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, 2021

or

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

For the Transition Period from _____ to _____

Commission file number: 001-36019

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**26-1434750**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

26 Main Street, Suite 101
Chatham, New Jersey 07928

(Address of principal executive offices) (zip code)

(862) 904-8182

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 5, 2021, there were 439,590,272 shares of registrant's common stock outstanding.

TONIX PHARMACEUTICALS HOLDING CORP.

INDEX

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, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 182,970	$ 77,068
Prepaid expenses and other	12,112	10,921
Total current assets	195,082	87,989
Property and equipment, net	18,233	8,571
Right-of-use assets, net	1,068	1,258
Security deposit	31	5
Restricted cash	240	240
Intangible asset	120	120
Total assets	$ 214,774	$ 98,183
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,964	$ 4,598
Accrued expenses and other current liabilities	3,479	4,626
Lease liability, current	583	595
Total current liabilities	12,026	9,819
Lease liability, net of current portion	530	716
Total liabilities	12,556	10,535
Commitments (See Note 16)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized		
Series B Convertible Preferred stock, $0.001 par value, 5,313 shares designated as of September 30, 2021 and December 31, 2020, 0 issued and outstanding	—	—
Series A Convertible Preferred stock, $0.001 par value, 7,938 shares designated as of September 30, 2021 and December 31, 2020, 0 issued and outstanding	—	—
Common stock, $0.001 par value; 800,000,000 and 400,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 403,673,156 and 206,008,683 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	404	206
Additional paid in capital	532,162	355,037
Accumulated deficit	(330,267)	(267,533)
Accumulated other comprehensive loss	(81)	(62)
Total stockholders' equity	202,218	87,648
Total liabilities and stockholders' equity	$ 214,774	$ 98,183

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,	
	2021	**2020**	**2021**	**2020**
COSTS AND EXPENSES:				
Research and development	$ 13,082	$ 8,813	$ 46,542	$ 24,060
General and administrative	5,453	3,186	16,291	9,428
	18,535	11,999	62,833	33,488
Operating loss	(18,535)	(11,999)	(62,833)	(33,488)
Interest income, net	7	9	99	46
Net loss	(18,528)	(11,990)	(62,734)	(33,442)
Warrant deemed dividend	—	—	—	(451)
Preferred stock deemed dividend	—	—	—	(1,260)
Net loss available to common stockholders	$ (18,528)	$ (11,990)	$ (62,734)	$ (35,153)
Net loss per common share, basic and diluted	$ (0.05)	$ (0.09)	$ (0.19)	$ (0.49)
Weighted average common shares outstanding, basic and diluted	366,425,157	127,199,834	329,550,525	71,329,221

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,	
	2021	**2020**	**2021**	**2020**
Net loss	$ (18,528)	$ (11,990)	$ (62,734)	$ (33,442)
Other comprehensive loss:				
Foreign currency translation loss (gain)	(10)	5	(19)	(18)
Comprehensive loss	$ (18,538)	$ (11,985)	$ (62,753)	$ (33,460)

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)

	Series B Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2020	—	$ —	206,008,683	$ 206	$ 355,037	$ (62)	$ (267,533)	$ 87,648
Issuance of common stock in exchange for exercise of warrants in March 2021 ($0.57 per share)	—	—	3,400	—	2	—	—	2
Issuance of common stock in January 2021 ($0.80 per share), net of transactional expenses of $3,096	—	—	50,000,000	50	36,854	—	—	36,904
Issuance of common stock in February 2021 ($1.20 per share), net of transactional expenses of $5,002	—	—	58,333,334	58	64,939	—	—	64,997
Issuance of common stock in January 2021 under At-the-market offering, net of transactional expenses of $230	—	—	9,517,867	10	6,769	—	—	6,779
Employee stock purchase plan	—	—	54,447	—	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	—	$ —	323,917,731	$ 324	$ 464,841	$ (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	—	—	15,658,426	16	18,686	—	—	18,702
Issuance of commitment shares under 2021 Purchase Agreement	—	—	1,280,000	—	—	—	—	—
Issuance of common stock under 2021 Purchase Agreement	—	—	2,750,000	3	3,344	—	—	3,347
Issuance of common stock in the acquisition of the OyaGen license	—	—	2,752,294	3	2,997	—	—	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	—	$ —	346,358,451	$ 346	$ 491,957	$ (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	—	—	17,198,200	17	11,711	—	—	11,728
Issuance of common stock under 2021 Purchase Agreement	—	—	40,000,000	40	26,125	—	—	26,165
Employee stock purchase plan	—	—	116,505	1	67	—	—	68
Stock-based compensation	—	—	—	—	2,302	—	—	2,302
Foreign currency transaction gain	—	—	—	—	—	(10)	—	(10)
Net loss	—	—	—	—	—	—	(18,528)	(18,528)
Balance, September 30, 2021	—	$ —	403,673,156	$ 404	$ 532,162	$ (81)	$ (330,267)	$ 202,218

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, 2020
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Series B Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2019	—	$ —	8,531,504	$ 9	$ 226,524	$ (46)	$ (217,070)	$ 9,417
Issuance of common stock in exchange for exercise of warrants in February and March 2020 ($0.57 per share)	—	—	13,111,999	13	7,461	—	—	7,474
Deemed dividend in connection with repricing of November 2019 warrants	—	—	—	—	451	—	—	451
Warrant deemed dividend	—	—	—	—	(451)	—	—	(451)
Issuance of Series B Convertible preferred stock and common stock warrants in February 2020 ($1,000.00 per share, net of transactional expenses of $711)	5,313	—	—	—	4,602	—	—	4,602
Beneficial conversion feature in connection with issuance of Series B Convertible preferred stock	—	—	—	—	1,260	—	—	1,260
Preferred stock deemed dividend	—	—	—	—	(1,260)	—	—	(1,260)
Issuance of common stock and common stock warrants in February 2020 ($0.57 per share, net of transactional expenses $292)	—	—	3,837,000	4	1,891	—	—	1,895
Issuance of common stock upon conversion of Series B Convertible preferred stock	(5,313)	—	9,321,053	9	(9)	—	—	—
Issuance of common stock in March 2020 ($1.10 per share, net of transactional expenses of $1,221)	—	—	14,550,000	14	14,770	—	—	14,784
Employee stock purchase plan	—	—	1,578	—	2	—	—	2
Stock-based compensation	—	—	—	—	360	—	—	360
Foreign currency transaction gain	—	—	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	—	—	(7,273)	(7,273)
Balance, March 31, 2020	—	—	49,353,134	49	255,601	(60)	(224,343)	31,247
Issuance of common stock in June 2020 under the equity line	—	—	464,471	1	277	—	—	278
Issuance of common stock in May and June 2020 under At-the-market offering, net of transaction expenses of $1,131	—	—	52,986,301	53	34,089	—	—	34,142
Issuance of common stock in the acquisition of Trigemina assets	—	—	2,000,000	2	1,358	—	—	1,360
Stock-based compensation	—	—	—	—	733	—	—	733
Foreign currency transaction gain	—	—	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	—	—	(14,179)	(14,179)
Balance, June 30, 2020	—	—	104,803,906	105	292,058	(69)	(238,522)	53,572
Issuance of common stock in July 2020, net of transaction expenses of $829	—	—	20,940,000	21	9,620	—	—	9,641
Issuance of common stock in September 2020 under At-the-market offering, net of transactional expenses of $267	—	—	9,282,236	9	7,997	—	—	8,006
Issuance of common stock in exchange for exercise of warrants in July and August 2020 (see Note 9)	—	—	4,533,404	5	2,417	—	—	2,422
Issuance of commitment shares under 2020 Purchase Agreement	—	—	600,000	—	—	—	—	—
Stock-based compensation	—	—	—	—	912	—	—	912
Foreign currency transaction loss	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	(11,990)	(11,990)
Balance, September 30, 2020	—	$ —	140,159,546	$ 140	$ 313,004	$ (64)	$ (250,512)	$ 62,568

