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, 2016

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, 2016, based on the closing sales price of the common stock as quoted on The NASDAQ Global Market was $42,675,460. 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 April 13, 2017, there were 7,486,026 shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2017 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, 2016.

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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.

Tonix Pharmaceuticals®, TONMYA® , Protectic™, Angstro-Technology™ 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.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for posttraumatic stress disorder, or PTSD, is an investigational new drug and has not been approved for any indication.

Business Overview

Tonix Pharmaceuticals Holding Corp., together with its subsidiaries (collectively “we,” “our,” “us,” “Tonix” or the “Company”), is a clinical-stage pharmaceutical company dedicated to the development of innovative pharmaceutical products to address public health challenges. Our most advanced drug development program is focused on delivering an efficacious and safe long-term treatment for PTSD. PTSD is characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in the fields of PTSD and other central nervous system disorders. In September 2016, we discontinued our fibromyalgia program in order to fully focus our resources on our PTSD program.

Our lead product candidate, TNX-102 SL, a proprietary low-dose cyclobenzaprine sublingual tablet, designed for bedtime administration, is in Phase 3 development as a potential treatment for PTSD. Our development pipeline includes: TNX-601 (tianeptine oxalate), a separate pre-IND (Investigational New Drug) candidate designed for daytime administration for the treatment of PTSD and cognitive dysfunction associated with steroid use; TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, or HPXV; TNX-301 an IND candidate for the treatment of alcohol use disorders, or AUD; and TNX-701, a biodefense development program for protection from radiation injury. We hold worldwide development and commercialization rights to all of our product candidates.

TNX-102 SL – Posttraumatic Stress Disorder Program

TNX-102 SL is a small, rapidly disintegrating tablet containing cyclobenzaprine, or CBP, for sublingual administration and transmucosal absorption. TNX-102 SL has a proprietary, Protectic™ protective eutectic formulation of cyclobenzaprine that allows for rapid systemic exposure and increased bioavailability through the transmucosal delivery. We are developing TNX-102 SL for the management of PTSD under an IND cleared by the U.S. Food and Drug Administration, or FDA, in June 2014.

An estimated 8.6 million adults in the U.S. suffer from PTSD, a chronic disorder that is characterized by hyperarousal, avoidance, emotional numbing, 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. Antidepressants, sedative-hypnotics and antipsychotics not approved for PTSD are commonly prescribed despite generally weak evidence in support of their use. Antianxiety drugs, also called anxiolytics, are not approved for PTSD, but are commonly prescribed despite the recommendations against their use by many experts. Anxiolytics are comprised of benzodiazepine and non-benzodiazepine drugs, which carry risks of tolerance and addiction and are also associated with potential serious side-effects, such as retrograde amnesia.

Our Strategy

Our objective is to develop and commercialize our product candidates. The principal components of our strategy are to:

- ***Develop TNX-102 SL for PTSD***. We currently are focusing on the development of TNX-102 SL for PTSD. Our broader development strategy is to leverage the patentable formulation to explore the clinical potential of TNX-102 SL in multiple other central nervous system disorders that are underserved by currently available medications and represent large unmet medical needs;

- ***Maximize the commercial potential of TNX-102 SL***. We plan to commercialize TNX-102 SL for PTSD, either on our own or through collaboration with partners. We believe TNX-102 SL 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;

- ***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. We recently received a Notice of Allowance from the U.S. Patent and Trademark Office, or PTO, for patent claims the will protect the pharmaceutical eutectic composition of TNX-102 SL until 2034. We plan to opportunistically apply for new patents to protect TNX-102 SL 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 case of TNX-102 SL, 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 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, 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 fibromyalgia, generalized anxiety disorder, depression, and fatigue related to disordered sleep.

Disease and Market Overview

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

Posttraumatic 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. Of those who experience significant trauma, approximately 20% of women and 8% of men develop PTSD. According to the U.S. Department of Veterans Affairs, the prevalence rate of PTSD in the military population is higher than that among civilians. As of 2015, there were approximately 638,000 veterans receiving treatment for PTSD in the Veterans Health Administration, or VHA. Based on March 2015 VHA data, more than 19% of military veterans involved in recent conflicts were seen at VHA facilities for potential or provisional PTSD.

The medications currently approved by the FDA for the treatment of PTSD show little evidence of a treatment effect in men, lack evidence of efficacy in those for whom the traumatic event was combat-related, and carry suicidality warnings. Sleep disturbances are central features of PTSD and are predictive of disease severity, depression, substance abuse, and suicidal ideation, yet are resistant to the approved medications and present a difficult therapeutic challenge. Current PTSD treatments include off-label use of anxiolytics, sedative-hypnotics, and antipsychotics, many of which lack reliable evidence of efficacy, and have significant safety liabilities and dependence risk.

TNX-102 SL

Overview

TNX-102 SL is a proprietary 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 PTSD. 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. Excipients used in TNX-102 SL are approved for pharmaceutical use. Some of the excipients were specially selected to promote a local oral environment that facilitates mucosal absorption of CBP.

The current TNX-102 SL sublingual tablets contain 2.8 mg of CBP. For the treatment of PTSD, 5.6 mg of TNX-102 SL, comprised of two TNX-102 SL 2.8 mg tablets administered simultaneously at bedtime, is in Phase 3 development. 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 long-term 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 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 PTSD, including the transporters that mediate serotonin and norepinephrine reuptake. In addition, TNX-102 SL also acts upon other receptors in the central nervous system not targeted by products approved for PTSD, including the serotonin 2A, alpha-1 adrenergic and histamine H-1 receptors.

CBP is the active ingredient of two 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). The FLEXERIL brand of cyclobenzaprine immediate-release tablet has been discontinued since May 2013. There are numerous generic versions of cyclobenzaprine immediate-release tablets on the market. CBP-containing products are not indicated for the treatment of PTSD. CBP-containing products are approved for short term use (two to three weeks) only as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. 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 taken once a day mimic, and flatten, the pharmacokinetic profile of three times per day immediate-release CBP tablets.

