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 June 30, 2015

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 August 6, 2015, there were 18,829,669 shares of registrant's common stock outstanding.

TONIX PHARMACEUTICALS HOLDING CORP.

INDEX

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,737	$ 38,184
Prepaid expenses and other	1,577	852
Total current assets	50,314	39,036
Property and equipment, net	316	328
Restricted cash	133	133
Intangible asset	120	-
Deposits, long term	45	45
Total assets	$ 50,928	$ 39,542
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,770	$ 1,487
Accrued expenses	1,849	1,895
Total current liabilities	4,619	3,382
Deferred rent payable, long term	65	68
Total liabilities	4,684	3,450
Commitments (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; 16,137,898 and 10,805,220 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively, and 18,021 and 13,978 shares to be issued as of June 30, 2015 and December 31, 2014, respectively	16	11
Additional paid in capital	122,010	90,423
Accumulated deficit	(75,788)	(54,344)
Accumulated other comprehensive income	6	2
Total stockholders' equity	46,244	36,092
Total liabilities and stockholders' equity	$ 50,928	$ 39,542

See the accompanying notes to the condensed consolidated financial statements

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
COSTS AND EXPENSES:				
Research and development	$ 8,871	$ 4,075	$ 15,700	$ 7,625
General and administrative	2,913	1,974	5,780	3,593
	11,784	6,049	21,480	11,218
Operating Loss	(11,784)	(6,049)	(21,480)	(11,218)
Interest and other financing costs, net	21	5	36	10
NET LOSS	$ (11,763)	$ (6,044)	$ (21,444)	$ (11,208)
Net loss per common share, basic and diluted	$ (0.73)	$ (0.61)	$ (1.44)	$ (1.20)
Weighted average common shares outstanding, basic and diluted	16,137,898	9,923,184	14,923,934	9,324,020

See the accompanying notes to the condensed consolidated financial statements

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Net loss	$ (11,763)	$ (6,044)	$ (21,444)	$ (11,208)
Other comprehensive income:				
Foreign currency translation gain	1	3	4	5
Total other comprehensive income	1	3	4	5
Comprehensive loss	$ (11,762)	$ (6,041)	$ (21,440)	$ (11,203)

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
SIX MONTHS ENDED JUNE 30, 2015
(Dollars In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Preferred stock		Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
Balance, December 31, 2014	-	$ -	10,805,220	$ 11	$ 90,423	$ 2	$ (54,344)	$ 36,092
Issuance of common stock in February 2015 ($5.85 per share) net of transaction expenses of $2,115	-	-	5,318,700	5	28,995	-	-	29,000
Employee stock purchase plan	-	-	13,978	-	70	-	-	70
Stock based compensation	-	-	-		2,522	-	-	2,522
Foreign currency translation adjustment	-	-	-	-	-	4	-	4
Net loss	-	-	-	-	-	-	(21,444)	(21,444)
Balance, June 30, 2015	-	$ -	16,137,898	$ 16	$ 122,010	$ 6	$ (75,788)	$ 46,244

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars In Thousands)
(unaudited)

	Six months ended June 30, 2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (21,444)	$ (11,208)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	45	9
Stock based compensation	2,522	1,204
Common stock issued in exchange for intellectual property	-	608
Changes in operating assets and liabilities:		
Prepaid expenses	(725)	(507)
Accounts payable	1,285	754
Accrued expenses	29	(577)
Security deposit	-	(45)
Deferred rent payable	(3)	(1)
Net cash used in operating activities	(18,291)	(9,763)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(33)	(35)
Purchase of intangible asset	(120)	-
Increase in restricted cash balance	-	(72)
Net cash used in investing activities	(153)	(107)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	-	4,889
Proceeds, net of expenses of $2,115 and $2,824 from sale of common stock	29,000	40,654
Net cash provided by financing activities	29,000	45,543
Effect of currency rate change on cash	(3)	(5)
Net increase in cash and cash equivalents	10,553	35,668
Cash and cash equivalents, beginning of the period	38,184	8,202
Cash and cash equivalents, end of period	$ 48,737	$ 43,870
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
Issuance of common stock under employee benefit plan	$ 70	$ -

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2015 AND 2014 (UNAUDITED)

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc., or Tonix Sub, is a clinical-stage pharmaceutical company dedicated to the invention and development of novel pharmaceutical products for medical conditions that it believes have broad societal impact, that are not well served by currently available therapies and that represent large potential commercial opportunities.

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

On May 15, 2015, Tonix Sub formed Tonix Medicines for the purpose of manufacturing and distributing pharmaceutical products in the U.S.

Tonix Pharmaceuticals (Barbados) Ltd., or Tonix Barbados, a wholly owned subsidiary of Tonix Sub, was liquidated and dissolved during the quarter ended June 30, 2015. All assets and liabilities were assumed by Tonix Pharma Holdings Limited.

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 Rule 8-03 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, 2014 contained herein has been derived from audited financial statements.

Operating results for the three and six months ended June 30, 2015 are not necessarily indicative of results that may be expected for the year ending December 31, 2015. 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, 2014 included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on February 27, 2015.

Risks and uncertainties

The Company's primary efforts are devoted to conducting research and development for the treatment of disorders of the central nervous system. 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.

At June 30, 2015, the Company had working capital of approximately $45.7 million, after raising approximately $29.0 million, net of expenses through the sale of common stock in an underwritten public offering in February 2015. In addition, in July 2015, the Company raised approximately $18.7 million, net of expenses, through the sale of common stock 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. The Company expects that cash used in operations for research and development will increase significantly over the next several years. In the event the funding obtained is not sufficient to complete the development and commercialization of its current product candidates, the Company intends to raise additional funds through equity or debt financing. If the Company is unsuccessful in raising additional financing, it will need to 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.

Intangible assets with indefinite lives

During the six months ended June 30, 2015, the Company purchased certain internet domain rights, which were determined to have an indefinite life. Identifiable intangibles with indefinite lives are reviewed for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable, or at least annually.

Research and development costs

The Company outsources 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 (see Note 6).

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, 2015 and 2014 would be fully offset by a valuation allowance, there is no federal or state income tax benefit for the periods ended June 30, 2015 and 2014 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 June 30, 2015 and 2014, there were outstanding warrants to purchase an aggregate of 1,731,217 and 1,975,431 shares, respectively, 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 1,607,643 and 905,100 were outstanding at June 30, 2015 and 2014, respectively, and restricted stock units issued to non-employee directors to acquire shares of the Company’s common stock of which 42,000 and -0- were outstanding at June 30, 2015 and 2014, respectively (see Note 4). In computing diluted net loss per share for the three and six months ended June 30, 2015 and 2014, no effect has been given to such options, warrants and restricted stock units as their effect would be anti-dilutive.

NOTE 3 – FEBRUARY 2015 FINANCING

On February 4, 2015, the Company entered into an underwriting agreement with Roth Capital Partners, LLC and Oppenheimer & Co Inc., as representatives of several underwriters (collectively, the “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 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 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 $0.2 million. The Company received net proceeds of approximately $26.7 million. On February 24, 2015, the Underwriters partially exercised the over-allotment option and purchased 418,700 shares of common stock for net proceeds of approximately $2.3 million.

