

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, 2016

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.)

509 Madison Avenue, Suite 306
New York, New York 10022

(Address of principal executive offices) (zip code)

(212) 980-9155

(Registrant's telephone number, including area code)

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(Do not check if a smaller reporting company)

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 8, 2016, there were 39,181,106 shares of registrant's common stock outstanding.

TONIX PHARMACEUTICALS HOLDING CORP.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,644	\$ 19,175
Marketable securities-available for sale, at fair value	11,094	23,841
Prepaid expenses and other	2,483	3,343
Total current assets	29,221	46,359
Property and equipment, net	315	350
Restricted cash	89	132
Intangible asset	120	120
Security deposits	56	57
Total assets	\$ 29,801	\$ 47,018
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 944	\$ 3,049
Accrued expenses	1,676	3,601
Total current liabilities	2,620	6,650
Deferred rent payable	76	106
Total liabilities	2,696	6,756
Commitments (See Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, none issued or outstanding	-	-
Common stock, \$0.001 par value; 150,000,000 shares authorized; 29,352,718 and 18,831,669 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively, and 17,595 shares to be issued as of December 31, 2015	29	19
Additional paid in capital	160,823	142,658
Accumulated deficit	(133,758)	(102,398)
Accumulated other comprehensive income (loss)	11	(17)
Total stockholders' equity	27,105	40,262
Total liabilities and stockholders' equity	\$ 29,801	\$ 47,018

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,	
	2016	2015	2016	2015
COSTS AND EXPENSES:				
Research and development	\$ 5,466	\$ 10,314	\$ 23,653	\$ 26,014
General and administrative	2,143	2,966	7,806	8,746
	<u>7,609</u>	<u>13,280</u>	<u>31,459</u>	<u>34,760</u>
Operating loss	(7,609)	(13,280)	(31,459)	(34,760)
Interest income, net	31	30	99	66
NET LOSS	<u>\$ (7,578)</u>	<u>\$ (13,250)</u>	<u>\$ (31,360)</u>	<u>\$ (34,694)</u>
Net loss per common share, basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.72)</u>	<u>\$ (1.45)</u>	<u>\$ (2.15)</u>
Weighted average common shares outstanding, basic and diluted	<u>26,131,085</u>	<u>18,423,816</u>	<u>21,601,574</u>	<u>16,103,382</u>

See the accompanying notes to the condensed consolidated financial statements

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Net loss	\$ (7,578)	\$ (13,250)	\$ (31,360)	\$ (34,694)
Other comprehensive (loss) income:				
Foreign currency translation (loss) gain	(7)	9	(2)	13
Unrealized gain on available for sale securities	-	2	30	2
Total other comprehensive (loss) income	(7)	11	28	15
Comprehensive loss	<u>\$ (7,585)</u>	<u>\$ (13,239)</u>	<u>\$ (31,332)</u>	<u>\$ (34,679)</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
NINE MONTHS ENDED SEPTEMBER 30, 2016
(In Thousands, Except Share and Per Share Amounts)
(Unaudited)

	Preferred stock		Common stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid in Capital	Other Comprehensive Income (Loss)	Deficit	
Balance, December 31, 2015	-	\$ -	18,831,669	\$ 19	\$ 142,658	\$ (17)	\$ (102,398)	\$ 40,262
Employee stock purchase plan	-	-	48,551	-	167	-	-	167
Issuance of common stock related to vested restricted stock units	-	-	42,000	-	-	-	-	-
Issuance of common stock in May and June 2016 (\$2.40 per share), net of transaction expenses of \$149	-	-	1,188,211	1	2,698	-	-	2,699
Issuance of common stock in June 2016 (\$2.00 per share), net of transaction expenses of \$916	-	-	5,000,000	5	9,079	-	-	9,084
Issuance of common stock in July 2016 (\$2.00 per share), net of transaction expenses of \$105	-	-	750,000	1	1,394	-	-	1,395
Issuance of common stock in September 2016 (\$0.74 per share), net of transaction expenses of \$124	-	-	3,492,287	3	2,460	-	-	2,463
Stock-based compensation	-	-	-	-	2,367	-	-	2,367
Foreign currency translation loss	-	-	-	-	-	(2)	-	(2)
Unrealized gain on available for sale securities	-	-	-	-	-	30	-	30
Net loss	-	-	-	-	-	-	(31,360)	(31,360)
Balance, September 30, 2016	-	\$ -	29,352,718	\$ 29	\$ 160,823	\$ 11	\$ (133,758)	\$ 27,105

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,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (31,360)	\$ (34,694)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	163	90
Stock-based compensation	2,367	3,384
Changes in operating assets and liabilities:		
Prepaid expenses	867	(1,290)
Accounts payable	(2,114)	948
Accrued expenses	(1,725)	948
Deferred rent payable	(70)	(2)
Net cash used in operating activities	<u>(31,872)</u>	<u>(30,616)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(66)	(68)
Maturities of marketable securities	12,715	-
Purchase of marketable securities	-	(22,058)
Proceeds from restricted cash	44	-
Purchase of intangible asset	-	(120)
Net cash provided by (used in) investing activities	<u>12,693</u>	<u>(22,246)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	-	9
Proceeds, net of expenses of \$1,294 and \$2,115 from sale of common stock	15,641	47,685
Net cash provided by financing activities	<u>15,641</u>	<u>47,694</u>
Effect of currency rate change on cash	<u>7</u>	<u>(7)</u>
Net decrease in cash and cash equivalents	(3,531)	(5,175)
Cash and cash equivalents, beginning of the period	<u>19,175</u>	<u>38,184</u>
Cash and cash equivalents, end of period	<u>\$ 15,644</u>	<u>\$ 33,009</u>
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
Issuance of common stock under employee benefit plan	<u>\$ 167</u>	<u>\$ 160</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2016 AND 2015 (UNAUDITED)

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiaries, is a clinical-stage pharmaceutical company dedicated to the identification and development of next-generation pharmaceutical products for common disorders of the central nervous system (“CNS”), with its lead program focusing on posttraumatic stress disorder. All drug product candidates are still in development.

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its wholly owned subsidiaries, Tonix Pharmaceuticals, Inc., Krele LLC, Tonix Pharmaceuticals (Canada), Inc., Tonix Medicines, Inc., Tonix Pharma Holdings Limited and Tonix Pharma Limited (collectively hereafter referred to as the “Company” or “Tonix”).

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, 2015 contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2016 are not necessarily indicative of results that may be expected for the year ending December 31, 2016. 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, 2015 included in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 3, 2016.

Recent accounting pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. Lessees (for capital and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. The Company is currently evaluating the impact of adopting this guidance.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718). The new guidance simplifies the accounting for stock-based compensation transactions, including tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This update is effective in fiscal years, including interim periods, beginning after December 15, 2016, and early adoption is permitted. The Company is currently evaluating the impact of this guidance.

Risks and uncertainties

The Company’s primary efforts are devoted to conducting research and development for the treatment of disorders of the CNS. 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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2016 AND 2015 (UNAUDITED)

At September 30, 2016, the Company had working capital of approximately \$26.6 million, after raising approximately \$10.5 million, net of expenses, through the sale of common stock in an underwritten public offering in June 2016 and from the exercise of the underwriter's overallotment option in July 2016, and approximately \$5.2 million, net of expenses, through the at-the-market ("ATM") offering during the nine months ended September 30, 2016 (see Note 4). In addition, in October 2016, the Company raised approximately \$4.6 million, net of expenses, through the sale of common stock and warrants in an underwritten public offering (see Note 8). Management believes that the Company has sufficient funds to meet its research and development and other funding requirements for at least the next 12 months. In addition to the funding already obtained or currently available to the Company, the Company intends to raise additional funds through equity or debt financing to complete the development and commercialization of its current product candidates. If the Company is unsuccessful in raising additional financing, it will need to further reduce costs and operations in the future.