We designed TNX-102 SL to be administered once-daily at bedtime and intended for long-term dosing regimen. We believe the selected dose of TNX-102 SL and its pharmacokinetic profile will enable it to achieve a desirable balance of efficacy, safety, and tolerability in 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. In clinical studies, TNX-102 SL 2.8 mg and TNX-102 SL 5.6 mg were generally well-tolerated, with no serious adverse events reported in these studies. Some subjects experienced transient numbness of the tongue after TNX-102 SL administration.

We expect that any applications we submit to the 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, for product candidates containing an active ingredient that is similar or identical to an already approved product. In general, the development timeline for a 505(b)(2) New Drug Application, or NDA, is shorter and less expensive than an NDA developed under Section 505(b)(1), which is for new chemical entities, or NCEs, that have never been approved in the United States. Currently, we are pursuing the development of TNX-102 SL for PTSD, for which TNX-102 SL is in Phase 3 development. We believe that TNX-102 SL has the potential to provide clinical benefit to this and possibly other CNS indications that are underserved by currently marketed products.

On March 10, 2017, we received a notice of allowance for the US patent application No. 14/214,433 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, which includes compositions of cyclobenzaprine HCl and methods of manufacturing the eutectic. The allowed claims will protect the pharmaceutical composition, since it is based on the eutectic. The allowed claims will also protect the method of manufacturing the eutectic. Eutectic tablets containing cyclobenzaprine HCl and mannitol eutectic have good pharmaceutical stability and manufacturability. A solid eutectic is a form of matter in which two solid crystals co-penetrate each other, such that the inter-molecular space between the units of one crystal lattice are occupied by the other crystal’s lattice. The distance between the molecular units is not changed. A Notice of Allowance signifies that we will be entitled to receive patent protection until 2034 in the U.S. for the allowed claims when the patent is issued.

TNX-102 SL – PTSD Program

We are developing TNX-102 SL for the treatment of PTSD under an effective IND application.

Clinical Development Plan

Phase 2 AtEase Study

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

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

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

Open-label Extension Study for AtEase

Patients who completed the AtEase study were eligible to enroll into a three-month open-label extension study with TNX-102 SL 2.8 mg. We conducted this open-label extension study to obtain additional safety information from patients in the AtEase Study. The clinical phase of this open-label extension study is complete. TNX-102 SL 2.8 mg was well tolerated for up to six months of treatment and no new safety signals were revealed in this open-label extension study.

Ongoing Phase 3 Study

We have commenced a randomized, double-blind placebo-controlled Phase 3 study of TNX-102 SL in approximately 550 patients with military-related PTSD in the first quarter of 2017. This first Phase 3 study, the "HONOR study," is an adaptive design study based on the results of the Phase 2 AtEase study. The study design is very similar to the Phase 2 AtEase study , except there will be one planned interim analysis and the involvement of an independent data monitoring committee, or IDMC, to review unblinded interim analysis results. The IDMC will make a recommendation to continue as planned, to continue but increase the number of recruited patients or to stop for success. In addition, there will be one active dose (5.6 mg administered as 2 x 2.8 mg tablets) and the entrance criterion is CAPS-5 $\geq$ 33 in this Phase 3 study. The interim analysis will be conducted when approximately 50% (approximately 250 – 300 patients) of the initially planned patient enrollment is evaluable for efficacy. We received FDA acceptance of the Phase 3 HONOR study design in January of 2017. The HONOR study involves approximately 35 U.S. centers. As in the case of the AtEase study, the primary efficacy endpoint of the HONOR study is the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale between those treated with TNX-102 SL 5.6 mg and those receiving placebo.

Prospective Phase 3 Study

A second, randomized, double-blind placebo-controlled Phase 3 study of TNX-102 SL in approximately 550 predominantly civilian PTSD patients will follow. We expect this study to be conducted at approximately 35 U.S. centers. As in the case of the HONOR and AtEase studies, the primary efficacy endpoint of this second Phase 3 study will be the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale between those treated with TNX-102 SL 5.6 mg and those receiving placebo.

Long-Term Safety Exposure Study for TNX-102 SL 5.6 mg

We plan to conduct the registration-required open-label extension studies of TNX-102 SL 5.6 mg in patients who complete either the HONOR study or the predominantly civilian PTSD Phase 3 study. The goal of the open-label extension studies is to obtain adequate 6- and 12-month safety exposure data from the maximum therapeutic dose to support the registration of TNX-102 SL for the treatment of PTSD, a chronic psychiatric condition.

Regulatory Update

Subsequent to reporting the Phase 2 AtEase study topline result, we held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in early August 2016 to discuss the Phase 3 program required to support the registration of TNX-102 SL 5.6 mg for the treatment of PTSD and the remaining data package for the NDA filing. Based on this meeting discussion and the official FDA meeting minutes, we expect that positive results from two adequate, well-controlled Phase 3 efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would provide sufficient evidence of efficacy and safety to support the clinical approval of TNX-102 SL 5.6 mg for the treatment of PTSD. As described below, the first Phase 3 study will be in patients with military-related PTSD and the second Phase 3 study will study predominately civilian PTSD patients.

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

In December 2016, the FDA granted Breakthrough Therapy designation to TNX-102 SL for the treatment of PTSD. The Breakthrough Therapy designation request was based on the preliminary clinical evidence of TNX 102-SL on military-related PTSD in the AtEase study.

Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The benefits of Breakthrough Therapy designation include the eligibility for priority review of the NDA within six months instead of 10 months and rolling submission of portions of the NDA, in addition to an organizational commitment involving FDA's senior managers contributing significant guidance. The FDA is committing to provide us timely advice and interactive communications related to the design and efficient execution of our drug development program.