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (62,734)	$ (33,442)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	23	20
Common stock issued to acquire in-process research and development	3,000	1,360
Stock-based compensation	5,603	2,005
Changes in operating assets and liabilities:		
Prepaid expenses and other	(1,217)	(3,662)
Accounts payable	3,370	(1,301)
Operating lease liabilities and ROU asset, net	(10)	8
Accrued expenses and other current liabilities	(1,147)	360
Net cash used in operating activities	(53,112)	(34,652)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(9,685)	(4,030)
Net cash used in investing activities	(9,685)	(4,030)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	2	9,896
Proceeds from ESPP	96	2
Proceeds, net of $0 and $711 expenses, from sale of preferred stock	—	4,602
Proceeds, net of $9,329 and $3,740 expenses, from sale of common stock and warrants	168,622	68,746
Net cash provided by financing activities	168,720	83,246
Effect of currency rate change on cash	(21)	(16)
Net increase in cash, cash equivalents and restricted cash	105,902	44,548
Cash, cash equivalents and restricted cash beginning of the period	77,308	11,349
Cash, cash equivalents and restricted cash end of period	$ 183,210	$ 55,897
Supplemental disclosures of cash flow information:		
Warrants deemed dividend	$ —	$ 451
Series B Convertible preferred stock and deemed dividend	$ —	$ 1,260

See the accompanying notes to the condensed consolidated financial statements

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. ("Tonix Sub"), is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. The therapeutics include small molecules and biologics and all drug product and diagnostic candidates are still in development.

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its wholly owned subsidiaries, Tonix Sub, Krele LLC, Tonix Pharmaceuticals (Canada), Inc., Tonix Medicines, Inc., Jenner 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, 2021, the Company had working capital of approximately $183.1 million. At September 30, 2021, the Company had an accumulated deficit of approximately $330.3 million. The Company held unrestricted cash and cash equivalents of approximately $183.0 million as of September 30, 2021.

The Company believes that its cash resources at September 30, 2021, and the gross proceeds of approximately $19.8 million, that it raised from equity offerings subsequent to the end of the third quarter of 2021 (See Note 12), will meet its operating and capital expenditure requirements through September 30, 2022, 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 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, our ability to achieve our 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

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, 2020 contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of results that may be expected for the year ending December 31, 2021. 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, 2020 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on March 15, 2021.

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 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, 2021 and December 31, 2020, cash equivalents, which consisted of money market funds, amounted to $100.4 million and $40.4 million, respectively. Restricted cash at both September 30, 2021 and December 31, 2020 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 15).

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, 2021	December 31, 2020
	(in thousands)	
Cash and cash equivalents	$ 182,970	$ 77,068
Restricted cash	240	240
Total	$ 183,210	$ 77,308

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 is 20 years for buildings, 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 placed in service. Depreciation and amortization expense for the three and nine months ended September 30, 2021 was $10,000 and $23,000, respectively, and $8,000 and $20,000, respectively, for the three and nine months ended September 30, 2020. All property and equipment are located in the United States and Ireland.

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, 2021, the Company believed that no impairment existed.

Leases

The Company determines if an arrangement is 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.

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 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.

Stock-based compensation

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

Foreign Currency Translation

Operations of the Company's Canadian subsidiary, Tonix Pharmaceuticals (Canada), Inc., are conducted in local currency, which represents its functional currency. The U.S. dollar is the functional currency of the other foreign subsidiaries. Balance sheet accounts of the Canadian subsidiary were translated from foreign currency into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated at the average rate of exchange prevailing during the period. Translation adjustments resulting from this process were included in accumulated other comprehensive loss on the 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, 2021, 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, 2021 and 2020 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 earnings per share ("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, 2021, as results of operations were a loss for the period.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share, as of September 30, 2021 and 2020, are as follows:

	2021	2020
Warrants to purchase common stock	644,906	650,806
Options to purchase common stock	25,780,349	10,209,286
Totals	26,425,255	10,860,092

NOTE 3 – PROPERTY AND EQUIPMENT, NET

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

	September 30 2021	December 31 2020
	(in thousands)	
Property and equipment, net:		
Land and Buildings	$ 5,713	$ 5,713
Construction in progress	12,374	2,800
Office furniture and equipment	496	385
Leasehold improvements	23	23
	18,606	8,921
Less: Accumulated depreciation and amortization	(373)	(350)
	$ 18,233	$ 8,571

On September 28, 2020, the Company completed the purchase of its 4.0 million square foot facility in Massachusetts for $4,000,000, 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 construction in progress, as the building was not ready for its intended use. Additionally, we have incurred approximately $ 9.6 million in work-in-process, which is included in construction in progress as of September 30, 2021. As of September 30, 2021, the asset has not been placed in service.

On December 23, 2020, the Company completed the purchase of its approximately 44-acre site in Hamilton, Montana for $4.4 million, for the construction of a vaccine development and commercial scale manufacturing facility. As of September 30, 2021, the asset has not been placed in service.

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, 2021, and December 31, 2020, the Company used Level 1 quoted prices in active markets to value cash equivalents of $100.4 million and $40.4 million, respectively. The Company did not have any Level 2 or Level 3 assets or liabilities as of both September 30, 2021 and December 31, 2020.

NOTE 5 – STOCKHOLDERS' EQUITY

On March 26, 2021, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 400,000,000 to 800,000,000.

On September 3, 2021, 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 55450(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 March 2, 2022, 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.

NOTE 6 – 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 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, 2021, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 7 – 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 Trigemina2,000,000 shares of the Company's common stock, valued at $0.68 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.

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, 2021, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 8 – 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. 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, 2021, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 9 – 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 agreed to pay a low-seven digit license fee to OyaGen, and agreed to issue to OyaGen and an affiliated entity an aggregate of 2,752,294 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, 2021, no milestone payments have been accrued or paid in relation to this agreement

NOTE 10 – 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 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, 2021, no milestone payments have been accrued or paid in relation to this agreement

NOTE 11 – 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 agreed 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%.