Use of estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets, 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 equivalents

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, 2016, cash equivalents, which consisted of money market funds, amounted to \$6.1 million.

Marketable securities

Marketable securities consist primarily of certificates of deposit and corporate, U.S. agency, and U.S. treasury bonds with maturities greater than three months and up to two years at the time of purchase. These securities, which are classified as available for sale, are carried at fair value, with unrealized gains and losses, net of any tax effect, reported in stockholders' equity as accumulated other comprehensive (loss) income. As investments are available for current operations, they are classified as current irrespective of their maturities. Amortization of premiums is included in interest income. For the three and nine months ended September 30, 2016, the amortization of bond premiums totaled \$16,000 and \$62,000, respectively. For each of the three and nine months ended September 30, 2015, the amortization of bond premiums totaled \$20,000. As of September 30, 2016, amortized cost basis of the securities approximated their fair value. The values of these securities may fluctuate as a result of changes in market interest rates and credit risk. Marketable securities with a principal balance aggregating \$12.7 million matured during the nine months ended September 30, 2016. Marketable securities owned at September 30, 2016, all of which have maturities of 1 year or less as of such date, were as follows (in thousands):

	1 Year or Less
U.S. treasury bonds	\$ 2,755
U.S. agency bonds	2,514
Certificates of deposit	5,825
Total	\$ 11,094

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 three years for computer assets, five years for furniture and all other equipment and term of lease for leasehold improvements. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization expense for the three and nine months ended September 30, 2016 was \$33,000 and \$100,000, respectively, and \$24,000 and \$69,000, respectively, for the three and nine months ended September 30, 2015. All property and equipment is located in the United States.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2016 AND 2015 (UNAUDITED)

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 reviewed for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable, or at least annually. As of September 30, 2016, the Company believed that the carrying value is fully recoverable.

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 nonemployee directors for their services as directors, including grants of restricted stock units ("RSUs"), and stock options, are measured at fair value on the grant date and recognized in the condensed consolidated statements of operations as compensation or other expense over the relevant service period. Stock-based payments to nonemployees are recognized as an expense over the period of performance. Such payments are measured at fair value at the earlier of the date a performance commitment is reached or the date performance is completed. In addition, for awards that vest immediately and are non-forfeitable, the measurement date is the date the award is issued.

Foreign currency translation

Operations of the Canadian subsidiary 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 income (loss) on the consolidated balance sheet.

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 and unrealized gains or losses from available for sale securities.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2016 AND 2015 (UNAUDITED)

Income taxes

Income tax provisions or benefits for interim periods are computed based on the Company's estimated annual effective tax rate. Based on the Company's historical losses and its expectation of continuation of losses for the foreseeable future, the Company has determined that it is more likely than not that deferred tax assets will not be realized and, accordingly, has provided a full valuation allowance. As the Company anticipates or anticipated that its net deferred tax assets at December 31, 2016 and 2015 would be fully offset by a valuation allowance, there is no federal or state income tax benefit for the periods ended September 30, 2016 and 2015 related to losses incurred during such periods.

Per share data

Basic and diluted net loss per common share is calculated by dividing net loss by the weighted average number of outstanding shares of common stock.

As of September 30, 2016 and 2015, there were outstanding warrants to purchase an aggregate of 1,729,217 shares of the Company's common stock. In addition, the Company has issued to employees, directors and consultants, options to acquire shares of the Company's common stock, of which 2,289,621 and 1,611,643 were outstanding at September 30, 2016 and 2015, respectively, and RSUs issued to non-employee directors to acquire shares of the Company's common stock, of which 112,500 and 42,000 were outstanding at September 30, 2016 and 2015, respectively (see Note 5). In computing diluted net loss per share for the three and nine months ended September 30, 2016 and 2015, no effect has been given to such options, warrants and unvested RSUs as their effect would be anti-dilutive.

NOTE 3 – 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 consists of U.S. government agency-backed debt securities.
- Level 3: Unobservable inputs in which there is little or no market data.

The following table summarizes the Company's financial assets measured at fair value on a recurring basis as of September 30, 2016 (in thousands):

Description	September 30, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents	\$ 6,070	\$ 6,070	\$ —
Marketable securities – available for sale	11,094	8,580	2,514
Total assets	\$ 17,164	\$ 14,650	\$ 2,514

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2016 AND 2015 (UNAUDITED)

NOTE 4 – SALE OF COMMON STOCK

June 2016 public offering

On June 15, 2016, the Company entered into an underwriting agreement with Roth Capital Partners, LLC and National Securities Corporation as underwriters (collectively, the “2016 Underwriters”), relating to the issuance and sale of 5,000,000 shares of the Company’s common stock, in an underwritten public offering (the “June 2016 Financing”). The public offering price for each share of common stock was \$2.00. The Company granted the 2016 Underwriters a 45-day option to purchase up to an additional 750,000 shares of common stock to cover over-allotments, if any.

The June 2016 Financing closed on June 21, 2016. The 2016 Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of \$0.7 million (or \$0.14 per share). The Company also paid offering expenses of approximately \$0.2 million. The Company received net proceeds of approximately \$9.1 million. On July 12, 2016, the 2016 Underwriters fully exercised the over-allotment option and purchased 750,000 shares of common stock for net proceeds of approximately \$1.4 million, net of an aggregate discount of \$0.1 million (or \$0.14 per share).

At-the-market offering

On April 28, 2016, the Company entered into a sales agreement (“Sales Agreement”) with Cowen and Company, LLC (“Cowen”), as sales agent, pursuant to which the Company may, from time to time, issue and sell common stock with an aggregate value of up to \$15.0 million in ATM sales. On the same day, the Company filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The Company’s common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. The first common stock sold pursuant to the Sales Agreement was on May 24, 2016. During the nine months ended September 30, 2016, the Company sold an aggregate of 4,680,498 shares of common stock using the ATM, resulting in net proceeds of \$5.2 million, net of expenses, which included Cowen’s commission of \$0.2 million.

July 2015 public offering

On July 14, 2015, the Company entered into an underwriting agreement with Roth Capital Partners, LLC and Oppenheimer & Co Inc. as representatives of several underwriters (collectively, the “2015 Underwriters”) relating to the issuance and sale of 2,325,000 shares of the Company’s common stock, in an underwritten public offering (the “July 2015 Financing”). The public offering price for each share of common stock was \$7.50. The Company granted the 2015 Underwriters a 45-day option to purchase up to an additional 348,750 shares of common stock to cover over-allotments, if any.

The July 2015 Financing closed on July 17, 2015. The 2015 Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of \$1.0 million (or \$0.45 per share). The Company also paid offering expenses of approximately \$0.2 million. The Company received net proceeds of approximately \$16.2 million. On July 17, 2015, the 2015 Underwriters fully exercised the over-allotment option and purchased 348,750 shares of common stock for net proceeds of approximately \$2.5 million, net of an aggregate discount of \$0.2 million (or \$0.45 per share).

February 2015 public offering

On February 4, 2015, the Company entered into an underwriting agreement with the 2015 Underwriters relating to the issuance and sale of 4,900,000 shares of the Company’s common stock, in an underwritten public offering (the “February 2015 Financing”). The public offering price for each share of common stock was \$5.85. The Company granted the 2015 Underwriters a 45-day option to purchase up to an additional 735,000 shares of common stock to cover over-allotments, if any.