In March 2017, we held the Initial Cross-Disciplinary Breakthrough Therapy Type B meeting with the FDA to discuss the opportunity to accelerate the development and submission of the TNX-102 SL NDA for the treatment of PTSD. Based on our discussions with the FDA and the FDA official meeting minutes, a single-study NDA approval could be possible based on topline data from the ongoing HONOR study. Additionally, due to the lack of evidence of potential abuse in clinical studies of TNX-102 SL, the FDA agreed that studies in assessing abuse potential of TNX-102 SL are not required to support the TNX-102 SL NDA.

Other NDA Requirements

An Agreed Initial Pediatric Study Plan, or Agreed iPSP, is required for the initial NDA submission. We submitted an Agreed iPSP in the first quarter of 2017, which incorporated the FDA comments received on our Initial Pediatric Study Plan submitted in the third quarter of 2016. A Final Pediatric Study Plan requirement will be determined at the time of the NDA approval.

Based on our discussions with the FDA and the FDA official meeting minutes, we will not have to conduct special populations (geriatric and renal/hepatic impaired), drug-drug interaction or cardiovascular safety studies to support the NDA filing. Due to the well-established safety profile of CBP at much higher doses than we proposed for PTSD and the long-term safety data (up to 15 months) on TNX-102 SL 2.8 mg in a prior fibromyalgia program, the FDA has not requested a risk management plan or medication guide for this product. Similarly, no drug abuse and dependence study is required for this NDA.

Phase 1 Bioequivalence, Bridging PK, Food-Effect and Dose-Proportionality Studies

Completed Bioequivalence Study

We completed a Phase 1 bioequivalence study that compared the pharmacokinetic profiles of single-dose of TNX-102 SL 2.8 mg tablets manufactured at two facilities: (i) the facility used to produce TNX-102 SL 2.8 mg tablets for the Phase 2 AtEase study; and (ii) the facility used to produce TNX-102 SL 2.8.mg tablets for our clinical studies required to support the PTSD NDA submission and the to-be-marketed product. This bioequivalence study demonstrated that the TNX-102 SL 2.8 mg tablets manufactured at these two facilities were bioequivalent, supporting the use of the AtEase study to support the Phase 3 studies.

Planned Multi-dose Bridging PK Study

We intend to seek FDA marketing approval for TNX-102 SL pursuant to Section 505(b)(2) of the FDCA using AMRIX extended-release capsules (30 mg) as our reference listed drug, or RLD. As agreed upon by the FDA, we plan to study TNX-102 SL 5.6 mg (two 2.8 mg tablets) in comparison to AMRIX 30 mg extended-release capsules in a multiple-dose bridging PK study to provide a systemic exposure bridge. If the exposures of TNX-102 SL (2 x 2.8 mg tablets) are less than the RLD maximum approved dose (30 mg) for the initial dose and at steady state, the results of this study will provide the necessary systemic exposure bridge of TNX-102 SL 5.6.mg to AMRIX 30 mg extended-release capsules and the approval of TNX-102 SL for PTSD can rely on the safety findings (clinical and nonclinical) of the currently approved cyclobenzaprine drug products.

Food Effect and Dose-proportionality Studies

To support the TNX-102 SL product registration, a randomized, open-label, 2-way crossover, food-effect, comparative bioavailability study of TNX-102 SL following a single dose in healthy subjects under fasting and fed conditions and a randomized, open-label, 2-way crossover, dose-proportionality, comparative bioavailability study of TNX-102 SL following a single dose in healthy subjects under fasting conditions will be completed for the TNX-102 SL NDA submission.

TNX-102 SL Nonclinical Development

The FDA has accepted our proposed nonclinical data package to support our PTSD NDA filing. In October 2016, we completed the six-month repeated-dose toxicology study of TNX-102 in rats and a nine-month repeated-dose toxicology study in dogs required for the NDA filing and to support Phase 3 clinical studies outside the U.S., if necessary. These chronic toxicity studies were requested by the FDA to augment the nonclinical information in the AMRIX approved prescribing information, or labeling, which is necessary to support the TNX-102 SL labeling for long-term use. Based on the prescribing information of AMRIX and the post-marketing surveillance information, there is no evidence of abuse for cyclobenzaprine. As a result, the FDA has advised that we will not have to assess the abuse potential of TNX-102 SL to support the TNX-102 SL 505(b)(2) NDA submission for the treatment of PTSD.

Manufacturing

The TNX-102 SL drug product 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 the HONOR study, the predominantly civilian PTSD Phase 3 study 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 is supported by the bioequivalence results of the single-dose pharmacokinetic study.

Additional Product Candidates

We also have a pipeline of other drug and biologic candidates, including two pre-IND candidates, TNX-601 for PTSD and TNX-801, a biologic vaccine product for the prevention of smallpox, as well as an IND candidate, TNX-301, a potential treatment for AUD.

TNX-601

TNX-601 is a novel oral formulation of tianeptine oxalate in the pre-IND stage of development for the treatment for PTSD. Currently there is no tianeptine-containing product approved in the U.S., but tianeptine sodium (amorphous) has been marketed in Europe, Asia, and Latin America for the treatment of depression since 1987. It is effective in various depressive states and also improves depression-associated anxiety and somatic complaints. We have discovered a novel oxalate salt and polymorph, which we believe may provide improved stability, consistency, and manufacturability relative to the known forms of tianeptine. Like cyclobenzaprine, tianeptine shares structural similarities with classic tricyclic antidepressants, but it has unique pharmacological and neurochemical properties. Tianeptine modulates the glutamatergic system indirectly and reverses the neuroplastic changes that are observed during periods of stress and corticosteroid use. It is a weak mu-opioid receptor (MOR) agonist, but does not have significant affinity for other known neurotransmitter receptors. Due to its use in Europe, Asia, and Latin America for several decades, tianeptine has an established safety profile. In addition to being used to treat depression, several published studies support the potential of tianeptine as a potentially effective and safe therapy for patients with PTSD. Leveraging our development expertise in PTSD, TNX-601 is being developed for daytime usage as a first-line monotherapy for PTSD. Tianeptine's reported pro-cognitive and anxiolytic effects as well as its ability to attenuate the neuropathological effects of excessive stress responses suggest that it may be used to treat PTSD by a different mechanism of action than TNX-102 SL.