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, 2021, 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 agreed to pay 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 first 50% of the license fee was paid by June 30, 2019, while the remaining50% license fee, was paid during the second quarter of 2020. Both installments of the license fee were recorded to research and development expenses in the 2019 statement of operations.

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, 2021, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 12 – SALE OF COMMON STOCK

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 has 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 1,280,000 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 approximately42.8 million shares of common stock under the 2021 Purchase Agreement, for gross proceeds of approximately $29.5 million. Subsequent to September 30, 2021, the Company has sold14.0 million shares of common stock under the 2021 Purchase Agreement, for net proceeds of approximately $7.6 million.

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 of58,333,334 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 $1.20. The February 2021 Financing closed on February 9, 2021. AGP received a cash fee of7% of the gross proceeds, for an aggregate 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 of50,000,000 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 $0.80. The January 2021 Financing closed on January 13, 2021. AGP received a cash fee of7% 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 $50.0 million in at-the-market offerings ("ATM") sales. On the same day, the Company filed a prospectus supplement under a shelf registration relating to the Sales Agreement. 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. On September 4, 2020, the Company filed an amended prospectus supplement under the shelf registration relating to the Sales Agreement to increase the aggregate offering price to $100.0 million in ATM sales under the Sales Agreement. On April 19, 2021, the Company filed an amended prospectus supplement under the shelf registration relating to the Sales Agreement to increase the aggregate offering price to $170.0 million in ATM sales under the Sales Agreement. During the nine months ended September 30, 2021, the Company sold approximately 42.4 million shares of common stock under the Sales Agreement, for net proceeds of approximately $37.2 million. Subsequent to September 30, 2021, the Company has sold 21.9 million shares of common stock under the Sales Agreement, for net proceeds of approximately $11.8 million.

July 2020 Financing

On July 13, 2020, the Company entered into an underwriting agreement with AGP, relating to the issuance and sale of 20,940,000 shares of common stock, in a registered direct public offering ("the July 2020 Financing"). The public offering price for each share of common stock was $0.50. The July 2020 Financing closed on July 15, 2020. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount of $0.7 million. The Company incurred other offering expenses of approximately $0.1 million. The Company received net proceeds of approximately $9.6 million, after deducting the underwriting discount and other offering expenses.

March 2020 Financing

On February 28, 2020, the Company entered into an underwriting agreement with AGP, relating to the issuance and sale of 14,550,000 shares of common stock, in a registered direct public offering ("the March 2020 Financing"). The public offering price for each share of common stock was $1.10. The March 2020 Financing closed on March 3, 2020. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount of $1.1 million. The Company incurred other offering expenses of approximately $0.1 million. The Company received net proceeds of approximately $14.8 million, after deducting the underwriting discount and other offering expenses.

February 2020 Financing

On February 7, 2020, the Company entered into an underwriting agreement with AGP pursuant to which the Company sold securities consisting of 3,837,000 Class A Units at a public offering price of $0.57 per unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, and 5,313 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series B Convertible Preferred Stock, with a conversion price of $0.57 per share, convertible into 1,754.386 shares of common stock and warrants to purchase 1,754.386 shares of common stock ("the February 2020 Financing"). The warrants have an exercise price of $0.57, are immediately exercisable and expire five years from the date of issuance.

The February 2020 Financing closed on February 11, 2020. AGP purchased the Class A and Class B Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately $0.5 million. The Company incurred other offering expenses of approximately $0.5 million. The Company received net proceeds of approximately $6.5 million, after deducting the underwriting discount and other offering expenses.

After allocating proceeds to the warrants issued with the Series B Convertible Preferred Stock, the effective conversion price of the Series B Convertible Preferred Stock was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature ("BCF") at that date. Since the Series B Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF of $1.3 million, based on intrinsic value, was charged to additional paid in capital as a non-cash "deemed dividend" and included in net loss to common stockholders.

During the first quarter of 2020, all 5,313 shares of Series B Convertible Preferred Stock were converted into common stock.

During February and March 2020, 10.8 million of the warrants issued in the February 2020 Financing, with an exercise price of $0.57, were exercised for proceeds of approximately $6.2 million.

November 2019 Financing

On November 14, 2019, the Company sold securities consisting of 547,420 Class A Units at a public offering price of $1.94 per unit, with each unit consisting of one share of common stock, one warrant to purchase one share of common stock ("primary warrant") and one-half of one warrant to purchase one half of one share common stock ("common warrant"), and 7,938 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of $1.94 per share, convertible into 515.464 shares of common stock, primary warrants to purchase 515.464 shares of common stock, and common warrants to purchase 257.732 shares of common stock (the "November 2019 Financing"). The primary warrants have an exercise price of $1.94, are immediately exercisable and expire five years from the date of issuance. The common warrants had an exercise price of $1.94 and expired 12 months from the date of issuance. The common warrants were exercisable on a cashless basis at the option of the holder on the earlier of 30 days from issuance and the date by which an aggregate of $9.0 million of the Company's securities were traded.

As a result of the issuance of common stock in February 2020 for less than the November 2019 warrant exercise price, a repricing of the warrants issued in the November 2019 Financing was triggered. The Company recognized a one-time non-cash "deemed dividend" of $0.5 million, representing the increase in the fair value of the warrants. The non-cash "deemed dividend" was charged to additional paid in capital and included in net loss to stockholders. During February and March 2020, 2.3 million of the warrants issued in the November 2019 financing, with an exercise price of $0.57, were exercised for proceeds of approximately $1.3 million.

2019 Lincoln Park Transaction

On August 20, 2019, the Company entered into a purchase agreement (the "2019 Purchase Agreement") and a registration rights agreement (the "2019 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2019 Purchase Agreement, Lincoln Park has agreed to purchase from us up to $15,000,000 of the Company's common stock (subject to certain limitations) from time to time during the term of the 2019 Purchase Agreement. Pursuant to the terms of the 2019 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 2019 Purchase Agreement.

Pursuant to the terms of the 2019 Purchase Agreement, at the time the Company signed the 2019 Purchase Agreement and the 2019 Registration Rights Agreement, the Company issued 35,529 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2019 Purchase Agreement. The commitment shares were valued at $200,000 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 2019 Purchase Agreement.

As a result of receiving stockholder approval on January 16, 2020, the Company may sell more thanl9.9% of it's common stock outstanding pursuant to the 2019 Purchase Agreement without violating Nasdaq Marketplace Rules, including Rule 5635(d), requiring shareholder approval for the sale, issuance or potential issuance by an issuer of common stock (or securities convertible into or exercisable for common stock) at a price less than the greater of book or market value.

During the nine months ended September 30, 2020, the Company sold an aggregate of approximately464,471 shares of common stock under the 2019 Purchase Agreement, for gross proceeds of approximately $0.3 million.