NOTE 4 – SHARE BASED COMPENSATION

Incentive stock option plans

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. On February 12, 2013, the 2012 Plan was amended and restated to increase the number of shares reserved under the plan to 550,000.

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 "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, 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 Company's board of directors ("Board of Directors") determines the exercise price, vesting and expiration period of the grants under the Plans. 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 Plans may not be more than five years and expiration period not more than ten years from the grant date. The Company reserved 1,800,000 shares of its common stock for future issuance under the terms of the 2014 Plan.

A summary of the stock option activity and related information for the Plans for the six months ended June 30, 2015 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2015	1,226,800	$ 12.40	9.00	
Grants	464,243	$ 5.96	9.66	$ -
Exercised	-			
Forfeitures or expirations	(83,400)	$ 8.17		
Outstanding at June 30, 2015	1,607,643	$ 10.76	8.80	$ 2,033,125
Vested and expected to vest at June 30, 2015	1,607,643	$ 10.76	8.80	$ 2,033,125
Exercisable at June 30, 2015	515,541	$ 16.68	7.85	$ 21,572

On February 25, 2015, 419,500 and 30,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan (of which 415,700 employee/director options and 30,000 consultant options were outstanding at June 30, 2015) 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 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, 2015, the fair value related to consultant grants was $7.79.

On April 14, 2015, 7,600 options were granted to employees under the 2014 Plan (all of which were outstanding at June 30, 2015) with an exercise price of $6.34, a 10 year life and fair value of $4.56.

During the six months ended June 30, 2015, 3,800, 39,800 and 39,800 unvested options with exercise prices of $5.95, $9.87 and $6.68, respectively, were cancelled.

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 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, with the exception of 7,143 stock options granted on February 25, 2015, which were fully vested at the date of grant. Share-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

The assumptions used in the valuation of stock options granted during the six months ended June 30, 2015 and 2014 were as follows:

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Risk-free interest rate	1.47% to 2.35%	2.19% to 2.27%
Expected term of option	6.0 to 9.91 years	6.0 years
Expected stock price volatility	85.05% to 92.13%	97.56% to 100.73%
Expected dividend yield	$ 0.0	$ 0.0

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

Share-based compensation expense relating to options granted of $1.1 million and $2.4 million was recognized for the three and six month periods ended June 30, 2015, respectively; and $0.7 million and $1.2 million was recognized for the three and six month periods ended June 30, 2014, respectively.

As of June 30, 2015, the Company had approximately $6.2 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 2.13 years.

Restricted stock units (RSUs)

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

The following table summarizes the restricted stock activity for the six months ended June 30, 2015:

Restricted stock units as of January 1, 2015	-
Granted	42,000
Forfeited	-
Total Restricted stock units at June 30, 2015	42,000
Vested at June 30, 2015	-
Unvested restricted stock units as of June 30, 2015	42,000

Stock based compensation expense related to RSUs of $65,520 and $87,360 was recognized for the three and six months ended June 30, 2015, respectively; and $-0- for the three and six months ended June 30, 2014. As of June 30, 2015, the stock-based compensation relating to RSUs of $0.2 million remains unamortized and is expected to be amortized over the remaining period of approximately eight months.

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 June 30, 2015, after giving effect to shares purchased as described below, there were 268,001 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. As of June 30, 2015, approximately $90,000 of employee payroll deductions which have been withheld since January 1, 2015, the commencement of the offering period ended June 30, 2015, are included in accrued expenses in the accompanying balance sheet. The compensation expense related to the 2014 ESPP for the three and six months ended June 30, 2015 was $21,171 and $43,234, respectively. In July 2015, 18,021 shares that were purchased as of June 30, 2015, were issued under the 2014 ESPP, and approximately $90,000 of employee payroll deductions accumulated at June 30, 2015, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital. In February 2015, 13,978 shares that were purchased as of December 31, 2014, were issued under the 2014 ESPP, and approximately $70,000 of employee payroll deductions accumulated at December 31, 2014, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital.

NOTE 5 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at June 30, 2015:

Exercise Price	Number Outstanding	Expiration Date
$ 4.25	920,979	August 2018
12.00	456,009	December 2017 to February 2018
25.00	354,229	January 2017 to February 2019
	1,731,217	

In January 2015, 14,538 warrants with an exercise price of $20.00 expired.

NOTE 6 – RELATED PARTY TRANSACTIONS

Consulting agreement

Tonix previously entered into a consulting agreement with Lederman & Co., LLC, a company controlled by Dr. Seth Lederman, the Company's Chief Executive Officer and Chairman of the Board. The agreement was terminated on February 11, 2014 and replaced with the employment agreement entered into on that date. Total expenses paid under this agreement were $-0- and $37,723 during the three and six months ended June 30, 2014, respectively.

Intellectual property acquired

On March 18, 2014, Tonix Barbados entered into an agreement with Leder Laboratories, Inc. ("Leder"), to acquire intellectual property related to novel smallpox vaccines. As consideration, $0.1 million was paid in cash and 25,000 shares of the Company's common stock valued at $0.3 million ($12.15 per share, which was the closing price of the common shares on the date of the transaction) were issued to Leder.

On March 18, 2014, Tonix Barbados entered into an agreement with Starling Pharmaceuticals, Inc. ("Starling"), to acquire intellectual property related to radio- and chemo-protective agents. As consideration, $0.1 million was paid in cash and 25,000 shares of the Company's common stock valued at $0.3 million ($12.15 per share, which was the closing price of the common shares on the date of the transaction) were issued to Starling.

Seth Lederman is the Chairman, CEO and majority owner (through majority-owned entities) of Starling and Leder.

NOTE 7 – COMMITMENTS

Research and development contracts

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $24.0 million at June 30, 2015 for future work to be performed.

Operating leases

On February 11, 2014, the Company entered into a lease amendment and expansion agreement, whereby the Company agreed to lease additional premises for office space, commencing May 1, 2014 and expiring on April 30, 2019. In connection therewith, the original letter of credit was increased by $72,354 to $132,417 and the Company deposited an additional $72,354 into the restricted cash account maintained at the bank that issued the letter of credit.

On April 28, 2014, the Company entered into a lease for approximately 3,578 square feet of office space in San Jose, California, whereby the Company agreed to lease premises, commencing August 1, 2014 and expiring on October 31, 2018 (51 months). In connection therewith, the Company paid a security deposit of $44,546.

On June 17, 2015, the Company entered into a lease for approximately 2,450 square feet of office space in Dublin, Ireland, whereby the Company agreed to lease premises, commencing June 1, 2015 and expiring on May 31, 2018.

Future minimum lease payments under these three agreements are as follows (in thousands):

Year Ending December 31,	
2015	$ 251
2016	556
2017	569
2018	488
2019	99
	$ 1,963

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 $56,283 and $104,390 for the three and six months ended June 30, 2015, respectively, and $30,664 for the three and six months ended June 30, 2014, respectively, for contributions under the 401(k) Plan.

NOTE 8 – SUBSEQUENT EVENT

July financing

On July 14, 2015, the Company entered into an underwriting agreement with the Representatives of the 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 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 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 Underwriters fully exercised the over-allotment option and purchased 348,750 shares of common stock for net proceeds of approximately $2.5 million.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a number of forward-looking statements that reflect Management's current views with respect to future events and financial performance. You can identify these statements by forward-looking words such as "may," "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. Those statements include statements regarding the intent, belief or current expectations of us and members of 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.

