scale back or eliminate some 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.

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 clinical trials and the build out of recently acquired research and development and manufacturing facilities. We will not have enough resources to meet our operating requirements for the one-year 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 capital in order to fund future research and development activities and the build out of our recently acquired research and development and manufacturing facilities. 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.

Convertible Redeemable Preferred stock

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 has 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 \$4.00 per share, at the option of the holder, and at our option upon the fulfillment of certain conditions and subject to certain limitations. The Company and the holders of the Preferred Stock also entered into a registration rights agreement to register the resale of the shares of common stock issuable in the event of the conversion of the Preferred Stock. The \$28.5 million in gross proceeds of the Offering were 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 have been necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock.

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

2022 Lincoln Park Transaction

On August 16, 2022, we entered into a purchase agreement (the “2022 Purchase Agreement”) and a registration rights agreement (the “2022 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2022 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$50,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2022 Purchase Agreement. Pursuant to the terms of the 2022 Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2022 Purchase Agreement.

Pursuant to the terms of the 2022 Purchase Agreement, at the time we signed the 2022 Purchase Agreement and the 2022 Registration Rights Agreement, we issued 625,000 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 nine months ended September 30, 2022, no shares of common stock were sold under the 2022 Purchase Agreement. Subsequent to September 30, 2022, we sold 1.0 million shares of common stock under the 2022 Purchase Agreement, for net proceeds of approximately \$0.5 million.

Purchase Agreement with Lincoln Park

On December 3, 2021, we 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 us up to \$80,000,000 of our 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, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement with Lincoln Park.

Pursuant to the terms of the Purchase Agreement with Lincoln Park, at the time we signed the Purchase Agreement with Lincoln Park and the Lincoln Park Registration Rights Agreement, we issued 90,910 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, we sold 2.9 million shares of common stock under the Purchase Agreement with Lincoln Park, for net proceeds of approximately \$8.7 million.

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 (approximately 2.9 million shares) with Lincoln Park under the Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the Purchase Agreement equals or exceeds a threshold amount. As we have issued approximately 2.9 million shares to Lincoln Park under the Purchase Agreement at less than the threshold amount, we will not sell any additional shares under the Purchase Agreement without shareholder approval.

2021 Lincoln Park Transaction

On May 14, 2021, we entered into a purchase agreement (the “2021 Purchase Agreement”) and a registration rights agreement (the “2021 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2021 Purchase Agreement, Lincoln Park agreed to purchase from us up to \$80,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2021 Purchase Agreement. Pursuant to the terms of the 2021 Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2021 Purchase Agreement.

Pursuant to the terms of the 2021 Purchase Agreement, at the time we signed the 2021 Purchase Agreement and the 2021 Registration Rights Agreement, we issued 40,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2021 Purchase Agreement. 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 2021 Purchase Agreement.

During the nine months ended September 30, 2021, we sold an aggregate of approximately 1.3 million shares of common stock under the 2021 Purchase Agreement, for gross proceeds of approximately \$29.5 million.

Under applicable rules of the NASDAQ Global Market, we could not issue or sell more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the 2021 Purchase Agreement (approximately 2.0 million shares) to Lincoln Park under the 2021 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 2021 Purchase Agreement equals or exceeds a threshold amount. As we have issued approximately 2.0 million shares to Lincoln Park under the 2021 Purchase Agreement, at less than the threshold amount, we will not sell any additional shares under the 2021 Purchase Agreement without shareholder approval.

February 2021 Financing

On February 8, 2021, we entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.8 million shares of our common stock, in a registered direct public offering (the “February 2021 Financing”), with A.G.P./Alliance Global Partners (“AGP”), acting as placement agent. The public offering price for each share of common stock was \$38.40. The February 2021 Financing closed on February 9, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate amount of \$4.9 million. We incurred other offering expenses of approximately \$0.1 million. We received net proceeds of approximately \$65.0 million, after deducting the fees and other offering expenses.

January 2021 Financing

On January 11, 2021, we entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.6 million shares of our common stock in a registered direct public offering (the “January 2021 Financing”), with AGP as placement agent. The public offering price for each share of common stock was \$25.60. The January 2021 Financing closed on January 13, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate of \$2.8 million. We incurred other offering expenses of approximately \$0.3 million. We received net proceeds of approximately \$36.9 million, after deducting the fees and other offering expenses.