NOTE 13 – 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 140,000 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 600,000 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 10,000,000 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the Amended and Restated 2020 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and100% 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, 2021, 16,085,796 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, 2021 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	10,209,286	$ 2.93	9.26	$ 131,558
Grants	15,572,190	$ 1.28		
Exercised	—			
Forfeitures or expirations	(1,127)	2,032.78		
Outstanding at September 30, 2021	25,780,349	$ 1.84	9.08	$ 90,655
Exercisable at September 30, 2021	4,949,472	$ 4.46	8.44	$ 48,057

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

The weighted average fair value of options granted during the three and nine months ended September 2021 was $0.67 per share and $1.06 per share, respectively. The weighted average fair value of options granted during the nine months ended September 2020 was $0.66 per share. No stock options were granted during the three months ended September 30, 2020.

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, 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 vesting period using the straight-line method.

The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2021 and 2020 were as follows:

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Risk-free interest rate	0.79% to 1.63 %	0.36% to 1.25 %
Expected term of option	5.5 to 6 years	5.5 to 6 years
Expected stock price volatility	124.37% - 137.73 %	120.62 -129.29 %
Expected dividend yield	0.0	0.0

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

Stock-based compensation expense relating to options granted of $2.3 million, of which $1.6 million and $0.7 million, related to General and Administration and Research and Development, respectively was recognized for the three-months period ended September 30, 2021. Stock-based compensation expense relating to options granted of $0.9 million, of which $0.6 million and $0.3 million, related to General and Administration and Research and Development, respectively was recognized for the three-months period ended September 30, 2020.

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. Stock-based compensation expense relating to options granted of $2.0 million, of which $1.4 million and $0.6 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2020.

As of September 30, 2021, the Company had approximately $16.5 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 2.11 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").

The 2020 ESPP allows eligible employees to purchase up to an aggregate of 300,000 shares of the Company's common stock. Under the 2020 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 2020 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 2020 ESPP, subject to the statutory limit under the Code. As of September 30, 2021, 129,048 shares were available for future sales under the 2020 ESPP.

The 2020 and 2019 ESPP are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the three and nine months ended September 30, 2021, $42,000 and $89,000, respectively, was expensed, and for the three and nine months ended September 30, 2020, $23,000 and $23,000, respectively, was expensed. In January 2020, 1,578 shares that were purchased as of December 31, 2019, under the 2019 ESPP, were issued. Accordingly, during the first quarter of 2020, approximately $2,000 of employee payroll deductions accumulated at December 31, 2019, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $7,000 was returned to the employees. As of December 31, 2020, approximately $32,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses. In January 2021, 54,447 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 July 2021,116,505 shares that were purchased as of June 30, 2021, under the 2020 ESPP, were issued. Accordingly, during July 2021, approximately $ 68,000 of employee payroll deductions accumulated at June 30, 2021, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $7,000 was returned to the employees. As of September 30, 2021, approximately $43,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses.

NOTE 14 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at September 30, 2021:

Exercise Price	Number Outstanding	Expiration Date
$ 0.50	24,920	November 2024
$ 0.57	123,500	February 2025
$ 35.00	490,571	December 2023
$ 630.00	5,441	October 2021
$ 687.50	474	October 2021
	644,906	

During the nine months September 30, 2021,3,400 warrants from the February 2020 Financing, with an exercise price of $0.57, were exercised for proceeds of approximately $2,000.

During the nine months ended September 30, 2020,2.3 million warrants from the November 2019 financing, with an exercise price of $0.57, were exercised for proceeds of approximately $1.3 million. During the nine months ended September 30, 2020,2.3 million warrants from the November 2019 financing, with an exercise price of $0.50, were exercised for proceeds of approximately $1.2 million.

During the nine months ended September 30, 2020,13.0 million warrants from the February 7th financing, with an exercise price of $0.57, were exercised for proceeds of approximately $7.5 million.

NOTE 15 – 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, 2021, the Company has right-of-use assets of $1.1 million and a total lease liability for operating leases of $1.1 million of which $0.5 million is included in long-term lease liabilities and $0.6 million is included in current lease liabilities.

At September 30, 2021, future minimum lease payments for operating leases with non-cancelable terms of more than one year were as follows (in thousands):

Year Ending December 31,	
Remainder of 2021	$ 158
2022	512
2023	169
2024	145
2025	149
	1,133
Included interest	(20)
	$ 1,113

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.

During the nine months ended September 30, 2020, the Company entered into new operating leases and lease amendments, resulting in the Company recognizing an additional operating lease liability of approximately $1.2 million based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately $1.2 million.

Operating lease expense was $0.2 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively.

Operating lease expense was $0.5 and $0.3 million for the nine-months ended September 30, 2021 and 2020, respectively.

Other information related to leases is as follows:

Cash paid for amounts included in the measurement of lease liabilities:	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Operating cash flow from operating leases (in thousands)	$ 479	$ 354
Weighted Average Remaining Lease Term		
Operating leases	2.79 years	3.52 years
Weighted Average Discount Rate		
Operating leases	1.34%	1.48%

NOTE 16 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $1.2 million at September 30, 2021 for future work to be performed.

On July 26, 2021, the Company entered into a $17.5 million contingent non-binding Purchase and Sales Agreement in connection with a property in Maryland. The property is intended for process development activities. The purchase and sale closed on October 1, 2021.

On March 3, 2021, the Company entered into a $2.9 million contingent non-binding Purchase and Sales Agreement in connection with a property in Massachusetts. The property is intended for process development activities. The purchase and sale is expected to close during the fourth quarter of 2021.

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 $38,000 and $149,000 for the three and nine months ended September 30, 2021, respectively, and $21,000 and $100,000 for the three and nine months ended September 30, 2020, respectively, for contributions under the 401(k) Plan.

NOTE 17 – SUBSEQUENT EVENTS

On October 1, 2021, the Company completed the acquisition of a research and development facility in Maryland totaling $17.5 million. (See Note 16).

Subsequent to September 30, 2021, the Company has sold 21.9 million shares of common stock under the ATM Sales Agreement, for net proceeds of approximately $11.8 million.

Subsequent to September 30, 2021, the Company has sold 14.0 million shares of common stock under the 2021 Purchase Agreement, for net proceeds of approximately $7.6 million.

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

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

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

Business Overview

We are a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. We are building capabilities in synthetic biology, precision medicine, protein engineering and vaccine manufacturing through internal efforts, collaborations with academic institutions and contract research organizations. The therapeutics under development include small molecules and biologics. All of our drug and diagnostic candidates are still in development. Tonix's portfolio is primarily composed of immunology and central nervous system, or CNS, product candidates. Tonix's immunology portfolio includes a live virus vaccine to prevent COVID-19, a small molecule antiviral to treat acute COVID-19, a centrally acting small molecule to treat Long COVID as well as a synthetic peptide-based skin test to detect and monitor functional T cell immunity to SARS-CoV-2, the virus that causes COVID-19. Tonix's immunology portfolio also includes biologics to address organ transplant rejection, cancer, and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Our most advanced CNS product candidate is a sublingual small molecule drug in mid-Phase 3 development for the management of fibromyalgia, or FM, which is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. Our biologic antidote for cocaine intoxication is expected to enter a Phase 2 trial before year end.