In addition to announcing material financial information through our investor relations website, press releases, SEC filings and public conference calls and webcasts, we also intend to use the following social media channels as a means of disclosing information about the company, its services and other matters and for complying with our disclosure obligations under Regulation FD:

Tonix's Twitter Account (https://twitter.com/tonixpharma)
Tonix's Facebook Page (https://www.facebook.com/TonixPharma)
Tonix's Company Blog (http://www.thechairmansblog.com/tonix-pharmaceuticals/)
Tonix's Google+ Page (https://plus.google.com/+Tonixpharma/posts)
Tonix's LinkedIn Company Page (https://www.linkedin.com/company/tonix-pharmaceuticals)

The information we post through these social media channels may be deemed material. Accordingly, investors should monitor these accounts and the blog, in addition to following our press releases, SEC filings and public conference calls and webcasts. This list may be updated from time to time. We have not incorporated by reference into this report the information in, or that can be accessed through, our website or social media channels, and you should not consider it to be a part of this report.

Business Overview

We are a clinical-stage pharmaceutical company dedicated to the invention and development of novel pharmaceutical products for medical conditions that we believe have broad societal impact, that are not well served by currently available therapies and that represent large potential commercial opportunities. Our most advanced drug development programs are directed toward disorders affecting the central nervous system, or CNS. Our lead product candidate, Tonmya™ (cyclobenzaprine HCl sublingual tablet, 2.8 mg) is in Phase 3 clinical development as a potential treatment for fibromyalgia, or FM. TNX-102 SL, the same proprietary product candidate as Tonmya, is in Phase 2 clinical development as a potential treatment for post-traumatic stress disorder, or PTSD. Our second product candidate, TNX-201 (dexisometheptene mucate), is in Phase 2 development as a potential treatment for episodic tension-type headache, or ETTH. Our pipeline includes a nonclinical development program for the treatment of alcohol use disorder as well as two nonclinical 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.

Our clinical-stage product candidates are as follows:

Tonmya / TNX-102 SL

TNX-102 SL is a small, rapidly disintegrating tablet containing low dose cyclobenzaprine for sublingual administration and transmucosal absorption. We are currently evaluating TNX-102 SL as a potential treatment for FM and PTSD, chronic disorders in which poor sleep quality is recognized to play a role. We designed TNX-102 SL to be administered once-daily at bedtime in a chronic dosing regimen. We believe the dose and pharmacokinetic properties of TNX-102 SL will enable it to achieve a desirable balance of efficacy, safety and tolerability in FM and PTSD. Tonix is developing TNX-102 SL to seek United States Food and Drug Administration, or FDA, approval in accordance with Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA. The trade name Tonmya has received conditional acceptance by the FDA for TNX-102 SL in the FM indication.

Fibromyalgia

FM is a chronic and debilitating syndrome that occurs in five to 15 million U.S. adults and is associated with a substantial negative impact on social and occupational function, including disrupted relationships with family and friends, social isolation, reduced activities of daily living and leisure activities, avoidance of physical activity, and loss of career or inability to advance in careers or education. Based on our market research, we believe that U.S. FM sales of FDA approved medications were approximately $1.2 billion in 2014, representing approximately 5.6 million prescriptions. However, the majority of patients fail to adequately respond to therapy or discontinue therapy due to poor tolerability. Prescription pain and sleep medications not approved for FM are frequently taken for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic effect, and many of these medications carry significant safety risks and risk of dependence. We believe that Tonmya has the potential to treat a broad spectrum of the core symptoms of FM with a tolerability profile that is suitable for first-line therapy and for chronic use.

Phase 2b "BESTFIT" Study

In September 2013, we commenced enrollment of the BESTFIT study, a randomized, double-blind, placebo-controlled Phase 2b clinical trial of Tonmya in FM. We reported preliminary top-line results from the BESTFIT study in September 2014. In the BESTFIT study, 205 patients with FM were randomized at 17 U.S. centers to treatment with either Tonmya or placebo sublingual tablets at bedtime daily for 12 weeks. The primary outcome measure of the BESTFIT study was the mean change in week 12 average daily pain intensity from baseline on the 11-point Numeric Rating Scale, using a daily telephonic diary. In the BESTFIT study, Tonmya did not achieve statistical significance in the primary outcome measure ($p=0.172$). However, the study demonstrated that Tonmya had a statistically significant effect on pain as measured by a 30% responder analysis of the primary pain data ($p=0.033$), in which a responder is defined as a subject for whom pain intensity was reduced by at least 30% at week 12 as compared to baseline. The 30% response rate in this analysis was 34.0% in the active treatment arm as compared to 20.6% in the control arm. The BESTFIT study also showed statistically significant improvements with Tonmya in the declared secondary analyses of the Patient Global Impression of Change ($p=0.025$) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R ($p=0.014$). The study showed statistically significant improvements with Tonmya on measures of sleep quality, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, Sleep Disturbance instrument ($p=0.005$). In addition, statistically significant improvements with TNX-102 SL were observed on several FIQ-R items (pain, sleep quality, anxiety, stiffness, and sensitivity) as well as on the overall symptom subdomain.

Tonmya was well tolerated in the BESTFIT study. The most common adverse events were local and related to sublingual administration. Mild and transient tongue or mouth numbness occurred in 42% of participants on Tonmya vs. 1% on placebo, and bitter taste in 8% on Tonmya compared to none on placebo. These local adverse events were not correlated with efficacy according to a variety of measures, including the rate of 30% pain response. Systemic adverse events were similar between Tonmya and placebo. No serious adverse events were reported. Among subjects randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period.

Phase 3 "AFFIRM" Study

Following our report of the results of the BESTFIT study, we requested guidance from the FDA on our proposed use of a 30% pain responder analysis as the primary efficacy endpoint in our prospective Phase 3 clinical program. In January 2015, we announced receipt of the written guidance, whereby the FDA accepted our proposal to use a 30% pain responder analysis as the primary efficacy endpoint in our Phase 3 program to support the approval of Tonmya for the management of FM.

In the second quarter of 2015, we commenced the AFFIRM study, a 500 patient, randomized, double-blind Phase 3 clinical trial comparing Tonmya to placebo as administered sublingually once daily at bedtime for 12 weeks. The AFFIRM study is being conducted at approximately 35 U.S. centers. The primary endpoint of the AFFIRM study is the 30% pain responder analysis accepted by the FDA. We expect to report top line results from the AFFIRM study in the second half of 2016.

We intend to commence a second randomized, double-blind, placebo-controlled Phase 3 clinical trial of Tonmya in the second quarter of 2016. We expect that the design of the second Phase 3 trial will be similar to that of the AFFIRM trial.

Post-Traumatic Stress Disorder

We are also developing TNX-102 SL for the management of PTSD, a chronic syndrome that may develop after a person is exposed to one or more traumatic events, such as warfare, sexual assault, serious injury, or threats of imminent death. PTSD is characterized by intrusive thoughts, emotional and behavioral avoidance, negative alterations in cognitions and mood, and alterations in arousal and reactivity. People with PTSD suffer significant impairment in their functioning, including occupational activities and social relations. In addition, PTSD patients are at elevated risk for impulsive, violent behaviors toward others and themselves, including suicide. Each year, an estimated 8.5 million U.S. adults meet the diagnostic criteria for PTSD. The prevalence of PTSD in the military population is higher than that among civilians. Among veterans seen in the United States Veterans Affairs, or VA, health system in 2012, there were approximately 638,000 with the diagnosis of PTSD. Based on March 2014 Veterans Administration data, approximately 20% of military personnel involved in more recent conflicts have been evaluated at VA facilities for potential or provisional PTSD.

