UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2014

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)		(IRS Employer Identification No.)
509 Madison Avenue, Suite 306 **New York, New York**	**10022**	**(212) 980-9155**
(Address of principal executive office)	(Zip Code)	(Registrant's telephone number, including area code)

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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 (§ 229.405 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 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 ☒

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2014, based on the closing sales price of the common stock as quoted on The NASDAQ Capital Market was $123,101,977. For purposes of this computation, all officers, directors, and 5 percent beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed an admission that such directors, officers, or 5 percent beneficial owners are, in fact, affiliates of the registrant.

As of February 25, 2015, there were 16,137,898 shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2015 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2014.

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PART I

ITEM 1 - BUSINESS

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our Management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading “Risks Factors” below, as well as those discussed elsewhere in this Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We file reports with the Securities and Exchange Commission (“SEC”). You can read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-K. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

This Annual Report on Form 10-K includes the accounts of Tonix Pharmaceuticals Holding Corp., a Nevada corporation (“Tonix”), together with its wholly-owned subsidiaries, as follows, collectively referred to as “we”, “us” or the “Company”: Tonix Pharmaceuticals, Inc., a Delaware corporation (“Tonix Sub”), Krele LLC, a Delaware limited liability company (“Krele”), Tonix Pharmaceuticals (Canada), Inc., a corporation incorporated under the laws of the province of New Brunswick, Canada (“Tonix Canada”), Tonix Pharmaceuticals (Barbados) Ltd., a corporation incorporated under the laws of Barbados (“Tonix Barbados”), Tonix Pharma Holdings Limited, a company limited by shares incorporated under the laws of Ireland (“Tonix International Holding”), and Tonix Pharma Limited, a company limited by shares incorporated under the laws of Ireland (“Tonix Ireland”). Tonix Sub is a wholly-owned subsidiary of Tonix, and Krele and Tonix International Holding are wholly-owned subsidiaries of Tonix Sub. Tonix Canada is a wholly-owned subsidiary of Tonix Ireland and Tonix Barbados is a wholly-owned subsidiary of Tonix International Holding.

“Tonix Pharmaceuticals” and other trademarks and intellectual property of ours appearing in this report are our property. This report contains additional trade names and trademarks of other companies. We do not intend our use or display of other companies’ trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

Corporate Structure

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. From inception through October 2011, we were involved in the acquisition, exploration and development of natural resource properties in the State of Nevada. On October 7, 2011, we executed and consummated the share exchange transaction, or the Share Exchange, by and among the Company, Tonix Sub and the stockholders of Tonix Sub, or the Tonix Shareholders.

In the Share Exchange, the Tonix Shareholders exchanged their shares of Tonix Sub for newly issued shares of common stock. As a result, upon completion of the Share Exchange, Tonix Sub became our wholly-owned subsidiary.

Upon completion of the Share Exchange, the Tonix Shareholders received an aggregate of 1,133,334 shares of our common stock. 75,000 shares of common stock were returned to us from the prior officer, which were retired, and our existing shareholders retained 200,000 shares of common stock. The 1,133,334 shares issued to the Tonix Shareholders constituted approximately 85% of our 1,333,334 issued and outstanding shares of common stock immediately after the consummation of the Share Exchange.

As a result of the Share Exchange, we acquired 100% of the capital stock of Tonix Sub and consequently, control of the business and operations of Tonix Sub and Krele. From and after the consummation of the Share Exchange, our primary operations consist of the business and operations of Tonix Sub.

On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp. to reflect our new business.

Corporate Background

In 1996, Seth Lederman, MD, and Donald Landry, MD, PhD, formed L & L Technologies LLC, or L&L, to develop medications for central nervous system, or CNS, conditions. Dr. Lederman is our Chairman and Chief Executive Officer and Dr. Landry is a Director. L&L was a founder of Janus Pharmaceuticals, Inc., which later became Vela Pharmaceuticals, Inc., or Vela, which developed various therapeutics, including a very low dose, or VLD, version of cyclobenzaprine, or CBP, under an agreement with L&L. Vela decided to focus its resources on other programs and transferred the rights to VLD CBP and certain other technologies to L&L in March 2006.

Tonix Sub formed in June 2007 as Krele Pharmaceuticals, Inc. by L&L and Plumbline LLC, or Plumbline. Dr. Lederman is Managing Partner of Plumbline. Plumbline possessed rights to certain technology for the treatment of alcohol dependence and abuse. In connection with founding Tonix Sub, L&L and Plumbline entered into an intellectual property transfer and assignment agreement with Tonix Sub for the purpose of assigning patents and transferring intellectual property and know-how in exchange for shares of common stock of Tonix Sub. As a result of economic conditions related to the financial crisis of 2007 and 2008, Tonix Sub was not successful in raising money to fund its programs until 2009. As a result, Tonix Sub was unable to advance the development programs and had little activity except for prosecuting and maintaining patents and maintaining contracts.

In 2009, Tonix Sub contracted with the Toronto Psychiatric Research Foundation to analyze the sleep data from a Phase 2a trial of nighttime VLD CBP in fibromyalgia, or FM ("the Moldofsky Study"). The Moldofsky Study was conducted in Canada by the Toronto Psychiatric Research Foundation, and Tonix Sub obtained the data from this study from L&L. In addition, in 2009, Tonix Sub contracted with Caliper Life Sciences Inc., or Caliper, to analyze the interactions of CBP with certain receptors. In June 2010, Tonix Sub entered into consulting agreements with L&L and Lederman & Co., LLC, or Lederman & Co, and also acquired certain rights to develop isometheptene mucate as a treatment for certain types of headaches from Lederman & Co. Dr. Lederman is managing partner of Lederman & Co. Between June 2010 and October 2011, Tonix Sub was active in recruiting new officers and directors and initiating preclinical and clinical development of novel CBP formulations.

In July 2010, Tonix Sub changed its name to Tonix Pharmaceuticals, Inc. In August 2010, we formed Krele to commercialize products that are generic versions of predicate New Drug Application, or NDA, products. We anticipate that when our branded products lose patent protection, Krele may market authorized generic versions of them. Krele also may develop or acquire generic products approved under ANDAs and we may market branded versions (branded generics) of such products. Krele has been issued a state license in New York.

On April 23, 2013, Tonix Sub formed Tonix Canada. Tonix Canada is intended to perform research and development efforts in Canada. As a Canadian entity, we expect Tonix Canada will be entitled to receive certain reimbursable tax credits for research expenditures in Canada.

On October 29, 2014, Tonix Sub formed Tonix International Holding for the purpose of acquiring the rights to develop and commercialize Tonix products. Tonix International Holding formed Tonix Ireland for the purpose of manufacturing, trading and developing Tonix products. On December 15, 2014, Tonix Sub and Tonix International Holding entered into an intercompany license agreement whereby Tonix Sub granted Tonix International Holding a non-exclusive right to exercise certain product technologies and related intangible rights. As consideration, Tonix International Holding paid licensing fees to Tonix Sub.

On October 24, 2013, Tonix Sub formed Tonix Barbados. Tonix Barbados had previously entered into a license agreement and a cost-sharing agreement with Tonix Sub, pursuant to which Tonix Barbados acquired the rights to develop and commercialize certain products (TNX-102 SL and TNX-201) for non-U.S. markets. In the first quarter of 2015, Tonix Barbados is expected to be dissolved and its assets are to be transferred to Tonix International Holding.

Business Overview

We are a clinical-stage pharmaceutical company dedicated to the development of novel prescription products for common yet challenging medical disorders. Our clinical-stage product candidates, TNX-102 SL (cyclobenzaprine HCl sublingual tablet) and TNX-201 ((R)-isometheptene mucate), are directed toward conditions affecting the CNS. In the second quarter of 2015, we expect to initiate a Phase 3 clinical trial of our most advanced candidate, TNX-102 SL, for the treatment of FM. We are also developing TNX-102 SL as a potential treatment for post-traumatic stress disorder, or PTSD, and we commenced a Phase 2 trial for this indication in January 2015. We expect to begin a Phase 2 trial of TNX-201 in episodic tension-type headache, or ETTH, in the second quarter of 2015. Our pipeline includes a preclinical program for the treatment of alcohol abuse and dependence as well as two preclinical biodefense programs (for protection from smallpox virus and from radiation injury). We hold worldwide development and commercialization rights to all of our product candidates.

Our pipeline addresses disorders that are not well served by currently available therapies and represent large potential commercial opportunities. We believe that our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. Our clinical-stage product candidates are as follows:

TNX-102 SL

TNX-102 SL is a small, rapidly disintegrating tablet containing cyclobenzaprine for sublingual administration that we are developing for two indications, both of which are underserved by currently available therapies. These indications are:

Fibromyalgia. Fibromyalgia is a debilitating syndrome that occurs in up to 15% of 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. Many patients fail to adequately respond to the medications approved for FM, 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. We believe that TNX-102 SL has the potential to broadly and effectively treat the core symptoms of FM with a tolerability profile that is suitable as a first-line therapy and for chronic use.

Post-traumatic stress disorder. An estimated 3.5% of adults in the U.S. suffer from PTSD, a chronic disorder that is characterized by avoidance, emotional numbing, hyperarousal, and sleep disturbances. People with PTSD suffer significant impairment in their functioning, including occupational activities and social relations, and are at elevated risk for impulsive, violent behaviors toward others and themselves, including suicide. Many patients fail to adequately respond to the medications approved for PTSD, and antidepressants, sedative-hypnotics and antipsychotics not approved for PTSD are commonly prescribed despite generally weak evidence in support of their use. We believe that TNX-102 SL may be ideally suited to address the need for a treatment for PTSD that is effective, safe, and well-tolerated.

TNX-201

TNX-201 is an oral formulation of (R)-isometheptene mucate that we are developing for ETTH. It is estimated that approximately 75 million U.S. adults experience frequent ETTH episodes (one to 15 headaches per month over a three-month period), and although the majority of people who suffer ETTH are able to adequately manage their symptoms through the use of over-the-counter products, many seek prescription options, all of which contain barbiturates. Although the approved prescription products for ETTH may have some therapeutic value in treating the primary headache condition, they are associated with significant safety liabilities and pose a risk of abuse and addiction. We are developing TNX-201 with the goal of introducing a safe, effective, and non-addictive prescription treatment option for ETTH.

We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in the fields of FM, PTSD, ETTH and other central nervous system disorders.

Our Strategy

Our objective is to develop and commercialize our product candidates, including TNX-102 SL and TNX-201. The principal components of our strategy are to:

- ***Develop TNX-102 SL and TNX-201 for multiple central nervous system disorders***. We currently are pursuing the development of TNX-102 SL for two separate indications, FM and PTSD, and we are developing TNX-201 for ETTH. Our broad development strategy is designed to explore the clinical potential of TNX-102 SL and TNX-201 in disorders that are underserved by currently available medications and represent large unmet medical needs;

- ***Maximize the commercial potential of TNX-102 SL and TNX-201***. We plan to commercialize TNX-102 SL and TNX-201 for their respective indications either on our own or through collaboration with partners. We believe TNX-102 SL and TNX-201 can be marketed to U.S. physicians either by an internal sales force that we will build or by a contract sales organization, which we would engage. An alternative strategy would be to enter into partnership agreements with drug companies that already have significant marketing capabilities in the same, or similar, therapeutic areas. If we determine that such a strategy would be more favorable than developing our own sales capabilities, we would seek to enter into collaborations with pharmaceutical or biotechnology companies for the commercialization of TNX-102 SL or TNX-201;

- ***Pursue a broad intellectual property strategy to protect our product candidates***. We are pursuing a broad patent strategy for our product candidates, and we endeavor to generate new patent applications as supported by our innovations and conceptions as well as to advance their prosecution. In the case of TNX-102 SL, we own patents and patent applications protecting its composition-of-matter, certain methods of its use, its formulation, and its pharmacokinetic properties. In the case of TNX-201, we own patent applications protecting its composition-of-matter as well as our discoveries which relate to its molecular target. We plan to opportunistically apply for new patents to protect TNX-102 SL, TNX-201, and our other product candidates;

- ***Provide value propositions to merit market demand and reimbursement for our product candidates***. We are designing the development programs for our product candidates to demonstrate their value propositions to patients, prescribers, and third-party payors. In the cases of TNX-102 SL and TNX-201, we have been engaged in market research and commercial assessment activities, the results of which we may use to inform future commercial strategy. We plan to continue these activities in tandem with our clinical development of TNX-102 SL and TNX-201, and to conduct similar work in relation to our other product candidates as they advance in their development; and

- ***Pursue additional indications and commercial opportunities for our product candidates***. We will seek to maximize the value of TNX-102 SL, TNX-201, and our other product candidates by pursuing other indications and commercial opportunities for such candidates. For example, we own rights related to the development and commercialization of CBP for generalized anxiety disorder, depression, and fatigue related to disordered sleep. In the future, we may explore the development of TNX-201 for the treatment of migraine headaches.

Disease and Market Overview

Our product candidates address diseases that are not well served by currently available therapies and represent large potential commercial market opportunities. Background information on the diseases and related commercial markets that may be addressed by our clinical-stage product candidates is set forth below.

Fibromyalgia

FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. According to published estimates, there are approximately five to fifteen million people suffering from FM in the U.S. (Vincent et al, Arthritis Care Res 2013;65:786-792; Lawrence et al, Arthritis Rheum 2008;58:26-35). The peak incidence of FM occurs between 20-50 years of age, and 80-90% of diagnosed patients are female. FM may have 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.

Three drugs, pregabalin (Lyrica®), duloxetine (Cymbalta®), and milnacipran (Savella®), are approved by the FDA for the management of FM, and a variety of drugs are used off-label by FM patients. Despite these interventions, FM remains a significant unmet medical need. Many patients fail to adequately respond to the approved medications, or discontinue therapy due to poor tolerability. Prescription pain and sleep medications are widely used for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic effect. An important goal of FM treatment is to reduce the use of opiate analgesics as well as of benzodiazepine and non-benzodiazepine sedative-hypnotic medications typically used by FM patients.

Post-traumatic stress disorder

PTSD is 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 threat of imminent death. The core symptom clusters of PTSD are avoidance, emotional numbing, hyperarousal, and intrusion, where the triggering event is commonly re-experienced by the individual through intrusive, recurrent recollections, flashbacks, and nightmares. People with PTSD suffer significant impairment in their daily functioning, including occupational activities and social relations, and are at elevated risk for impulsive, violent behaviors toward others and themselves, including suicide. An estimated 3.5% of American adults, or approximately 8.5 million individuals, suffer from PTSD, of whom we believe only about half seek some form of treatment (Kessler et al, Arch Gen Psych 2005;62:617-627; Wang et al, Arch Gen Psych 2005;62:629-640). PTSD is a significant problem among armed forces veterans and other military personnel, but also occurs frequently in the civilian population.

The treatment of PTSD typically involves a multidimensional approach that includes pharmacologic and psychosocial interventions. Two antidepressant drugs, paroxetine (Paxil®) and sertraline (Zoloft®), are FDA-approved for the treatment of PTSD. Other antidepressants, as well as sedative-hypnotics and antipsychotics, are commonly prescribed off-label despite generally weak clinical evidence in support of their use. With the exception of certain antidepressants, there is also little evidence to support relapse prevention in the chronic setting for those who initially improve with acute pharmacotherapy. Patients often take several medications concurrently to address multiple symptoms. Sleep disturbances play a central role in PTSD, and present a difficult therapeutic challenge. For example, in 2009, although 30% of veterans with PTSD were prescribed benzodiazepines, a class of sedative-hypnotic medication (Lund et al, J Clin Psych 2012;73:292-296), evidence suggests that these drugs interfere with recovery from, and increase the incidence of, PTSD (van Minnen et al, Behav Res Ther 2002;40:439-57) and are not recommended per current guidelines (Department of Veterans Affairs, 2010). Co-morbid alcohol and substance abuse and dependence, which occur frequently in the PTSD population, generally complicate the use of sedative-hypnotics in these patients.

Episodic tension-type headache

ETTH is the most common type of headache, estimated to account for over 60% of headaches (Stovner et al, Cephalalgia 2007;27:193-210). Tension-type headache pain is often described as a constant pressure on both sides of the head, and typically lasts from thirty minutes to several days. It is estimated that approximately 75 million U.S. adults experience frequent ETTH episodes, defined as one to 15 tension-type headaches per month over a three-month period (derived from Schwartz et al, JAMA 1998;279:381-383; Chowdhury, Ann Ind Acad Neurol 2012;15:83-88). Approximately 60% receive treatment (derived from Scher et al, Cephalalgia 2010;30:321-328). Non-migraine headaches, of which approximately 80% are estimated to be ETTH (Stovner et al, 2007), lead to 9.2 million visits to emergency departments or physician offices each year (IMS Health, National Disease and Therapeutic Index, period 2008-2014).

Many people who suffer from ETTH are able to adequately manage their symptoms through the use of over-the-counter products containing aspirin, acetaminophen, or non-steroidal anti-inflammatory drugs (NSAIDs). However, an analysis of IMS data (period 2008-2014) indicates that approximately 10 million prescriptions for medications intended to treat non-migraine headaches are issued each year in the U.S., a figure that excludes prescriptions for NSAIDs, indicating that many people who suffer from ETTH seek prescription options. All of the products that are FDA-approved for the treatment of ETTH contain butalbital, a barbiturate that is a Drug Enforcement Agency Schedule III substance. Due to its potential for addiction and abuse, extended use of butalbital is not recommended, and this agent is banned in several European countries. Although butalbital-containing products may have initial therapeutic value in treating the primary headache condition, they pose a significant risk of inducing analgesic-overuse headache over time due to their tendency for overuse, driven by tolerance and physical and psychological dependence (Young et al, Curr Pain Headache Rep 2002;6:151-155).