Tonix's lead candidate within its immunology portfolio is a vaccine for COVID-19, TNX-1800*. This candidate is a live virus vaccine based on Tonix's recombinant pox vaccine, or "RPV" platform, being developed to protect against COVID-19 primarily by eliciting a T cell response. The COVID-19 vaccines that are approved for use, or have emergency use authorization, or EUA, in the U.S. have provided significant health benefits to the vaccinated population, however, they are showing limitations in the durability of protection conferred and in their ability to block forward transmission. Live virus vaccines that protect against other viral diseases by eliciting T cell responses have shown durability of protection that lasts years to decades and some live virus vaccines have significantly inhibited forward transmission. We reported positive efficacy data from animal challenge studies using live SARS-CoV-2 in the first quarter of 2021. In this study, TNX-1800 vaccinated, SARS-CoV-2 challenged animals had undetectable SARS-CoV-2 in the upper airways, which we believe relates to potential inhibition of forward transmission of this respiratory pathogen. Tonix expects to start a Phase 1 study of TNX-1800 in humans in the second half of 2022. TNX-801*, a live horsepox virus vaccine for percutaneous administration, is in the pre-IND stage of development to protect against smallpox and monkeypox. It is also based on the proprietary RPV platform, which was developed by synthetic biology.

TNX-2100* is an *in vivo* diagnostic skin test we are developing to measure SARS-CoV-2 exposure and T cell immunity. T cell immunity is more durable than antibody immunity, since serum antibodies wane between six months and one year after vaccination. TNX-2100 is an intradermal test to measure delayed-type hypersensitivity (DTH) response to SARS-CoV-2. The DTH response for other pathogens, notably tuberculosis, can serve as an *in vivo* measure of functional T cell immunity. TNX-2100 is comprised of GMP peptides designed to mimic SARS-CoV-2 proteins and stimulate SARS-CoV-2 specific T cells. We expect to initiate a first-in-human clinical study in the fourth quarter of 2021 pending clearance of the IND.

TNX-3500* (sangivamycin) is an antiviral inhibitor of SARS-CoV-2. It has demonstrated broad-spectrum activity in laboratory-based assays against the coronaviruses SARS-CoV-2 and MERS-CoV. Tonix licensed this technology from OyaGen, Inc. and intends to develop it as a treatment for COVID-19 and potentially other viral diseases. The active ingredient of TNX-3500 has been studied for safety in humans in prior studies with cancer patients at the U.S. National Cancer Institute but has not been approved for marketing in any jurisdiction. Tonix intends to conduct further animal studies in preparation for filing an IND.

TNX-1500* is a humanized monoclonal antibody, or mAb, directed against CD40-ligand, or CD40L, engineered to modulate binding to Fc receptors, that is being developed to prevent and treat organ transplant rejection as well as to treat autoimmune conditions. In experiments at the Massachusetts General Hospital, a teaching hospital of Harvard Medical School, TNX-1500 is being studied as monotherapy or in combination with mycophenolate mofetil in heart and kidney organ transplants in non-human primates. Preliminary results from an ongoing experiment in heart transplants indicates that TNX-1500 appears to have comparable efficacy to historical experiments using the chimeric mouse/primate version of the anti-CD40L monoclonal antibody (mAb) 5c8. In the non-human primate studies with TNX-1500 no evidence of thrombosis has been observed so far. We expect to start a Phase 1 study of TNX-1500 in the second half of 2022.

As part of our infectious disease research and development programs, we expanded our research collaboration with Columbia University during the third quarter to better understand immune responses to SARS-CoV-2 in healthy individuals who have recovered from COVID-19, which is expected to provide a foundation for tailoring vaccines and therapeutics to appropriate individuals using precision medicine. Our preclinical immunology pipeline also includes TNX-1700* and TNX-701**. TNX-1700 is a recombinant modified form of Trefoil Family Factor 2, or rTFF2, that was licensed from Columbia University in 2019. TNX-1700 is a biologic being developed to treat gastric and pancreatic cancers by an immune-oncology mechanism. TNX-701 is an undisclosed small molecule, which is being developed to prevent deleterious effects of radiation exposure which has the potential to be used as a medical countermeasure to improve biodefense.

Our most advanced CNS product candidate is TNX-102 SL**, a proprietary sublingual tablet formulation of cyclobenzaprine, or CBP, designed for bedtime administration. TNX-102 SL has active IND's for FM, posttraumatic stress disorder, or PTSD, agitation in Alzheimer's disease, or AAD, and alcohol use disorder, or AUD. TNX-102 SL is in mid-Phase 3 development for the management of FM which is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. In December 2020, we reported positive results from the Phase 3 RELIEF study of TNX-102 SL 5.6 mg for the management of FM. In July 2021, we reported pre-planned interim analysis results from a second Phase 3 study, RALLY. Based on the recommendation from the independent data monitoring committee that the RALLY trial was unlikely to demonstrate a statistically significant improvement in the primary endpoint, we stopped enrollment of new participants but allowed those participants who were currently enrolled to complete the study. We expect to report topline data from the completed study in the fourth quarter of 2021. We expect to analyze the RALLY results to improve the design of subsequent Phase 3 studies. In addition, we plan to employ pharmacogenomic techniques to compare the RALLY and RELIEF study populations, which may provide a path to precision medicine-based companion diagnostics for TNX-102 SL in FM.

For TNX-102 SL in PTSD, we completed the Phase 3 RECOVERY trial and reported topline results in the fourth quarter of 2020 in which TNX-102 SL did not meet the primary efficacy endpoint. PTSD is a serious psychiatric condition that develops in response to experiencing a traumatic event. We subsequently completed a meeting with the U.S. Food and Drug Administration, or FDA, to discuss potential new endpoints for the indication of treatment of PTSD, and we expect to begin enrolling a Phase 2 study of TNX-102 SL in police in Kenya in the first quarter of 2022. The AAD program is Phase 2 ready with an active IND and FDA Fast Track designation. AAD, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of the behavioral complications of Alzheimer's disease. The AUD program is also Phase 2 ready with an active IND. AUD is a chronic relapsing brain disease characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using alcohol.

We also plan to develop TNX-102 SL as a potential treatment for Long COVID Syndrome (Long COVID) which is known officially as Post-Acute Sequelae of COVID-19 (PASC). We met with the FDA in the third quarter of 2021 to seek agreement on the design of a Phase 2 potential pivotal study and the overall clinical development plan to qualify TNX-102 SL as an indicated treatment for Long COVID. We intend to focus our clinical development on the subgroup of Long COVID patients whose symptoms overlap with FM, particularly with respect to widespread pain. We received the official minutes from this meeting in the third quarter of 2021 and intend to initiate a Phase 2 study in the first half of 2022 following IND clearance.