Two drugs are currently approved by the FDA for the treatment of PTSD. Both are antidepressants and carry suicidality warnings. Evidence of their treatment effect in men is weak, and both lack evidence of efficacy in those for whom the traumatic event was combat-related. Sleep disturbances are central to PTSD and are predictive of disease severity, depression, substance abuse, and suicidal ideation, yet are resistant to the approved antidepressant medications and present a difficult therapeutic challenge. In the U.S., treatments for PTSD include off-label use of anxiolytics, sedative-hypnotics, opiate narcotics, and antipsychotics, many of which lack reliable evidence of efficacy, and have significant safety liabilities and dependence risk.

Phase 2 “AtEase” Study

In the first quarter of 2015, we initiated the AtEase study, a randomized, double-blind, placebo-controlled, 12-week Phase 2 clinical trial of TNX-102 SL in approximately 220 patients with military-related PTSD. Patients are randomized in a 2:1:2 ratio to TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg, or placebo, respectively, sublingually once daily at bedtime. The AtEase study is being conducted at approximately 25 U.S. centers. The primary objective of the AtEase study is to evaluate the efficacy of TNX-102 SL 2.8 mg as compared to placebo following eight weeks of treatment according to the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). If the AtEase study achieves success in its primary outcome measure, it could serve as one of the two pivotal studies required to establish substantial evidence of efficacy and safety to support the approval of TNX-102 SL for PTSD.

TNX-201

We are developing TNX-201 for the treatment of ETTH, the most common form of headache. ETTH is estimated to have an annual prevalence rate of 38%, meaning that about 75 million U.S. adults suffer ETTH each year. There are more than 10 million visits to emergency departments or physicians’ offices each year by individuals who suffer non-migraine headaches, of which ETTH is the major indication. Among those who suffer ETTH, 28%, or about 21 million U.S. adults, have frequent ETTH, as defined by the International Headache Society. Many patients with frequent ETTH are resistant to over-the-counter options and prescription non-steroidal anti-inflammatory drug products, leaving physicians with limited treatment options. The only prescription medications indicated by the FDA for the treatment of ETTH are combination products that contain butalbital, a barbiturate that is a Drug Enforcement Agency Schedule III substance. According to IMS Health, from August 2013 to July 2014, there were approximately 8.2 million prescriptions issued for these products. Approximately 44% of these, or an estimated 3.5 million prescriptions, were for non-migraine headaches. In addition, opioid narcotics are used off-label for ETTH, accounting for an estimated 5.3 million prescriptions in that period. Butalbital and opioid narcotics have well-known abuse potential and can lead to addiction, and are not recommended for extended use. In addition, Butalbital is banned in several European countries. We are developing TNX-201 with the goal of introducing an effective, safe, and non-addictive prescription treatment option for ETTH.

The active ingredient in TNX-201, dexisometheptene mucate, contains (R)-isometheptene, one of the two optical isomers of isometheptene. Isometheptene mucate had been widely used as a single-agent prescription medicine and as a component of combination drug products (e.g., Midrin®) for many decades in the U.S. for various indications including tension-type headache and migraine. Although certain combination drug products containing isometheptene are marketed, they are listed in the “unapproved drug other” category in the FDA National Drug Code Directory and may be subject to FDA enforcement actions. Tonix is developing TNX-201 as a new chemical entity pursuant to Section 505(b)(1) of the FDCA.

Based on our pharmacology studies, we believe that TNX-201 is primarily responsible for the activity associated with isometheptene in the treatment of headache and migraine. In receptor binding assays, the (R)-isometheptene had approximately a 10 to 100-fold higher affinity for the imidazoline-1 receptor as compared to the (S)-isometheptene. In our nonclinical studies, TNX-201 increased the pain threshold in animal models of acute pain, and increased trigeminal pain thresholds in animal models that feature aspects of chronic migraine. Based on these studies, we believe that the imidazoline-1 receptor is the primary site of action of TNX-201, and may represent a novel target for the treatment of headache as well as other pain conditions.

Phase 2 Proof-of-Concept Study

In a Phase 1 study in healthy volunteers, TNX-201 was well-tolerated at all doses studied (35 mg, 70 mg, and 140 mg). In the second quarter of 2015, we initiated a Phase 2 proof-of-concept clinical trial of TNX-201 in ETTH, in which approximately 200 patients will be randomized to receive TNX-201 140 mg or placebo capsules. This trial is being conducted at approximately 10 U.S. centers. The primary efficacy endpoint will be the difference between the two study arms in the number of subjects who report complete relief from their headache pain at two hours following a dose of study medication. This study will also assess efficacy according to a variety of other measures at several time points. This study is designed to test the activity and tolerability of TNX-201 to support future efficacy and safety studies. We expect to report top line results from this study in the first quarter of 2016.

Additional Product Candidates

We also have a pipeline of pre-investigational new drug product candidates, including TNX-301. 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 alcohol use disorder, and we have commenced formulation development work on TNX-301. 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 nonclinical 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 other NCEs or new biologic candidates.

Current Operating Trends

Our current research and development efforts are focused on developing TNX-102 SL and TNX-201, but we also expend increasing effort on our other pipeline programs, including TNX-301. Our research and development expenses consist of manufacturing work and the cost of drug ingredients used in such work, fees paid to consultants for work related to clinical trial design and regulatory activities, fees paid to providers for conducting various clinical studies as well as for the analysis of the results of such studies, and for other medical research addressing the potential efficacy and safety of our drugs. We believe that significant investment in product development is a competitive necessity, and we plan to continue these investments in order to be in a position to realize the potential of our product candidates and proprietary technologies.

We are currently conducting a Phase 3 clinical trial of Tonmya in FM, a Phase 2 clinical trial of TNX-102 SL in PTSD, and a Phase 2 proof-of-concept trial of TNX-201 in ETTH. Clinical trials can be very expensive. If these and additional necessary clinical trials are successful, we plan to prepare and submit applications to the FDA for marketing approval for our drug candidates. This process entails significant costs. As a result of these and other factors, we expect our research and development expenses to increase significantly over the next 12 to 24 months.

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 preclinical 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 preclinical 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 trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. 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, 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 inflows 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 June 30, 2015 Compared to Three Months Ended June 30, 2014

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the three months ended June 30, 2015 and 2014.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2015 were $8.9 million, an increase of $4.8 million, or 117%, from $4.1 million for the three months ended June 30, 2014. This increase is primarily due to increased development work related to Tonmya/TNX-102 SL and TNX-201, including formulation development, manufacturing, human safety and efficacy as well as pharmacokinetic studies. During the three months ended June 30, 2015, we incurred $3.9 million, $1.2 million, $0.8 million and $0.8 million in clinical, non-clinical, manufacturing and medical research, respectively, as compared to $1.5 million, $0.4 million, $0.8 million and $0.4 million for the same period last year, respectively. Included in the three months ended June 30, 2015 was cash related compensation of $0.5 million as compared to $0.3 million for the three months ended June 30, 2014, the increase of $0.2 million as a result of added personnel. We incurred $0.3 million in stock-based compensation in connection with the vesting of stock options in the three months ended June 30, 2015 that were previously issued to officers and consultants, as compared to $0.1 million in stock based compensation for the same period last year. Regulatory and legal costs remained approximately the same for both three month periods at $0.4 million.