The February 2015 Financing closed on February 9, 2015. The 2015 Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of \$1.7 million (or \$0.35 per share). The Company also paid offering expenses of approximately \$0.3 million. The Company received net proceeds of approximately \$26.7 million. On February 24, 2015, the 2015 Underwriters partially exercised the over-allotment option and purchased 418,700 shares of common stock for net proceeds of approximately \$2.3 million, net of an aggregate discount of \$0.1 million (or \$0.35 per share).

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2016 AND 2015 (UNAUDITED)

NOTE 5 – STOCK-BASED COMPENSATION

2012 incentive stock option plan

In April 2012, the Company's stockholders approved the 2012 Incentive Stock Option Plan (the "2012 Plan"). The 2012 Plan provides for the issuance of options to purchase up to 200,000 shares of the Company's common stock to officers, directors, employees and consultants of the Company. Under the terms of the 2012 Plan, the Company may issue incentive stock options as defined by the Internal Revenue Code of 1986, as amended (the "Code") to employees of the Company and may also issue nonstatutory options to employees and others. The Company's board of directors ("Board of Directors") determines the exercise price, vesting and expiration period of the grants under the 2012 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 vesting period of the grants under the 2012 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 200,000 shares of its common stock for future issuance under the terms of the 2012 Plan. On February 12, 2013, the 2012 Plan was amended and restated to increase the number of shares reserved under the plan to 550,000. At September 30, 2016, all reserved shares under the 2012 Plan were subject to granted awards outstanding. With the adoption of the 2016 Plan (as defined below), no further grants may be made under the 2012 Plan, and the only current activity relates to the administration of existing options under the 2012 Plan.

2014 incentive stock plan

On June 9, 2014, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan (the "2014 Plan" and together with the 2012 Plan, the "Prior Plans").

Under the terms of the 2014 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 2014 Plan provides for the issuance of up to 1,800,000 shares of common stock, provided, however, that, of the aggregate number of 2014 Plan shares authorized, no more than 200,000 of such shares may be issued pursuant to stock-settled awards other than options (that is, restricted stock, RSUs, SARs, performance awards, other stock-based awards and dividend equivalent awards, in each case to the extent settled in shares of common stock). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2014 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 vesting period of the grants under the 2014 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 1,800,000 shares of its common stock for future issuance under the terms of the 2014 Plan. With the adoption of the 2016 Plan, no further grants may be made under the 2014 Plan, and the only current activity relates to the administration of existing options under the 2014 Plan.

2016 incentive stock plan

On May 11, 2016, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2016 Stock Incentive Plan (the "2016 Plan" and together with the Prior Plans, the "Plans"). As a result of adoption of the 2016 Plan by the stockholders, no further grants may be made under the Prior Plans.

Under the terms of the 2016 Plan, the Company 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 2016 Plan provides for the issuance of up to 2,785,000 shares of common stock, which amount will be (a) reduced by awards granted under the 2014 Plan after December 31, 2015, and (b) increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2016 Plan). In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after December 31, 2015, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.25 shares for every one share that was subject to an award other than an option or SAR. Of the aggregate number of 2016 Plan shares authorized, no more than 750,000 of such shares may be issued pursuant to stock-settled awards other than options (that is, restricted stock, RSUs, SARs, performance awards, other stock-based awards and dividend equivalent awards, in each case to the extent settled in shares of common stock). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2016 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 vesting period of the grants under the 2016 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 2,785,000 shares of its common stock for future issuance under the terms of the 2016 Plan. As of September 30, 2016, 1,968,096 shares were available for future grants under the 2016 Plan.

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Restricted stock units

On February 9, 2016, the Company granted an aggregate of 56,250 RSU's to its non-employee directors for board services in 2016, in lieu of cash, which vest one year from the grant date with a fair value of \$3.81.

On May 27, 2016, the Company granted an aggregate of 56,250 RSU's to its non-employee directors for board services through the first half of 2017, in lieu of cash, which vest one year from the grant date with a fair value of \$2.29.

In February 2016, 42,000 RSUs that were granted to our non-employee directors for board services in 2015, in lieu of cash, with a one year vesting from the grant date and a fair value of \$6.24 at the date of grant, vested and 42,000 shares of the Company's common stock were issued in settlement of those RSUs during the first quarter of 2016.

The following table summarizes the RSU activity for the nine months ended September 30, 2016:

Unvested restricted stock units as of January 1, 2016	42,000
Granted	112,500
Forfeited	-
Vested	(42,000)
Unvested restricted stock units as of September 30, 2016	<u>112,500</u>

Stock-based compensation expense related to RSU grants was \$86,000 and \$66,000 for the three months ended September 30, 2016 and 2015, respectively, and \$230,000 and \$153,000 for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, the stock-based compensation relating to RSU's of \$0.2 million remains unamortized and is expected to be amortized over a weighted average period of seven months.

General

A summary of the stock option activity and related information for the Plans for the nine months ended September 30, 2016 is as follows:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2016	1,656,643	\$ 10.64		\$ 1,125,299
Grants	698,000	\$ 4.67		\$ -
Exercised	-	\$ -		\$ -
Forfeitures or expirations	(65,022)	\$ 5.52		\$ -
Outstanding at September 30, 2016	2,289,621	\$ 8.97	8.11	\$ -
Vested and expected to vest at September 30, 2016	2,289,621	\$ 8.97	8.11	\$ -
Exercisable at September 30, 2016	1,185,602	\$ 11.95	7.34	\$ -

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

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The Company measures the fair value of stock options on the date of grant, based on a Binomial option pricing model using certain assumptions discussed in the following paragraph, and the closing market price of the Company's common stock on the date of the grant. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. Stock options granted pursuant to the Plans generally 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. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

On May 27, 2016, 35,000 options were granted to employees with an exercise price of \$2.42, a 10 year life and fair value of \$1.47 per share. Additionally, the Company granted options to purchase 60,000 shares of the Company's common stock to an employee with an exercise price of \$2.42, exercisable for a period of ten years, at an average fair value of \$0.08 per share and vesting 1/3 each upon the Company's common stock having an average closing sale price equal to or exceeding each of \$6.00, \$7.00 and \$8.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

On February 9, 2016, 403,000 options were granted to employees with an exercise price of \$5.03, a 10 year life and fair value of \$2.49 per share. Additionally, the Company granted options to purchase 200,000 shares of the Company's common stock to employees with an exercise price of \$5.03, exercisable for a period of ten years, at an average fair value of \$0.17 per share and vesting 1/3 each upon the Company's common stock having an average closing sale price equal to or exceeding each of \$6.00, \$7.00 and \$8.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

During the nine months ended September 30, 2016, 1,600, 6,613, 14,309 and 42,500 unvested options with exercise prices of \$9.87, \$6.68, \$5.95 and \$5.03, respectively, were forfeited.

On February 25, 2015, 419,500 and 30,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan (of which 408,533 employee/director options and 30,000 consultant options were outstanding at September 30, 2016) with an exercise price of \$5.95, a 10 year life and fair value of \$4.69. Additionally, the Company granted options to purchase 7,143 shares of the Company's common stock to Seth Lederman, the Company's Chief Executive Officer, as a non-cash bonus, with an exercise price of \$5.95, a 10 year life and fair value of \$4.43. As of September 30, 2016, the fair value related to consultant grants was \$0.29.

During the nine months ended September 30, 2015, 3,800, 39,800 and 39,800 unvested options with exercise prices of \$5.95, \$9.87 and \$6.68, respectively, were forfeited.