Other CNS candidates in development include TNX-1300* (double-mutant cocaine esterase) is also in Tonix's CNS portfolio and is in Phase 2 development for the treatment of life-threatening cocaine intoxication. TNX-1300 has been granted Breakthrough Therapy designation, or BTD by the FDA. TNX-1300 was licensed from Columbia University in 2019 after a Phase 2 study showed that it rapidly and efficiently disintegrates cocaine in the blood of volunteers who had received intravenous, or *i.v.*, cocaine. We expect to initiate a Phase 2 open-label safety study of TNX-1300 in an emergency room setting in the fourth quarter of 2021.

TNX-601 CR** (tianeptine oxalate and naloxone controlled-release tablets) is a CNS product candidate in development as a treatment for major depressive disorder, or depression, for PTSD, and for neurocognitive dysfunction associated with corticosteroid use. We completed a Phase 1 trial for formulation development outside of the U.S. Based on official minutes from a pre-IND meeting with the FDA, we expect to initiate a Phase 2 study for the treatment of depression in the first half of 2022, pending results of toxicology studies and IND clearance.

TNX-1900** (intranasal potentiated oxytocin) is in development as a candidate for prophylaxis of chronic migraine and for the treatment of craniofacial pain, insulin resistance and related conditions. TNX-1900 was acquired from Trigemina, Inc. in 2020 and licensed from Stanford University in 2020. The potentiated formulation includes magnesium, which has been shown in animals to potentiate binding of oxytocin to the oxytocin receptor in the trigeminal ganglion. We intend to initiate a Phase 2 study in migraine in the second half of 2022 pending IND clearance. Tonix also licensed technology to use TNX-1900 for the treatment of insulin resistance from the University of Geneva. TNX-2900** is another intranasal oxytocin-based therapeutic in development for the treatment of Prader-Willi syndrome, or PWS. The technology for TNX-2900 was licensed from the French National Institute of Health and Medical Research. PWS, an orphan condition, is a rare genetic disorder of failure to thrive in infancy, associated with uncontrolled appetite beginning in childhood with complications of obesity and diabetes.

Finally, our preclinical CNS pipeline includes TNX-1600** which is an inhibitor of the reuptake of neurotransmitters serotonin, norepinephrine and dopamine, or a triple reuptake inhibitor. TNX-1600 was licensed from Wayne State University in 2019 and is being developed as a treatment for PTSD, depression and attention-deficit/hyperactivity disorder, or ADHD.

Relating to our COVID-19 and other infectious disease development programs, we are developing the resources necessary to enable internal research, development and manufacturing capabilities necessary to meet the goal of producing new vaccine candidates within 100 days and new diagnostics within weeks of obtaining sequence information. As articulated in the American Pandemic Preparedness Plan, or AP3 released by the U.S. Office of Science and Technology Policy, this 100-day goal for vaccines is a key component of preparedness for future pandemics. We are establishing the infrastructure necessary to support the pandemic preparedness goals established in the AP3, specifically with respect to our RPV vaccine and skin test platforms and potentially to other vaccine, diagnostic and therapeutic platforms. This infrastructure consists of (i) our infectious disease R&D Center or "RDC", (ii) our Advanced Development Center or ADC, and (iii) our Commercial Manufacturing Center or CMC. We acquired the infectious disease RDC in Frederick, Maryland consisting of two buildings totaling approximately 48,000 square feet. The acquisition closed in October 2021 and was operational at closing. The RDC facility will focus on our development of vaccines and antiviral drugs against COVID-19, its variants, and other infectious diseases. The RDC facility is currently biosafety level 2 (BSL-2) but we intend to upgrade components to BSL-3. We are in the process of a substantial renovation of the ADC located in the New Bedford business park in Dartmouth, Massachusetts. This facility is intended to accelerate development and clinical scale manufacturing of live-virus vaccines to support Phase 1 and Phase 2 clinical trials. It is currently under construction and will be an approximately 45,000 square foot BSL-2 facility, once completed. It is expected to be operational in the first half of 2022. We also intend to build the CMC in Hamilton, Montana where we purchased approximately 44 acres of land. The CMC will focus on developing and manufacturing commercial scale live-virus vaccines and is also intended to be BSL-2. Construction is expected to be initiated for the CMC in 2022. Together, we expect these facilities may qualify the RPV vaccine and skin test platforms for programs that are designed to carry out the goals of AP3.

*TNX-1800, TNX-801, TNX-2100, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600, TNX-1900, TNX-2900, TNX-3500 and TNX-701 are investigational new drugs 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, 2021 Compared to Three Months Ended September 30, 2020

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2021 were $13.1 million, an increase of $4.3 million, or 49%, from $8.8 million for the three months ended September 30, 2020. This increase is predominately due to increased manufacturing expenses of $1.8 million, non-clinical expenses of $1.6 million, employee-related expenses of $1.0 million and regulatory/legal expenses of $0.6 million offset by a decrease in clinical expenses of $0.7 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.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2021 were $5.5 million, an increase of $2.3 million, or 72%, from $3.2 million incurred in the three months ended September 30, 2020. The increase in primarily due to an increase in employee-related expenses of $1.3 million, an increase in investor relations/public relations expenses of $0.2 million, an increase in legal expenses of $0.2 million, an increase in accounting fees of $0.2 million and an increase in insurance premiums of $0.1 million.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2021 was $18.5 million, compared to a net loss of $12 million for the three months ended September 30, 2020.

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2021 were $46.5 million, an increase of $22.4 million, or 93%, from $24.1 million for the nine months ended September 30, 2020. This increase is predominately due to increased non-clinical expenses of $11.6 million, manufacturing expenses of $8.8 million, employee-related expenses of $3.0 million and regulatory/legal expenses of $1.3 million offset by a decrease in clinical expenses of $2.6 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.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2021 were $16.3 million, an increase of $6.9 million, or 73%, from $9.4 million incurred in the nine months ended September 30, 2020. The increase is primarily due to employee-related expenses of $3.1 million, an increase in legal fees of $0.8 million due to increased patent prosecution costs, an increase in investor relations/public relations expenses of $0.5 million, an increase in financial reporting expenses of $1.2 million, an increase in accounting fees of $0.2 million, and an increase in insurance premiums of $0.3 million.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2021 was $62.7 million, compared to a net loss of $33.4 million for the nine months ended September 30, 2020.

License Agreements

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 2,752,294 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 September30, 2021, no milestone payments have been accrued or paid in relation to this agreement.

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, 2021, 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 have agreed 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, 2021, 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 agreed to pay 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. The first 50% of the license fee was paid by June 30, 2019, while the remaining 50% license fee, was paid during the second quarter of 2020. Both installments of the license fee were recorded to research and development expenses in the 2019 statement of operations.

We agreed 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, 2021, 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. 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 FDA, 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, 2021, 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 2,000,000 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, 2021, 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 September30, 2021, 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, 2021, no milestone payments have been accrued or paid in relation to this agreement.