On April 19, 2016, we were issued US patent 9,314,469 B2 "Method for treating neurocognitive dysfunction," which includes using tianeptine for cognitive dysfunction associated with corticosteroid use. We intend to develop TNX-601 under Section 505(b)(1) of the FDCA as a potential treatment for PTSD and cognitive dysfunction associated with corticosteroid use. Pharmaceutical development work on TNX-601 has been initiated.

TNX-801

TNX-801 is a novel potential smallpox-preventing vaccine based on a live synthetic version of HPXV grown in cell culture. TNX-801 was synthesized by Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada in collaboration with us. HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection. Vaccine manufacturing activities have been initiated to support further nonclinical testing of TNX-801. We are developing TNX-801 as a potential smallpox-preventing vaccine for widespread immunization and for the U.S. strategic national stockpile. Though it shares structural characteristics with vaccinia-based vaccines, TNX-801 has unique virulence properties that we believe may suggest lower toxicity and potential safety advantages over existing vaccinia-based vaccines, which have been associated with adverse side effects such as myopericarditis.

We intend to develop TNX-801 under 21 CFR 601 Subpart H, pursuant to which the FDA may grant marketing approval for a biological product for which safety has been established in humans and for which the requirements for efficacy are met based on adequate and well-controlled animal studies, where human studies are not ethical or feasible. This approval pathway has been described as the "Animal Rule". In the 1970s, vaccination against smallpox was discontinued in the U.S.; however, smallpox remains a material threat to national security. We recently filed a patent on the novel virus vaccine. In addition, 12 years of non-patent based exclusivity is expected under the Patient Protection and Affordable Care Act. Following the recent passage of the 21st Century Cures Act, we believe TNX-801 qualifies as a medical countermeasure, and therefore should be eligible for a Priority Review Voucher upon FDA approval. We are currently working to develop a vaccine that meets cGMP quality to support an IND.

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 AUD, and we have commenced development work on TNX-301 formulations. A pre-IND meeting was held in February 2016 to discuss the clinical development program of TNX-301 for AUD. At that meeting, the FDA advised us of the nonclinical studies required for this CDP IND application to support the initiation of the first-in-man study with TNX-301. IND planning activities are underway.

TNX-701

In addition, we own rights to intellectual property on a biodefense technology relating to the development of protective agents against radiation exposure, which we refer to as TNX-701. We have begun nonclinical research and development on TNX-701. Similar to the regulatory pathway intended for TNX-801, we plan to develop TNX-701 under 21 CFR 601 Subpart H, or the "Animal Rule". We expect significant reduction in 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 PTSD and other CNS conditions are well developed and populated with established drugs marketed by large and small pharmaceutical, biotechnology and generic drug companies. 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.

Certain other companies and institutions are known to be developing prescription medications for PTSD, including Bionomics (BNC-201), Otsuka/Lundbeck (Rexulti® [brexpiprazole]), Uniformed Services University of the Health Sciences (riluzole) and the Multidisciplinary Association of Psychedelic Studies (methylenedioxymethamphetamine [MDMA]). BNC-201 is in Phase 2 for civilian PTSD and is an allosteric modulator of the alpha 7 nicotinic acetylcholine receptor. Rexulti is in Phase 2 for PTSD and is an atypical antipsychotic. Riluzole is in a Phase 2 trial for active duty military members and veterans with PTSD and is a blocker of certain sodium channels and a modulator of the glutamatergic system. MDMA is Phase 3 ready for PTSD and is a Drug Enforcement Administration, or DEA, schedule 1 hallucinogen that is being studied for drug-assisted psychotherapy. Brainsway Ltd., a medical device company, is currently recruiting patients for a pivotal Phase 3 trial using a deep transcranial magnetic stimulation device. A number of other companies have or may be developing prescription medications for PTSD, including Actavis, Johnson and Johnson, Marinus Pharmaceuticals, Merck, 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. Additionally, a number of companies are working on vaccines/treatments for smallpox, including Bavarian Nordic, SIGA and Chimerix. Bavarian Nordic is developing Modified Virus Ankara, or MVA, which is a vaccine. SIGA is developing Arestvy ® (tecovirimat), which is an antiviral. Chimerix is developing brincidofovir (CMX001), which is an antiviral.

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 March 31, 2017, the patents we are either the owner of record of or own the contractual right to include three issued U.S. patents and 16 issued non-U.S. patents. We are actively pursuing an additional 15 U.S. patent applications, of which four are provisional and 11 are non-provisional, one international patent application, and 71 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 PTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another 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 March 31, 2017 are summarized below.

TNX-102 SL — CNS

Our patent portfolio for TNX-102 SL includes patent applications directed to compositions of matter of CBP, formulations containing CBP, and methods for treating CNS conditions utilizing these compositions and formulations. U.S. Patent No. 9,474,728 is expected to expire in 2031, excluding any patent term 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 PTSD and other CNS conditions utilizing eutectic CBP compositions and formulations, 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 or 2035, excluding any patent term adjustments or extensions.

On March 10, 2017, we received a notice of allowance from the PTO for the US patent No. 14/214,433 "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride," which includes compositions of cyclobenzaprine HCl and methods of manufacturing the eutectic. The allowed claims will protect the pharmaceutical composition since it is based on the eutectic. The allowed claims will also protect the method of manufacturing the eutectic. Eutectic tablets containing cyclobenzaprine HCl and mannitol eutectic have good pharmaceutical stability and manufacturability. A solid eutectic is a form of matter in which two solid crystals co-penetrate each other, such that the inter-molecular space between the units of one crystal lattice are occupied by the other crystal lattice. The distance between the molecular units is not changed.

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 compositions of matter of CBP, formulations containing CBP, and methods for treating PTSD and other CNS conditions utilizing these compositions and formulations. 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.