Our Product Candidates

We currently are focused on developing a portfolio of product candidates, including two product candidates in clinical development for registration in three indications. We believe that our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. The following table summarizes our most advanced product candidates, for which we plan to complete the required clinical and nonclinical studies to support their NDA filings:

Product Candidate	Indication	Stage of Development	Commercialization Rights
TNX-102 SL	Fibromyalgia	Phase 3	Worldwide
TNX-102 SL	Post-traumatic stress disorder	Phase 2	Worldwide
TNX-201	Episodic tension-type headache	Phase 2	Worldwide

TNX-102 SL

Overview

TNX-102 SL is a sublingual tablet formulation of CBP that efficiently delivers CBP across the oral mucosal membrane into the systemic circulation. We are developing TNX-102 SL for fibromyalgia and post-traumatic stress disorder. We own all rights to TNX-102 SL in all geographies, and we bear no obligations to third-parties for any future development or commercialization.

In addition to CBP, TNX-102 SL contains excipients, which are well-characterized, are listed in the Inactive Ingredient Guide and are approved for pharmaceutical use. TNX-102 SL contains sublingual absorption-enabling ingredients that promote a local oral environment that facilitates mucosal absorption of CBP. These include agents that favor a mildly basic salivary pH.

TNX-102 SL contains 2.8 mg of CBP. We selected this dose with the goal of providing a balance of efficacy, safety, and tolerability that would be acceptable as a first-line therapy and for chronic use, and in patient populations characterized by burdensome symptoms and sensitivity to medications.

TNX-102 SL is a serotonin 2A and alpha-1 adrenergic receptor antagonist as well as an inhibitor of serotonin and norepinephrine reuptake, and we refer to it as a Serotonin and Norepinephrine receptor Antagonist and Reuptake Inhibitor, or SNARI. In FM, pregabalin is believed to exert its clinical benefit primarily by blocking calcium channels, and both duloxetine and milnacipran are believed to exert their clinical benefit mainly by inhibiting the reuptake of serotonin and norepinephrine. In PTSD, both paroxetine and sertraline are believed to exert their clinical benefit primarily by blocking serotonin reuptake. As such, TNX-102 SL acts upon cellular receptors that play important roles in the treatment of FM and PTSD, yet also acts upon other receptors in the central nervous system not targeted by products approved for these indications.

CBP is the active ingredient of two products, or CBP products, that are approved in the U.S. for the treatment of muscle spasm: Flexeril® (oral immediate-release tablet, 5 mg and 10 mg dosage forms) and Amrix® (oral extended-release capsule, 15 mg and 30 mg dosage forms). CBP products are not indicated for the treatment of FM or PTSD, and are approved for acute use (two to three weeks) only. Immediate-release, or IR, CBP tablets are recommended for three times per day dosing, which results in relatively stable blood levels of CBP after several days of treatment. Extended-release CBP capsules mimic, and flatten, the pharmacokinetic profile of three times per day immediate-release CBP tablets.

TNX-102 SL is intended for the treatment of chronic disorders for which poor sleep quality is recognized to play an intrinsic role, including FM and PTSD. We designed TNX-102 SL to be administered once-daily at bedtime in a chronic dosing regimen. We believe the dose and pharmacokinetic parameters of TNX-102 SL will enable it to achieve a desirable balance of efficacy, safety, and tolerability in FM and PTSD. Our Phase 1 comparative trials showed that, on a dose-adjusted basis, TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following sublingual administration relative to oral immediate-release CBP tablets. TNX-102 SL was generally well-tolerated, with no serious adverse events reported in these studies. Some subjects experienced transient numbness on the tongue after TNX-102 SL administration, and other side-effects reported were similar to those reported with approved CBP products.

We expect that any applications we submit to the Food and Drug Administration, or FDA, for approval of TNX-102 SL will be submitted under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which we believe will allow for a shorter timeline of clinical and non-clinical development as compared to that needed to fulfill the requirements of Section 505(b)(1), under which new chemical entities, or NCEs, that have never been approved in the United States, are generally developed to meet the FDA's new drug registration requirements. Currently, we are pursuing the development of TNX-102 SL for two separate indications. These indications are fibromyalgia, for which TNX-102 SL is advancing into Phase 3 development, and post-traumatic stress disorder, for which TNX-102 SL is in Phase 2 development. We believe that TNX-102 SL has the potential to effectively treat these and possibly other CNS indications that are underserved by currently marketed products.

TNX-102 SL – Fibromyalgia Program

We are developing TNX-102 SL for the treatment of FM under an effective investigational new drug, or IND, application. Our therapeutic approach to FM was initially supported by results from a randomized, double-blind, placebo-controlled Phase 2a clinical trial of TNX-102 immediate release capsules, or TNX-102 capsules, which we have also referred to as VLD CBP (Moldofsky et al, J Rheumatol 2011;38:2653-63). This study demonstrated significant decreases in pain and other symptoms in subjects treated with TNX-102 capsules daily between dinner and bedtime for eight weeks. This study also demonstrated that treatment with TNX-102 capsules led to a significant improvement in objective measures of sleep quality, which we believe relates to the mechanism by which CBP leads to improvement of FM symptoms.

Clinical Development Plan

At an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in February 2013, we discussed the design of our clinical program, including the acceptability of the pivotal study design and the proposed registration plan, to support the approval of TNX-102 SL for the management of FM. On the basis of our discussions with the FDA, we believe that positive results from two adequate, well-controlled efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would provide sufficient evidence of efficacy and safety to support FDA approval of TNX-102 SL for the management of FM.

Phase 2b "BESTFIT" Study

In September 2013, we commenced enrollment of our BESTFIT trial, a randomized, double-blind, placebo-controlled Phase 2b clinical trial of TNX-102 SL in FM. We reported preliminary top-line results from the BESTFIT trial in September 2014. In the BESTFIT trial, 205 patients with FM were randomized at 17 U.S. centers to treatment with either TNX-102 SL 2.8 mg or placebo sublingual tablets at bedtime daily for 12 weeks. The primary outcome measure of the BESTFIT trial 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 trial, TNX-102 SL did not achieve statistical significance in the primary outcome measure ($p=0.172$). However, the trial demonstrated that TNX-102 SL 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 the final analysis was 34.0% in the active treatment arm as compared to 20.6% in the control arm. The BESTFIT trial also showed statistically significant improvements with TNX-102 SL 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 improvement with TNX-102 SL 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.

TNX-102 SL was well tolerated in the BESTFIT trial. Among subjects randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 42% of participants on TNX-102 SL vs. 1% on placebo, and bitter taste in 8% on TNX-102 SL compared to none on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Prospective First Phase 3 Study

Following our report of the results of the BESTFIT trial, 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 trial. 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 trial to support the approval of TNX-102 SL for the management of FM. We expect to initiate a randomized, double-blind, placebo-controlled, 12-week Phase 3 trial of TNX-102 SL in 500 patients with FM in the second quarter of 2015. We expect to report top line results from this trial in the second half of 2016.

Long-Term Safety Exposure Study

In December 2013, we commenced Study F203, a 12-month open-label extension study of TNX-102 SL in patients who had completed the BESTFIT trial. The goal of Study F203 is to obtain the prerequisite six- and 12-month safety exposure data to support NDA filing for approval for the management of FM, a chronic indication. We expect to complete Study F203 in August 2015.

Prospective Second Phase 3 Study

We expect to conduct a second randomized, double-blind, placebo-controlled Phase 3 clinical trial of TNX-102 SL to support product registration. We may elect to conduct this trial in Europe to support our plan to seek European Medicines Agency registration for TNX-102 SL in FM.

Prospective Multi-dose Pharmacokinetic Study

Since CBP will be used chronically in TNX-102 SL, we plan to study TNX-102 SL in comparison to IR CBP in a multiple-day dosing (once daily) study. The results of this study will provide information regarding blood levels of CBP resulting from use of the marketed IR tablet and our sublingual TNX-102 SL tablet when taken in a multiple day regimen. We expect the data from this study to serve as a 'bridge', in that it will allow us to use the IR CBP tablet as the reference product in our submission of a Section 505(b)(2) NDA for TNX-102 SL.

Prospective Safety and Tolerability Comparative Study of TNX-102 SL and CBP Products

We plan to conduct a small study designed to evaluate next morning drowsiness and other cognitive measures following the bedtime use of TNX-102 SL and the bedtime use of CBP products. The goal of this study is to determine the potential advantages of TNX-102 SL to CBP products on next morning drowsiness and on other cognitive functions.

Nonclinical

In addition to the clinical studies necessary to support the TNX-102 SL 505(b)(2) NDA filing for the fibromyalgia indication, the FDA has accepted our proposal on the nonclinical studies to support the NDA filing, since the information from the reference product is either unavailable for reference or failed to meet the current regulatory standard. In 2014, we completed dose-ranging studies to identify the doses requested by the FDA for the chronic toxicity studies to improve the existing CBP labeling. In January 2015, we engaged an FDA-certified Good Laboratory Practices laboratory to conduct a six month repeated-dose toxicology study of TNX-102 SL in rats, a nine month repeated-dose toxicology study in dogs and a peri- and post-natal Segment II study required for the NDA filing. These studies will be performed concurrently with our Phase 3 studies and will be completed ahead of the NDA submission. Based on the Flexeril labeling and post-marketing surveillance information, there is no evidence of abuse for CBP. As a result, the FDA has advised we will not have to assess the abuse potential of TNX-102 SL for the NDA submission.

Manufacturing

The TNX-102 SL drug product manufactured for our BESTFIT study was manufactured in a small-scale current Good Manufacturing Practice, or cGMP, facility that is licensed to manufacture clinical trial materials, but not equipped for large-scale commercial production. For Phase 3 trials and for the commercial product, we have engaged a commercial cGMP facility that is capable of manufacturing the registration batches to support the NDA. The product's comparability will be supported by the bioequivalence results from the multiple-dose "bridging" study, if necessary.

Other NDA Requirements

We have submitted a Pediatric Study Plan, or PSP, which contains a partial waiver of the requirement to submit pediatric assessments of TNX-102 SL per Section 505B(a)(4)(A)(i) of the FDCA. Final PSP requirement will be determined at the time of NDA approval.

Based our discussions with the FDA and the FDA formal meeting minutes, we will not have to conduct special populations (geriatric and renal/hepatic impaired), drug-drug interaction or a cardiovascular safety study to support the NDA filing. Due to the well-established safety profile of CBP at much higher doses than we proposed for FM, the FDA requests no risk management plan or medication guide for this product.

Regulatory Strategy

We expect to register TNX-102 SL with the FDA through the provisions of Section 505(b)(2). This regulatory pathway may help to accelerate product development and reduce overall business risk. The 505(b)(2)-based product development plan for TNX-102 SL is designed to leverage the safety data that have been generated by other manufacturers for CBP-containing products and accepted by the FDA in support of their product registrations, in addition to the safety data we generate. TNX-102 SL contains significantly less CBP than other marketed products that contain CBP. We believe that the safety data package from these products and the CBP prescriptions utilization database analyzed by IMS Health Incorporated will provide adequate safety margin to support TNX-102 SL development. At our End-of-Phase 2/Pre-Phase 3 meeting we held with the FDA in February 2013, we discussed the nature and extent of the clinical trials we need to conduct in order to receive regulatory acceptance of our proposed NDA plan for TNX-102 SL for the management of FM.

If NDA approval of TNX-102 SL is granted, in addition to the three-year marketing exclusivity provided by law, we expect this product to be protected by patents that extend through at least 2021, during which time it should not be subject to generic substitution. We plan to continue to support the TNX-102 SL program with new patent applications as we obtain data from the clinical evaluation of our new formulation in healthy human subjects and in FM patients. For example, we have recently filed patent applications on TNX-102 SL which, if issued, would be expected to provide protection from generic substitution until at least 2033.

TNX-102 SL – Post-traumatic Stress Disorder Program

We are developing TNX-102 SL for the management of PTSD under a separate IND allowed by the FDA in June 2014, and we are currently conducting our AtEase trial, a Phase 2 clinical trial of TNX-102 SL in military-related PTSD.

Parallels between Fibromyalgia and Post-traumatic Stress Disorder

The clinical presentations of FM and PTSD share a number of similarities and clinical overlap. For example, in a survey of males with PTSD or major depression, 49% of PTSD patients met the American College of Rheumatology criteria for FM compared to 5% of major depression patients (Amital et al, J Psychosom Res 2006;61:663-669). Conversely, in a different survey of FM patients, 57% of the patients had symptoms associated with PTSD (Cohen et al, Semin Arthritis Rheum 2002;32:38-50).

As with FM, a core feature of PTSD is sleep disturbance. Sleep disturbances are believed to exacerbate daytime symptoms of PTSD, including irritability, poor concentration, and diminished interest in significant activities. The sleep disturbances of PTSD, which include nightmares and night terrors, may be more pronounced than those typically experienced by FM patients.

Development Rationale

Our rationale for developing TNX-102 SL for treatment of PTSD derives from the following:

- Results from our BESTFIT study, which showed that treatment with TNX-102 SL: 1) improves FM symptoms, a disorder having significant overlap with PTSD; and 2) improves sleep quality in FM, which is impaired in PTSD; and

- In research from peer-reviewed scientific publications, we have identified a number of compounds that are antagonists of the serotonin 2A or alpha-1 adrenergic receptors that have been shown to have beneficial effects in treating PTSD. Therefore, it is our belief that TNX-102 SL, a serotonin 2A and alpha-1 adrenergic receptor antagonist, will have a therapeutic effect in treating PTSD.

Clinical Development Plan

In January 2015, we commenced the AtEase trial, a 220-patient, randomized, double-blind, placebo-controlled, 12-week Phase 2 trial of TNX-102 SL in subjects with military-related PTSD. This trial will be conducted at approximately 25 U.S. centers. The AtEase trial is designed to study the efficacy and safety of two doses of TNX-102 SL (2.8 mg and 5.6 mg) administered once daily at bedtime. The primary objective of the AtEase trial is to evaluate the efficacy of TNX-102 SL 2.8 mg as compared to placebo sublingual tablet following eight weeks of treatment using the Clinician-Administered PTSD Scale.

If the results of the AtEase trial are positive, we intend to meet with the FDA to finalize the design of the registration program that would be required to support approval of an NDA for this indication. Based on our communications with the FDA to date, we believe that positive results from two adequate, well-controlled efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would support FDA approval of TNX-102 SL for the management of PTSD. If we achieve our primary outcome measure in the AtEase study, it could qualify as one of the two studies required to support the NDA. We expect that we can use the long-term safety exposure data generated by our clinical development of TNX-102 SL in FM to supplement the long-term safety exposure data required for the PTSD NDA.

Regulatory Strategy

The approvals by the FDA of Paxil and Zoloft for treating PTSD established a regulatory approval pathway for symptom reduction in PTSD. We believe our clinical development program of TNX-102 SL and the long term safety data generated from the TNX-102 SL NDA for FM will result in a differentiated product suitable for chronic use for the treatment of PTSD. We believe that our ongoing and planned clinical trials in PTSD, if successful, will provide sufficient evidence of clinical efficacy and safety to support a 505(b)(2) NDA for TNX-102 SL for the management of PTSD.

We plan to meet with the FDA when we complete the AtEase study to further discuss our development plan for TNX-102 SL for PTSD, especially the proposed design of the pivotal studies. If the results from the AtEase study are positive, we plan to seek a Breakthrough Therapy designation for TNX-102 SL in PTSD. The Breakthrough Therapy designation process is a new and uncertain process, in which the majority of requests for designation have been denied.

Given TNX-102 SL's pharmacological mode of action, its ability to significantly improve sleep quality as demonstrated in the BESTFIT trial, and the lack of Drug Enforcement Agency scheduling of CBP, we believe TNX-102 SL, if approved, has the potential to serve as an important and differentiated new option for the management of PTSD.

TNX-201 – Episodic Tension-Type Headache Program

We are developing TNX-201 for the treatment of ETTH under an IND cleared by the FDA in October 2014. TNX-201 is an oral formulation of (R)-isometheptene mucate, a single isomer of isometheptene mucate, or IMH, which we are developing for episodic tension-type headache. We own all rights to TNX-201 in all geographies, and we bear no obligations to third-parties for any future development or commercialization.

Although currently not approved for any indication, IMH has an extensive history of use as a prescription pharmaceutical in the U.S. as a racemic mixture, which consists of two mirror-image isomers, or IMH enantiomers. Racemic IMH has been marketed as Octin® for conditions including tension and vascular headache. In addition, racemic IMH has been marketed in combination products for the relief of tension and vascular headaches (examples include Midrin®, MigraTen® and Prodrin®). Between 1990 and 1998, Midrin was the second most-widely prescribed headache medication in the U.S. (Gibbs et al, Headache 2003;43:330-335).

Products containing IMH were first commercialized in the U.S. between 1938 and 1962. As introduced in 1938, the FDCA required that new drugs be approved for evidence of safety, with no requirement for evidence of efficacy. In 1962, Congress amended the FDCA to require substantial evidence of efficacy, as well as safety, for a drug to be granted FDA approval, and at that time the FDA introduced the Drug Efficacy Study Implementation program, or DESI, to evaluate the effectiveness of drugs approved between 1938 and 1962. Under the DESI, products containing IMH are currently sanctioned from marketing by the FDA, although certain combination drug products containing IMH remain on the market in the "Unapproved Drug Other" category.