Liquidity and Capital Resources

As of September 30, 2021, we had working capital of $183.1 million, comprised primarily of cash and cash equivalents of $183.0 million and prepaid expenses and other of $12.1 million, offset by $8.0 million of accounts payable, $3.5 million of accrued expenses and current lease liabilities of $0.6 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 and our vaccine program. For the nine months ended September, 2021 and 2020, we used approximately $53.1 million and $34.7 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The increase in cash outlays principally resulted from an increase in research and development activities. For the nine months ended September 30, 2021 and 2020, net proceeds from financing activities were $168.7 million and $83.2 million, respectively, predominately from the sale of our common stock and warrants.

Cash used in investing activities for the nine months ended September 30, 2021 and 2020, was $9.7 million and $4.0 respectively, related to the purchase of property and equipment.

We believe that our cash resources at September 30, 2021, and the proceeds that we raised from equity offerings subsequent to the end of the third quarter of 2021 will meet our operating and capital expenditure requirements through September 30, 2022, but not beyond.

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

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 has 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 1,280,000 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 42.8 million shares of common stock under the 2021 Purchase Agreement, for gross proceeds of approximately $29.5 million. Subsequent to September 30, 2021, we sold 14.0 million shares of common stock under the 2021 Purchase Agreement, for net proceeds of approximately $7.6 million.

February 2021 Financing

On February 8, 2021, we entered into a securities agreement ("the February 2021 Financing") with A.G.P/Alliance Global Partners ("AGP"), relating to the issuance and sale of 58,333,334 shares of our common stock, in a registered direct public offering. The public offering price for each share of common stock was $1.20. The February 2021 Financing closed on February 9, 2021. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount 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 underwriting discount and other offering expenses.

January 2021 Financing

On January 11, 2021, we entered into a securities purchase agreement ("the January 2021 Financing") with AGP, relating to the issuance and sale of 50,000,000 shares of our common stock, in a registered direct public offering. The public offering price for each share of common stock was $0.80. The January 2021 Financing closed on January 13, 2021. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount 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 underwriting discount 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 $50.0 million in at-the-market offerings ("ATM") sales. On the same day, we filed a prospectus supplement under a shelf registration relating to the Sales Agreement. 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. On September 4, we filed an amended prospectus supplement under the shelf registration relating to the Sales Agreement to increase the aggregate offering price to $100.0 million in ATM sales under the Sales Agreement. On April 19, 2021, we filed an amended prospectus supplement under the shelf registration relating to the Sales Agreement to increase the aggregate offering price to $170.0 million in ATM sales under the Sales Agreement. During the nine months ended September 30, 2021, we sold approximately 42.4 million shares of common stock under the Sales Agreement, for net proceeds of approximately $37.2 million. Subsequent to September 30, 2021, we have sold 21.9 million shares of common stock under the Sales Agreement, for net proceeds of approximately $11.8 million.

July 2020 Financing

On July 13, 2020, we entered into an underwriting agreement with AGP, relating to the issuance and sale of 20,940,000 shares of our common stock, in a registered direct public offering ("the July 2020 Financing"). The public offering price for each share of common stock was $0.50. The July 2020 Financing closed on July 15, 2020. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount of $0.7 million. We incurred other offering expenses of approximately $0.1 million. We received net proceeds of approximately $9.6 million, after deducting the underwriting discount and other offering expenses.

March 2020 Financing

On February 28, 2020, we entered into an underwriting agreement ("the March Financing") with AGP, relating to the issuance and sale of 14,550,000 shares of our common stock, in a registered direct public offering. The public offering price for each share of common stock was $1.10. The March Financing closed on March 3, 2020. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount of $1.1 million. We incurred other offering expenses of approximately $0.1 million. We received net proceeds of approximately $14.8 million, after deducting the underwriting discount and other offering expenses.

February 2020 Financing

On February 7, 2020, we entered into an underwriting agreement ("the February 2020 Financing") with AGP pursuant to which we sold securities consisting of 3,837,000 Class A Units at a public offering price of $0.57 per unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, and 5,313 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series B Convertible Preferred Stock, with a conversion price of $0.57 per share, convertible into 1,754.386 shares of common stock and warrants to purchase 1,754.386 shares of our common stock. The warrants have an exercise price of $0.57, are immediately exercisable and expire five years from the date of issuance.

The February 2020 Financing closed on February 11, 2020. AGP purchased the Class A and Class B Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately $0.5 million. We incurred other offering expenses of approximately $0.5 million. We received net proceeds of approximately $6.5 million, after deducting the underwriting discount and other offering expenses.

After allocating proceeds to the warrants issued with the Series B Convertible Preferred Stock, the effective conversion price of the Series B Convertible Preferred stock was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature ("BCF") at that date. Since the Series B Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF of $1.3 million, based on intrinsic value, was charged to additional paid in capital as a "deemed dividend" and included in net loss to common stockholders.

During the first quarter of 2020, all 5,313 shares of Series B Convertible Preferred Stock were converted into common stock.

During February and March 2020, 10.8 million of the warrants issued in the February 2020 Financing, with an exercise price of $0.57, were exercised for proceeds of approximately $6.2 million.

November 2019 Financing

On November 14, 2019, we sold securities consisting of 547,420 Class A Units at a public offering price of $1.94 per unit, with each unit consisting of one share of common stock, one warrant to purchase one share of common stock ("primary warrant") and one-half of one warrant to purchase one half of one share common stock ("common warrant"), and 7,938 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of $1.94 per share, convertible into 515.464 shares of common stock, primary warrants to purchase 515.464 shares of common stock, and common warrants to purchase 257.732 shares of our common stock. The primary warrants have an exercise price of $1.94, are immediately exercisable and expire five years from the date of issuance. The common warrants had an exercise price of $1.94 and expired 12 months from the date of issuance. The common warrants were exercisable on a cashless basis at the option of the holder on the earlier of 30 days from issuance and the date by which an aggregate of $9.0 million of our securities were traded.

With the February 2020 Financing, warrants that were issued as part of the November 2019 Financing were repriced at $0.57. As a result of the issuance of common stock in February 2020 for less than the November 2019 warrant exercise price, a repricing of the warrants issued in the November 2019 Financing was triggered. We recognized a one-time non-cash "deemed dividend" of $0.5 million, representing the increase in the fair value of the warrants. The "deemed dividend" was charged to additional paid in capital and included in net loss to stockholders. During February and March 2020, 2.3 million of the warrants issued in the November 2019 Financing, with an exercise price of $0.57, were exercised for proceeds of approximately $1.3 million.

2019 Lincoln Park Transaction

On August 20, 2019, we entered into a purchase agreement (the "2019 Purchase Agreement") and a registration rights agreement (the "2019 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2019 Purchase Agreement, Lincoln Park has agreed to purchase from us up to $15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2019 Purchase Agreement. Pursuant to the terms of the 2019 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 2019 Purchase Agreement.

Pursuant to the terms of the 2019 Purchase Agreement, at the time we signed the 2019 Purchase Agreement and the 2019 Registration Rights Agreement, we issued 35,529 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2019 Purchase Agreement. The commitment shares were valued at $200,000 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 2019 Purchase Agreement.