Travel, meals and entertainment costs for the three months ended June 30, 2015 were $0.6 million, an increase of $0.4 million, or 200%, from $0.2 million incurred in the three months ended June 30, 2014. Travel, meals and entertainment costs include travel related to clinical development and medical-related conferences, which primarily accounted for the increase from 2014. Other research and development costs totaled $0.5 million for the three months ended June 30, 2015, an increase of $0.3 million, or 150%, from $0.2 million incurred for the six months ended June 30, 2014. 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 June 30, 2015 were $2.9 million, an increase of $0.9 million, or 45%, from $2.0 million incurred in the three months ended June 30, 2014. This increase is primarily due to compensation related expenses and professional services.

Compensation related expenses increased to $1.2 million for the three months ended June 30, 2015, from $0.9 million for the three months ended June 30, 2014, an increase of $0.3 million, or 33%. We incurred $0.8 million in stock-based compensation in connection with the vesting of stock options in the three months ended June 30, 2015 that were previously issued to board members, officers and consultants, as compared to $0.5 million in stock based compensation for the same period last year. The cash compensation related costs of $0.4 million remained approximately the same for both three month periods.

Professional services for the three months ended June 30, 2015 totaled $1.0 million, an increase of $0.5 million or 100%, over the $0.5 million incurred for the three months ended June 30, 2014. Of professional services, legal fees totaled $0.4 million for the three months ended June 30, 2015, an increase of $0.3 million, or 300%, from $0.1 million incurred for the three months ended June 30, 2014. The increase is mainly due to international legal work and legal fees related to patent activity. Other consulting fees and other professional fees totaled $0.6 million for the three months ended June 30, 2015, an increase of $0.2 million, or 50%, from $0.4 million incurred for the three months ended June 30, 2014. 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 June 30, 2015 were $0.2 million, an increase of $0.1 million, or 100%, from $0.1 million incurred in the three months ended June 30, 2014. Travel, meals and entertainment costs include travel related to business development and investor relations activities, which accounted for the primary increase from 2014. Office and other administrative expenses remained approximately the same for both three month periods at $0.5 million. 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 June 30, 2015 was $11.8 million, compared to a net loss of $6.0 million for the three months ended June 30, 2014.

Six Months Ended June 30, 2015 Compared to Six Months Ended June 30, 2014

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the six months ended June 30, 2015 and 2014.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2015 were $15.7 million, an increase of $8.1 million, or 107%, from $7.6 million for the six months ended June 30, 2014. This increase is primarily due to increased development work related to Tonmya/TNX-102 SL and TNX-201, including formulation development, manufacturing, human safety and efficacy as well as pharmacokinetic studies. During the six months ended June 30, 2015, we incurred $5.9 million, $2.5 million, $1.4 million and $1.5 million in clinical, non-clinical, manufacturing and medical research, respectively, as compared to $2.5 million, $0.7 million, $1.1 million and $0.8 million for the same period last year, respectively. During the six months ended June 30, 2014, we acquired $0.9 million of intellectual property rights as compared to $-0- in the current period. Included in the six months ended June 30, 2015 was cash related compensation of $1.2 million as compared to $0.4 million for the six months ended June 30, 2014, the increase of $0.8 million as a result of added personnel. We incurred $0.8 million in stock-based compensation in connection with the vesting of stock options in the six months ended June 30, 2015 that were previously issued to officers and consultants as compared to $0.2 million in stock based compensation for the same period last year. Regulatory and legal costs for the six months ended June 30, 2015 were $0.8 million, an increase of $0.1 million, or 14%, from $0.7 million incurred in the six months ended June 30, 2014. The increase in regulatory and legal costs is primarily due to the increase in active trials.

Travel, meals and entertainment costs for the six months ended June 30, 2015 were $0.9 million, an increase of $0.7 million, or 350%, from $0.2 million incurred in the six months ended June 30, 2014. Travel, meals and entertainment costs include travel related to clinical development and medical-related conferences, which primarily accounted for the increase from 2014. Other research and development costs totaled $0.7 million for the six months ended June 30, 2015, an increase of $0.5 million, or 250%, from $0.2 million incurred for the six months ended June 30, 2014. Other research and development costs include rent, insurance and other office related expenses.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2015 were $5.8 million, an increase of $2.2 million, or 61%, from $3.6 million incurred in the six months ended June 30, 2014. This increase is primarily due to compensation related expenses and professional services.

Compensation related expenses increased to $2.6 million for the six months ended June 30, 2015 from $1.7 million for the six months ended June 30, 2014, an increase of $0.9 million, or 53%. We incurred $1.7 million in stock-based compensation in connection with the vesting of stock options in the six months ended June 30, 2015 that were previously issued to board members, officers and consultants as compared to $1.0 million in stock based compensation for the same period last year. The increase in cash compensation related costs of $0.2 million was primarily a result of annual salary increases and added personnel.

Professional services for the six months ended June 30, 2015 totaled $1.8 million, an increase of $0.8 million or 80%, over the $1.0 million incurred for the six months ended June 30, 2014. Of professional services, legal fees totaled $0.8 million for the six months ended June 30, 2015, an increase of $0.4 million, or 100%, from $0.4 million incurred for the six months ended June 30, 2014. The increase is mainly due to international legal work and legal fees related to patent activity. Other consulting fees and other professional fees totaled $1.0 million for the six months ended June 30, 2015, an increase of $0.4 million, or 67%, from $0.7 million incurred for the six months ended June 30, 2014. 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 six months ended June 30, 2015 were $0.5 million, an increase of $0.3 million, or 150%, from $0.2 million incurred in the six months ended June 30, 2014. Travel, meals and entertainment costs include travel related to business development and investor relations activities, which accounted for the primary increase from 2014. Office and other administrative expenses totaled $0.9 million for the six months ended June 30, 2015 as compared to of $0.7 million for the same period last year. 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 six months ended June 30, 2015 was $21.4 million, compared to a net loss of $11.2 million for the six months ended June 30, 2014.

Liquidity and Capital Resources

As of June 30, 2015, we had working capital of $45.7 million, comprised primarily of cash and cash equivalents of $48.7 million and prepaid expenses and other of $1.6 million offset by $2.8 million of accounts payable and $1.8 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our ongoing clinical trials of Tonmya in FM and TNX-102 SL in PTSD. For the six months ended June 30, 2015 and 2014, we used approximately $18.3 million and $9.8 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 six months ended June 30, 2015, net proceeds from financing activities were from the sale of our common stock of approximately $29.0 million. In the comparable 2014 period, approximately $40.7 million was raised through the sale of shares of common stock and the exercise of warrants of $4.9 million. Our cash and cash equivalents are held in bank deposit accounts.

We did not have any material investing activities for the six months ended June 30, 2015 or 2014.