Based on our evaluation studies, we believe that (R)-isometheptene mucate, which we are developing as TNX-201, is primarily responsible for the efficacy associated with racemic IMH in the treatment of headache, and that (S)-isometheptene mucate, the other IMH enantiomer, may be associated with toxic or undesirable pharmacologic effects. As a result, we believe that TNX-201 may possess an improved clinical profile as compared to the unapproved, but previously marketed, racemic IMH for headache indications. According to the FDA's Stereoisomeric Drugs Development Policy, the development of a single enantiomer of a racemic drug is particularly desirable in cases in which one enantiomer has a toxic or undesirable pharmacologic effect and the other does not.

Preclinical studies conducted under our direction have shown that TNX-201 significantly increases the pain threshold in standard animal models of acute pain response. These studies have also shown that TNX-201 strongly and selectively binds to receptors in the CNS known as imidazoline type-1 (I1) receptors, where it acts as a receptor agonist.

In January 2014, we held a pre-IND meeting with the FDA to discuss the regulatory pathway for the development of TNX-201 for the treatment of ETTH. We have completed a comparative Phase 1 single ascending dose safety, tolerability, and pharmacokinetic study of TNX-201 in 45 healthy volunteers, from which we reported top line results in January 2015. The clinical results showed that TNX-201 was well-tolerated at all doses studied (35 mg, 70 mg, and 140 mg), and pharmacokinetic analyses demonstrated dose-proportionality of parameters including area under the curve and maximum concentration. The absence of any appreciable amount of (S)-isometheptene in TNX-201 study samples indicated the lack of conversion of (R)-isometheptene to the other enantiomer, a finding which supports the rationale of developing TNX-201, a single isomer of IMH.

We are preparing to commence a 200-patient Phase 2 study in ETTH in the second quarter of 2015, in which patients will be randomized at approximately 10 U.S. centers to receive TNX-201 140 mg (4 x 35 mg) or placebo capsules. 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. We expect to report top line results from this study in the fourth quarter of 2015. Although the clinical development of TNX-201 can be accelerated based on the available information on racemic IMH, approval of any NDA will be as a new chemical entity pursuant to Section 505(b)(1) of the FDCA. We are developing TNX-201 with the goal of introducing a safe, effective, and non-addictive treatment option for ETTH.

Additional Product Candidates

We also have a pipeline of other 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 abuse and dependence, and we have commenced development work on TNX-301 formulations. In addition, we own rights to intellectual property on two biodefense technologies: one relating to the development of novel smallpox vaccines; and the other to the development of protective agents against radiation exposure. We have begun non-clinical research and development on these programs. The FDA Animal Efficacy Rule provides a mechanism for product licensure when human efficacy studies are not feasible or ethical. As a result, the licensure of these biodefense products in the U.S. may not require human efficacy studies, which we believe will reduce our development costs and risks compared to the development of other NCEs or new biologic candidates.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe that key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, price and reimbursement level. Many of our potential competitors, including many of the organizations named below, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Further, the development of new treatment methods for the conditions we are targeting could render our drugs non-competitive or obsolete.

The markets for medicines to treat FM, PTSD, ETTH and other CNS conditions are well developed and populated with established drugs marketed by large and small pharmaceutical, biotechnology and generic drug companies. Eli Lilly (Cymbalta), Forest Laboratories (Savella), and Pfizer (Lyrica) market FDA approved drugs for FM. Cymbalta lost its U.S. patent exclusivity in December 2013. GlaxoSmithKline (Paxil) and Pfizer (Zoloft) market FDA approved drugs for PTSD. Paxil and Zoloft lost their U.S. patent exclusivities in 2003 and 2006, respectively. Medications that are FDA approved for ETTH include Fiorinal, Fiorinal with Codeine, Fioricet, and their generic equivalents. Non-prescription medications used for ETTH include non-steroidal anti-inflammatory drugs, including ibuprofen and naproxen; acetaminophen; and aspirin.

A number of companies are developing prescription medications for FM, including Allergan, Daiichi Sankyo, Meda, Merck, Pfizer, RiboCor and Theravance. Clinical trials in the U.S. are registered with the FDA and reported on the website *www.clinicaltrials.gov.* Medications that are used off-label for the treatment of FM include gabapentin; anti-depressants, such as amitriptyline, venlafaxine, and trazodone; muscle relaxants, such as cyclobenzaprine; tramadol; opioids; and benzodiazepine, as well as non-benzodiazepine sedative hypnotics.

A number of companies are developing prescription medications for PTSD, including Actavis, Johnson and Johnson, Lundbeck, Marinus Pharmaceuticals, Merck, Otsuka, and Pfizer. Medications that are used off-label for the treatment of PTSD include anti-depressants, such as nefazodone and trazodone; the antihistamine cyproheptadine; and certain atypical antipsychotics, such as olanzapine and risperidone.

A number of companies are developing prescription medications for ETTH, including Bayer, GlaxoSmithKline, and Pfizer. Medications that are used off-label for the treatment of ETTH include simple and combination analgesics, which may include opioids, anti-depressants, such as amitriptyline, and drugs approved for the treatment of migraine, such as sumatriptan.

Intellectual Property

We believe that we have an extensive patent portfolio and substantial know-how relating to TNX-102 SL and our other product candidates. Our patent portfolio, described more fully below, includes claims directed to TNX-102 SL compositions and methods of use. As of February 23, 2015, we are either the owner of record of or own the contractual right to five issued U.S. patents and 10 issued non-U.S. patents covering 26 jurisdictions. We are actively pursuing an additional 16 U.S. patent applications, of which six are provisional and 10 are non-provisional, three international patent applications, and 36 non-U.S./non-international patent applications.

We strive to protect the proprietary technology that we believe is important to our business, including our proprietary technology platform, our product candidates, and our processes. We seek patent protection in the United States and internationally for our products, their methods of use and processes of manufacture, and any other technology to which we have rights, where available and when appropriate. We also rely on trade secrets that may be important to the development of our business.

Our success will depend on 1) the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, 2) the validity and enforceability of our patents, 3) the continued confidentiality of our trade secrets, and 4) our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be certain that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors — Risks Relating to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the first non-provisional priority application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or PTO, in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the statutory 20-year term of the patent for the approved product if the active ingredient has not been previously approved in the U.S. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and some other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a new drug application, or NDA, we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

The patent portfolios for our proprietary technology platform and our three most advanced product candidates as of February 23, 2015 are summarized below.

TNX-102 SL

Our patent portfolio for TNX-102 SL includes patent applications directed to pharmaceutical compositions containing CBP, CBP formulations, and methods for treating FM and other CNS conditions utilizing CBP. The portfolio includes issued U.S. patents, such as U.S. Patent Nos. 6,541,523, 6,395,788 and 6,358,944, and corresponding issued foreign counterpart patents or applications. U.S. Patent Nos. 6,541,523, 6,395,788 and 6,358,944 are expected to expire in 2020, unless they are eligible for patent term extensions on the basis of FDA approvals.

The unique pharmacokinetic profile of TNX-102 SL was discovered by Tonix and its development partners and is termed the "PK Technology." The patent portfolio for TNX-102 SL relating to the PK Technology includes patent applications directed to pharmaceutical compositions containing CBP, CBP formulations, and methods for treating FM and other CNS conditions utilizing CBP. The PK Technology patent portfolio includes U.S. Patent Application No. 13/918,692. If U.S. and non-U.S. patents claiming priority from those applications issue, those patents would expire in 2033, excluding any patent term adjustments or extensions.

Certain eutectic compositions were discovered by development partners and are termed the "Eutectic Technology." The patent portfolio for TNX-102 SL relating to the Eutectic Technology includes patent applications directed to eutectic compositions containing CBP, eutectic CBP formulations, methods for treating FM and other CNS conditions utilizing eutectic CBP compositions, and methods of manufacturing eutectic CBP compositions. The Eutectic Technology patent portfolio includes U.S. patent applications, such as U.S. Patent Application No. 14/214,433. If U.S. and non-U.S. patents claiming priority from those applications issue, those patents would expire in 2034, excluding any patent term adjustments or extensions.

TNX-201 — Isometheptene Isomers

Our patent portfolio for TNX-201, relating to isometheptene isomers and termed the "Isometheptene Technology", includes patent applications directed to a purified isomer of isometheptene, pharmaceutical compositions containing isometheptene, isometheptene formulations, methods for modulating headache and other CNS conditions and treating CNS conditions utilizing isometheptene isomers, and methods of manufacturing isometheptene isomers. The Isometheptene Technology patent portfolio includes U.S. Patent Application No. 14/158,735 as well as U.S. Provisional Patent Application No 61/953,715. If U.S. and non-U.S. patents claiming priority from those applications issue, those patents would expire in 2034, excluding any patent term adjustments or extensions.

TNX-301 — Alcoholism Treatment

Our patent portfolio for disulfiram and selegiline combinations includes patents and patent applications. It includes claims directed to disulfiram and selegiline, pharmaceutical compositions containing disulfiram and selegiline, disulfiram and selegiline formulations, methods of treating an alcohol use disorder, and methods of modulating alcohol abuse and dependence. It includes issued U.S. Patent Nos. 8,093,300 and 8,481,599. The patent expiring last is expected to expire in 2024, excluding any patent term extensions.

Biodefense Technologies

In March 2014, we acquired the rights to develop two additional biodefense technologies: a new drug candidate that potentially protects humans from certain effects of radiation and a new vaccine candidate against smallpox. With respect to the radioprotection drug candidate, we acquired U.S. non-provisional Patent Application No. 14,203,733 and related intellectual property rights. The radio- and chemo-protective technology relates to proprietary forms of a small molecular pharmaceutical agent, which is believed to protect against ionizing radiation after oral administration. With respect to the smallpox vaccine candidate, we acquired U.S. non-provisional Patent Application No. 14,207,727 and related intellectual property rights. The smallpox vaccine technology relates to proprietary forms of live vaccinia vaccines which may be safer than ACAM2000, the only currently available replication competent, live vaccinia vaccine to protect against smallpox disease. We believe that these technologies, after further development, may be of interest to biodefense agencies in the U.S. and other countries.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary technology platform are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to rights in related or resulting inventions and know-how.

Issued Patents

Our current patents owned are as follows:

Very-Low Dose Cyclobenzaprine

Patent No.	Title	Country / Region	Expiration Date
6,541,523	Methods for Treating or Preventing Fibromyalgia Using Very Low Doses of Cyclobenzaprine	U.S.A	Aug. 11, 2020
6,395,788	Methods and Compositions for Treating or Preventing Sleep Disturbances and Associated Illnesses Using Very Low Doses of Cyclobenzaprine	U.S.A.	Aug. 11, 2020
6,358,944	Method and Compositions for Treating Generalized Anxiety Disorder	U.S.A.	Aug. 23, 2020
299369	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Austria	Aug. 11, 2020
1202722	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Belgium, France, Ireland, Luxembourg, Monaco, Portugal, Switzerland, U.K.	Aug. 11, 2020
60021266.1	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Germany	Aug. 11, 2020
2245944	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Spain	Aug. 11, 2020
1047691	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Hong Kong	Aug. 11, 2020
516749	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	New Zealand	Aug. 11, 2020

Alcoholism Treatment

Patent No.	Title	Country / Region	Expiration Date
8,093,300	Compositions and Methods for Increasing Compliance with Therapies Using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism	U.S.A.	May 23, 2024
8,481,599	Compositions and Methods for increasing compliance with therapies using aldehyde dehydrogenase inhibitors and treating alcoholism	U.S.A.	Nov. 4, 2022
2002354017	Compositions and Methods for Increasing Compliance with Therapies Using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism	Australia	Nov. 4, 2022
2463987	Compositions and Methods for Increasing Compliance with Therapies Using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism	Canada	Nov. 4, 2022
1441708	Compositions and Methods for Increasing Compliance with Therapies Using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism	Austria, Belgium, Denmark, France, Germany, Luxembourg, Monaco, Portugal, Switzerland, U.K.	Nov. 4, 2022
532583	Compositions and Methods for Increasing Compliance with Therapies Using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism	New Zealand	Nov. 4, 2022

Pending Patent Applications

Our current pending patent applications are as follows:

Sublingual Cyclobenzaprine/Amitriptyline

Application No.	Title	Country / Region
13/918,692	Compositions and Methods for Transmucosal Absorption	U.S.A.
P20130102101	Compositions and Methods for Transmucosal Absorption	Argentina
2013274003	Compositions and Methods for Transmucosal Absorption	Australia
BR112014031394-6	Compositions and Methods for Transmucosal Absorption	Brazil
Not yet assigned	Compositions and Methods for Transmucosal Absorption	Canada
Not yet assigned	Compositions and Methods for Transmucosal Absorption	China
13804115.7	Compositions and Methods for Transmucosal Absorption	European Patent Office
2013/24661	Compositions and Methods for Transmucosal Absorption	Gulf Cooperation Council
P-00 2015 00202	Compositions and Methods for Transmucosal Absorption	Indonesia
236268	Compositions and Methods for Transmucosal Absorption	Israel
139/KOLNP/2015	Compositions and Methods for Transmucosal Absorption	India
Not yet assigned	Compositions and Methods for Transmucosal Absorption	Japan
MX/a/2014/015436	Compositions and Methods for Transmucosal Absorption	Mexico
PI 2014703784	Compositions and Methods for Transmucosal Absorption	Malaysia
631144	Compositions and Methods for Transmucosal Absorption	New Zealand
11201408318R	Compositions and Methods for Transmucosal Absorption	Singapore
102121267	Compositions and Methods for Transmucosal Absorption	Taiwan
2013-000737	Compositions and Methods for Transmucosal Absorption	Venezuela
Not yet assigned	Compositions and Methods for Transmucosal Absorption	South Africa

Sublingual Doxepin/Imipramine

Application No.	Title	Country / Region
PCT/US14/29688	Compositions and Methods for Transmucosal Absorption	PCT

PTSD Treatment

Application No.	Title	Country / Region
12/948,828	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	U.S.A.
10831895.7	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	European Patent Office
13103530.6	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	Hong Kong

Sleep Disorder Treatment

Application No.	Title	Country / Region
14/477,981	Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine	U.S.A.

Depression Treatment

Application No.	Title	Country / Region
13/412,571	Methods and Compositions for Treating Depression Using Cyclobenzaprine	U.S.A.
2012225548	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia
2,829,200	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Canada
12755254.5	Methods and Compositions for Treating Depression Using Cyclobenzaprine	European Patent Office
2013-557811	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Japan
614725	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand

Cyclobenzaprine/Amitriptyline Eutectics

Application No.	Title	Country / Region
14/214,433	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
PCT/US14/29872	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	PCT
103109816	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan
2014-000391	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Venezuela
62/052,238	Eutectic Formulations of Cyclobenzaprine Hydrochloride	U.S.A.
631152	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand

Isometheptene Isomer

Application No.	Title	Country / Region
14/158,735	Isometheptene Isomer	U.S.A.
PCT/US14/12142	Isometheptene Isomer	PCT
61/953,715	Eutectic Isometheptene Mucate	U.S.A.
62/011723	Novel Isometheptene Compositions and Uses	U.S.A.
62/034,571	(R)-IMH Synthesis	U.S.A.
62/095,679	Imidazoline Receptor Type 1 Ligands for use as Analgesics	U.S.A.
62/095,684	Imidazoline Receptor Type 1 Ligands for use as Analgesics	U.S.A

Cocaine Addiction Treatment

Application No.	Title	Country / Region
13/820,338	Treatment for Cocaine Addiction	U.S.A.
2809966	Treatment for Cocaine Addiction	Canada
2011314358	Treatment for Cocaine Addiction	Australia
11832859.0	Treatment for Cocaine Addiction	European Patent Office
2013-527062	Treatment for Cocaine Addiction	Japan
10-2013-7008187	Treatment for Cocaine Addiction	Republic of Korea
13114135.2	Treatment for Cocaine Addiction	Hong Kong

Neurocognitive Dysfunction Treatment

Application No.	Title	Country / Region
12/151,200	Method for Treating Neurocognitive Dysfunction	U.S.A.
09743321.2	Method for Treating Neurodegenerative Dysfunction	European Patent Office
2723688	Method for Treating Neurodegenerative Dysfunction	Canada

Novel Smallpox Vaccines

Application No.	Title	Country / Region
14207727	Novel Smallpox Vaccines	U.S.A.

Radio and Chemo Protective Agents

Application No.	Title	Country / Region
14203733	Radio and Chemo Protective Agents	U.S.A.

Trademarks and Service Marks

We seek trademark and service mark protection in the United States and outside of the United States where available and when appropriate. On December 16, 2014, we received U.S. registration number 4,656,463 as a service mark for "Tonix Pharmaceuticals" in the United States.

Research and Development

We have eight employees dedicated to research and development. We anticipate that our research and development expenditures will increase several fold as we advance TNX-102 SL into late-stage clinical development and advance other candidates in our pipeline. We need to raise additional capital to fund our development plans and there is no certainty that we will be successful in continuing to attract new investments. Our research and development operations are located in New York, NY and San Jose, CA. We have used, and expect to continue to use, third parties to conduct our preclinical and clinical studies.

Manufacturing

We have contracted with third-party cGMP-compliant contract manufacturing organizations, or CMOs, for the manufacture of TNX-102 SL and TNX-201 drug substances and drug products for investigational purposes, including nonclinical and clinical testing. For TNX-102 SL, we have engaged a cGMP facility for manufacturing of to-be-marketed product for Phase 3 clinical and commercial.

All of our compounds are small molecules, synthesized using industry standard processes, and our drug products are formulated using commercially available pharmaceutical grade excipients.

Government Regulation

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the FDCA and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some nonclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.

Clinical Trials

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified medical investigators according to approved protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety. Each protocol for a U.S. study is submitted to the FDA as part of the IND.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap, or be combined.