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 nine months ended September 30, 2022, we sold approximately 34.2 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$76.2 million. During the nine months ended September 30, 2021, we sold approximately 1.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$37.2 million. Subsequent to September 30, 2022, we sold 3.2 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$1.6 million.

Stock Compensation

On May 3, 2019, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the “2019 Plan”). The 2019 Plan provided for the issuance of up to 4,375 shares of our common stock. With the adoption of the 2020 Plan (as defined below), no further grants may be made under the 2019 Plan. On January 16, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan (the “2020 Plan”). The 2020 Plan provided for the issuance of up to 18,750 shares of our common stock. With the adoption of the Amended and Restated 2020 Plan (as defined below), no further grants may be made under the 2020 Plan.

On May 1, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan (“Amended and Restated 2020 Plan”), and together with the 2020 Plan and the 2019 Plan, the “Plans”).

Under the terms of the Amended and Restated 2020 Plan, we may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights (“SARs”), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 312,500 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, 2022, 625,496 shares 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 our common stock on the date of the grant. For employees and directors, the fair value of the award is measured on the grant date. Most stock options granted pursuant to the Plans typically vest 1/3rd 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, we issue options to directors which vest over a one-year period. We also issue premium options to executive officers, which have an exercise price greater than the grant date fair value, subject to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

The weighted average fair value of options granted during the three and nine months ended September 2022 was \$0 per share and \$5.25 per share, respectively. The weighted average fair value of options granted during the three and nine months ended September 2021 was \$21.46 per share and \$33.78 per share, respectively.

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

Stock-based compensation expense relating to options granted of \$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 \$2.3 million, of which \$1.6 million and \$0.7 million, related to General and Administration and Research and Development, respectively was recognized for the quarter ended September 30, 2021.

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. Stock-based compensation expense relating to options granted of \$5.6 million, of which \$3.9 million and \$1.7 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2021.

As of September 30, 2022, we had approximately \$14.3 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 1.9 years.

Employee Stock Purchase Plans

On May 3, 2019, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2019 Employee Stock Purchase Plan (the “2019 ESPP”). As a result of adoption of the 2020 ESPP, as defined below, by the stockholders, no further grants may be made under the 2019 ESPP Plan. On May 1, 2020, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2020 Employee Stock Purchase Plan (the “2020 ESPP”). As a result of the adoption of the 2022 ESPP, as defined below, by the stockholders, no further grants may be made under the 2020 ESPP Plan. On May 6, 2022, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan (the “2022 ESPP”, and together with the 2019 ESPP and the 2020 ESPP, the “ESPP Plans”).

The 2022 ESPP allows eligible employees to purchase up to an aggregate of 93,750 shares of our common stock. Under the 2022 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of our common stock at the end of the offering period. Each offering period under the 2022 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 2022 ESPP, subject to the statutory limit under the Code. As of September 30, 2022, 1 share was available for future sales under the 2020 ESPP and 93,750 shares were available for future sales under the 2022 ESPP.

The 2022 and 2020 ESPP are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the three months ended September 30, 2022 and 2021, \$46,000 and \$42,000, respectively, was expensed. For the nine months ended September 30, 2022 and 2021, \$46,000 and \$89,000, respectively were expensed. In January 2021, 1,703 shares that were purchased as of December 31, 2020, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2021, approximately \$28,000 of employee payroll deductions accumulated at December 31, 2020, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$4,000 was returned to the employees. In January 2022, 4,033 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. As of September 30, 2022, approximately \$40,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses.

Commitments

Contractual agreements

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$61.4 million at September 30, 2022 for future work to be performed.

We have entered into a construction contract with outstanding commitments aggregating approximately \$3.3 million at September 30, 2022 for future work to be performed.

Operating leases

As of September 30, 2022, future minimum lease payments are as follows (in thousands):

Year Ending December 31,	
2022	135
2023	438
2024	163
2025	159
2026 and beyond	11
Included interest	(20)
	<u>\$ 886</u>

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.