The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2016 and 2015 were as follows:

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Risk-free interest rate	0.85% to 1.86%	1.47% to 2.35%
Expected term of option	6.0 to 9.06 years	6.0 to 9.91 years
Expected stock price volatility	73.46% to 81.59%	80.91% to 92.13%
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 comparable companies' historical stock price volatility since the Company does not have sufficient historical exercise or volatility data because its equity shares have been publicly traded for only a limited period of time.

Stock-based compensation expense relating to options granted of \$0.7 million and \$2.1 million was recognized for the three and nine month periods ended September 30, 2016, respectively, and \$0.8 million and \$3.1 million was recognized for the three and nine month periods ended September 30, 2015, respectively.

As of September 30, 2016, the Company had approximately \$2.9 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.46 years.

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2014 employee stock purchase plan

On June 9, 2014, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2014 Employee Stock Purchase Plan (the "2014 ESPP"). The 2014 ESPP allows eligible employees to purchase up to an aggregate of 300,000 shares of the Company's common stock. Under the 2014 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 2014 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 2014 ESPP, subject to the statutory limit under the Code. As of September 30, 2016, there were 219,450 shares available for future issuance under the 2014 ESPP.

The compensation expense related to the 2014 ESPP for the nine months ended September 30, 2016 and 2015, was \$69,000 and \$98,000, respectively. As of September 30, 2016, approximately \$11,000 of employee payroll deductions, which had been withheld since July 1, 2016, the commencement of the offering period ending December 31, 2016, are included in accrued expenses in the accompanying balance sheet. In July 2016, 30,956 shares that were purchased as of June 30, 2016 were issued under the 2014 ESPP, and the employee payroll deductions accumulated at June 30, 2016, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital. In January 2016, 17,595 shares that were purchased as of December 31, 2015, were issued under the 2014 ESPP, and the employee payroll deductions accumulated at December 31, 2015, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital.

NOTE 6 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at September 30, 2016:

Exercise Price	Number Outstanding	Expiration Date
\$ 4.25	918,979	August 2018
12.00	456,009	December 2017 to February 2018
25.00	354,229	January 2017 to February 2019
	1,729,217	

NOTE 7 – COMMITMENTS

Research and development contracts

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$14.6 million at September 30, 2016 for future work to be performed.

Operating leases

As of September 30, 2016, future minimum lease payments are as follows (in thousands):

Year Ending December 31,	
2016	\$ 168
2017	683
2018	607
2019	181
	<u>\$ 1,639</u>

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Defined contribution plan

Approved by the Company's Board of Directors on March 3, 2014, effective April 1, 2014, the Company established a qualified defined contribution plan (the "401(k) Plan") pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) Plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 100 percent of each participant's pretax contributions of up to 19 percent of his or her eligible compensation, and the Company is also required to make a contribution equal to six percent of each participant's salary, on an annual basis, subject to limitations under the Code. The Company charged operations \$52,000 and \$253,000 for the three and nine months ended September 30, 2016, respectively, and \$57,000 and \$161,000 for the three and nine months ended September 30, 2015, respectively, for contributions under the 401(k) Plan.

NOTE 8 – SUBSEQUENT EVENT

On October 26, 2016, the Company entered into an underwriting agreement with Dawson James Securities, Inc. ("Dawson") relating to the issuance and sale of an aggregate of 9,500,000 units ("Unit", and collectively, the "Units") at a public offering price of \$0.55 per Unit in an underwritten public offering (the "October 2016 Financing"). Each Unit consisted of one share of the Company's common stock, par value \$0.001 per share, and a warrant to purchase one-half share of common stock. Because the Company is prohibited from issuing fractional shares, the warrants can only be exercised in lots of two, which means that each holder must exercise two warrants to receive one share of common stock, or an aggregate of 4,750,000 shares of common stock. The warrants have an initial exercise price of \$0.63 per share and have a term of five years. The exercise price and number of shares of common stock issuable upon exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, as described in the warrants.

The Company also granted Dawson a 45-day option to purchase up to 1,425,000 additional shares of common stock and/or warrants to purchase up to 712,500 shares of common stock, to cover over-allotments, if any.

The October 2016 Financing closed on October 31, 2016. Dawson purchased the Units at an eight-percent discount to the public offering price, for an aggregate discount of approximately \$0.4 million (or \$0.04 per unit). Dawson also received warrants to purchase up to an aggregate of 473,605 shares of common stock, or approximately five percent of the total number of shares included in the Units. The Company will receive estimated net proceeds from the October 2016 Financing of approximately \$4.6 million, after deducting the underwriting discount and other offering expenses of approximately \$0.3 million. Additionally, Dawson fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 712,500 shares of common stock for net proceeds of approximately \$700.

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 our 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 currently known to Management 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 our 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 our assumptions. Factors that could cause differences include, but are not limited to, expected market demand for our products, fluctuations in pricing for materials, and competition.

TNX-102 SL for posttraumatic stress disorder (PTSD) is an investigational new drug (IND) and has not been approved for any indication.

Business Overview

We are a clinical-stage pharmaceutical company dedicated to the invention and development of next-generation medicines for common disorders of the central nervous system, or CNS, with our lead program focusing on posttraumatic stress disorder, or PTSD. PTSD is characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in the fields of PTSD and other central nervous system disorders.

Our lead product candidate, TNX-102 SL, is ready to commence Phase 3 clinical development as a potential treatment for PTSD. Our preclinical pipeline includes a pre-IND-stage development candidate for the treatment of alcohol use disorders, or AUD, a separate development candidate for the treatment of PTSD and cognitive dysfunction associated with steroid use, as well as two biodefense development programs for protection from smallpox virus and from radiation injury. We hold worldwide development and commercialization rights to all of our product candidates.

TNX-102 SL – Posttraumatic Stress Disorder Program

In the first quarter of 2015, we commenced the AtEase study, a randomized, double-blind, placebo-controlled, 12-week Phase 2 study of TNX-102 SL in patients with military-related PTSD. We reported topline results from the AtEase study in May 2016. In the AtEase study, patients were randomized in a 2:1:2 ratio to TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg, or placebo sublingual tablets at bedtime daily for 12 weeks. This study was conducted at 24 U.S. centers and enrolled 231 patients in the modified intent-to-treat population. The primary objective of the AtEase study was to evaluate the potential clinical benefit of using TNX-102 SL to treat military-related PTSD at a dose of 2.8 mg or 5.6 mg. The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual-5, or CAPS-5, between those treated with TNX-102 SL and those receiving placebo. The CAPS-5 scale is a standardized structured clinician interview and is considered the gold standard in clinical research and regulatory approval for measuring the symptom severity of PTSD.

AtEase was adequately designed to evaluate whether a 2.8 mg dose would be efficacious, which would have provided an opportunity for this study to be used as one of the two pivotal efficacy studies required to support approval of TNX-102 SL for the treatment of PTSD. Although the 2.8 mg dose trended in the direction of a therapeutic effect, it did not reach statistical significance on the primary endpoint. The 5.6 mg dose had a therapeutic effect as assessed by the CAPS-5 scale, which was statistically significant by Mixed-effect Model Repeated Measures, or MMRM, with Multiple Imputation, or MI, analysis (p-value = 0.031), even though this arm of the study, by design, included only approximately half the number of patients of the 2.8 mg and placebo arms. TNX-102 SL demonstrated a dose-effect on multiple efficacy and safety measurements in the AtEase study.