February 2015 Financing

On February 4, 2015, we entered into an underwriting agreement with Roth Capital Partners, LLC and Oppenheimer & Co Inc., as representatives of several underwriters (collectively, the "Underwriters"), relating to the issuance and sale of 4,900,000 shares of our common stock in an underwritten public offering (the "February 2015 Financing"). The public offering price for each share of common stock was $5.85. We granted the 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 Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of approximately $1.7 million (or $0.35 per share). The Company also paid offering expenses of approximately $0.2 million. The Company received net proceeds of approximately $26.7 million. On February 24, 2015, the Underwriters partially exercised the over-allotment option and purchased 418,700 shares of common stock for net proceeds of approximately $2.3 million.

July 2015 Financing

On July 14, 2015, we entered into an underwriting agreement with Roth and Oppenheimer & Co Inc., as representatives of the Underwriters, relating to the issuance and sale of 2,325,000 shares of our common stock, in an underwritten public offering (the "July 2015 Financing"). The public offering price for each share of common stock was $7.50. We granted the 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 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). We also paid offering expenses of approximately $0.2 million. We received net proceeds of approximately $16.2 million. On July 17, 2015, the Underwriters fully exercised the over-allotment option and purchased 348,750 shares of common stock for net proceeds of approximately $2.5 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 increase in the future as we expand our business development, add infrastructure and incur additional costs related to being a public company, including incremental audit fees, investor relations programs and increased professional services.

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 believe our existing cash is sufficient to fund our operating expenses and planned clinical trials for at least the next 12 months.

We presently do not have any available credit, bank financing or other external sources of liquidity. Due to our history and historical operating losses, our operations have not been a source of liquidity. We may 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.

Transactions with Related Parties

Consulting Agreement

We previously entered into a consulting agreement with Lederman & Co., LLC, a company controlled by Dr. Seth Lederman, our Chief Executive Officer and Chairman of the Board. Total expenses paid under this agreement were $-0- during the three and six months ended June 30, 2015 and $-0- and $37,723 during the three and six months ended June 30, 2014, respectively. The agreement was terminated on February 11, 2014 and replaced with the employment agreement entered into on that date.

Intellectual Property Acquired

On March 18, 2014, Tonix Pharmaceuticals (Barbados) Ltd., or Tonix Barbados, entered into an agreement with Leder Laboratories, Inc. ("Leder"), to acquire intellectual property related to novel smallpox vaccines. As consideration, $0.1 million was paid in cash and 25,000 shares of our common stock valued at $0.3 million ($12.15 per share, which was the closing price of the common shares on the date of the transaction) were issued to Leder.

On March 18, 2014, Tonix Barbados entered into an agreement with Starling Pharmaceuticals, Inc. ("Starling"), to acquire intellectual property related to radio- and chemo-protective agents. As consideration, $0.1 million was paid in cash and 25,000 shares of our common stock valued at $0.3 million ($12.15 per share, which was the closing price of the common shares on the date of the transaction) were issued to Starling.

Seth Lederman is the Chairman, CEO and majority owner (through majority-owned entities) of Starling and Leder.

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.

On June 9, 2014, we approved the Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan (the "2014 Plan" and together with the 2012 Plan, the "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 its common stock for future issuance under the terms of the 2014 Plan.

On February 25, 2015, 419,500 and 30,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan (of which 415,700 employee/director options and 30,000 consultant options were outstanding at June 30, 2015) 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, 2015, the fair value related to consultant grants was $7.79.

On April 14, 2015, 7,600 options were granted to employees under the 2014 Plan (all of which were outstanding at June 30, 2015) with an exercise price of $6.34, a 10 year life and fair value of $4.56.

During the six months ended June 30, 2015, 3,800, 39,800 and 39,800 unvested options with exercise prices of $5.95, $9.87 and $6.68, respectively, were cancelled.

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 June 30, 2015, after giving effect to shares purchased as described below, there were 268,001 shares available for future purchase 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. As of June 30, 2015, approximately $90,000 of employee payroll deductions which have been withheld since January 1, 2015, the commencement of the offering period ended June 30, 2015, are included in accrued expenses in the accompanying balance sheet. The compensation expense related to the 2014 ESPP for the three and six months ended June 30, 2015 was $21,171 and $43,234, respectively. In July 2015, 18,021 shares that were purchased as of June 30, 2015, were issued under the 2014 ESPP, and approximately $90,000 of employee payroll deductions accumulated at June 30, 2015, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital. In February 2015, 13,978 shares that were purchased as of December 31, 2014, were issued under the 2014 ESPP, and approximately $70,000 of employee payroll deductions accumulated at December 31, 2014, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital.

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 the RSU grants was $65,520 and $87,360 for the three and six months ended June 30, 2015. As of June 30, 2015, the stock-based compensation relating to restricted stock of $0.2 million remains unamortized and is expected to be amortized over the remaining period of approximately eight months.

Lease Commitments

On February 11, 2014, in connection with office space in New York City, we entered into a lease amendment and expansion agreement, whereby we agreed to lease additional premises for office space, commencing May 1, 2014 and expiring on April 30, 2019. In connection therewith, the original letter of credit was increased by $72,354 to $132,417 and we deposited an additional $72,354 into the restricted cash account maintained at the bank that issued the letter of credit.

On April 28, 2014, we entered into a lease for approximately 3,578 square feet of office space in San Jose, California, whereby we agreed to lease premises, commencing August 1, 2014 and expiring on October 31, 2018 (51 months). In connection therewith, we paid a security deposit of $44,546.

On June 17, 2015, we entered into a lease for approximately 2,450 square feet of office space in Dublin, Ireland, whereby we agreed to lease premises, commencing June 1, 2015 and expiring on May 31, 2018.

Future minimum lease payments under these three agreements are as follows (in thousands):

Year Ending December 31,		
2015	$	251
2016		556
2017		569
2018		488
2019		99
	$	1,963

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 of America. 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. Tonix outsources its research and development efforts and expenses 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.

Stock Based Compensation. All stock-based payments to employees and to nonemployee directors for their services as directors consisted of grants of restricted stock and stock options, which are measured at fair value on the grant date and recognized in the consolidated statements of operations as compensation expense over the relevant vesting period. 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. The Company records 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. The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

As of June 30, 2015, we had cash and cash equivalents of $48.7 million deposited in highly rated financial institutions in the United States. Our cash equivalents primarily consist of money market deposits managed by commercial banks. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term money marketable funds. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

Foreign Currency Risk

We do not hold more than a *de minimus* amount of foreign currency denominated financial instruments.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices three or six months ended June 30, 2015 and 2014 had a significant impact on our results of operations.

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 June 30, 2015, 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.

During the quarter ended June 30, 2015, we completed the installation and migration of our accounting software system from QuickBooks to Microsoft Dynamics GP, which is part of our normal business process to evaluate and upgrade or replace our systems software and related business processes to support our evolving operational requirements, as needed. Other than the change to our accounting software system, there were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2015 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

Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on February 27, 2015. Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part 1, Item 1A, of our Annual Report, on Form 10-K for the fiscal year ended December 31, 2014, provide additional disclosure and context for these supplemental risks and are incorporated herein by reference.

RISKS RELATED TO OUR BUSINESS

We have a history of operating losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability.