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are generally conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks. Phase 2 clinical trials, in particular Phase 2b trials, can be undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites.
- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Clinical testing must satisfy extensive FDA regulations. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted for serious and unexpected adverse events. Success in early-stage clinical trials does not assure success in later-stage clinical trials. The FDA, an IRB or we may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

New Drug Applications

Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality product within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market.

Section 505(b) NDAs

There are two types of NDAs: the Section 505(b)(1) NDA, or full NDA, and the Section 505(b)(2) NDA. We intend to file Section 505(b)(2) NDAs for TNX-102 SL for FM and PTSD, and for certain other products, that might, if accepted by the FDA, save time and expense in the development and testing of our product candidates. Although the clinical development of TNX-201 can be accelerated due to existing marketing experience, we expect to file a Section 505(b)(1) NDA for TNX-201 and for certain other products. A full NDA is submitted under Section 505(b)(1) of the FDCA, and must contain full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug. A Section 505(b)(2) NDA may be submitted for a drug for which one or more of the investigations relied upon by the applicant was not conducted by or for the applicant and for which the applicant has no right of reference from the person by or for whom the investigations were conducted. A Section 505(b)(2) NDA may be submitted based in whole or in part on published literature or on the FDA's finding of safety and efficacy of one or more previously approved drugs, which are known as reference drugs. Thus, the filing of a Section 505(b)(2) NDA may result in approval of a drug based on fewer clinical or nonclinical studies than would be required under a full NDA. The number and size of studies that need to be conducted by the sponsor depends on the amount and quality of data pertaining to the reference drug that are publicly available, and on the similarity of and differences between the applicant's drug and the reference drug. In some cases, extensive, time-consuming, and costly clinical and nonclinical studies may still be required for approval of a Section 505(b)(2) NDA.

Our drug approval strategy for our new formulations of approved chemical entities is to submit Section 505(b)(2) NDAs to the FDA. As such, we plan to submit NDAs under Section 505(b)(2) for TNX-102 SL for FM and PTSD. The FDA may not agree that this product candidate is approvable for FM or PTSD as Section 505(b)(2) NDAs. If the FDA determines that Section 505(b)(2) NDAs are not appropriate and that full NDAs are required for TNX-102 SL, the time and financial resources required to obtain FDA approval for TNX-102 SL could substantially and materially increase, and TNX-102 SL might be less likely to be approved. If the FDA requires full NDAs for TNX-102 SL, or requires more extensive testing and development for some other reason, our ability to compete with alternative products that arrive on the market more quickly than our product candidates would be adversely impacted. 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 our anticipated TNX-102 SL 505(b)(2) NDA, and we may be required to follow the requirements of Section 505(b)(1).

Patent Protections

An applicant submitting a Section 505(b)(2) NDA must certify to the FDA with respect to the patent status of the reference drug upon which the applicant relies in support of approval of its drug. With respect to every patent listed in the FDA's Orange Book, which is the FDA's list of approved drug products, as claiming the reference drug or an approved method of use of the reference drug, the Section 505(b)(2) applicant must certify that: (1) there is no patent information listed by the FDA for the reference drug; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date; (4) the listed patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the product in the Section 505(b)(2) NDA; or (5) if the patent is a use patent, that the applicant does not seek approval for a use claimed by the patent. If the applicant files a certification to the effect of clause (1), (2) or (5), FDA approval of the Section 505(b)(2) NDA may be made effective immediately upon successful FDA review of the application, in the absence of marketing exclusivity delays, which are discussed below. If the applicant files a certification to the effect of clause (3), the Section 505(b)(2) NDA approval may not be made effective until the expiration of the relevant patent and the expiration of any marketing exclusivity delays.

If the Section 505(b)(2) NDA applicant provides a certification to the effect of clause (4), referred to as a paragraph IV certification, the applicant also must send notice of the certification to the patent owner and the holder of the NDA for the reference drug. The filing of a patent infringement lawsuit within 45 days of the receipt of the notification may prevent the FDA from approving the Section 505(b)(2) NDA for 30 months from the date of the receipt of the notification unless the court determines that a longer or shorter period is appropriate because either party to the action failed to reasonably cooperate in expediting the action. However, the FDA may approve the Section 505(b)(2) NDA before the 30 months have expired if a court decides that the patent is invalid, unenforceable, or not infringed, or if a court enters a settlement order or consent decree stating the patent is invalid or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged in court, the FDA may be required to change its interpretation of Section 505(b)(2) which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit. The pharmaceutical industry is highly competitive, and it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Moreover, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of Section 505(b)(2) NDAs, thereby delaying a Section 505(b)(2) product from entering the market. The FDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for an NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity prohibits the submission of a Section 505(b)(2) NDA for any drug product containing the active ingredient during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years, but if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the Section 505(b)(2) NDA may automatically be stayed until 7½ years after the NCE approval date. The FDCA also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application. Five-year and three-year exclusivity will not delay the submission or approval of another full NDA; however, as discussed above, an applicant submitting a full NDA under Section 505(b)(1) would be required to conduct or obtain a right of reference to all of the preclinical and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other types of exclusivity in the United States include orphan drug exclusivity and pediatric exclusivity. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or a Section 505(b)(2) NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Section 505(b)(2) NDAs are similar to full NDAs filed under Section 505(b)(1) in that they are entitled to any of these forms of exclusivity if they meet the qualifying criteria. They also are entitled to the patent protections described above, based on patents that are listed in the FDA's Orange Book in the same manner as patents claiming drugs and uses approved for NDAs submitted as full NDAs.

Breakthrough Therapy Designation

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, was signed. FDASIA Section 902 provides for a new drug designation –Breakthrough Therapy. A Breakthrough Therapy is a drug:

- intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition; and
- preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

If a drug is designated as Breakthrough Therapy, the FDA will expedite the development and review of such drug. In the event that our AtEase study of TNX-102 SL in PTSD is successful, we will request Breakthrough Therapy designation for TNX-102 SL. The Breakthrough Therapy designation process is relatively new, and the majority of requests for designation have been denied. We cannot predict the likelihood of success in seeking Breakthrough Therapy designation.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution and disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Food and Drug Administration Amendments Act of 2007

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, became law. This legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, the new law significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

The FDA has not yet implemented many of the provisions of the FDAAA, so we cannot predict the impact of the new legislation on the pharmaceutical industry or our business. However, the requirements and changes imposed by the FDAAA may make it more difficult, and more costly, to obtain and maintain approval for new pharmaceutical products, or to produce, market and distribute existing products. In addition, the FDA's regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our products. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

Employees

As of February 27, 2015, we had 16 full-time employees, of whom seven hold M.D., PharmD. and/or Ph.D. degrees. We have eight employees dedicated to research and development. Our research and development operations are located in New York, NY and San Jose, CA. We have used, and expect to continue to use, third parties to conduct our preclinical and clinical studies as well as part-time employees. None of our employees are represented by a collective bargaining agreement, and we believe that our relations with our employees are good.

ITEM 1A - RISK FACTORS

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 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, pre-clinical 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 studies 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 annual 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 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 TNX-102 SL 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 CMOs to supply or manufacture our products;
- our dependence on third party contract research organizations, or CROs, to conduct our clinical trials and non-clinical 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 have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

To date, we have no approved product on the market and have generated no product revenues. We have funded our operations primarily from sales of our securities. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

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: TNX-102 SL for the management of FM and PTSD, 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 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.

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 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 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 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 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 twelve 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 studies 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 face intense competition in the markets targeted by our product candidates. Many of our competitors have substantially greater resources than we do, and we expect that all of our product candidates under development will face intense competition from existing or future drugs.

We expect that all of our product candidates under development, if approved, will face intense competition from existing and future drugs marketed by large companies. These competitors may successfully market products that compete with our products, successfully identify drug candidates or develop products earlier than we do, or develop products that are more effective, have fewer side effects or cost less than our products.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years.

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

If we fail to protect our intellectual property rights, our ability to pursue the development of our technologies and products would be negatively affected.

Our success will depend in part on our ability to obtain patents and maintain adequate protection of our technologies and products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies to produce and market drugs in direct competition with us and erode our competitive advantage. Some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the United States. Many companies have had difficulty protecting their proprietary rights in these foreign countries. We may not be able to prevent misappropriation of our proprietary rights.

We have received, and are currently seeking, patent protection for numerous compounds and methods of treating diseases. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following: patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage; our competitors, many of which have substantially greater resources than us and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets; there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

Moreover, any patents issued to us may not provide us with meaningful protection, or others may challenge, circumvent or narrow our patents. Third parties may also independently develop products similar to our products, duplicate our unpatented products or design around any patents on products we develop. Additionally, extensive time is required for development, testing and regulatory review of a potential product. While extensions of patent term due to regulatory delays may be available, it is possible that, before any of our product candidates can be commercialized, any related patent, even with an extension, may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent.

In addition, the United States Patent and Trademark Office (the "PTO") and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

Our success depends on our patents, patent applications that may be licensed exclusively to us and other patents to which we may obtain assignment or licenses. We may not be aware, however, of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our product candidates to us or our licensors, or by covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our product candidates.

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technology, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access to our trade secrets, which could impair any competitive advantage we may have.

Patent protection and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

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 additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO 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. 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 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 U.S. Patent and Trademark Office 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 we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

If preclinical 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 testing or clinical trials involving our product candidates. We have less control over the timing and other aspects of these preclinical testing or clinical trials than if we performed the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our preclinical testing or clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in preclinical and clinical testing 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
- 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 rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that our clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's current good clinical practices requirements, or cGCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with cGCPs. In addition, our clinical trials, including our planned Phase 3 trial of TNX-102 SL in FM, will require a sufficiently large number of test subjects to evaluate the effectiveness and safety of TNX-102 SL. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical trials. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also rely on other third parties to store and distribute drug products for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

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

If our planned Phase 3 trial of TNX-102 SL in FM is successful, we then expect to conduct a second Phase 3 confirmatory study in support of product registration. As these trials are intended to provide evidence to support marketing approval by the FDA, they are considered pivotal 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 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 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 TNX-102 SL or any of our other product candidates cause serious adverse events or undesirable side effects:

- 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 labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- 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;
- 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 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 TNX-102 SL 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 TNX-102 SL for FM and 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 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 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 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 studies 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.

Our executive officers and other key personnel are critical to our business, and our future success depends on our ability to retain them.

Our success depends to a significant extent upon the continued services of Dr. Seth Lederman, our President and Chief Executive Officer. Dr. Lederman has overseen Tonix Pharmaceuticals, Inc., a wholly-owned subsidiary, since inception and provides leadership for our growth and operations strategy as well as being an inventor on many of our patents. Loss of the services of Dr. Lederman would have a material adverse effect on our growth, revenues, and prospective business. The loss of any of our key personnel, or the inability to attract and retain qualified personnel, may significantly delay or prevent the achievement of our research, development or business objectives and could materially adversely affect our business, financial condition and results of operations.

Any employment agreement we enter into will not ensure the retention of the employee who is a party to the agreement. In addition, we have only limited ability to prevent former employees from competing with us. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire, and retain additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly.

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 and non-clinical 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 TNX-102 SL. 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 pre-clinical, clinical, and commercial purposes. Although we are in discussions with other manufacturers we have identified as potential alternative CMOs of TNX-102 SL, 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 clinical studies. 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.

Failure by our third-party manufacturers to comply with the regulatory guidelines set forth by the FDA with respect to our product candidates could delay or prevent the completion of clinical trials, the approval of any product candidates or the commercialization of our products.

Such third-party manufacturers must be inspected by FDA for cGMP compliance before they can produce commercial product. We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Manufacturers are obligated to operate in accordance with FDA-mandated requirements. A failure of any of our third-party manufacturers to establish and follow cGMP requirements and to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials, may delay or prevent filing or approval of marketing applications for our products, and may cause delays or interruptions in the availability of our products for commercial distribution following FDA approval. This could result in higher costs to us or deprive us of potential product revenues.

Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection may significantly delay FDA approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations may be materially harmed.

Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the Drug Enforcement Agency and corresponding state and foreign agencies to ensure strict compliance with cGMP requirements and other requirements under Federal drug laws, other government regulations and corresponding foreign standards. If we or our third-party manufacturers fail to comply with applicable regulations, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure by the government to grant marketing approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions.

Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of drug candidates is heavily dependent on our entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties. Our current strategy assumes that we will successfully establish these collaborations, or similar relationships; however, there can be no assurance that we will be successful establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from such collaborations, or that any collaborator will not compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and our business. If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

Our product candidates are novel and still in development.

We are a clinical-stage pharmaceutical company focused on the development of drug product candidates, all of which are still in development. Our drug development methods may not lead to commercially viable drugs for any of several reasons. For example, we may fail to identify appropriate targets or compounds, our drug candidates may fail to be safe and effective in clinical trials, or we may have inadequate financial or other resources to pursue development efforts for our drug candidates. Our drug candidates will require significant additional development, clinical trials, regulatory clearances and additional investment by us or our collaborators before they can be commercialized.

Successful development of our products is uncertain.

Our development of current and future product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including: delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing; failure to receive regulatory approvals; emergence of superior or equivalent products; inability to manufacture on its own, or through any others, product candidates on a commercial scale; and failure to achieve market acceptance.

Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially successfully, our business, financial condition, and results of operations may be materially harmed.

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 products 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 clinical testing, 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 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 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 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.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payors; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any pharmaceutical product that we develop will depend on a number of factors, including:

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects (including drowsiness and dry mouth), as compared to alternative products or treatment methods;
- the timing of market entry as compared to competitive products;
- the rate of adoption of our products by doctors and nurses;
- product labeling or product insert required by the FDA for each of our products;

- reimbursement policies of government and third-party payors;
- effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and
- unfavorable publicity concerning our products or any similar products.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

If we fail to establish marketing, sales and distribution capabilities, or fail to enter into arrangements with third parties, we will not be able to create a market for our product candidates.

Our strategy with our product candidates is to control, directly or through contracted third parties, all or most aspects of the product development process, including marketing, sales and distribution. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidates that receive regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution channels, or enter into arrangements with third parties, we will experience delays in product sales and incur increased costs.

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the government or third-party payors, the market for our products will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Recent proposals to change the health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices.

Our business strategy might involve out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will be able to successfully establish marketing, sales, or distribution relationships; that such relationships, if established, will be successful; or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties. If we are unable to establish such third-party sales and marketing relationships, or choose not to do so, we will have to establish and rely on our own in-house capabilities.

We, as a company, have no experience in marketing or selling pharmaceutical products and currently have no sales, marketing, or distribution infrastructure. To market any of our products directly, we would need to develop a marketing, sales, and distribution force that both has technical expertise and the ability to support a distribution capability. The establishment of a marketing, sales, and distribution capability would significantly increase our costs, possibly requiring substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we may not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities. If we are unable to, or choose not to establish these capabilities, or if the capabilities we establish are not sufficient to meet our needs, we will be required to establish collaborative marketing, sales, or distribution relationships with third parties.

In the event that we are successful in bringing any products to market, our revenues may be adversely affected if we fail to obtain acceptable prices or adequate reimbursement for our products from third-party payors.

Our ability to commercialize pharmaceutical products successfully may depend in part on the availability of reimbursement for our products from:

- government and health administration authorities;
- private health insurers; and
- other third party payors, including Medicare.

We cannot predict the availability of reimbursement for health care products to be approved in the future. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for any of our products.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payors do not provide adequate coverage and reimbursement for any prescription product we bring to market, doctors may not prescribe them or patients may ask to have their physicians prescribe competing drugs with more favorable reimbursement. In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. In addition, we expect that increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we receive for any products in the future. Further, cost control initiatives could impair our ability to commercialize our products and our ability to earn revenues from this commercialization.

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 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.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' drugs harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. While we currently carry clinical trial insurance and product liability insurance, we cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold now or in the future may not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our drug candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could cause our stock price to fall.

We use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

Our research and development processes and/or those of our third party contractors may involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste products, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations.

Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks.

If we enter into collaborations with third parties, they might also work with hazardous materials in connection with our collaborations. We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We carry insurance for most categories of risk that our business may encounter, however, we may not have adequate levels of coverage. We currently maintain general liability, clinical trial, key man, property, workers' compensation, products liability and directors' and officers' insurance, along with an umbrella policy, which collectively costs approximately $200,000 per annum. We cannot provide any assurances that we will be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

If we retain collaborative partners and our partners do not satisfy their obligations, we will be unable to develop our partnered product candidates.

In the event we enter into any collaborative agreements, we may not have day-to-day control over the activities of our collaborative partners with respect to any of these product candidates. Any collaborative partner may not fulfill its obligations under these agreements. If a collaborative partner fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the products covered by that agreement or enter into alternative arrangements with a third party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of the agreement. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements will be dependent on the efforts of our collaborative partner. We could also become involved in disputes with a collaborative partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our collaborators' commitment to us and reduce the resources they devote to developing and commercializing our products. Conflicts or disputes with our collaborators, and competition from them, could harm our relationships with our other collaborators, restrict our ability to enter future collaboration agreements and delay the research, development or commercialization of our product candidates. If any collaborative partner terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing or commercializing these product candidates would be materially and adversely affected. We may not be able to enter into collaborative agreements with partners on terms favorable to us, or at all. Our inability to enter into collaborative arrangements with collaborative partners, or our failure to maintain such arrangements, would limit the number of product candidates that we could develop and ultimately, decrease our sources of any future revenues.

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 February 2015, we and our directors and officers have entered into lock-up agreements for 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.