In the AtEase study, TNX-102 SL was well tolerated and the patient retention rate was 73% on placebo, 79% on TNX-102 SL 2.8 mg and 84% on TNX-102 SL 5.6 mg. Four distinct serious adverse events, or SAEs, were reported in the study; three were in the placebo group, and one (proctitis/peri-rectal abscess), in the TNX-102 SL arm that was determined to be unrelated to TNX-102 SL. The most common non-dose related adverse events were mild and transient local administration site conditions and of these oral hypoesthesia, or numbness, was the most frequent and occurred in 39% of patients treated with the 2.8 mg dose and 36% of the patients treated with the 5.6 mg dose, compared to 2% of the patients receiving placebo. Oral paresthesia, or tingling, occurred in 16% of patients treated with the 2.8 mg dose and 4% of patients treated with the 5.6 mg dose, compared to 3% of the patients receiving placebo. Glossodynia, or a burning or stinging sensation in the mouth, occurred in 3% of patients treated with the 2.8 mg dose and 6% of patients treated with the 5.6 mg dose, compared to 1% of patients receiving placebo. Systemic adverse events that were potentially dose-related and occurred in greater than or equal to 5% of patients treated with the 5.6 mg dose or placebo included: somnolence in 16% versus 6% of the patients receiving placebo; dry mouth in 16% versus 11% of the patients receiving placebo; headache in 12% versus 4% of the patients receiving placebo; insomnia in 6% versus 9% of the patients receiving placebo; sedation in 12% versus 1% of the patients receiving placebo; upper respiratory tract infection in 4% versus 5% of the patients receiving placebo; abnormal dreams in 2% versus 5% of the patients receiving placebo; and weight increase in 2% versus 5% of the patients receiving placebo. For the patients treated with the 2.8 mg dose, the incidence of the most common systemic adverse events reported above were less frequent than patients treated with the 5.6 mg dose with the exception of insomnia, which was 8%.

Patients who completed the AtEase study were eligible to enroll into a three-month open-label extension study with TNX-102 SL 2.8 mg. We conducted this open-label extension study to obtain additional safety information from patients in the AtEase Study. The clinical phase of this open-label extension study is complete. Preliminary result did not reveal any new safety signals.

Regulatory Update

We held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in early August 2016 to discuss the Phase 3 program required to support the registration of TNX-102 SL 5.6 mg for the treatment of PTSD and the remaining data package for the New Drug Application, or NDA, filing. Based on this meeting discussion and the official FDA meeting minutes, we expect that positive results from two adequate, well-controlled Phase 3 efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would provide sufficient evidence of efficacy and safety to support the clinical approval of TNX-102 SL 5.6 mg for the treatment of PTSD. In addition, we were advised by the FDA that a Breakthrough Therapy designation request can be submitted based on the preliminary clinical evidence of TNX 102-SL on patients with military-related PTSD in the AtEase study.

Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A Breakthrough Therapy designation conveys all of the fast track program features, more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review.

We held an End-of-Phase 2 Chemistry, Manufacturing and Controls, or CMC, meeting with the FDA in February 2016 to discuss the quality data requirement for a New Drug Application, or NDA, submission for TNX-102 SL. In general, our proposed NDA CMC plan for TNX-102 SL was acceptable to the FDA and can be applied to the PTSD NDA.

As described below, the first Phase 3 study will be in patients with military-related PTSD and the second Phase 3 study will study predominately civilian PTSD patients.

Clinical Development Plan

Once we receive FDA acceptance of the first Phase 3 study design and interim statistical analysis proposal, we plan to commence the HONOR study, a randomized, double-blind Phase 3 study of TNX-102 SL in approximately 550 patients with military-related PTSD in the first quarter of 2017. This phase 3 HONOR study is an adaptive design study based on the results of the Phase 2 AtEase study. The study design is very similar to the Phase 2 AtEase study, except there will be up to two planned interim analyses for the purposes of sample size reassessment and to assess stopping early for success. The first interim analysis will be conducted when approximately 30% (approximately 165-180 patients) of the total planned enrollment is evaluable for efficacy and the second analysis when approximately 50% (approximately 270 – 330 patients) of the initially planned patient enrollment is evaluable for efficacy.

A second, randomized, double-blind Phase 3 study of TNX-102 SL in approximately 550 predominantly civilian PTSD patients will follow. We expect each of the studies to be conducted at approximately 30 U.S. centers. As in the case of the AtEase study, the primary efficacy endpoint of each of these Phase 3 studies will be the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale between those treated with TNX-102 SL 5.6 mg and those receiving placebo.

We plan to conduct the registration-required 12-month open-label extension study of TNX-102 SL 5.6 mg in patients who complete either the Phase 3 HONOR study or the predominantly civilian PTSD Phase 3 study. The goal of the open-label extension study is to obtain long-term safety exposure data from the maximum therapeutic dose to support an NDA filing for TNX-102 SL for the treatment of PTSD, a chronic psychiatric condition. Based on the estimated sample size of the Phase 3 PTSD studies, we believe that we will have sufficient long-term exposure data on TNX-102 SL 5.6 mg from the open-label extension study to support an NDA filing for TNX-102 SL 5.6 mg.

Additional Product Candidates

We also have a pipeline of other drug product candidates, including a pre-IND program, TNX-301 and a preclinical candidate TNX-601.

TNX-301 is a fixed-dose combination drug product, or CDP, containing two FDA-approved drugs, disulfiram and selegiline. We intend to develop TNX-301 CDP under Section 505(b)(2) of the FDCA as a potential treatment for AUD, and we have commenced development work on TNX-301 formulations. A pre-IND meeting was held in February 2016 to discuss the clinical development program of TNX-301 for AUD. At that meeting, the FDA advised us the nonclinical studies required for this CDP IND application to support the initiation of the first-in-man study with TNX-301. We are preparing plans to address these requirements.

TNX-601 is a new formulation of tianeptine, which will be developed as a potential clinical candidate for PTSD and cognitive impairment associated with corticosteroid use. Tianeptine has never been approved in the U.S., but a different formulation of tianeptine is approved in certain countries in Europe, Asia and South America for treating major depressive disorder. On April 19, 2016, Tonix was issued US patent 9,314,469 B2 “Method for treating neurocognitive dysfunction” which includes using tianeptine for cognitive dysfunction associated with corticosteroid use. We intend to develop TNX-601 under Section 505(b)(1) of the FDCA as a potential treatment for PTSD and cognitive dysfunction associated with corticosteroid use. Pharmaceutical development work on TNX-601 has been initiated.

In addition, we own rights to intellectual property on two biodefense technologies: one relating to the development of novel smallpox vaccines; and the other to the development of protective agents against radiation exposure. We have begun non-clinical research and development on these programs. The FDA Animal Efficacy Rule provides a mechanism for product licensure when human efficacy studies are not feasible or ethical. As a result, the licensure of these biodefense products in the U.S. may not require human efficacy studies, which we believe will reduce our development costs and risks compared to the development of a new pharmaceutical or biological product.

Current Operating Trends

We expect that all of our research and development expenses in the near-term future will be incurred in support of our current and future nonclinical and clinical development programs rather than technology development. These expenditures are subject to numerous uncertainties relating to timing and cost to completion. We test compounds in numerous animal studies for safety, toxicology and efficacy. At the appropriate time, subject to the approval of regulatory authorities, we expect to conduct early-stage clinical trials for each drug candidate. We anticipate funding these trials ourselves, and possibly with the assistance of federal grants. As we obtain results from these early-stage trials, we may elect to discontinue or delay clinical advancement for certain products in order to focus our resources on more promising product candidates. Completion of clinical trials may take several years, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate.