TNX-601 — PTSD

Our patent portfolio for tianeptine oxalate includes U.S. provisional Patent Application No. 62/439,533. It includes claims directed to composition, including pharmaceutical compositions, and methods of use.

TNX-801 — Live HPXV Vaccine for Prevention of Smallpox

We own the rights to develop a potential biodefense technology, TNX-801, a live HPXV that is a new vaccine candidate against smallpox. We have patent applications directed to synthetic chimeric poxviruses and methods of using these poxviruses to protect individuals against smallpox. These applications include U.S. provisional Patent Application Nos. 62/416,577 and 62/434,794. We also own the rights to develop some different vaccine candidates against smallpox. With respect to this smallpox vaccine candidate, we own U.S. non-provisional Patent Application No. 14,207,727 and related intellectual property rights. The smallpox vaccine technologies relate to proprietary forms of live HPXV and 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 this technology, after further development, may be of interest to biodefense agencies in the U.S. and other countries.

TNX-301 — Alcohol Use Disorders

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 AUD, 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.

TNX-701 — Radioprotection Biodefense Technology

We own the rights to develop a potential biodefense technology, which is a potential radioprotective therapy. For protection of intellectual property, we have not disclosed the identity of the new development candidate.

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 include:

Sublingual Cyclobenzaprine/Amitriptyline

Patent No.	Title	Country / Region	Expiration Date
631144	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033

Depression Treatment

Patent No.	Title	Country / Region	Expiration Date
2012225548	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia	March 6, 2032
614725	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand	March 6, 2032

Neurocognitive Dysfunction Treatment

Patent No.	Title	Country / Region	Expiration Date
9,314,469	Method for Treating Neurocognitive Dysfunction	U.S.A.	September 24, 2030

AUD 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:

Cyclobenzaprine/Amitriptyline Eutectics

Application No.	Title	Country / Region
14/214,433	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
15/459,093	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
14/776,624	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
15/511,287	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
2014233277	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Australia
BR112015022095-9	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Brazil
112017005231-8	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Brazil
2,904,812	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Canada
Not Yet Assigned	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Canada
201480024011.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	China
Not Yet Assigned	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China
14762323.5	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Europe
16106690.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
P-00 2015 06570	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia
241353	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Israel
251218	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Israel
3392/KOLNP/2015	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	India
2016-503239	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan
Not Yet Assigned	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan
MX/a/2015/012622	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico
Not Yet Assigned	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Mexico
PI 2015703142	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Malaysia
PI 2017700889	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Malaysia
631152	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand
730061	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand
730379	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand
517381123	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Saudi Arabia
515361124	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Saudi Arabia
11201507124X	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Singapore
11201701995P	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Singapore
2015/07443	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	South Africa
2017/01637	Eutectic Formulations of Cyclobenzaprine Hydrochloride	South Africa
103109816	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan
2014-000391	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Venezuela
PCT/US2015/051068	Eutectic Formulations of Cyclobenzaprine Hydrochloride	PCT

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
2,876,902	Compositions and Methods for Transmucosal Absorption	Canada
201380039522.6	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
1515110186.6	Compositions and Methods for Transmucosal Absorption	Hong Kong
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
2015-517469	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
726488	Compositions and Methods for Transmucosal Absorption	New Zealand
10201605407T	Compositions and Methods for Transmucosal Absorption	Singapore
102121267	Compositions and Methods for Transmucosal Absorption	Taiwan
2013-000737	Compositions and Methods for Transmucosal Absorption	Venezuela
2015/00288	Compositions and Methods for Transmucosal Absorption	South Africa

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
15/266,035	Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine	U.S.A.

Esreboxetine for Fibromyalgia

Application No.	Title	Country / Region
62/430,864	Salts and Polymorphs of Esreboxetine for the treatment of Fibromyalgia	U.S.A.

Tianeptine for PTSD

Application No.	Title	Country / Region
62/439,533	Tianeptine Oxalate Salts and Polymorphs	U.S.A.

Novel Smallpox Vaccines

Application No.	Title	Country / Region
14/207,727	Novel Smallpox Vaccines	U.S.A.

Synthetic Chimeric Poxviruses

Application No.	Title	Country / Region
62/416,577	Synthetic Chimeric Poxviruses	U.S.A.
62/434,794	Synthetic Chimeric Poxviruses	U.S.A.

Depression Treatment

Application No.	Title	Country / Region
13/412,571	Methods and Compositions for Treating Depression Using Cyclobenzaprine	U.S.A.
2016222412	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
2016-7041	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Japan
714294	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand
730065	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand

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
2611440	Treatment for Cocaine Addiction	Austria, Belgium, Portugal, Denmark, Switzerland, 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
15/064,196	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

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. We are the owner of the following U.S. federally registered marks: TONIX PHARMACEUTICALS (Reg. No. 4656463, issued December 16, 2014) and TONMYA (Reg. No. 4868328, issued December 8, 2015).

We are the owner of the following marks for which applications for U.S. federal registration are currently pending: FYMRALIN (Serial No. 86/516046, filed January 27, 2015), MODALTIN (Serial No. 86/631228, filed May 15, 2015), RAPONTIS (Serial No. 86/631236, filed May 15, 2015), IMADAZIO (Serial No. 86/631242, filed May 15, 2015), PROTECTIC (Serial No. 86/636119, filed May 20, 2015), TONIX PHARMACEUTICALS (Serial No. 86/400401, filed September 19, 2014) and ANGSTRO-TECHNOLOGY (Serial No. 86/713402, filed August 3, 2015).

Research and Development

We have approximately 10 employees dedicated to research and development. We anticipate that our research and development expenditures will decrease as we focus our efforts on our late-stage clinical development of TNX-102 SL for PTSD. 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, San Diego, CA, Dublin, Ireland and Montreal, Canada. We have used, and expect to continue to use, third parties to conduct our nonclinical and clinical studies.