The market price for our common stock may be volatile, and your investment in our common stock could decline in value.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or disapproval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical trials;
- developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;
- developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization;
- announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;
- public concerns as to the safety or efficacy of our product candidates or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- developments involving corporate collaborators, if any;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

We do not anticipate paying dividends on our common stock and, accordingly, shareholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline.

Our quarterly operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of the research, development and regulatory pathways of our product candidates, which could cause our operating results to fluctuate.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our articles of incorporation give our board of directors the right to create new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be utilized as a method of discouraging, delaying or preventing a change of control. The possible impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to issue any shares of preferred stock or to create a series of preferred stock, we may issue such shares in the future.

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. As a result of our public float at June 30, 2014, effective January 1, 2015, we transitioned from a smaller reporting company to an accelerated filer. As a result, for the first time, the independent registered public accounting firm auditing our financial statements attested to and opined on the effectiveness of our internal controls over financial reporting in their report included in this 10-K filing for the year ended December 31, 2014.

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 February 24, 2015, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 30.0% 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.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

ITEM 1B – UNRESOLVED STAFF COMMENTS

There are no unresolved staff comments at December 31, 2014.

ITEM 2 – PROPERTIES

We maintain our principal office at 509 Madison Avenue, Suite 306, New York, New York 10022. Our telephone number at that office is (212) 980-9155 and our fax number is (212) 923-5700. On February 11, 2014, 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. Including the additional premises, the total square footage of our principal office space is approximately 4,800.

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.

Future minimum lease payments under these two agreements are as follows:

Year Ending December 31,	
2015	$ 420,120
2016	445,890
2017	459,295
2018	442,024
2019	98,758
	$ 1,866,087

Additionally, we rent a small office in Ireland on a month-to-month basis.

We believe that our existing facilities are suitable and adequate to meet our current business requirements. We maintain websites at www.tonixpharma.com and www.krele.com and the information contained on those websites is not deemed to be a part of this annual report.

ITEM 3 - LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5 - MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Price Range of Common Stock

Our common stock has been listed on The NASDAQ Global Market under the symbol "TNXP" since August 11, 2014. Previous to that date, our common stock was listed on The NASDAQ Capital Market under the symbol "TNXP." Prior to August 9, 2013, our common stock was traded on the OTCQB under the symbol "TNXP." The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported by The NASDAQ Stock Market.

	Fiscal Year 2013	
	High	Low
First Quarter	$ 14.60	$ 4.80
Second Quarter	$ 15.00	$ 2.25
Third Quarter	$ 7.99	$ 3.00
Fourth Quarter	$ 11.35	$ 3.60

	Fiscal Year 2014	
	High	Low
First Quarter	$ 21.00	$ 9.15
Second Quarter	$ 14.43	$ 8.14
Third Quarter	$ 15.21	$ 5.85
Fourth Quarter	$ 8.14	$ 5.33

On February 24, 2015, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was $6.10 per share. On February 24, 2015, there were 237 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never paid any cash dividends on our capital stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of the Board and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the Board deems relevant.

Equity Compensation Information

The following table summarizes information about our equity compensation plans as of December 31, 2014.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders	1,226,800	12.40	1,123,200
Equity compensation plans not approved by stockholders	—	—	—
Total	1,226,800	12.40	1,123,200

Recent Sales of Unregistered Securities

On October 1, 2014, we issued 37,647 shares of common stock to one investor upon the exercise of Warrants for proceeds of $160,000. The shares were issued pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

On December 17, 2014, we issued 3,530 shares of common stock to our Chief Financial Officer upon the exercise of Warrants for proceeds of $15,003. The shares were issued pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

On December 18, 2014, we issued 30,000 shares of common stock to one of our Directors upon the exercise of Warrants for proceeds of $127,500. The shares were issued pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered securities during the period covered by this Annual Report.

ITEM 6 – SELECTED FINANCIAL DATA

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

ITEM 7 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission. Important factors known to us could cause actual results to differ materially from those in forward-looking statements. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes in the future operating results over time. We believe that its assumptions are based upon reasonable data derived from and known about our business and operations and the business and operations of the Company. No assurances are made that actual results of operations or the results of our future activities will not differ materially from its assumptions. Factors that could cause differences include, but are not limited to, expected market demand for the Company's services, fluctuations in pricing for materials, and competition.

Business Overview

We are a clinical-stage pharmaceutical company dedicated to the development of novel prescription products for common yet challenging medical disorders. Our clinical-stage product candidates, TNX-102 SL and TNX-201, are directed toward conditions affecting the CNS. In the second quarter of 2015, we expect to initiate a Phase 3 clinical trial of our most advanced candidate, TNX-102 SL, for the treatment of FM. We are also developing TNX-102 SL as a potential treatment for PTSD, and we commenced a Phase 2 trial for this indication in January 2015. We expect to begin a Phase 2 trial of TNX-201 in ETTH in the second quarter of 2015. Our pipeline includes a preclinical program for the treatment of alcohol abuse and dependence as well as two preclinical biodefense programs (protection from smallpox virus and from radiation injury). We hold worldwide development and commercialization rights to all of our candidates.

Our therapeutic strategy in FM is supported by results from the randomized, double-blind, placebo-controlled Phase 2b BESTFIT trial of TNX-102 SL in FM. Although the BESTFIT trial demonstrated only a positive trend and did not achieve statistical significance for TNX-102 SL in the primary efficacy analysis of change in mean pain intensity at week 12, it demonstrated statistical significance ($p<0.05$) in a 30% responder analysis of the primary pain data, a declared secondary endpoint 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 BESTFIT trial also showed statistically significant improvements with TNX-102 SL in the declared secondary analyses of the Patient Global Impression of Change ($p<0.05$) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R ($p<0.05$). In addition, the study showed statistically significant improvement with TNX-102 SL on measures of sleep quality as well as on several FIQ-R items. TNX-102 SL was well tolerated in the BESTFIT trial, and the most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 42% of participants on TNX-102 SL vs. 1% on placebo, and bitter taste in 8% on TNX-102 SL compared to none on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL 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. We are conducting a 12-month open-label extension study of TNX-102 SL, into which patients who completed the BESTFIT study were eligible to enroll.

On the basis of our discussions with the FDA, we believe that positive results from two adequate, well-controlled efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would provide sufficient evidence of efficacy and safety to support FDA approval of TNX-102 SL for the management of FM. Following the BESTFIT study, we received written guidance from the FDA which 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 TNX-102 SL for the management of FM. We expect to initiate a randomized, double-blind, placebo-controlled, 12-week Phase 3 trial of TNX-102 SL in 500 patients with FM in the second quarter of 2015. We expect to report top line results from this trial in the second half of 2016.

We are evaluating TNX-102 SL for the treatment of military-related PTSD in the randomized, double-blind, placebo-controlled Phase 2 AtEase study, from which we expect to report initial results in the first half of 2016. The primary objective of the AtEase trial is to evaluate the efficacy of TNX-102 SL 2.8 mg as compared to placebo sublingual tablet following eight weeks of treatment using the Clinician-Administered PTSD Scale. Based on our communications with the FDA to date, we believe that positive results from two adequate, well-controlled efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would support FDA approval of TNX-102 SL for the management of PTSD. If we achieve our primary outcome measure in the AtEase study, it could qualify as one of the two studies required to support the NDA. We expect that we can use the data generated by our clinical development of TNX-102 SL in FM to supplement the long-term safety exposure data required for the PTSD NDA.

We are developing TNX-201 for the treatment of ETTH. We are preparing to commence a 200-patient Phase 2 study in ETTH in the second quarter of 2015, in which patients will be randomized at approximately 10 U.S. centers to receive TNX-201 140 mg (4 x 35 mg) or placebo capsules. 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. We expect to report top line results from this study in the fourth quarter of 2015. Although the clinical development of TNX-201 can be accelerated based on available information on the active ingredient of TNX-201, approval of any NDA will be as a new chemical entity pursuant to Section 505(b)(1) of the FDCA.

We also have a pipeline of other product candidates, including TNX-301. TNX-301 is a fixed dose 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 abuse and dependence, and we have commenced development work on TNX-301 formulations. In addition, we own rights to intellectual property on two biodefense technologies: one relating to the development of novel smallpox vaccines; and the other to the development of protective agents against radiation exposure. We have begun non-clinical research and development on these programs. The FDA Animal Efficacy Rule provides a mechanism for product licensure when human efficacy studies are not feasible or ethical. As a result, the licensure of these biodefense products in the U.S. may not require human efficacy studies, which we believe will reduce our development costs and risks compared to the development of 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 2 clinical trial of TNX-102 SL in PTSD. In the second quarter of 2015, we plan to begin both a Phase 3 trial of TNX-102 SL in FM as well as a Phase 2 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 in-flows from the relevant drug or program would be delayed or would not occur.

Results of Operations (in thousands except per share data)

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.

Fiscal year Ended December 31, 2014 Compared to Fiscal year Ended December 31, 2013

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the fiscal years ended December 31, 2014 and 2013.

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2014 were $18,617, an increase of $13,967, or 300%, from $4,650 for the fiscal year ended December 31, 2013. This increase is primarily due to increased development work related to TNX-102 SL, including formulation development, manufacturing, human safety and efficacy as well as pharmacokinetic studies. In 2014, we incurred $3,743, $5,948 and $1,501 in manufacturing cost, clinical activities and cost, and non-clinical activities and cost, respectively, as compared to $1,161, $1,733 and $432 in 2013, respectively. During the year ended December 31, 2014, we acquired intellectual property rights for $858 as compared to $0 in the same period last year. In addition, beginning in 2014, we began classifying certain salaries, bonuses, and stock-based compensation to research and development expenses based on individuals' responsibilities. Included in the year ended December 31, 2014 was $646 related to stock based compensation in connection with the vesting of stock options and cash compensation of $1,310, primarily as a result of added personnel.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2014 were $9,039, an increase of $2,801, or 45%, from $6,238 incurred in the fiscal year ended December 31, 2013. This increase is primarily due to compensation related expenses and professional services.

Compensation related expenses increased to $4,511 for the fiscal year ended December 31, 2014 from $3,248 for the fiscal year ended December 31, 2013, an increase of $1,263, or 39%. We incurred $2,434 in stock based compensation in connection with the vesting of stock options in 2014 previously issued to board members, officers and a consultant as compared to $1,717 in stock based compensation in 2013. The increase in cash compensation related costs of $546 was primarily a result of annual salary increases and added personnel, net with classification of wages and benefits related to research and development from general and administrative expenses.

Professional services for the fiscal year ended December 31, 2014 totaled $2,564, an increase of $682, or 36%, over the $1,882 incurred for the fiscal year ended December 31, 2013. Of professional services, legal fees totaled $1,003 for the fiscal year ended December 31, 2014, an increase of $100, or 11%, from $903 incurred for the fiscal year ended December 31, 2013. Of the legal fees incurred, $554 were patent related costs in the 2014 year as compared to $458 in 2013. Audit and accounting fees incurred in the fiscal years ended December 31, 2014 and 2013 amounted to $515 and $244, respectively, an increase of $271, or 111%. The increase is due to additional work required in 2014 related to Sarbanes Oxley as well additional audit and accounting fees related to our additional subsidiaries. Investor and public relations fees totaled $874 for the fiscal year ended December 31, 2014, an increase of $219 or 33%, from $655 incurred in fiscal year ended December 31, 2013. The increase is due to expenses incurred during our annual analyst day as well as costs incurred related to brand awareness and drug name development. Other consulting fees and other professional fees totaled $172 for the fiscal year ended December 31, 2014, an increase of $92, or 115%, from $80 for the fiscal year ended December 31, 2013. Other professional fees include human resources, finance and corporate consultants.

Travel, meals and entertainment costs for the fiscal year ended December 31, 2014 were $401, an increase of $87, or 28%, from $314 incurred in the fiscal year ended December 31, 2013. Travel, meals and entertainment costs include travel related to investor relations activities, which accounted for the primary increase from 2013. Rent for the fiscal years ended December 31, 2014 and 2013 totaled $246 and $124, respectively. In 2014, we increased the size of our corporate headquarters in New York and opened a satellite office in California. Market-related materials and analysis for the fiscal year ended December 31, 2014 was $210, an increase of $162, or 338%, from $48 incurred in the fiscal year ended December 31, 2013. The increase is mainly due to updated company materials presented updated at investor relations events. Depreciation expense in fiscal 2014 totaled $36, an increase of $19, or 112%, over the expense of $17 incurred in fiscal 2013, as a result of the purchase of new office computers.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2014 was $27,616, compared to a net loss of $10,884 for the year ended December 31, 2013.

Liquidity and Capital Resources (in thousands except per share data)

As of December 31, 2014, we had working capital of $35,654, comprised primarily of cash of $38,184 and prepaid expenses and other of $852, offset by $1,487 of accounts payable and $1,895 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 TNX-102 SL in FM and PTSD. For the years ended December 31, 2014 and 2013, we used approximately $22,840 and $8,517 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, pre-clinical and clinical cost and activities, regulatory cost, and payroll. For the year ended December 31, 2014, net proceeds from financing activities were from the sale of our common stock of approximately $47,836 and the exercise of warrants of $5,661, net with repayments of related party promissory notes of $280. In the comparable 2013 period, approximately $10,042 was raised through the sale of shares of common stock and warrants, the exercise of warrants of $4,628, and from the sale of promissory notes to related parties of $280. At December 31, 2013, we had cash of $8,202. Our cash is held in bank deposit accounts.

Cash used in investing activities for the year ended December 31, 2014 was approximately $392, reflecting purchase of equipment and leasehold improvements of $319 and payments into restricted funds for lease collateral of $73 as compared to cash used for the year ended December 31, 2013 of approximately $15 reflecting purchase of equipment.

January 2014 financing

On January 24, 2014, we entered into an underwriting agreement with Roth Capital Partners, LLC ("Roth"), as representative of several underwriters (collectively, the "Underwriters"), relating to the issuance and sale of 2,898,550 shares of our common stock in an underwritten public offering (the "January 2014 Financing"). The public offering price for each share of common stock was $15.00. We granted the Underwriters a 45-day option to purchase up to an additional 434,782 shares of common stock to cover over-allotments, if any.

The January 2014 Financing closed on January 29, 2014. The Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of approximately $2,608 (or $0.90 per share). The Company also paid offering expenses of approximately $216. The Company received net proceeds of approximately $40,654. The over-allotment option expired unexercised.

July 2014 financing

On July 11, 2014, the Company entered into subscription agreements with investors, relating to the issuance and sale of 657,000 shares of the Company's common stock in a registered direct offering. The purchase price for each share of common stock was $11.90.

Roth acted as the exclusive placement agent in this offering pursuant to the terms of a placement agent agreement, dated July 11, 2014, between us and Roth. Pursuant to the placement agent agreement, we agreed to pay Roth a placement agent fee equal to six percent of the gross proceeds of the offering.

The registered direct offering closed on July 16, 2014 and we received net proceeds of approximately $7,182, after deducting placement agent fees and offering expenses of approximately $636.

February 2015 financing

On February 4, 2015, we entered into an underwriting agreement with Roth and Oppenheimer & Co Inc., as representatives (the "Representatives") of several underwriters (collectively, the " Second 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 Second 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 Second Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of approximately $1,720 (or $0.35 per share). The Company also paid offering expenses of approximately $250. The Company received net proceeds of approximately $26,700. On February 24, 2015, the Second Underwriters partially exercised the over-allotment option and purchased 418,700 shares of common stock for net proceeds of approximately $2,300.

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

We have entered into an agreement with Lederman & Co., LLC ("Lederman & Co"), a company under the control of Dr. Seth Lederman, our Chief Executive Officer and Chairman of the Board of Directors. Effective October 15, 2013, Lederman & Co received $325 per annum for its consulting services. On February 11, 2014, the agreement with Lederman & Co was terminated, and we simultaneously entered into an employment agreement with Dr. Lederman.

On July 31 and August 1, 2013, we sold three promissory notes in the aggregate principal face amount of $280 to two related parties in exchange for $280. The notes were payable on demand at any time after one year from issuance and bear no interest, and were included in current liabilities on the consolidated balance sheet at December 31, 2013. On July 31, 2014 and August 1, 2014, we repaid $200 and $80, respectively.

On March 18, 2014, Tonix Barbados entered into an asset purchase agreement (the "Starling Agreement") with Starling Pharmaceuticals, Inc. ("Starling") and an asset purchase agreement (the "Leder Agreement") with Leder Laboratories, Inc. ("Leder"). Seth Lederman, the Company's Chairman and Chief Executive Officer, is the Chairman, CEO and majority owner (through majority-owned entities) of Starling and Leder.

Pursuant to the Starling Agreement, Tonix Barbados acquired from Starling rights to a United States patent application for radio- and chemo-protective agents and related intellectual property rights, in exchange for $125 and 25,000 shares of our common stock.

Pursuant to the Leder Agreement, Tonix Barbados acquired from Leder rights to a United States patent application for novel smallpox vaccines and related intellectual property rights, in exchange for $125 and 25,000 shares of our common stock.

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.

In May 2012, we issued options to purchase 175,000 shares of common stock pursuant to the 2012 Plan, with such options vesting 1/3rd on May 9, 2013 and 1/36th on the 9th of each month thereafter for 24 months, having an exercise price of $30.00 and expiring 10 years from date of issuance. In February 2013, we issued options to purchase 226,500 shares of common stock pursuant to the 2012 Plan, with such options vesting 1/3rd on February 12, 2014 and 1/36th on the 12th of each month thereafter for 24 months, having an exercise price of $10.20 and expiring 10 years from date of issuance. In February 2014, we issued options to purchase 173,500 shares of common stock pursuant to the 2012 Plan, with such options vesting 1/3rd on February 11, 2015 and 1/36th on the 12th of each month thereafter for 24 months, having an exercise price of $15.88 and expiring 10 years from date of issuance.