The commencement and completion of clinical trials for our products may be delayed by many factors, including lack of efficacy during clinical trials, unforeseen safety issues, lack of necessary funding, slower than expected patient recruitment, or government delays. In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support the intended safety or efficacy of our product candidates, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. As a result of these risks and uncertainties, we are unable to accurately estimate the specific timing and costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates. Our business, financial condition and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval, insofar as cash in-flows from the relevant drug or program would be delayed or would not occur.

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, 2016 Compared to Three Months Ended September 30, 2015

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the three months ended September 30, 2016 and 2015.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2016 were \$5.5 million, a decrease of \$4.8 million, or 47%, from \$10.3 million for the three months ended September 30, 2015. This decrease was primarily due to the winding down of the development work related to TNX-102 SL, including formulation development, manufacturing, human safety and efficacy studies. During the three months ended September 30, 2016, we incurred \$3.2 million, \$41,000 and \$0.5 million in clinical, non-clinical and manufacturing expenses, respectively, as compared to \$6.3 million, \$1.1 million, and \$1.2 million for the same period last year, respectively.

Compensation-related expenses were \$1.0 million for the three months ended September 30, 2016, compared to \$0.7 million for the three months ended September 30, 2015, an increase of \$0.3 million, or 43%. We incurred \$0.2 million in stock-based compensation for both reporting periods in connection with the vesting of stock options, which were previously issued to officers and consultants. Cash compensation-related expenses were \$0.8 million for the three months ended September 30, 2016, an increase of \$0.3 million, or 60%, from \$0.5 million for the three months ended September 30, 2015. The increase was primarily a result of annual salary increases and added personnel. Regulatory and legal costs were \$0.3 million for the three months ended September 30, 2016, a decrease of \$0.1 million, or 25%, from \$0.4 million for the three months ended September 30, 2015. The decrease in regulatory and legal costs was primarily due to the decrease in active trials.

Travel, meals and entertainment costs for the three months ended September 30, 2016 were \$0.1 million for both reporting periods. Other research and development costs totaled \$0.3 million for the three months ended September 30, 2016, a decrease of \$0.2 million, or 40%, from \$0.5 million for the three months ended September 30, 2015. Other research and development costs include rent, insurance and other office-related expenses.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2016 were \$2.1 million, a decrease of \$0.9 million, or 30%, from \$3.0 million incurred in the three months ended September 30, 2015. This decrease was primarily due to reduced professional services and office and other administrative expenses.

Compensation-related expenses decreased to \$1.0 million for the three months ended September 30, 2016, from \$1.1 million for the three months ended September 30, 2015, a decrease of \$0.1 million, or 9%. We incurred \$0.5 million in stock-based compensation in connection with the 2014 employee stock purchase plan and the vesting of restricted stock units and stock options in the three months ended September 30, 2016, which were previously issued to board members, officers and consultants, as compared to \$0.7 million in stock-based compensation for the same period last year. Cash compensation-related expenses were \$0.5 million for the three months ended September 30, 2016, an increase of \$0.1 million, or 25%, from \$0.4 million for the three months ended September 30, 2015. The increase was primarily a result of added personnel in late 2015.

Professional services for the three months ended September 30, 2016 totaled \$0.7 million, a decrease of \$0.4 million or 36%, from the \$1.1 million incurred for the three months ended September 30, 2015. Of professional services, legal fees totaled \$0.2 million for the three months ended September 30, 2016, a decrease of \$0.3 million, or 60%, from \$0.5 million incurred for the three months ended September 30, 2015. The decrease was mainly due to the reduction in international legal work and legal fees related to patent activity. Other consulting fees and other professional fees totaled \$0.5 million for the three months ended September 30, 2016, a decrease of \$0.1 million, or 17%, from \$0.6 million incurred for the three months ended September 30, 2015. Other professional fees include audit and accounting fees, investor and public relation fees, human resources and corporate consultants.

Travel, meals and entertainment costs for the three months ended September 30, 2016 were approximately \$50,000, a decrease of \$150,000, or 75%, from \$0.2 million incurred in the three months ended September 30, 2015, due to a reduction in travel-related activities from 2015. Office and other administrative expenses were \$0.3 million, a decrease of \$0.3 million, or 50%, from \$0.6 million incurred for the three months ended September 30, 2015. Office and other administrative expenses include rent, insurance and other office-related expenses.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2016 was \$7.6 million, compared to a net loss of \$13.3 million for the three months ended September 30, 2015.

Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the nine months ended September 30, 2016 and 2015.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2016 were \$23.7 million, a decrease of \$2.3 million, or 9%, from \$26.0 million for the nine months ended September 30, 2015. This decrease was primarily due to decreased development work related to TNX-102 SL and TNX-201, including formulation development, manufacturing, human safety and efficacy as well as pharmacokinetic studies. During the nine months ended September 30, 2016, we incurred \$14.2 million, \$1.2 million and \$2.8 million in clinical, non-clinical and manufacturing expenses, respectively, as compared to \$13.4 million, \$3.7 million and \$2.8 million for the same period last year, respectively.

Compensation-related expenses were \$3.0 million, an increase of \$0.3 million, or 11%, from \$2.7 million for the nine months ended September 30, 2015. We incurred \$0.6 million in stock-based compensation in connection with the vesting of stock options in the nine months ended September 30, 2016 that were previously issued to officers and consultants as compared to \$1.0 million in stock-based compensation for the same period last year. Cash compensation-related expenses were \$2.4 million for the nine months ended September 30, 2016, an increase of \$0.7 million, or 41%, from \$1.7 million for the nine months ended September 30, 2015. The increase was primarily a result of annual salary increases and added personnel. Regulatory and legal costs for the nine months ended September 30, 2016 were \$1.0 million, a decrease of \$0.2 million, or 17%, from \$1.2 million incurred in the nine months ended September 30, 2015. The decrease in regulatory and legal costs was primarily due to a shift in personnel related to then ongoing trials.

Travel, meals and entertainment costs for the nine months ended September 30, 2016 were \$0.5 million, a decrease of \$0.5 million, or 50%, from \$1.0 million incurred in the nine months ended September 30, 2015. Travel, meals and entertainment costs include travel related to clinical development and medical-related conferences, whereas such activities were reduced compared to 2015. Other research and development costs totaled \$1.0 million, a decrease of \$0.2 million, or 17% from \$1.2 million incurred in the nine months ended September 30, 2015. Other research and development costs include rent, insurance and other office-related expenses.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2016 were \$7.8 million, a decrease of \$0.9 million, or 10%, from \$8.7 million incurred in the nine months ended September 30, 2015. This decrease was primarily due to a reduction in professional services and travel, offset by an increase in compensation-related expenses.

Compensation-related expenses increased to \$4.0 million for the nine months ended September 30, 2016 from \$3.8 million for the nine months ended September 30, 2015, an increase of \$0.2 million, or 5%. We incurred \$1.8 million in stock-based compensation in connection with the employee stock purchase plan and the vesting of restricted stock units and stock options in the nine months ended September 30, 2016 that were previously issued to board members, officers and consultants as compared to \$2.4 million in stock-based compensation for the same period last year. Cash compensation-related expenses were \$2.2 million for the nine months ended September 30, 2016, an increase of \$0.8 million, or 57%, from \$1.4 million for the nine months ended September 30, 2015. The increase in cash compensation-related costs was primarily a result of annual salary increases and added personnel.