Manufacturing

We have contracted with third-party cGMP-compliant contract manufacturing organizations, or CMOs, for the manufacture of TNX-102 SL 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. Our manufacturing operations are managed and controlled in Dublin, Ireland.

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

Our smallpox-preventing vaccine candidate is a biologic uses live form of HPXV. Both the drug substance (horsepox virus and the cell bank) and the drug product (vaccine) will be manufactured by contract cGMP-compliant facilities capable of manufacturing for nonclinical/clinical testing and licensed product.

Government Regulations

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;
- 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 for drug products, or a Biologic License Application, or BLA, for biologic products;
- 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 or BLA 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. 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.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

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 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. We may need to file a Section 505(b)(1) NDA for certain other products in the future. 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 an NDA under Section 505(b)(2) for TNX-102 SL for PTSD. The FDA may not agree that this product candidate is approvable for PTSD as a Section 505(b)(2) NDA. If the FDA determines that a Section 505(b)(2) NDA is not appropriate and that a full NDA is 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 a full NDA 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 in the orange book 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 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 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 nonclinical 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.

In December 2016, the FDA granted Breakthrough Therapy designation to TNX-102 SL for the treatment of PTSD. The Breakthrough Therapy designation request was submitted based on the preliminary clinical evidence of TNX 102-SL on military-related PTSD in the AtEase study.

Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The benefits of Breakthrough Therapy designation include the eligibility for priority review of the NDA within six months instead of 10 months and rolling submission of portions of the NDA, in addition to an organizational commitment involving FDA's senior managers contributing significant guidance. The FDA is committing to provide us timely advice and interactive communications related to the design and efficient execution of our drug development program.

Material Threat Medical Countermeasures

In 2016, the 21st Century Cures Act, or the Act, was signed into law to support ongoing biomedical innovation. One part of the Act, Section 3086, is aimed at "Encouraging Treatments for Agents that Present a National Security Threat." The Act created a new priority review voucher program for "material threat medical countermeasures." The Act defines such countermeasures as drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat or to treat harm from a condition that may be caused by administering a drug or biological product against such an agent. The Department of Homeland Security has identified 13 such threats, including anthrax, smallpox, Ebola/Marburg, tularemia, and botulism. A priority review voucher can be applied to any other product; it shortens the FDA review timeline for a new application from 10 months to 6 months. The recipient of a priority review voucher may transfer it. We intend to seek a priority voucher for TNX-801 as a material threat medical countermeasure.

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.

The Impact of New Legislation and Amendments to Existing Laws

The FDCA is subject to routine legislative amendments with a broad range of downstream effects. In addition to new legislation, such as the 21st Century Cures Act in 2016, or the Food and Drug Administration Safety and Innovation Act in 2012, Congress introduces amendments to reauthorize drug user fees and address emerging concerns every five years. We cannot predict the impact of these new legislative acts and their implementing regulations on our business. The programs established or to be established under the legislation may have adverse effects upon us, including increased regulation of our industry. Compliance with such regulation may increase our costs and limit our ability to pursue business opportunities. 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. For example, the 21st Century Cures Act establishes a number of requirements, such as the public disclosure of information on experimental treatments, which may be costly and take time to implement. Additionally, the current legislative authority for the Prescription Drug User Fee Act expires in September 2017. The requirements and changes imposed by the legislation to reauthorize the act 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. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations will change, or what the impact of such changes, if any, may be.

Employees

As of April 12, 2017, we had 18 full-time employees, of whom five hold M.D. or Ph.D. degrees. We have 10 employees dedicated to research and development. Our research and development operations are located in New York, NY, San Diego, CA, Dublin, Ireland and Montreal, Canada. We have used, and expect to continue to use, third parties to conduct our nonclinical 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.

Corporate Information

Our principal executive offices are located at 509 Madison Avenue, Suite 306, New York, New York 10022, and our telephone number is (212) 980-9155. Our website addresses are www.tonixpharma.com, www.tonix.com, and www.krele.com. We do not incorporate the information on our websites into this annual report, and you should not consider such information part of this annual report.

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp.

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.

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

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

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

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

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

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

We are a development-stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to developing our technology and undertaking preclinical and nonclinical testing and clinical studies of our clinical-stage product candidate, TNX-102 SL for PTSD. We have not yet obtained regulatory approvals for TNX-102 SL 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 studies;
- the success of our clinical studies through all phases of clinical development, including studies of our most advanced product candidate TNX-102 SL for PTSD;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidate TNX-102 SL for PTSD or any of our other product candidates in the United States and foreign jurisdictions;
- potential nonclinical toxicity and/or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
- our dependence on third party CMOs to supply or manufacture our products;
- our dependence on third party contract research organizations, or CROs, to conduct our clinical studies and nonclinical research;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;

- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

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

We 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 couple of 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 candidate, TNX-102 SL for PTSD, and we cannot be certain that this product candidate 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 studies, 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 one product candidate, TNX-102 SL, in Phase 3 development for the treatment of PTSD, and the success of our business currently depends on its successful development, approval and commercialization. Any projected sales or future revenue predictions are predicated upon FDA approval and market acceptance of TNX-102 SL. 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 has not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for this product candidate anywhere in the world. The clinical development program for TNX-102 SL for PTSD 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 studies fail to demonstrate to their satisfaction that this product candidate is 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 study process. Any failure or delay in completing clinical studies or obtaining regulatory approvals for TNX-102 SL for PTSD 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 approval of TNX-102 SL for PTSD. 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 will need additional capital. If additional capital is not available or is available at unattractive terms, we may be forced to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations.

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

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

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

We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical and nonclinical testing and clinical studies, 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 or complete clinical studies 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 using our technologies and patents 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 and intellectual property rights in these and other countries.

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 related to them. 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 us any competitive advantage; our competitors, many of which have substantially greater resources than we 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; and countries other than the United States may have less robust 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 using our technologies and patents.

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 or propriety technologies 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 to us of the patent.