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, 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 Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2014 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the 2014 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 1,800,000 shares of its common stock for future issuance under the terms of the 2014 Plan.

On June 17, 2014, 295,100 and 60,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan (all of which were outstanding at December 31, 2014) with an exercise price of $9.87, a 10 year life and fair value of $8.76. As of December 31, 2014, the fair value related to consultant grants was $4.80.

On October 29, 2014, 321,700 options were granted to employees and directors under the 2014 Plan (all of which were outstanding at December 31, 2014) with an exercise price of $6.68, a 10 year life and fair value of $5.80.

On February 25, 2015, the Company granted options to purchase an aggregate of 449,500 shares of the Company's common stock to officers, directors, employees and consultants with an exercise price of $5.95, exercisable for a period of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months. As well, the Company granted an aggregate of 42,000 restricted stock units to its non-employee directors for board services in 2015 in lieu of cash, vesting one year from the grant date. 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, exercisable for a period of ten years, vesting immediately upon the grant date.

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 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 December 31, 2014, after giving effect to shares purchased as described below, there were 286,022 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 December 31, 2014, approximately $91 of employee payroll deductions which have been withheld since July 1, 2014, the commencement of the offering period are included in accrued expenses in the accompanying balance sheet. The compensation expense related to the 2014 ESPP for the year ended December 31, 2014 was $35. In February 2015, 13,978 shares that were purchased as of December 31, 2014, were issued under the 2014 ESPP.

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 to $133 and we deposited an additional $72 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 $45.

Future minimum lease payments under these two agreements are as follows:

Year Ending December 31,		
2015	$	420
2016		446
2017		459
2018		442
2019		99
	$	1,866

Additionally, we rent a small office in Ireland on a month-to-month basis.

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.

Recent Accounting Pronouncements

During the quarter ended June 30, 2014, we adopted Accounting Standards Update (ASU) No. 2014-10, *"Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation"*, which was issued in June 2014. The ASU is effective for annual reporting periods beginning after December 15, 2014 (and interim periods therein), with early adoption allowed. The amendments in this ASU eliminate the concept of a development stage entity from GAAP and remove the related incremental financial reporting requirements. Accordingly, we elected early adoption and are no longer presenting cumulative inception-to-date along with our current period amounts in our statements of operations and cash flows.

There were various other updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to a have a material impact on our consolidated financial position, results of operations or cash flows.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalents primarily consist of securities issued by the U.S. government, deposits, and 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. As of December 31, 2014, we had cash and cash equivalents and short-term investments of $38.2 million consisting of cash and highly liquid investments deposited in highly rated financial institutions in the United States.

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 any 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 during the years ended December 31, 2014 and 2013 had a significant impact on our results of operations.

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Tonix Pharmaceuticals Holding Corp.

We have audited the accompanying consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Tonix Pharmaceuticals Holding Corp. as of December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Tonix Pharmaceuticals Holding Corp's internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 27, 2015 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
February 27, 2015

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2014 AND 2013
(Dollars In Thousands)

	2014	2013
ASSETS		
Current assets:		
Cash	$ 38,184	$ 8,202
Prepaid expenses and other	852	429
Total current assets	39,036	8,631
Property and equipment, net	328	45
Restricted cash	133	60
Deposits, long term	45	-
Total assets	$ 39,542	$ 8,736
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable, including $95 and $46 to related parties as of December 31, 2014 and 2013, respectively	$ 1,487	$ 765
Accrued expenses, including $595 and $491 to related parties as of December 31, 2014 and 2013, respectively	1,895	1,166
Promissory notes, related party	-	280
Total current liabilities	3,382	2,211
Deferred rent payable	68	13
Total liabilities	3,450	2,224
Commitments (Note 9)	-	-
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; 10,805,220 and 5,823,081 shares issued and outstanding as of December 31, 2014 and 2013, respectively and 13,978 and 11,000 shares to be issued as of December 31, 2014 and 2013, respectively	11	6
Additional paid in capital	90,423	33,235
Accumulated deficit	(54,344)	(26,728)
Accumulated other comprehensive income (loss)	2	(1)
Total stockholders' equity	36,092	6,512
Total liabilities and stockholders' equity	$ 39,542	$ 8,736

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2014	2013
COSTS AND EXPENSES:		
Research and development	$ 18,617	$ 4,650
General and administrative	9,039	6,238
	27,656	10,888
Operating Loss	(27,656)	(10,888)
Interest income, net	40	4
NET LOSS	$ (27,616)	$ (10,884)
Net loss per common share, basic and diluted	$ (2.77)	$ (3.37)
Weighted average common shares outstanding, basic and diluted	9,985,515	3,231,311

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2014	2013
Net loss	$ (27,616)	$ (10,884)
Other comprehensive income (loss):		
Foreign currency translation gain (loss)	3	(1)
Total other comprehensive income (loss)	3	(1)
Comprehensive loss	$ (27,613)	$ (10,885)

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(Dollars In Thousands Except Per Share Amounts)

	Preferred stock		Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance at December 31, 2012	-	$ -	2,159,159	$ 2	$ 16,801	$ -	$ (15,844)	$ 959
Stock based compensation	-	-	-	-	1,717	-	-	1,717
Issuance of common stock in exchange for exercise of warrants in April 2013 ($8.00 per share)	-	-	38,334	-	307	-	-	307
Issuance of common stock and warrants in August 2013 ($4.25 per share) net of transaction expenses of $1,352	-	-	2,680,000	3	10,039	-	-	10,042
Issuance of common stock in exchange for exercise of warrants in December 2013 ($4.25 per share)	-	-	884,885	1	3,760	-	-	3,761
Issuance of common stock in exchange for exercise of warrants in December 2013 ($8.00 per share)	-	-	70,031	-	560	-	-	560
Issuance of common stock in exchange for 3,185 warrants exercised on a cashless basis	-	-	1,672	-	-	-	-	-
Warrants issued for services rendered	-	-	-	-	51	-	-	51
Foreign currency translation adjustment	-	-	-	-	-	(1)	-	(1)
Net loss	-	-	-	-	-	-	(10,884)	(10,884)
Balance at December 31, 2013		$ -	5,834,081	$ 6	$ 33,235	$ (1)	$ (26,728)	$ 6,512

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(Dollars In Thousands Except Per Share Amounts)

	Preferred stock		Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance at January 1, 2014	-	$ -	5,834,081	$ 6	$ 33,235	$ (1)	$ (26,728)	$ 6,512
Issuance of common stock in exchange for exercise of warrants ($4.25 per share)	-	-	1,331,911	1	5,660	-	-	5,661
Issuance of common stock in January 2014 ($15.00 per share) net of transaction expenses of $2,824	-	-	2,898,550	3	40,651	-	-	40,654
Issuance of common stock in July 2014 ($11.90 per share) net of transaction expenses of $636	-	-	657,000	1	7,181	-	-	7,182
Issuance of common stock to acquire intellectual property rights from related party in March 2014 ($12.15 per share)	-	-	50,000	-	608	-	-	608
Issuance of common stock in exchange for 48,240 warrants exercised on a cashless basis	-	-	33,678	-	-	-	-	-
Stock based compensation	-	-	-	-	3,088	-	-	3,088
Foreign currency translation adjustment	-	-	-	-	-	3	-	3
Net loss	-	-	-	-	-	-	(27,616)	(27,616)
Balance, December 31, 2014	-	$ -	10,805,220	$ 11	$ 90,423	$ 2	$ (54,344)	$ 36,092

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in Thousands)

	Year ended December 31, 2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (27,616)	$ (10,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36	17
Warrants issued for services rendered	-	51
Stock based compensation	3,088	1,717
Common stock issued in exchange for intellectual property	608	-
Changes in operating assets and liabilities:		
Prepaid expenses	(423)	(204)
Accounts payable	728	(60)
Accrued interest	-	(3)
Accrued expenses	729	856
Security deposit	(45)	-
Deferred rent payable	55	(7)
Net cash used in operating activities	(22,840)	(8,517)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(319)	(15)
Restricted cash deposit in connection with lease	(73)	-
Net cash used in investing activities	(392)	(15)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from related party promissory notes	-	280
Repayments of related party promissory notes	(280)	-
Proceeds from exercise of warrants	5,661	4,628
Proceeds, net of expenses of $3,460 and $3,454 from sale of common stock	47,836	10,042
Net cash provided by financing activities	53,217	14,950
Effect of currency rate change on cash	(3)	(1)
Net increase in cash	29,982	6,417
Cash, beginning of the period	8,202	1,785
Cash, end of period	$ 38,184	$ 8,202
Supplemental disclosures of cash flow information:		
Interest paid	$ -	$ 3

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2014 AND 2013

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 identification and development of novel pharmaceutical products for challenging disorders of the central nervous system ("CNS").

On October 29, 2014, Tonix Sub formed Tonix Pharma Holdings Ltd. ("Tonix International Holding"), which was incorporated under the laws of Ireland and tax resident in Bermuda, for the purpose of acquiring the rights to develop and commercialize Tonix products. Tonix International Holding formed Tonix Pharma Ltd ("Tonix Ireland") for the purpose of manufacturing, trading and developing Tonix products. On December 15, 2014, Tonix Sub and Tonix International Holding entered into an intercompany license agreement whereby Tonix Sub granted Tonix International Holding a non-exclusive right to exercise certain product technologies and related intangible rights. As consideration, Tonix International Holding paid licensing fees to Tonix Sub.

On October 24, 2013, Tonix Sub formed Tonix Pharmaceuticals (Barbados), Ltd. ("Tonix Barbados"). Tonix Barbados had previously entered into a license agreement and a cost-sharing agreement with Tonix Sub, pursuant to which Tonix Barbados acquired the rights to develop and commercialize certain products (TNX-102 SL and TNX-201) for non-US markets. In the first quarter of 2015, Tonix Barbados is expected to be dissolved and its assets are to be transferred to Tonix International Holding.

On April 23, 2013, Tonix Sub formed a wholly owned subsidiary, Tonix Pharmaceuticals (Canada), Inc. ("Tonix Canada"), in the province of New Brunswick, Canada for the purpose of obtaining research and development credits from the Canadian government for any research and development studies performed in Canada.

On August 16, 2010, Tonix Sub formed Krele LLC ("Krele") in the state of Delaware. Krele is a limited liability corporation whose sole member is Tonix Pharmaceuticals Inc. Krele was established to commercialize products that are generic versions of predicate new drug application products or versions of drug efficacy study implementation products. Tonix Pharmaceuticals, Inc. expects that its relationship to Krele will be similar to that of several other pharmaceutical companies and their subsidiaries that market generic versions of the parent's branded products at different periods in their product life-cycle.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Consolidation

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its direct and indirect wholly owned subsidiaries referred to in Note 1 (hereafter referred to as the "Company" or "Tonix").

All significant intercompany balances and transactions have been eliminated in consolidation.

Recent accounting pronouncement adopted

During the quarter ended June 30, 2014, the Company adopted Accounting Standards Update (ASU) No. 2014-10, *"Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation"*, which was issued in June 2014. The ASU is effective for annual reporting periods beginning after December 15, 2014 (and interim periods therein), with early adoption allowed. The amendments in this ASU eliminate the concept of a development stage entity from GAAP and remove the related incremental financial reporting requirements. Accordingly, the Company elected early adoption and is no longer presenting cumulative inception-to-date along with their current period amounts in its statements of operations and cash flows.

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 approval of their products is received 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 December 31, 2014, the Company had working capital of $35,655,643, after raising $47,836,469 through the sale of common stock and $5,660,622 upon the exercise of previously issued warrants during 2014. In addition, the Company raised approximately $29,000,000 in February 2015 through the sale of common stock (see Note 12). 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.

Research and development costs

The Company outsources its research and development efforts and expenses related costs as incurred, including the cost of manufacturing product 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 is expensed as research and development costs, as such property related to particular research and development projects and had no alternative future uses (see note 11).

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life, which is three years for computer assets, five years for furniture and all other equipment and term of lease for lease improvements. Expenditures for maintenance and repairs are expensed as incurred.

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. As of December 31, 2014 and 2013, the Company has not recorded any unrecognized tax benefits.

Stock-based compensation

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

Foreign currency translation

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

Comprehensive income (loss)

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

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, adjusted to give effect to the 20-for-1 reverse stock split, which was effected on May 1, 2013 (see Note 6).

As of December 31, 2014 and 2013, there were outstanding warrants to purchase an aggregate of 1,745,755 and 3,126,656 shares, respectively, of the Company's common stock (see Note 8). In addition, the Company has issued to employees, directors and consultants, options to acquire shares of the Company's common stock of which 1,226,800 and 376,500 were outstanding at December 31, 2014 and 2013, respectively. In computing diluted net loss per share for the years ended December 31, 2014 and 2013, no effect has been given to such options and warrants as their effect would be anti-dilutive.

NOTE 3 – PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2014 and 2013 is summarized as follows:

	2014	2013
Office furniture and equipment	$ 240,139	$ 93,188
Leasehold improvements	171,847	-
Total	411,986	93,188
Less: accumulated depreciation and amortization	(83,791)	(48,232)
	$ 328,195	$ 44,956

Depreciation and amortization expense for the years ended December 31, 2014 and 2013 was $35,559 and $16,591, respectively.

NOTE 4 – RESTRICTED CASH

Restricted cash at December 31, 2014 and 2013 of approximately $133,000 and $60,000, respectively, collateralizes a letter of credit issued in connection with the lease of office space in New York City (see Note 9).

NOTE 5 – SALE OF COMMON STOCK

January 2014 financing

On January 24, 2014, the Company entered into an underwriting agreement with Roth Capital Partners, LLC ("Roth"), as representative of several underwriters (collectively, the "Underwriters"), relating to the issuance and sale of 2,898,550 shares of its common stock in an underwritten public offering (the "January 2014 Financing"). The public offering price for each share of common stock was $15.00. The Company granted the Underwriters a 45-day option to purchase up to an additional 434,782 shares of common stock to cover over-allotments, if any.

The January 2014 Financing closed on January 29, 2014. The Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of $2,608,695 (or $0.90 per share). The Company also paid offering expenses of $215,756. The Company received net proceeds of $40,653,799. The over-allotment option expired unexercised.

July 2014 financing

On July 11, 2014, the Company entered into subscription agreements with investors, relating to the issuance and sale of 657,000 shares of the Company's common stock in a registered direct offering. The purchase price for each share of common stock was $11.90.

Roth acted as the exclusive placement agent in this offering pursuant to the terms of a placement agent agreement, dated July 11, 2014, between the Company and Roth. Pursuant to the placement agent agreement, the Company agreed to pay Roth a placement agent fee equal to six percent of the gross proceeds of the offering.

The registered direct offering closed on July 16, 2014 and the Company received net proceeds of $7,182,670, after deducting placement agent fees and offering expenses of approximately $0.6 million.

August 2013 financing

On August 9, 2013, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Roth, as representative of the underwriters named therein (the "First Underwriters"), pursuant to which the Company agreed to offer to the public through the First Underwriters an aggregate of 2,680,000 units (each a "Unit", and collectively, the "Units") at a public offering price of $4.25 per Unit in an underwritten public offering (the "August 2013 Financing"). Each Unit consisted of (i) one share of common stock and (ii) one Series A Warrant (the "Warrants") to purchase one share of common stock. The Warrants are exercisable at an exercise price of $4.25 per share, subject to anti-dilutive adjustment, and expire on the fifth anniversary of the date of issuance. The Warrants will be exercisable on a "cashless" basis in certain circumstances. Pursuant to the Underwriting Agreement, the Company also granted the First Underwriters an option for a period of 45 days to purchase up to (i) 402,000 additional Units or (ii) 402,000 additional shares of common stock and/or additional Warrants to purchase up to 402,000 shares of common stock, on the same terms, to cover over-allotments, if any.

The August 2013 Financing closed on August 14, 2013. The First Underwriters purchased the Units at an eight percent discount to the public offering price, for an aggregate discount of approximately $911,200 (or $0.34 per unit). The Company received net cash proceeds of $10,038,013 after deducting underwriting discounts and commissions and offering expenses of $440,787. On August 14, 2013, the First Underwriters exercised their over-allotment option by purchasing for $4,020 additional Warrants to purchase 402,000 shares of common stock.

The First Underwriters received warrants to purchase up to an aggregate of 107,200 shares of common stock, or four percent of the total number of shares included in the Units, which warrants have an exercise price of $4.25.

NOTE 6 – STOCKHOLDERS' EQUITY

On May 1, 2013, the Company filed an amendment to its Articles of Incorporation and effected a 20-for-1 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value, whereby 43,182,599 outstanding shares of the Company's common stock were exchanged for 2,159,159 shares of the Company's common stock. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split, resulting in the transfer of $41,024 from common stock to additional paid in capital at December 31, 2012.

NOTE 7 – SHARE-BASED COMPENSATION

2012 incentive stock option plan

In April, 2012, the Company's stockholders approved the 2012 Incentive Stock Option Plan (the "2012 Plan"). The 2012 Plan provides for the issuance of options to purchase up to 200,000 shares of the Company's common stock to officers, directors, employees and consultants of the Company. Under the terms of the 2012 Plan, the Company may issue incentive stock options as defined by the Internal Revenue Code of 1986, as amended (the "Code") to employees of the Company and may also issue nonstatutory options to employees and others. The Company's board of directors ("Board of Directors") determines the exercise price, vesting and expiration period of the grants under the 2012 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the 2012 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 200,000 shares of its common stock for future issuance under the terms of the 2012 Plan.