As a result of receiving stockholder approval on January 16, 2020, we may sell more than 19.9% of its common stock outstanding pursuant to the 2019 Purchase Agreement without violating Nasdaq Marketplace Rules, including Rule 5635(d), requiring shareholder approval for the sale, issuance or potential issuance by an issuer of common stock (or securities convertible into or exercisable for common stock) at a price less than the greater of book or market value.

During the nine months ended September 30, 2020, we sold an aggregate of approximately 464,471 shares of common stock under the 2019 Purchase Agreement, for gross proceeds of approximately $0.3 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 140,000 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, 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 600,000 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, 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) 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 10,000,000 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the Amended and Restated 2020 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the expiration period of grants under the Amended and Restated 2020 Plan may not be more than ten years. As of September 30, 2021, 16,085,796 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 six months ended September 2021 was $0.67 per share and $1.06 per share, respectively. The weighted average fair value of options granted during the nine months ended September 2020 was $0.66 per share. No stock options were granted during the three months ended September 30, 2020.

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

Stock-based compensation expense relating to options granted of $2.3 million, of which $1.6 million and $0.7 million, related to General and Administration and Research and Development, respectively was recognized for the three-month period ended September 30, 2021. Stock-based compensation expense relating to options granted of $0.9 million, of which $0.6 million and $0.3 million, related to General and Administration and Research and Development, respectively was recognized for the three-month period ended September 30, 2020.

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. Stock-based compensation expense relating to options granted of $2.0 million, of which $1.4 million and $0.6 million, related to General and Administration and Research and Development, respectively was recognized for the nine-month period ended September 30, 2020.

As of September 30, 2021, we had approximately $16.5 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 2.11 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 our 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").

The 2020 ESPP allows eligible employees to purchase up to an aggregate of 300,000 shares of our common stock. Under the 2020 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 2020 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 2020 ESPP, subject to the statutory limit under the Code. As of September 30, 2021, 129,048 shares were available for future sales under the 2020 ESPP.

The 2020 and 2019 ESPP are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the three and nine months ended September 30, 2021, $42,000 and $89,000, respectively, was expensed, and for the three and nine months ended September 30, 2020, $23,000 and $23,000, respectively, was expensed. In January 2020, 1,578 shares that were purchased as of December 31, 2019, under the 2019 ESPP, were issued. Accordingly, during the first quarter of 2020, approximately $2,000 of employee payroll deductions accumulated at December 31, 2019, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $7,000 was returned to the employees. As of December 31, 2020, approximately $32,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses. In January 2021, 54,447 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 July 2021, 116,505 shares that were purchased as of June 30, 2021, under the 2020 ESPP, were issued. Accordingly, during July 2021, approximately $68,000 of employee payroll deductions accumulated at June 30, 2021, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $7,000 was returned to the employees. As of September 30, 2021, approximately $43,000 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 $41.2 million at September 30, 2021 for future work to be performed.

On July 26, 2021, we entered into a $17.5 million contingent non-binding Purchase and Sales Agreement in connection with a property in Maryland. The property is intended for process development activities. The purchase and sale closed on October 1, 2021.

On March 3, 2021, we entered into a $2.9 million contingent non-binding Purchase and Sales Agreement in connection with a property in Massachusetts. The property is intended for process development activities. The purchase and sale is expected to close during the fourth quarter of 2021.

Operating leases

As of September 30, 2021, future minimum lease payments are as follows (in thousands):

Year Ending December 31,	
Remainder of 2021	$ 158
2022	512
2023	169
2024	145
2025	149
	1,133
Included interest	(20)
	$ 1,113

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.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the nine months ended September 30, 2021, and 2020.

	Nine months ended September 30, (in thousands)		
	2021	**2020**	**Change**
Research and development expenses:			
Direct expenses – TNX - 102 SL	$ 9,520	$ 12,236	$ (2,716)
Direct expenses – TNX - 1800	6,100	2,285	3,815
Direct expenses – TNX - 1300	5,116	1,105	4,011
Direct expenses – TNX - 1500	2,804	536	2,268
Direct expenses – TNX - 1900	1,355	2,603	(1,248)
Direct expenses – TNX - 2100	2,115	86	2,029
Direct expenses – TNX - 3500	5,123	137	4,986
Direct expenses – Other programs	5,825	1,252	4,573
Internal staffing, overhead and other	8,584	3,820	4,764
Total research & development	$ 46,542	$ 24,060	$ 22,482

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.

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.

*Accounting for sale of Class B Units in November 2019 and February 2020 including beneficial conversion feature.*In connection with the November 2019 and February 2020 underwritten offerings, we issued warrants to purchase our common stock and convertible preferred stock. To account for the transaction, we calculated the relative fair value of each instrument issued in the financing. We also determined if a beneficial conversion feature existed. A beneficial conversion feature is defined as a nondetachable conversion feature that is in the money at the commitment date. A conversion feature is in the money if its conversion price is less than the current fair value of the share. For purposes of measuring a beneficial conversion feature, the effective conversion price should be based on the proceeds allocated to the convertible instrument.

We determined the fair value of the warrants to purchase common stock issued in the November 2019 Financing using a Monte Carlo simulation, which is a statistical method used to generate a defined number of share price paths to develop a reasonable estimate of the range of future expected share prices. We determined the fair value of the warrants, using the black-scholes method, for the February 2020 warrants. Estimates and assumptions impacting the fair value measurement include the number of shares for which the warrants are exercisable, remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying common shares. We estimate expected share volatility based on our historical volatility for a term equal to the contractual term of the warrants adjusted for a discount that a market participant would have taken when pricing the instrument. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We estimated a 0% expected dividend yield based on the fact that we have never paid or declared dividends and do not intend to do so in the foreseeable future. In general, the assumptions used in calculating the fair value of the warrant represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment. We determine the fair value of the convertible preferred stock utilizing the price of the common stock on the commitment date. We then allocated the relative fair value between the preferred shares and the warrants. Since the effective conversion price of the Preferred Stock is less than the fair value of the underlying common stock at the date of commitment, there is a beneficial conversion feature at the commitment date. Since the Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the beneficial conversion feature was charged to additional paid in capital as a "deemed dividend" and impacted earnings per share, reflected as an increase to loss to common stockholders.

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, 2021, 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, 2021 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, 2020, and under Part II, Item 1A., "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 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, 2020, 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, 2020 and our Quarterly Report on Form 10-Q for the quarter ended March 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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

31.01	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01	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 8, 2021

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

Date: November 8, 2021

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

Exhibit 31.01

CERTIFICATION

I, Seth Lederman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tonix Pharmaceuticals Holding Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are 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 8, 2021

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

Exhibit 31.02

CERTIFICATION

I, Bradley Saenger, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tonix Pharmaceuticals Holding Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are 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 8, 2021

/s/ BRADLEY SAENGER
Bradley Saenger
Chief Financial Officer

Exhibit 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended September 30, 2021 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 8, 2021

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, 2021 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 8, 2021

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