Professional services for the nine months ended September 30, 2016 totaled \$2.3 million, a decrease of \$0.6 million, or 21%, from the \$2.9 million incurred for the nine months ended September 30, 2015. Of professional services, legal fees totaled \$0.8 million for the nine months ended September 30, 2016, a decrease of \$0.5 million, or 38%, from \$1.3 million incurred for the nine months ended September 30, 2015. The decrease was mainly due to a reduction in international legal work and legal fees related to patent activity. Other consulting fees and other professional fees totaled \$1.5 million for the nine months ended September 30, 2016, a decrease of \$0.1 million, or 7%, from \$1.6 million incurred for the nine months ended September 30, 2015. Other professional fees include audit and accounting fees, investor and public relation fees, human resources and corporate consultants.

Travel, meals and entertainment costs for the nine months ended September 30, 2016 were \$0.2 million, a decrease of \$0.4 million, or 67%, from \$0.6 million incurred in the nine months ended September 30, 2015. Travel, meals and entertainment costs include travel related to business development and investor relations activities, which were significantly reduced from 2015. Office and other administrative expenses totaled \$1.3 million, a decrease of \$0.1 million, or 7%, from \$1.4 million incurred in the nine months ended September 30, 2015. Office and other administrative expenses include rent, insurance and other office-related expenses.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2016 was \$31.4 million, compared to a net loss of \$34.7 million for the nine months ended September 30, 2015.

Liquidity and Capital Resources

As of September 30, 2016, we had working capital of \$26.6 million, comprised primarily of cash, cash equivalents and marketable securities of \$26.7 million and prepaid expenses and other of \$2.5 million, which was offset by \$0.9 million of accounts payable and \$1.7 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to the winding down of clinical trials of TNX-102 SL in PTSD and fibromyalgia. For the nine months ended September 30, 2016 and 2015, we used approximately \$31.9 million and \$30.6 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. Increases in cash outlays principally resulted from manufacturing, non-clinical and clinical cost and activities, regulatory cost, and payroll. For the nine months ended September 30, 2016, net proceeds from financing activities were approximately \$15.6 million from the sale of our common stock. In the comparable 2015 period, approximately \$47.7 million was raised through the sale of shares of common stock.

Cash provided by investing activities for the nine months ended September 30, 2016 was approximately \$12.7 million, related to the maturity of marketable securities. During the nine months ended September 30, 2015, we used approximately \$22.2 million from investing activities, of which \$22.1 million related to the purchase of marketable securities.

October 2016 Financing

On October 26, 2016, we entered into an underwriting agreement with Dawson James Securities, Inc. (“Dawson”) relating to the issuance and sale of an aggregate of 9,500,000 units (“Unit”, and collectively, the “Units”) at a public offering price of \$0.55 per Unit in an underwritten public offering (the “October 2016 Financing”). Each Unit consisted of one share of our common stock, par value \$0.001 per share, and a warrant to purchase one-half share of common stock. Because we are prohibited from issuing fractional shares, the warrants can only be exercised in lots of two, which means that each holder must exercise two warrants to receive one share of common stock, or an aggregate of 4,750,000 shares of common stock. The warrants have an initial exercise price of \$0.63 per share and have a term of five years. The exercise price and number of shares of common stock issuable upon exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, as described in the warrants.

We also granted Dawson a 45-day option to purchase up to 1,425,000 additional shares of common stock and/or warrants to purchase up to 712,500 shares of common stock, to cover over-allotments, if any.

The October 2016 Financing closed on October 31, 2016. Dawson purchased the Units at an eight-percent discount to the public offering price, for an aggregate discount of approximately \$0.4 million (or \$0.04 per unit). Dawson also received warrants to purchase up to an aggregate of 473,605 shares of common stock, or approximately five percent of the total number of shares included in the Units. We will receive estimated net proceeds from the October 2016 Financing of approximately \$4.6 million, after deducting the underwriting discount and other offering expenses of approximately \$0.3 million. Additionally, Dawson fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 712,500 shares of common stock for net proceeds of approximately \$700.

June 2016 Financing

On June 15, 2016, we entered into an underwriting agreement with Roth Capital Partners, LLC and National Securities Corporation (collectively, the “Underwriters”), relating to the issuance and sale of 5,000,000 shares of our common stock, in an underwritten public offering (the “June 2016 Financing”). The public offering price for each share of common stock was \$2.00. We granted the Underwriters a 45-day option to purchase up to an additional 750,000 shares of common stock to cover over-allotments, if any.

The June 2016 Financing closed on June 21, 2016. The Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of \$0.7 million (or \$0.14 per share). We also paid offering expenses of approximately \$0.2 million. We received net proceeds of approximately \$9.1 million. On July 12, 2016, the Underwriters fully exercised the over-allotment option and purchased 750,000 shares of common stock for net proceeds of approximately \$1.4 million, net of an aggregate discount of \$0.1 million (or \$0.14 per share).

At-the-Market Offering

On April 28, 2016, we entered into a sales agreement (“Sales Agreement”) with Cowen and Company, LLC (“Cowen”), as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to \$15.0 million in an at-the-market (“ATM”) offering. On the same day, we filed a prospectus supplement under our existing shelf registration relating to the Sales Agreement. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. The first common stock issuance using the ATM was on May 24, 2016. During the nine months ended September 30, 2016, we sold an aggregate of 4,680,498 shares of common stock using the ATM, resulting in net proceeds of \$5.2 million, net of expenses, which included Cowen’s commission of \$0.2 million.

Future Liquidity Requirements

We expect to incur losses from operations for the near future. We expect to incur increasing research and development expenses, including expenses related to additional clinical trials. We expect that our general and administrative expenses will decrease in the near term, as we have taken certain measures to reduce costs in order to preserve cash to fund our upcoming Phase 3 HONOR study in military-related PTSD through the first interim analysis. We believe our existing cash is sufficient to fund our operating expenses and planned clinical trial for at least the next 12 months.

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

We will need to obtain additional capital in order to fund future research and development activities. 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.

Contractual Obligations

The following table sets forth our contractual obligations as of September 30, 2016 (in thousands):

	Payment Due By Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
Research and Development Obligations	\$ 14,597	\$ -	\$ -	\$ -	\$ 14,597
Operating Lease Obligations	679	960	-	-	1,639
Total	\$ 15,276	\$ 960	\$ -	\$ -	\$ 16,236

We are a party to research and development agreements in the normal course of business with contract research organizations (“CROs”) for clinical trials and clinical manufacturing, with vendors for preclinical research studies and for other services and products for operating purposes. We have included as purchase obligations our commitments under agreements to the extent they are quantifiable and are not cancelable.

Stock Compensation

In February 2012, we approved the 2012 Incentive Stock Options Plan, which was amended and restated in February 2013 (“2012 Plan”). The 2012 Plan provides for the issuance of options to purchase up to 550,000 shares of our common stock to officers, directors, employees and consultants. Under the terms of the 2012 Plan, we may issue Incentive Stock Options, as defined by the Internal Revenue Code, and nonstatutory options. The Board of Directors determines the exercise price, vesting and expiration period of the options granted under the 2012 Plan. However, the exercise price of an Incentive Stock Option must be at least 100% of fair value of the common stock at the date of the grant (or 110% for any shareholder that owns 10% or more of our common stock). The fair market value of the common stock determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in a good faith. Additionally, the vesting period of the grants under the 2012 Plan should not be more than five years and expiration period not more than ten years. We reserved 550,000 shares of our common stock for future issuance under the terms of the 2012 Plan. At September 30, 2016, all reserved shares under the 2012 Plan were subject to granted awards outstanding. With the adoption of the 2016 Plan (as defined below), no further grants may be made under the 2012 Plan, and the only current activity relates to the administration of existing options under the 2012 Plan.