We are focused on product development, and we have not generated any revenues to date. We have incurred losses in each year of our operations, and we expect to continue to incur operating losses for the foreseeable future. These operating losses have adversely affected and are likely to continue to adversely affect our working capital, total assets and shareholders' equity.

The Company and its prospects should be examined in light of the risks and difficulties frequently encountered by new and early-stage companies in new and rapidly evolving markets. These risks include, among other things, the speed at which we can scale up operations, our complete dependence upon development of products that currently have no market acceptance, our ability to establish and expand our brand name, our ability to expand our operations to meet the commercial demand of our clients, our development of and reliance on strategic and customer relationships and our ability to minimize fraud and other security risks.

The process of developing our products requires significant clinical development and laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical and nonclinical testing and clinical trials, and regulatory compliance activities.

Our ability to generate revenues and achieve profitability will depend on numerous factors, including success in:

- developing and testing product candidates;
- receiving regulatory approvals;
- commercializing our products; and
- establishing a favorable competitive position.

Many of these factors will depend on circumstances beyond our control. We cannot assure you that we will ever have a product approved by the FDA, that we will bring any product to market or, if we are successful in doing so, that we will ever become profitable.

We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical and nonclinical testing, and clinical trial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the near future, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the development of our product candidates; obtaining necessary regulatory approvals from the FDA; establishing manufacturing, sales, and marketing arrangements with third parties; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a development-stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to developing our technology and undertaking preclinical and nonclinical testing and clinical trials of our clinical-stage product candidates, TNX-102 SL and TNX-201. We have not yet obtained regulatory approvals for TNX-102 SL, TNX-201 or any of our other product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this report and also include:

- our ability to obtain additional funding to develop our product candidates;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our clinical trials through all phases of clinical development, including our trials of Tonmya, TNX-102 SL and TNX-201;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for Tonmya, TNX-102 SL and TNX-201 or any of our other product candidates in the United States and foreign jurisdictions;
- potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
- our dependence on third party contract manufacturing organizations, or CMOs, to supply or manufacture our products;
- our dependence on third party contract research organizations, or CROs, to conduct our clinical trials and preclinical and nonclinical research;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We are largely dependent on the success of our clinical-stage product candidates, TNX-102 SL and TNX-201, and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two product candidates in clinical stages of development for three indications: Tonmya and TNX-102 SL for the management of FM and PTSD, respectively, and TNX-201 for the treatment of ETTH, and the success of our business currently depends on their successful development, approval and commercialization. Any projected sales or future revenue predictions are predicated upon FDA approval and market acceptance of Tonmya, TNX-102 SL and TNX-201. If projected sales do not materialize for any reason, it would have a material adverse effect on our business and our ability to continue operations.

Tonmya, TNX-102 SL and TNX-201 have not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for these product candidates anywhere in the world. The clinical development programs for Tonmya, TNX-102 SL and TNX-201 may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or foreign regulatory authorities because our clinical trials fail to demonstrate to their satisfaction that these product candidates are safe and effective or a clinical program may be put on hold due to unexpected safety issues. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approvals for Tonmya, TNX-102 SL or TNX-201 in a timely manner would have a material adverse impact on our business and our stock price.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we are currently focusing on the regulatory approvals of Tonmya, TNX-102 SL and TNX-201. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We may need additional capital. If additional capital is not available or is available at unattractive terms, we may be forced to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations.

In order to develop and bring our product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical and nonclinical testing, clinical trials and marketing activities. We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations for at least the next 12 months. We anticipate using our cash and cash equivalents to fund further research and development with respect to our lead product candidates. We may, however, need to raise additional funding sooner if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. Our requirements for additional capital will depend on many factors, including:

- successful commercialization of our product candidates;
- the time and costs involved in obtaining regulatory approval for our product candidates;
- costs associated with protecting our intellectual property rights;
- development of marketing and sales capabilities;
- payments received under future collaborative agreements, if any; and
- market acceptance of our products.

To the extent we raise additional capital through the sale of equity securities, the issuance of those securities could result in dilution to our shareholders. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. In addition, we may be required to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical and nonclinical testing and clinical trials, regulatory approvals and eventual commercialization. Such additional sources of financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to commence clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our shareholders.

There is no assurance that we will be successful in raising the additional funds needed to fund our business plan. If we are not able to raise sufficient capital in the near future, our continued operations will be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or interference proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine the priority of inventions. The defense and prosecution of intellectual property suits, USPTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable in court litigation. Third parties may also assert that our patents are invalid in patent office administrative proceedings. These proceedings include oppositions in the European Patent Office and *inter partes* review and post-grant review proceedings in the USPTO. The success rate of these administrative challenges to patent validity in the United States is higher than it is for validity challenges in litigation. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation or administrative proceedings could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the USPTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If preclinical and nonclinical testing or clinical trials for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines.

We rely and expect to continue to rely on third parties, including CROs and outside consultants, to conduct, supervise or monitor some or all aspects of preclinical and nonclinical testing and clinical trials involving our product candidates. We have less control over the timing and other aspects of these preclinical and nonclinical testing activities and clinical trials than if we performed the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our preclinical and nonclinical testing and clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in preclinical and nonclinical testing, and clinical trials could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated recruitment or retention rate of patients in clinical trials;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials;
- negative results of clinical trials; or
- nonclinical or clinical safety observations, including adverse events and serious adverse events.

If clinical trials are unsuccessful, and we are not able to obtain regulatory approvals for our product candidates under development, we will not be able to commercialize these products, and therefore may not be able to generate sufficient revenues to support our business.

We have never conducted a Phase 3 clinical trial or submitted an NDA before, and may be unable to do so for Tonmya, TNX-102 SL or other product candidates we are developing.

In addition to our ongoing AFFIRM trial of Tonmya in FM, we plan to initiate a second Phase 3 confirmatory trial in support of product registration prior to completion of the ongoing AFFIRM trial. As these trials are intended to provide evidence to support marketing approval by the FDA, they are considered pivotal, or registration, trials. The conduct of pivotal clinical trials and the submission of a successful NDA is a complicated process. Although members of our management team have extensive industry experience, including in the development, clinical testing and commercialization of drug candidates, our company has never conducted a pivotal clinical trial before, has limited experience in preparing, submitting and prosecuting regulatory filings, and has not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete these planned clinical trials in a way that leads to NDA submission and approval of Tonmya, TNX-102 SL and other product candidates we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent or delay commercialization of Tonmya, TNX-102 SL and other product candidates we are developing.

Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects from TNX-102 SL or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials, including TNX-102 SL, may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If Tonmya, TNX-102 SL or any of our other product candidates cause serious adverse events or undesirable side effects or suffer from quality control issues:

- regulatory authorities may impose a clinical hold or risk evaluation and mitigation strategies, or REMS, which could result in substantial delays, significantly increase the cost of development, and/or adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of statements, specific warnings, or contraindications to the product label, or restrict the product's indication to a smaller potential treatment population;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the patients who can receive the product;
- we may be subject to limitations on how we promote the product;
- we may, voluntarily or involuntarily, initiate field alerts for product recall, which may result in shortages;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

If we are unable to file for approval of Tonmya or TNX-102 SL under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing NDAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for our product candidates and therefore possibly obtain a shortened review period for the applications. We held an End-of-Phase 2 meeting with the FDA in February 2013 to discuss our most advanced development program, in which we are developing Tonmya for the management of FM. In late 2014, following the results of the BESTFIT trial, we corresponded with the FDA to further discuss our Phase 3 registration program plan. We held a pre-IND meeting with the FDA in October 2012 to discuss the development of TNX-102 SL in PTSD. Although our interactions with the FDA have encouraged our efforts to continue to develop Tonmya for FM and TNX-102 SL for PTSD, there is no assurance that we will satisfy the FDA's requirements for approval in these indications. The timeline for filing and review of our NDAs for Tonmya and TNX-102 SL is based on our plan to submit those NDAs under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any of our product candidates. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us. In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to obtain shortened review of our applications for Tonmya or TNX-102 SL, and the FDA may not agree that any of our products qualify for marketing approval. If CBP-containing products are withdrawn from the market by the FDA for any reason, we may not be able to reference such products to support a 505(b)(2) NDA for Tonmya or TNX-102 SL, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our product candidates.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we advance our product candidates through preclinical and nonclinical testing and clinical trials and develop new product candidates, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing, distribution and sales infrastructure if we seek to market our products directly; and
- continue to improve our operational, manufacturing, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time we will need to hire additional qualified personnel with expertise in drug development, product registration, clinical, preclinical and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

We rely on third parties to manufacture the compounds used in our trials, and we intend to rely on them for the manufacture of any approved products for commercial sale. If these third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates could be delayed, prevented or impaired.

We have no manufacturing facilities, and we have no experience in the clinical or commercial-scale manufacture of drugs or in designing drug manufacturing processes. We intend to rely on CMOs to manufacture some or all of our product candidates in clinical trials and our products that reach commercialization. Completion of our clinical trials and commercialization of our product candidates requires the manufacture of a sufficient supply of our product candidates. We have contracted with outside sources to manufacture our development compounds, including Tonmya, TNX-102 SL and TNX-201. If, for any reason, we become unable to rely on our current sources for the manufacture of our product candidates, either for clinical trials or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for nonclinical, preclinical, clinical, and commercial purposes. Although we are in discussions with other manufacturers we have identified as potential alternative CMOs of Tonmya, TNX-102 SL and TNX-201, we may not be successful in negotiating acceptable terms with any of them.

We believe that there are a variety of manufacturers that we may be able to retain to produce these products. However, once we retain a manufacturing source, if our manufacturers do not perform in a satisfactory manner, we may not be able to develop or commercialize potential products as planned. Certain specialized manufacturers are expected to provide us with modified and unmodified pharmaceutical compounds, including finished products, for use in our preclinical and nonclinical testing and clinical trials. Some of these materials are available from only one supplier or vendor. Any interruption in or termination of service by such sole source suppliers could result in a delay or interruption in manufacturing until we locate an alternative source of supply. Any delay or interruption in manufacturing operations (or failure to locate a suitable replacement for such suppliers) could materially adversely affect our business, prospects, or results of operations. We do not have any short-term or long-term manufacturing agreements with many of these manufacturers. If we fail to contract for manufacturing on acceptable terms or if third-party manufacturers do not perform as we expect, our development programs could be materially adversely affected. This may result in delays in filing for and receiving FDA approval for one or more of our products. Any such delays could cause our prospects to suffer significantly.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA approval to market a new drug product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct "adequate and well controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: inability to manufacture sufficient quantities of qualified materials under cGMP, for use in clinical trials; slower than expected rates of patient recruitment; failure to recruit a sufficient number of patients; modification of clinical trial protocols; changes in regulatory requirements for clinical trials; the lack of effectiveness during clinical trials; the emergence of unforeseen safety issues; delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates.

Our clinical trials may be conducted in patients with CNS conditions, and in some cases, our product candidates are expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our product candidates. We cannot ensure that safety issues will not arise with respect to our product candidates in clinical development.

The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and nonclinical testing and clinical studies, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of biopharmaceutical products. The FDA regulates small molecule chemical entities as drugs, subject to an NDA under the FDCA. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes preclinical and nonclinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials. We or our collaborators must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical, nonclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy, and in the case of biologics also potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates.

Following completion of clinical trials, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of an NDA in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to an NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study and other commitments or reporting requirements or other restrictions on product distribution, or may deny the application. The FDA has established performance goals for review of NDAs: six months for priority applications and ten months for standard applications. However, the FDA is not required to complete its review within these time periods. The timing of final FDA review and action varies greatly, but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Product sales in the United States may commence only when an NDA is approved.

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our products in the United States or in any foreign jurisdiction. None of our product candidates have been determined to be safe and effective, and we have not submitted an NDA to the FDA or an equivalent application to any foreign regulatory authorities for any of our product candidates.

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, may adversely affect the successful commercialization of any drugs or biologics that we or our partners develop, may impose additional costs on us or our collaborators, may diminish any competitive advantages that we or our partners may attain, and/or may adversely affect our receipt of revenues or royalties.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If Tonmya, TNX-102 SL, TNX-201 or any of our other product candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, hurricanes, floods and fires; and
- difficulty in importing and exporting clinical trial materials and study samples.

RISKS RELATED TO OUR STOCK

Sales of additional shares of our common stock, including by us or our directors and officers following expiration or early release of the lock-up periods, could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale, by us or others, including the issuance of common stock upon exercise of outstanding options and warrants, could adversely affect the price of our common stock. In connection with a public offering in July 2015, we and our directors and officers have entered into lock-up agreements for a period of 90 days following such offering (which period may be extended under certain circumstances). We and our directors and officers may be released from lock-up prior to the expiration of the lock-up periods at the sole discretion of Roth Capital Partners, LLC and Oppenheimer & Co., Inc. Upon expiration or earlier release of the lock-up, we and our directors and officers may sell shares into the market, which could adversely affect the market price of shares of our common stock.

Efforts to comply with recently enacted changes in securities laws and regulations will increase our costs and require additional management resources, and we still may fail to comply.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on their internal controls over financial reporting in their annual reports on Form 10-K. Effective January 1, 2015, we became subject to the requirement that our independent registered public accounting firm auditing our financial statements attest to and opine on the effectiveness of our internal controls over financial reporting as of December 31, 2014. We incurred substantial additional audit expenses to comply with this requirement and will continue to do so in future periods.

If we are unable to conclude that we have effective internal controls over financial reporting or if our independent registered public accounting firm is unable to provide us with a report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of August 6, 2015, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 27.3% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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: August 7, 2015

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

Date: August 7, 2015

By: /s/ LELAND GERSHELL
Leland Gershell
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.01

CERTIFICATION

I, Seth Lederman, certify that:

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

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

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

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

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

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

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

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

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: August 7, 2015

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

EXHIBIT 31.02

CERTIFICATION

I, Leland Gershell, 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: August 7, 2015

/s/ LELAND GERSHELL
Leland Gershell
Chief Financial Officer

EXHIBIT 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Tonix Pharmaceuticals Holding Corp. on Form 10-Q for the fiscal quarter ended June 30, 2015 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: August 7, 2015

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

I, Leland Gershell, 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 June 30, 2015 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: August 7, 2015

By: /s/ LELAND GERSHELL
Name: Leland Gershell
Title: *Chief Financial Officer*