On May 9, 2012, 175,000 options were granted under the 2012 Plan. Of such options, 25,000 were cancelled and 150,000 were outstanding at December 31, 2014 with an exercise price of $30.00, a 10 year life and fair value of $23.50.

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 February 12, 2013, 226,500 options were granted under the 2012 Plan (all of which were outstanding at December 31, 2014) with an exercise price of $10.20, a 10 year life and fair value of $7.83.

On February 11, 2014, 173,500 options were granted under the 2012 Plan (all of which were outstanding at December 31, 2014) with an exercise price of $15.88, a 10 year life and fair value of $11.52.

2014 incentive stock option plan

On June 9, 2014, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan (the "2014 Plan" and together with the 2012 Plan, the "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 Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2014 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the 2014 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 1,800,000 shares of its common stock for future issuance under the terms of the 2014 Plan.

On June 17, 2014, 295,100 and 60,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan (all of which were outstanding at December 31, 2014) with an exercise price of $9.87, a 10 year life and fair value of $8.76. As of December 31, 2014, the fair value related to consultant grants was $4.80.

On October 29, 2014, 321,700 options were granted to employees and directors under the 2014 Plan (all of which were outstanding at December 31, 2014) with an exercise price of $6.68, a 10 year life and fair value of $5.80.

General

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. 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 years ended December 31, 2014 and 2013 were as follows:

	2014	2013
Risk-free interest rate	2.03% to 2.52%	2.02%
Expected term of option	6.0 to 9.72 years	6.0 years
Expected stock price volatility	92.87% to 100.73 %	99.96%
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 $3,053,223 and $1,717,037 was recognized for the years ended December 31, 2014 and 2013, respectively.

As of December 31, 2014, the Company had approximately $6,489,902 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 2.23 years.

A summary of the stock option activity and related information for the Plans for the years ended December 31, 2014 and 2013 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2013	150,000	$ 30.00	9.35	
Grants	226,500	$ 10.20	10.00	$ -
Exercised	-			
Forfeitures or expirations	-			
Outstanding at January 1, 2014	376,500	$ 18.09	8.81	$ 24,915
Grants	850,300	$ 9.53	10.00	$ -
Exercised	-			
Forfeitures or expirations	-			
Outstanding at December 31, 2014	1,226,800	$ 12.40	9.00	$ -
Vested and expected to vest at December 31, 2014	1,226,800	$ 12.40	9.00	$ -
Exercisable at December 31, 2014	267,583	$ 19.76	7.75	$ -

The aggregate intrinsic value in the preceding tables represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price at the respective dates of issuance. As of December 31, 2014, based on the closing stock price of $5.84, the outstanding options had no intrinsic value.

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 December 31, 2014, after giving effect to shares purchased as described below, there were 286,022 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 December 31, 2014, approximately $91,000 of employee payroll deductions which have been withheld since July 1, 2014, the commencement of the offering period are included in accrued expenses in the accompanying balance sheet. The compensation expense related to the 2014 ESPP for the year ended December 31, 2014 was $34,688. In February 2015, 13,978 shares that were purchased as of December 31, 2014, were issued under the 2014 ESPP.

NOTE 8 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company, all of which were vested and exercisable, at December 31, 2014:

Exercise Price	Number Outstanding	Expiration Date
$ 4.25	920,979	August 2018
$ 12.00	456,009	December 2017 to February 2018
$ 20.00	14,538	January 2015
$ 25.00	354,229	January 2017 to February 2019
	1,745,755	

On January 1, 2013, the Company issued warrants to non-employees to purchase 10,800 shares of the Company's common stock at an exercise price of $12.00 per share expiring five years from the date of issuance vesting ratably over twelve months beginning January 1, 2013 in connection with services.

In connection with the August 2013 Financing, the Company issued to investors Warrants to purchase 2,680,000 shares of the Company's common stock. The Warrants are exercisable at $4.25 per share, expire five years from the date of issuance, and may be exercised on a cashless basis under certain circumstances. In addition, the Company issued to the First Underwriters warrants to purchase 509,200 shares of the Company's common stock. The warrants are exercisable at $4.25 per share, expire five years from the date of issuance, and may be exercised on a cashless basis.

The Company measures the fair value of the vested portion of the issued warrants 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 fair value determination.

The assumptions used in the valuation of warrants, which vested during the year ended December 31, 2013, were as follows:

Risk-free interest rate	0.77 to 1.75%
Life of warrant	4.75 to 4.01 years
Expected stock price volatility	91.31% to 102.46%
Expected dividend yield	$ 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 life of the warrants as of the grant date. The expected stock price volatility is based on comparable companies' historical stock price volatility since the Company does not have sufficient historical volatility data because its equity shares have been publicly traded for only a limited period of time.

Compensation of $51,114 related to vested warrants was recognized for the year ended December 31, 2013.

In April 2013, the Company issued an aggregate of 38,334 shares of its common stock upon the exercise of warrants at $8.00 per share.

In December 2013, the Company issued an aggregate of 884,885 and 70,031 shares of its common stock upon the exercise of warrants at $4.25 and $8.00 per share, respectively.

In December 2013, the Company issued 1,672 shares of its common stock upon the exercise of 3,185 warrants exercisable at $4.25 per share on a cashless basis.

In January 2014, 750 warrants with an exercise price of $20.00 expired.

In August 2014, the Company issued 33,678 shares of its common stock upon the exercise of 48,240 warrants exercisable at $4.25 per share on a cashless basis.

During the year ended December 31, 2014, the Company issued an aggregate of 1,331,911 shares of its common stock upon the exercise of warrants at $4.25 per share.

NOTE 9 – COMMITMENTS

Operating leases

On February 11, 2014, in connection with office space in New York City, 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 (see Note 4).

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.

Future minimum lease payments under these two agreements are as follows:

Year Ending December 31,		
2015	$	420,120
2016		445,890
2017		459,295
2018		442,024
2019		98,758
	$	1,866,087

Rent expense charged to operations, which differs from rent paid due to rent credits and to increasing amounts of base rent, is calculated by allocating total rental payments on a straight-line basis over the term of the lease. During the years ended December 31, 2014 and 2013, rent expense was $245,863 and $123,634, respectively and as of December 31, 2014 and 2013, net deferred rent payable was $51,835 and $19,710, respectively, including the current portion, which at December 31, 2014, is $17,299, is included in prepaid expenses and other. Included in rent expense for the year ended December 31, 2014, is $3,251 related to our Irish entity, where we rent a small office on a month-to-month basis.

Research and development agreements

During 2014 and 2013, the Company entered into contracts with various contract research organizations for which there are outstanding commitments aggregating approximately $11.5 million at December 31, 2014 for future work to be performed.

Lederman employment agreement

On February 11, 2014, the Company entered into an employment agreement (the "Agreement") with Dr. Seth Lederman ("Lederman") to continue to serve as President, Chief Executive Officer and Chairman of the Board of Directors of the Company. Previously, the Company entered into a consulting agreement with Lederman & Co, pursuant to which Lederman received compensation for serving as the Company's President and Chief Executive Officer. On February 11, 2014, the consulting agreement was terminated.

The Agreement, which has an initial term of one year and automatically renews for successive one year terms unless either party delivers written notice not to renew at least 60 days prior to the end of the current term, provides for various payments and benefits to Lederman in the event Lederman's employment is terminated without cause (as defined therein), Lederman resigns for Good Reason (as defined therein) or in the event employment is terminated as a result of death or permanent disability.

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. For the year ended December 31, 2014, the Company charged operations $383,642 for contributions under the 401(k) Plan.

NOTE 10 – INCOME TAXES

Components of the Net Loss consist of the following:

	December 31,	
	2014	2013
Foreign	(14,692,723)	(502,052)
Domestic	(12,923,447)	(10,381,992)
	(27,616,170)	(10,884,044)

In 2014, the foreign losses were primarily comprised of $8,975,522 related to the Bermudan operations of Tonix International Holding, which includes a licensing fee of $8,000,000 charged by Tonix Sub and $5,728,347 related to Tonix Barbados pursuant to a cost sharing agreement with Tonix Sub. In 2013, the foreign losses are comprised of $498,017 related to Tonix Canada and $4,035 related to Tonix Barbados.

The operations and management of Tonix International Holding are located in Bermuda, and accordingly, are not subject to income taxes in Ireland, which is its country of incorporation. The operations of Tonix International Holding and Tonix Barbados are not subject to income tax in Bermuda and Barbados, respectively.

There is no income tax benefit for the years ended December 31, 2014 and 2013 since the Company has established a valuation allowance equal to the total deferred tax asset related to losses incurred during such periods.

Deferred tax assets and liabilities and related valuation allowance as of December 31, 2014 and 2013 are as follows:

	December 31, 2014	2013
Deferred tax assets:		
Research and development credit carryforward (1)	6,188	6,188
Net operating loss carryforwards	11,320,229	9,040,045
Stock-based compensation	1,335,776	-
Accrued bonuses	200,113	223,397
Other	363,868	159,656
Total deferred tax assets	13,226,174	9,429,286
Valuation allowance	(13,226,174)	(9,429,286)
Net deferred tax assets	$ 0	$ 0

(1) The Company has incurred research and development ("R&D") expenses, a portion of which may qualify for tax credits. The Company has not conducted an R&D credit study to quantify the amount of credits and has not claimed an R&D credit on its federal tax returns filed except for $6,188 in 2007. The Company may conduct the study in future years and may establish the R&D credit carryforward for prior years. In such event, the net operating loss carryforward will be correspondingly reduced by the amount of the credit.

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 not more likely than not that the deferred tax assets will be realized and accordingly, has provided a valuation allowance. The increase in the valuation allowance for the years ended December 31, 2014 and 2013 was $3.8 million and $4.1 million, respectively.

At December 31, 2014, the Company has available unused net operating loss ("NOL") carryforwards of approximately $25 million that expire from 2027 to 2034 for federal tax purposes. The Company also has approximately $25 million of NOL carryforwards for New York State and New York City purposes expiring from 2030 to 2034. At December 31, 2014, the Company has a research and development carryforward of $6,188 for federal tax purposes that expires in 2027. A portion of these NOL and research and development credit carryforwards are subject to annual limitations in their use in accordance with Internal Revenue Code ("IRC") section 382. The NOL carryforwards at December 31, 2014 have been reduced to reflect IRC section 382 ownership changes through December 31, 2013 and the resultant inability due to annual limitations, to utilize a portion of the NOL prior to its expiration. Additional adjustments may be required based on ownership activity during 2014.

The Company's federal and state tax returns remain open and subject to examination by the tax authorities for the tax years 2011 and after.

A reconciliation of the effect of applying the federal statutory rate to the net loss and the effective income tax rate used to calculate the Company's income tax provision is as follows:

	Year Ended December 31, 2014	2013
Statutory federal income tax	(35.0)%	(34.0)%
State income tax, net of federal tax effect	(10.2)%	(10.5)%
Permanent difference	0.3%	6.7%
Increase in valuation allowance	22.0%	37.8%
Foreign loss not subject to income tax	24.0%	0.0%
Other	(1.1)%	0.0%
Income tax provision	0%	0%

NOTE 11 – RELATED PARTY TRANSACTIONS

Dr. Seth Lederman, our Chief Executive Officer and Chairman of the Board is one of the primary founders of the Company. We previously entered into an agreement with a company under his control, Lederman & Co. Total expenses paid under this agreement were $37,723 and $271,875 during the years ended December 31, 2014 and 2013, respectively.

On July 31, 2013, the Company sold two promissory notes in the principal face amounts of $150,000 and $50,000 to Lederman & Co and Eli Lederman, respectively, in exchange for $150,000 and $50,000, respectively. On August 1, 2013, the Company sold a promissory note in the principal face amount of $80,000 to Lederman & Co in exchange for $80,000. The notes were payable on demand at any time after one year from issuance and bear no interest, and were included in current liabilities on the consolidated balance sheet at December 31, 2013. On July 31, 2014 and August 1, 2014, the Company repaid $200,000 and $80,000, 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, $125,000 was paid in cash and 25,000 shares of the Company's common stock valued at $303,750 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, $125,000 was paid in cash and 25,000 shares of the Company's common stock valued at $303,750 were issued to Starling.

Seth Lederman, the Company's Chairman and Chief Executive Officer, is the Chairman, CEO and majority owner (through majority-owned entities) of Starling and Leder.

NOTE 12 – SUBSEQUENT EVENTS

February 2015 financing

On February 4, 2015, the Company entered into an underwriting agreement with Roth and Oppenheimer & Co Inc., as representatives (the "Representatives") of several underwriters (collectively, the "Second 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 Second 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 Second Underwriters purchased the shares at a six- percent discount to the public offering price, for an aggregate discount of $1,719,900 (or $0.35 per share). The Company also paid offering expenses of approximately $250,000. The Company received net proceeds of approximately $26,700,000. On February 24, 2015, the Second Underwriters partially exercised the over-allotment option and purchased 418,700 shares of common stock for net proceeds of approximately $2,300,000.

Options granted

On February 25, 2015, the Company granted options to purchase an aggregate of 449,500 shares of the Company's common stock to officers, directors, employees and consultants with an exercise price of $5.95, exercisable for a period of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months. 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, exercisable for a period of ten years, vesting immediately upon the grant date.

Restricted stock units

On February 25, 2015, the Company granted an aggregate of 42,000 restricted stock units to its non-employee directors for board services in 2015 in lieu of cash, vesting one year from the grant date.

ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A – 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 Exchange Act. 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 management's evaluation, our Chief Executive Officer and Chief Financial Officer concluded that 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.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2014. Management reviewed the results of its assessment with our Audit Committee. The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by EisnerAmper LLP, an independent registered public accounting firm, as stated in its report below.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Tonix Pharmaceuticals Holding Corp.

We have audited the internal controls over financial reporting of Tonix Pharmaceuticals Holding Corp. (the "Company") as of December 31, 2014, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Tonix Pharmaceuticals Holding Corp. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of Tonix Pharmaceuticals Holding Corp. as of and for the year ended December 31, 2014, and our report dated February 27, 2015 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
February 27, 2015

ITEM 9B – OTHER INFORMATION

None.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2014.

ITEM 11 - EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2014.

ITEM 12- SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for the 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2014.

ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2014.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2014.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibits:

2.01	Share Exchange Agreement, dated as of October 7, 2011 by and among Tamandare Explorations Inc., David J. Moss, Tonix Pharmaceuticals, Inc. and the shareholders of Tonix Pharmaceuticals, Inc. filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
3.01	Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "Commission") on April 9, 2008 and incorporated herein by reference.
3.02	Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.
3.03	Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 19, 2014 and incorporated herein by reference.
10.01	Lease Agreement, dated as of September 28, 2010, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the amended Current Report on Form 8-K/A, filed with the Commission on February 3, 2012 and incorporated herein by reference.
10.02	Form of Class A Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 23, 2012 and incorporated herein by reference.
10.03	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Leland Gershell, dated April 1, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on April 5, 2012 and incorporated herein by reference.
10.04	Form of Class A Warrant, dated December 4, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 5, 2012 and incorporated herein by reference.
10.05	Form of Class A Warrant, dated December 21, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 27, 2012 and incorporated herein by reference.
10.06	Form of Demand Promissory Note, filed as an exhibit to the amended registration statement on Form S-1/A filed with the Commission on August 8, 2013 and incorporated herein by reference.
10.07	Amendment to Consulting Agreement, between Tonix Pharmaceuticals, Inc. and Lederman & Co., LLC, dated October 15, 2013, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 17, 2013 and incorporated herein by reference.
10.08	Amendment to Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Leland Gershell, dated October 15, 2013, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 17, 2013 and incorporated herein by reference.
10.09	Amendment to Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Bruce Daugherty, dated October 15, 2013, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 17, 2013 and incorporated herein by reference.
10.10	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Seth Lederman, dated February 11, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 14, 2014 and incorporated herein by reference.
10.11	Letter of Termination, between Tonix Pharmaceuticals Holding Corp. and Lederman & Co., LLC, dated February 11, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 14, 2014 and incorporated herein by reference.
10.12	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Donald Kellerman, dated April 1, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on April 1, 2014 and incorporated herein by reference.

10.13	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Gregory Sullivan, dated June 3, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on June 3, 2014 and incorporated herein by reference.
10.14	Form of Subscription Agreement, dated July 11, 2014 between Tonix Pharmaceuticals Holding Corp. and the investors named therein, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on July 11, 2014 and incorporated herein by reference.
10.15	Placement Agent Agreement, dated July 11, 2014 between Tonix Pharmaceuticals Holding Corp. and Roth Capital Partners, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on July 11, 2014 and incorporated herein by reference.
10.16	Lease Amendment and Expansion Agreement, dated February 11, 2014, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed herewith.
14.01	Code of Ethics and Business Conduct for Officers, Directors and Employees, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on February 23, 2012 and incorporated herein by reference.
21.01	List of Subsidiaries, filed herewith.
23.01	Consent of Independent Registered Public Accounting Firm, filed herewith.
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

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: February 27, 2015

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

Date February 27, 2015

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ SETH LEDERMAN Seth Lederman	Director	February 27, 2015
/s/ STUART DAVIDSON Stuart Davidson	Director	February 27, 2015
/s/ PATRICK GRACE Patrick Grace	Director	February 27, 2015
/s/ DONALD W. LANDRY Donald W. Landry	Director	February 27, 2015
/s/ ERNEST MARIO Ernest Mario	Director	February 27, 2015
/s/ CHARLES MATHER IV Charles Mather IV	Director	February 27, 2015
/s/ JOHN RHODES John Rhodes	Director	February 27, 2015
/s/ SAMUEL SAKS Samuel Saks	Director	February 27, 2015

Exhibit 10.16

LEASE AMENDMENT AND EXPANSION AGREEMENT

LEASE AMENDMENT AND EXPANSION AGREEMENT (this "Amendment") made as of the ___ day of February, 2014, by and between **509 MADISON AVENUE ASSOCIATES, LP**, a New York limited partnership, having an address c/o Kensico Management, Inc., 509 Madison Avenue, New York, New York 10022 ("Landlord"), and **TONIX PHARMACEUTICALS, INC.**, a Delaware corporation, having an address at 509 Madison Avenue, Suite 306, New York, New York 10022 ("Tenant").