We measure the fair value of stock options on the date of grant, based on a Binomial option pricing model using certain assumptions discussed in the following paragraph, 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 and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. 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. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

On June 9, 2014, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan (the “2014 Plan” and together with the 2012 Plan, the “Prior Plans”). Under the terms of the 2014 Plan, we may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights, or SARs, (4) restricted stock units, or RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2014 Plan provides for the issuance of up to 1,800,000 shares of common stock, provided, however, that, of the aggregate number of 2014 Plan shares authorized, no more than 200,000 of such shares may be issued pursuant to stock-settled awards other than options (that is, restricted stock, RSUs, SARs, performance awards, other stock-based awards and dividend equivalent awards, in each case to the extent settled in shares of common stock). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2014 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 vesting period of the grants under the 2014 Plan may not be more than five years and expiration period not more than ten years. We reserved 1,800,000 shares of our common stock for future issuance under the terms of the 2014 Plan. With the adoption of the 2016 Plan, no further grants may be made under the 2014 Plan, and the only current activity relates to the administration of existing options under the 2014 Plan.

On May 11, 2016, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2016 Stock Incentive Plan (the “2016 Plan” and together with the Prior Plans, the “Plans”). As a result of adoption of the 2016 Plan, no further grants may be made under the Prior Plans. Under the terms of the 2016 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 2016 Plan provides for the issuance of up to 2,785,000 shares of common stock, which amount will be (a) reduced by awards granted under the 2014 Plan after December 31, 2015, and (b) increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2016 Plan). In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after December 31, 2015, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.25 shares for every one share that was subject to an award other than an option or SAR. Of the aggregate number of 2016 Plan shares authorized, no more than 750,000 of such shares may be issued pursuant to stock-settled awards other than options (that is, restricted stock, RSUs, SARs, performance awards, other stock-based awards and dividend equivalent awards, in each case to the extent settled in shares of common stock). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2016 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 vesting period of the grants under the 2016 Plan may not be more than five years and expiration period not more than ten years. We reserved 2,785,000 shares of our common stock for future issuance under the terms of the 2016 Plan. As of September 30, 2016, 1,968,096 shares were available for future grants under the 2016 Plan.

On May 27, 2016, 35,000 options were granted to employees with an exercise price of \$2.42, a 10 year life and fair value of \$1.47 per share. Additionally, we granted options to purchase 60,000 shares of our common stock to an employee with an exercise price of \$2.42, exercisable for a period of ten years, at an average fair value of \$0.08 per share and vesting 1/3 each upon our common stock having an average closing sale price equal to or exceeding each of \$6.00, \$7.00 and \$8.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

On February 9, 2016, 403,000 options were granted to employees with an exercise price of \$5.03, a 10 year life and fair value of \$2.49. Additionally, we granted options to purchase 200,000 shares of our common stock to employees with an exercise price of \$5.03, exercisable for a period of ten years, at an average fair value of \$0.17 per share and vesting 1/3 each upon our common stock having an average closing sale price equal to or exceeding each of \$6.00, \$7.00 and \$8.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

During the nine months ended September 30, 2016, 1,600, 6,613, 14,309 and 42,500 unvested options with exercise prices of \$9.87, \$6.68, \$5.95 and \$5.03, respectively, were forfeited.

On February 25, 2015, 419,500 and 30,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan with an exercise price of \$5.95, a 10 year life and fair value of \$4.69. Additionally, we granted options to purchase 7,143 shares of our common stock to Seth Lederman as a non-cash bonus, with an exercise price of \$5.95, a 10 year life and fair value of \$4.43. As of June 30, 2016, the fair value related to consultant grants was \$1.12.

During the nine months ended September 30, 2015, 3,800, 39,800 and 39,800 unvested options with exercise prices of \$5.95, \$9.87 and \$6.68, respectively, were forfeited.

On June 9, 2014, we approved the Tonix Pharmaceuticals Holdings Corp. 2014 Employee Stock Purchase Plan (the “2014 ESPP”). The 2014 ESPP allows eligible employees to purchase up to an aggregate of 300,000 shares of our common stock. Under the 2014 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 2014 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 2014 ESPP, subject to the statutory limit under the Code. As of September 30, 2016, there were 219,450 shares available for future issuance under the 2014 ESPP.

The 2014 ESPP is considered a compensatory plan with the related compensation cost written off over the six month offering period. The compensation expense related to the 2014 ESPP for the nine months ended September 30, 2016 and 2015, was \$69,000 and \$98,000, respectively. As of September 30, 2016, approximately \$11,000 of employee payroll deductions, which had been withheld since July 1, 2016, the commencement of the offering period ending December 31, 2016, are included in accrued expenses in the accompanying balance sheet. In July 2016, 30,956 shares that were purchased as of June 30, 2016 were issued under the 2014 ESPP, and the employee payroll deductions accumulated at June 30, 2016, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital. In January 2016, 17,595 shares that were purchased as of December 31, 2015, were issued under the 2014 ESPP, and the employee payroll deductions accumulated at December 31, 2015, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital.

On February 9, 2016, we granted an aggregate of 56,250 RSU’s to its non-employee directors for board services in 2016, in lieu of cash, which vest one year from the grant date with a fair value of \$3.81.

On May 27, 2016, we granted an aggregate of 56,250 RSU’s to its non-employee directors for board services through the first half of 2017, in lieu of cash, which vest one year from the grant date with a fair value of \$2.29.

On February 25, 2015, we granted an aggregate of 42,000 RSUs to our non-employee directors for board services in 2015, in lieu of cash, which vest one year from the grant date with a fair value of \$6.24.

Stock-based compensation expense related to RSU grants was \$86,000 and \$66,000 for the three months ended September 30, 2016 and 2015, respectively, and \$230,000 and \$153,000 for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, the stock-based compensation relating to RSU’s of \$0.2 million remains unamortized and is expected to be amortized over a weighted average period of seven months.

Lease Commitments

Future minimum lease payments are as follows (in thousands):

Year Ending December 31,	
2016	\$ 168
2017	683
2018	607
2019	181
	\$ 1,639

Critical Accounting Policies and Estimates

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

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

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

We estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants and clinical research organizations and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We account for trial expenses according to the progress of the trial as measured by patient 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. Restricted stock payments to nonemployees are recognized as an expense over the period of performance. Such payments are measured at fair value at the earlier of the date a performance commitment is reached or the date performance is completed. In addition, for awards that vest immediately and are nonforfeitable, the measurement date is the date the award is issued.

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. We record an estimated 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. We recognized a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. Lessees (for capital and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. We are currently evaluating the impact of adopting this guidance.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718). The new guidance simplifies the accounting for stock-based compensation transactions, including tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This update is effective in fiscal years, including interim periods, beginning after December 15, 2016, and early adoption is permitted. We are currently evaluating the impact of this guidance.

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, 2016, 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, 2016 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

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

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
101 DEF	XBRL Taxonomy Extension Definition Linkbase Document

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 10, 2016

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

Date: November 10, 2016

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

CERTIFICATION

I, Seth Lederman, certify that:

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

Date: November 10, 2016

/s/ SETH LEDERMAN

Seth Lederman

Chief Executive Officer

CERTIFICATION

I, Bradley Saenger, certify that:

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

Date: November 10, 2016

/s/ BRADLEY SAENGER

Bradley Saenger
Chief Financial Officer

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended September 30, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: November 10, 2016

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, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: November 10, 2016

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