Research and Development. We outsource 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 condensed 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.

Off-Balance Sheet Arrangements

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.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required under Regulation S-K for “smaller reporting companies.”

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, 2022, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

There were no material changes from the risk factors set forth under Part I, Item 1A., “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. You should carefully consider the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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, 2021, as well as other reports and statements that we file with the SEC, are not the only risks and uncertainties facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also have a material adverse effect on our financial position, results of operations or cash flows.

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

On October 25, 2022, 1,400,000 shares of Series A Preferred Stock and 100,000 shares of Series B Preferred Stock (together, the Preferred Stock”) were issued to certain institutional investors in a private placement. The Preferred Stock has an aggregate stated value of \$15,000,000 and each share of the Preferred Stock has a purchase price of \$9.50. The Company and the holders of the Preferred Stock entered into a registration rights agreement to register the resale of the shares of common stock issuable upon conversion of the Preferred Stock. The \$14.3 million, representing a 5% original issue discount, in gross proceeds from the sale of the Preferred Stock is being held in escrow and is expected to be used to fund the redemption of the Preferred Stock, which is expected to occur in 2022.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

On October 25, 2022, we 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 met the requirement to maintain a minimum bid price of \$1 per share (the “Minimum Bid Price Requirement”). In accordance with Nasdaq listing rules, we have until April 24, 2023 to regain compliance with the Minimum Bid Price Requirement. In the event we do not regain compliance during this period, we may be eligible to seek an additional 180 calendar day compliance period if we meet the Nasdaq continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the Minimum Bid Price Requirement, and provide written notice to Nasdaq of our intent to cure the deficiency during this second compliance period.

Item 6. Exhibits

- [1.01](#) Form of Securities Purchase Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated June 22, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 22, 2022 and incorporated herein by reference.
- [1.02](#) Form of Registration Rights Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated June 22, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 22, 2022 and incorporated herein by reference.
- [1.03](#) Form of Side Letter between Tonix Pharmaceuticals Holding Corp. and each investor, dated June 22, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 22, 2022 and incorporated herein by reference.
- [3.01](#) Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the “Commission”) on April 9, 2008 and incorporated herein by reference.
- [3.02](#) 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.
- [3.03](#) 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.
- [3.04](#) 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.
- [3.05](#) Certificate of Amendment to Articles of Incorporation, effective June 16, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 16, 2017 and incorporated herein by reference.
- [3.06](#) 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.
- [3.07](#) Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.’s Articles of Incorporation, as amended, filed with the Secretary of State of the State of Nevada on May 3, 2019.
- [3.08](#) Form of Certificate of Designation of Series A Convertible Redeemable Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference
- [3.09](#) Form of Certificate of Designation of Series B Convertible Redeemable Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference
- [3.10](#) Form of Securities Purchase Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference

<u>3.11</u>	Form of Registration Rights Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference
<u>3.12</u>	Form of Side Letter between Tonix Pharmaceuticals Holding Corp. and each investor, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
<u>4.01</u>	Specimen Common Stock Certificate of the Registrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 24, 2018 and incorporated herein by reference.
<u>4.02</u>	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.
<u>31.01</u>	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.
<u>31.02</u>	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.
<u>32.01</u>	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.
101 INS	XBRL Instance Document
101 SCH	XBRL Taxonomy Extension Schema Document
101 CAL	XBRL Taxonomy Calculation Linkbase Document
101 LAB	XBRL Taxonomy Labels Linkbase Document
101 PRE	XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: November 7, 2022

By: /s/ SETH LEDERMAN

Seth Lederman

Chief Executive Officer (Principal Executive Officer)

Date: November 7, 2022

By: /s/ BRADLEY SAENGER

Bradley Saenger

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

CERTIFICATION

I, Seth Lederman, certify that:

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

Date: November 7, 2022

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

CERTIFICATION

I, Bradley Saenger, certify that:

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

Date: November 7, 2022

/s/ BRADLEY SAENGER

Bradley Saenger
Chief Financial Officer

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended September 30, 2022 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 7, 2022

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, 2022 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 7, 2022

By: /s/ BRADLEY SAENGER

Name: Bradley Saenger

Title: *Chief Financial Officer*