In addition, the United States Patent and Trademark Office, or USPTO, 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 innovations specifically 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 and patent applications that may be licensed exclusively to us and other patents and patent applications 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. These patents, patent applications, and published literature may 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 present and future patents and other proceedings of our competitors. The defense and prosecution of intellectual property suits are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation 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. Third parties may assert that our patents are invalid and/or unenforceable in these proceedings. Such litigation 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.

Third parties may also assert that our patents are invalid in patent office administrative proceedings. These proceedings include oppositions in the European Patent Office and *inter partes* review and post-grant review proceedings in the USPTO. The success rate of these administrative challenges to patent validity in the United States is higher than it is for validity challenges in litigation.

Interference or derivation proceedings brought before the USPTO may be necessary to determine priority of invention with respect to innovations disclosed in our patents or patent applications. During these proceedings, 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 or derivation 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 or derivation 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.

There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation or administrative proceedings could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

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

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical study;
- reaching agreement on acceptable terms with prospective CROs and study sites;
- developing a stable formulation of a product candidate;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approval to conduct a clinical study at a prospective site.

Once a clinical study 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 studies;
- failure to conduct clinical studies in accordance with regulatory requirements;
- lower than anticipated recruitment or retention rate of patients in clinical studies;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical studies;
- negative results of clinical studies;
- investigational drug product out-of-specification; or
- nonclinical or clinical safety observations, including adverse events and serious adverse events.

If clinical studies 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 studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical study sites to ensure the proper and timely conduct of our clinical studies. 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 studies 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 studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. The FDA enforces these cGCPs through periodic inspections of study sponsors, principal investigators and clinical study sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical studies may be deemed unreliable and the FDA may require us to perform additional clinical studies before approving any marketing applications. Upon inspection, the FDA may determine that our clinical studies did not comply with cGCPs. In addition, our clinical studies, including our ongoing Phase 3 HONOR study in military-related PTSD, 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 studies may be delayed or we may be required to repeat such clinical studies, 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 studies. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, 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 studies 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 studies. 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 limited experience in completing a Phase 3 clinical study and have never submitted an NDA before, and may be unable to do so for TNX-102 SL or other product candidates we are developing.

We initiated a Phase 3 study in military-related PTSD in the first quarter of 2017. As this study is intended to provide efficacy and safety evidence to support marketing approval by the FDA, it is considered a pivotal, confirmatory or registration, study. The conduct of pivotal clinical studies 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, we have conducted only one pivotal clinical study before (the AFFIRM study in fibromyalgia patients), have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete this planned clinical study 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 studies 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 studies, 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 studies, 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 or suffer from quality control issues:

- regulatory authorities may impose a clinical hold or risk evaluation and mitigation strategies, or REMS, which could result in substantial delays, significantly increase the cost of development, and/or adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of statements, specific warnings, or contraindications to the product label, or restrict the product's indication to a smaller potential treatment population;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the patients who can receive the product;

- we may be subject to limitations on how we promote the product;
- we may, voluntarily or involuntarily, initiate field alerts for product recall, which may result in shortages;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

If a competing drug shows efficacy in military-related PTSD prior to the FDA approval of TNX-102 SL or if TNX-102 SL fails to confirm the results of the AtEase Phase 2 study in showing activity in military-related PTSD in the Phase 3 HONOR study, then the FDA may rescind the Breakthrough Therapy designation.

In December 2016, the FDA granted TNX-102 SL for PSTD Breakthrough Therapy designation based on several factors, including that TNX-102 SL has the potential to be an improvement over existing therapies for military-related PTSD. If another therapy is shown to be effective in military-related PTSD before FDA approval of TNX-102 SL, then the FDA may rescind the designation. In addition, if TNX-102 SL fails to confirm the activity from the AtEase study in treating military-related PTSD, then the FDA may rescind the Breakthrough Therapy designation.

Breakthrough Therapy designation for TNX-102 SL may not lead to faster development or regulatory processes nor does it increase the likelihood that TNX-102 SL will receive marketing approval for PTSD.

There is no guarantee that the receipt of Breakthrough Therapy designation will result in a faster development, review or approval process for TNX-102 SL for PTSD or increase the likelihood that TNX-102 SL will be granted marketing approval for PTSD. Likewise, any future Breakthrough Therapy designation for any other potential indication of TNX-102 SL neither guarantees a faster development process, review or approval nor improves the likelihood of the granting of marketing approval by the FDA for any such potential indication of TNX-102 SL compared to drugs considered for approval under conventional FDA procedures. We may seek a Breakthrough Therapy designation for other of our product candidates, but the FDA may not grant this status to any of our proposed product candidates.

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 reduce the development time. We held a pre-IND meeting with the FDA in October 2012 to discuss the development of TNX-102 SL in PTSD. Following the results of the AtEase Study, we held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in August 2016 to discuss our most advanced development program, in which we are developing TNX-102 SL for the treatment of PTSD. Although our interactions with the FDA have encouraged our efforts to continue to develop TNX-102 SL for PTSD, there is no assurance that we will satisfy the FDA's requirements for approval in this indication. The timeline for filing and review of our NDA for TNX-102 SL for PTSD is based on our plan to submit this NDA 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 realize a shortened development timeline for TNX-102 SL for PTSD, and the FDA may not approve our NDA based on their review of the submitted data. If CBP-containing products are withdrawn from the market by the FDA for any safety 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 lead product candidate.