WITNESSETH:

WHEREAS, pursuant to that certain Standard Form of Office Lease and Rider thereto, both dated as of September 28, 2010 (collectively, the "Original Lease", and together with this Amendment, collectively, the "Lease"), between Landlord and Tenant, Landlord did demise and let to Tenant, and Tenant did hire and take from Landlord, certain premises (the "Original Premises") on the third (3rd) floor (also known as Suite 306) of the building located at and commonly known as 509 Madison Avenue, New York, New York (the "Building"), as more particularly identified in the Original Lease; and

WHEREAS, Tenant desires to lease from Landlord, and Landlord desires to lease to Tenant, certain additional premises on the third (3rd) floor of the of the Building (also known as Suite 310), as more particularly shown on the floor plan attached hereto as Exhibit A (the "Expansion Premises"), upon all of the terms and conditions of the Original Lease, except as amended hereby; and

WHEREAS, Landlord and Tenant desire to extend the term of the Original Lease and to otherwise modify and amend the terms and conditions of the Original Lease in connection therewith as set forth below.

NOW, THEREFORE, in consideration of the mutual covenants herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. **Defined Terms.** All capitalized terms used herein shall have the meaning ascribed to them in the Original Lease, unless specifically set forth herein to the contrary.

2. **Extension of Term**. The term of the Lease is hereby extended for a five (5) year period (the "Extension Term") commencing on May 1, 2014 (the "Extension Term Commencement Date") and expiring on April 30, 2019 (the "Expiration Date"), or on such earlier date upon which said term may expire or be terminated pursuant to any other conditions in the Lease as hereby amended or pursuant to law, upon all of the terms, covenants and conditions contained in the Original Lease, except as otherwise expressly set forth in this Amendment.

3. **Lease of Expansion Premises.** Effective as of the Extension Term Commencement Date, (i) Landlord hereby leases to Tenant and Tenant hereby hires from Landlord, upon and subject to the terms, covenants, provisions and conditions of the Original Lease and this Amendment, the Expansion Premises, and (ii) all references in the Lease to the "Demised Premises" shall be deemed to mean the Original Premises and the Expansion Premises, collectively, and all of Tenant's rights and obligations with respect to the Original Premises shall apply to the Expansion Premises, except as expressly modified herein.

4. **Extension Term Base Rent and Additional Rent.** Effective as of the Extension Term Commencement Date, the Lease shall be amended as follows:

(A) The annual Base Rent (as defined in Article 37 of the Original Lease) for the Demised Premises, payable in equal monthly installments, shall be as follows:

(i) $264,833.48 for the period commencing on the Extension Term Commencement Date and ending on April 30, 2015;

(ii) $272,348.64 for the period commencing on May 1, 2015 and ending on April 30, 2016;

(iii) $280,089.26 for the period commencing on May 1, 2016 and ending on April 30, 2017; and

(iv) $288,062.10 for the period commencing on May 1, 2017 and ending on April 30, 2018; and

(v) $296,274.12 for the period commencing on May 1, 2018 and ending on the Expiration Date.

(B) The term "Tenant's Percentage" as defined in Article 43(A)(4) of the Original Lease shall mean 3.56%.

(C) The amount for electrical services as set forth in Article 46(2) and (5) of the Original Lease shall be "FOURTEEN THOUSAND THREE HUNDRED TWENTY-EIGHT AND 00/100 ($14,328.00) DOLLARS"; and

(D) The rentable square footage of the demised premises for purposes of Article 46(5)(C)(6) of the Original Lease shall be 4,776.

5. **Condition of Expansion Premises; Landlord's Work.** Tenant acknowledges that it has inspected the Expansion Premises and agrees to accept possession thereof in its then "as-is" and broom clean condition on the Extension Term Commencement Date, it being understood and agreed that Landlord shall not be obligated to make any improvements, alterations or repairs to the Expansion Premises, except that Landlord, at its sole cost and expense, agrees to perform, prior to the Extension Term Commencement Date, the work in the Expansion Premises in accordance with the plans attached hereto as Exhibit B ("Landlord's Work"), all of which shall be of material, manufacture, design, capacity and finish selected by Landlord as standard of the Building. Further, Landlord agrees to commence Landlord's Work promptly subsequent to the mutual execution and delivery of this Amendment and to perform Landlord's Work in a good and workmanlike manner in accordance with all applicable laws, rules and regulations.

6. **Continued Lease of Original Premises.** Tenant hereby acknowledges and agrees that, at all times until the Extension Term Commencement Date, Tenant shall continue to lease the Original Premises upon all of the terms and conditions of the Original Lease.

7. **Condition of Original Premises.** Tenant hereby represents that it is currently in possession of the Original Premises and that it is fully familiar with the physical condition and state of repair thereof, and Tenant does hereby agree to continue to accept the same in its existing condition and state of repair, subject to any and all defects therein, "as is" as of the date hereof, and that Landlord shall have no obligation to perform any work or make any installation, repair or alteration of any kind to or in respect thereof in connection with Tenant's continued occupancy of the Original Premises.

8. **Security.**

(A) As of the Extension Term Commencement Date, Article 34 of the Original Lease shall be amended to provide that the Security Deposit shall be increased to $132,416.74. Prior to the Extension Term Commencement Date, Tenant shall deliver to Landlord a replacement Letter of Credit in the increased Security Deposit amount of $132,416.74 or an amendment to the original Letter of Credit previously deposited by Tenant in the amount of $72,354.24, which conforms to the requirements set forth in Article 69 of the Original Lease. Upon Landlord's receipt of a replacement Letter of Credit, Landlord shall promptly return to Tenant the original Letter of Credit previously deposited by Tenant.

(B) Notwithstanding anything to the contrary contained in the Lease, provided the Lease is in full force and effect and Tenant is not then in default under the Lease beyond the expiration of any applicable notice and cure periods, Tenant shall have the right to reduce the amount of the Security Deposit to the sum of $88,277.83 ("Reduced Security Amount") as of the second (2nd) anniversary of the Extension Term Commencement Date (the "Security Reduction Date"). If Tenant is entitled to such reduction on the Security Reduction Date in accordance with this Section 8, then Landlord shall either accept an amendment to the original Letter of Credit to reflect the Reduced Security Amount or simultaneously return the original Letter of Credit to Tenant upon receipt of a replacement Letter of Credit in the Reduced Security Amount, which conforms to the requirements set forth in Article 69 of the Original Lease. Any fees or charges imposed by the Issuing Bank in connection with a reduction in the Letter of Credit in accordance with this Section 8 shall be payable solely by Tenant.

9. **Guaranty**. As of the Extension Term Commencement Date, provided that Tenant is not then in default under the Lease beyond the expiration of any applicable notice and cure periods, that certain Good Guy Guaranty, dated as of September 28, 2010 (the "Guaranty"), executed by Seth Lederman in favor of Landlord, shall terminate and be of no further force or effect.

10. **Broker.** Landlord and Tenant each represents and warrants to the other that it has not dealt with any broker, finder or like agent in connection with this Amendment. Landlord and Tenant each does hereby agree to indemnify and hold the other harmless of and from any and all loss, costs, damage or expense (including, without limitation, attorneys' fees and disbursements) incurred by the other by reason of any claim of or liability to any broker, finder or like agent, who shall claim to have dealt with such party in connection with this Amendment. Landlord acknowledges and agrees that Landlord shall be obligated to pay any commission due and payable to NAI Global of New York City, Inc. ("NAI") in connection with this Amendment if Landlord previously obligated itself to do so in any brokerage agreement with NAI executed in connection with the Lease. This Section 10 shall survive the expiration or earlier termination of the Lease.

11. **Representations and Warranties.** Tenant represents and warrants to Landlord that, as of the date hereof, (i) the Lease is in full force and effect and has not been modified except pursuant to this Amendment; (ii) to the best of Tenant's knowledge, there are no defaults existing under the Lease; (iii) to the best of Tenant's knowledge, there exist no valid abatements, causes of action, counterclaims, disputes, defenses, offsets, credits, deductions, or claims against the enforcement of any of the terms and conditions of the Lease; (iv) this Amendment has been duly authorized, executed and delivered by Tenant and constitutes the legal, valid and binding obligation of Tenant; and (v) to the best of Tenant's knowledge, Landlord is not in default of any of its obligations or covenants under the Lease.

12. **Miscellaneous.**

(A) Except as set forth herein, nothing contained in this Amendment shall be deemed to amend or modify in any respect the terms of the Original Lease. The terms, covenants and conditions of the Original Lease are hereby ratified and confirmed and shall continue to be and remain in full force and effect throughout the remainder of the term hereof, as modified hereby. If there is any inconsistency between the terms of this Amendment and the terms of the Original Lease, the terms of this Amendment shall be controlling and prevail.

(B) This Amendment contains the entire agreement of the parties with respect to its subject matter and all prior negotiations, discussions, representations, agreements and understandings heretofore had among the parties with respect thereto are merged herein. This Amendment may not be modified, amended or terminated nor may any of its provisions be waived except by an agreement in writing signed by the party against whom enforcement of any modification, amendment, termination or waiver is sought.

(C) This Amendment shall not be binding upon Landlord or Tenant unless and until Landlord shall have delivered a fully executed counterpart of this Amendment to Tenant.

(D) This Amendment shall be binding upon and inure to the benefit of Landlord and Tenant and their successors and permitted assigns.

(E) This Amendment shall be governed by the laws of the State of New York without giving effect to conflict of laws principles thereof.

(F) This Amendment may be executed in duplicate counterparts, each of which shall be deemed an original and all of which, when taken together, shall constitute one and the same instrument.

[Signatures on following page]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed as of the day and year first above written.

LANDLORD:

509 MADISON AVENUE ASSOCIATES, L.P.

By: Kensico Management, Inc.
General Partner

By: _____
Alan Zimmerman, Secretary

TENANT:

TONIX PHARMACEUTICALS, INC.

By: _____
Name: Seth Lederman
Title: Chairman

Exhibit A

Expansion Premises

509 Madison Avenue – 3rd Floor

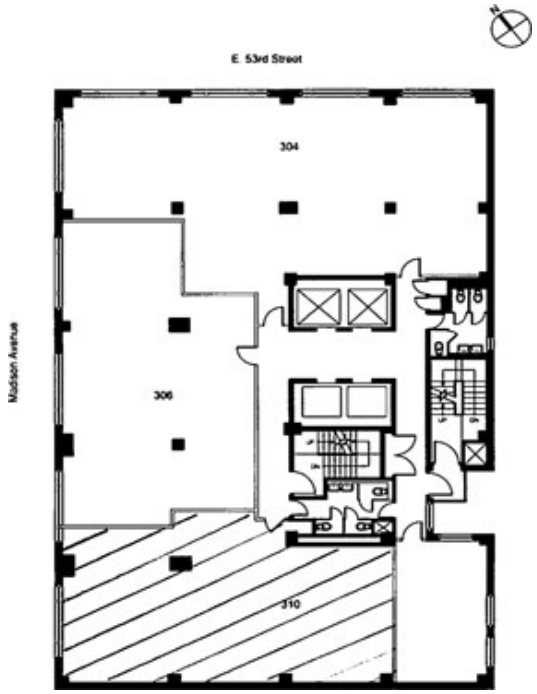

Exhibit B

Landlord's Work

(See Attached Plan)

1. New coat closet at Location "A." To include shelf and pole.
2. Remove door and side walls to make connection to the Additional Premises at location "B."
3. Install slab channeled floor box at location "C." To include data pull and electric.
4. New door, wall and glass panel at location "D."
5. Remove current demising wall at location "E" to make connection to the Additional Premises.
6. New pantry at location "F." To be similar in content and finishes to existing pantry.
7. Remove wall at location "G."
8. Patch carpet and paint at affected areas.
9. All dimensions and locations are approximate.

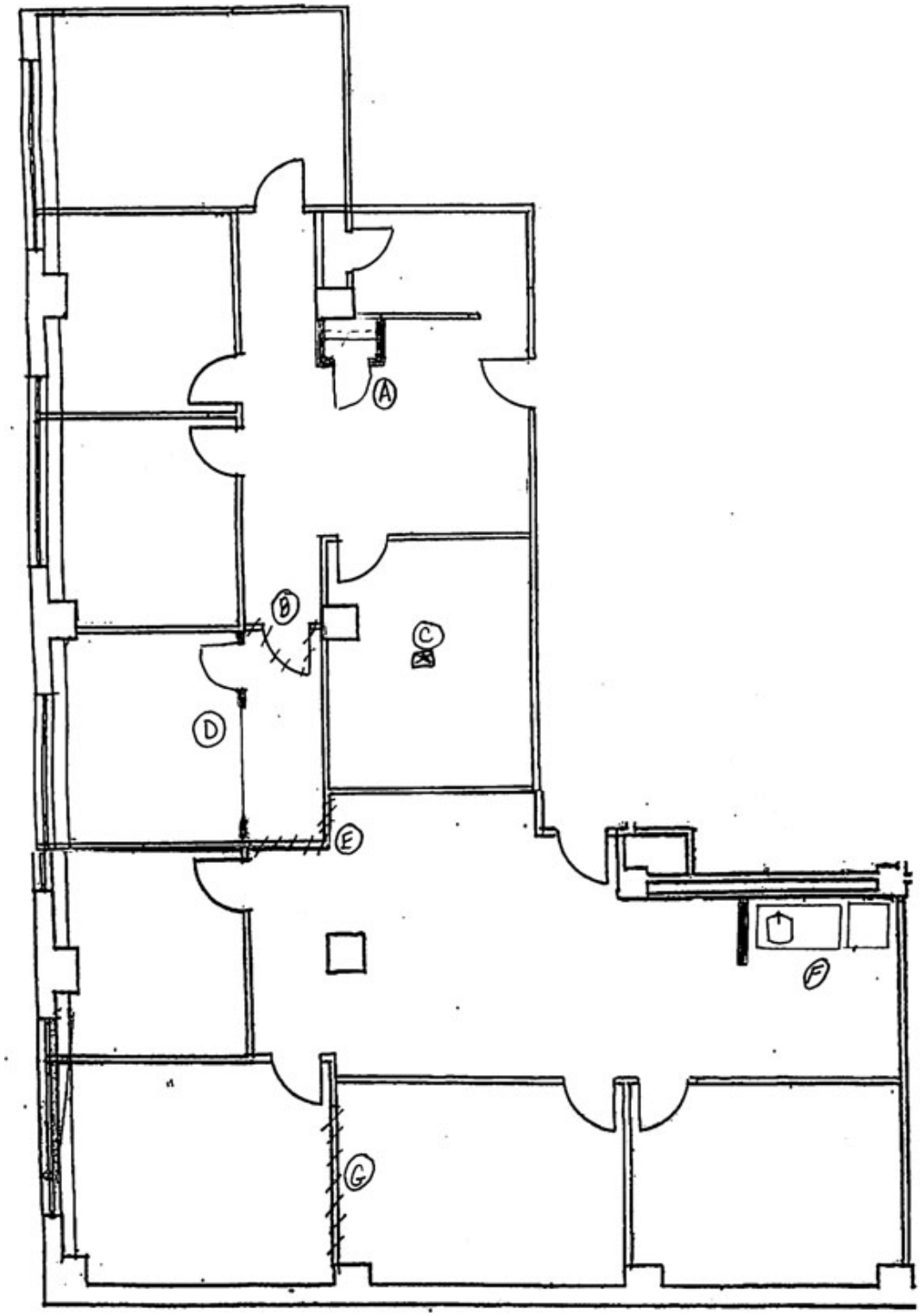
A
B
C
D
E
F
G

Exhibit 21.01

SUBSIDIARIES OF THE COMPANY

Subsidiary Name	State/ Jurisdiction of Incorporation/Formation
Tonix Pharmaceuticals, Inc.	Delaware
Krele, LLC	Delaware
Tonix Pharmaceuticals (Canada), Inc.	New Brunswick, Canada
Tonix Pharmaceuticals (Barbados) Ltd.	Barbados
Tonix Pharma Holdings Limited	Ireland
Tonix Pharma Limited	Ireland

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements [Form S-3 No. 333-192541 and Form S-8 No. 333-202006] of Tonix Pharmaceuticals Holding Corp. of our report dated February 27, 2015, with respect to the consolidated financial statements of Tonix Pharmaceuticals Holding Corp. and our report dated February 27, 2015 with respect to the effectiveness of Tonix Pharmaceuticals Holding Corp.'s internal controls over financial reporting included in this Annual Report on Form 10-K for the year ended December 31, 2014.

/s/ EisnerAmper LLP

New York, New York
February 27, 2015

Exhibit 31.01

CERTIFICATION

I, Seth Lederman, certify that:

1. I have reviewed this annual report on Form 10-K 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: February 27, 2015

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

Exhibit 31.02

CERTIFICATION

I, Leland Gershell, certify that:

1. I have reviewed this annual report on Form 10-K 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: February 27, 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 Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2014 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 Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: February 27, 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 Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2014 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 Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: February 27, 2015

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