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

As we advance our product candidates through preclinical and nonclinical testing and clinical studies, and develop new product candidates, we will need to increase our product development, scientific, regulatory and compliance 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 in addition to a post-marketing surveillance program if we seek to market our products directly; and
- continue to improve our operational, manufacturing, quality assurance, 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 and Dr. Gregory M. Sullivan, our Chief Medical 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. Dr. Sullivan has served as our Chief Medical Officer since 2014 and directed the Phase 2 AtEase study and is directing the Phase 3 HONOR study. Loss of the services of Drs. Lederman or Sullivan 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, preclinical and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

We rely on third parties to manufacture the compounds used in our studies, 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 studies and our products that reach commercialization. Completion of our clinical studies 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 studies or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for nonclinical, preclinical, clinical, and commercial purposes. Although we are in discussions with other manufacturers we have identified as potential alternative CMOs of 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 nonclinical testing 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 studies, 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 studies, 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 DEA 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 studies, 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 studies, 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 studies, 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 studies 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 studies. Conducting clinical studies 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 study. Delays associated with products for which we are directly conducting clinical studies may cause us to incur additional operating expenses. The commencement and rate of completion of clinical studies may be delayed by many factors, including, for example: inability to manufacture sufficient quantities of stable and qualified materials under cGMP, for use in clinical studies; slower than expected rates of patient recruitment; failure to recruit a sufficient number of patients; modification of clinical study protocols; changes in regulatory requirements for clinical studies; the lack of effectiveness during clinical studies; the emergence of unforeseen safety issues; delays, suspension, or termination of the clinical studies 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 studies.

The results from early clinical studies are not necessarily predictive of results obtained in later clinical studies. Accordingly, even if we obtain positive results from early clinical studies, we may not be able to confirm the results in future clinical studies. For example, in our Phase 3 AFFIRM trial in fibromyalgia, we were not able replicate the results we received from our Phase 2b BESTFIT trial. Clinical studies may not demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates.

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

The failure of clinical studies 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 studies 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 studies could materially harm our business, financial condition, and results of operations.

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and nonclinical testing and clinical studies, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of biopharmaceutical products. The FDA regulates small molecule chemical entities as drugs, subject to an NDA under the FDCA. The FDA applies the same standards for biologics, requiring an IND application, followed by a BLA prior to licensure. Other products, such as vaccines, are also regulated under the Public Health Service Act. FDA has conflated the standards for approval of NDAs and BLAs so that they require the same types of information on safety, effectiveness, and chemistry, manufacturing and controls. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

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

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

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

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

Following completion of clinical studies, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of an NDA or BLA in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to an NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study and other commitments or reporting requirements or other restrictions on product distribution, or may deny the application. The FDA has established performance goals for review of NDAs or BLAs: 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 or BLA 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 or BLA 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.

Our product candidates may face competition sooner than expected.

We intend to seek data exclusivity or market exclusivity for our product candidates provided under the FDCA and similar laws in other countries. We believe that TNX-801 could qualify for 12 years of data exclusivity under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act. Under the BPCIA, an application for a biosimilar product or BLA cannot be submitted to the FDA until four years, or if approved by the FDA, until 12 years, after the original brand product identified as the reference product is approved under a BLA. The BPCIA provides an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. The new law is complex and is only beginning to be interpreted and implemented by the FDA. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for any of our product candidates that are biologics. There is also a risk that President Trump's administration could repeal or amend the BPCIA to shorten this exclusivity period, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection. Although there is no current discussion of repeal or modification of the BPCIA, the future remains uncertain. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Our product candidates that are not, or are not considered, biologics that would qualify for exclusivity under the BPCIA may be eligible for market exclusivity as drugs under the FDCA. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent.

Even if, as we expect, our product candidates are considered to be reference products eligible for 12 years of exclusivity under the BPCIA or five years of exclusivity under the FDCA, another company could market competing products if the FDA approves a full BLA or full NDA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the BPCIA could result in a shorter exclusivity period for our product candidates, which could have a material adverse effect on our business.

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 studies.

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 and Medicaid.

We cannot predict the availability of reimbursement for health care products to be approved in the future. Third-party payors, including Medicare and Medicaid, 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 whether approved under Section 505(b)(1), 505(b)(2), or 505(j) of the FDCA, through direct payment mechanisms and through cost containment programs such as the Medicaid Drug Rebate Program. 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 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 study 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 study 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 study 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 study, property, workers' compensation, products liability and directors' and officers' insurance, along with an umbrella policy, which collectively costs approximately $600,000 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.

We may be unsuccessful in obtaining a priority voucher for material threat medical countermeasures.

In 2016, the 21st Century Cures Act, or the Act, was signed into law to support ongoing biomedical innovation. One part of the Act, Section 3086, is aimed at "Encouraging Treatments for Agents that Present a National Security Threat." The Act created a new priority review voucher program for "material threat medical countermeasures." The Act defines such countermeasures as drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat or to treat harm from a condition that may be caused by administering a drug or biological product against such an agent. The Department of Homeland Security has identified 13 such threats, including anthrax, smallpox, Ebola/Marburg, tularemia, and botulism. A priority review voucher can be applied to any other product; it shortens the FDA review timeline for a new application from 10 months to 6 months. The recipient of a priority review voucher may transfer it.

We intend to seek a priority voucher for TNX-801 as a material threat medical countermeasure. However, the structure of voucher programs limits the number of medical countermeasures eligible for a priority review voucher. Further, the medical countermeasure must qualify for priority review in order to be eligible and may not include any commercially approved indication. As such, the market for the TNX-801 will be limited if we are successful in obtaining a priority voucher.

There may not be market interest in TNX-801.

The government is the only market for most medical countermeasures. This is because unlike other drugs and vaccines, these products are not sold to doctors, hospitals, or pharmacies. The BioShield Special Reserve Fund, or SRF, has been the sole medical countermeasures market for the last decade; a 10 year advance appropriation of $5.6 billion was available to procure successful candidate medical countermeasures. The SRF expired in 2013 and all funds were used to add 12 new medical countermeasures to the national stockpile. Congress reauthorized the SRF but adequate funding has not yet followed; the SRF is now appropriated annually and has not kept pace with the need for purchasing products ready for stockpiling. Further, similar products are being developed by other companies, such as Bavarian Nordic, which is developing MVA, which may compete with TNX-801. As such, even if TNX-801 were to receive FDA approval, the commercial success of TNX-801 remains uncertain.

If technology developed for the purposes of developing new medicines or vaccines can be applied to the creation or development of biological weapons, then our technology may be considered "dual use" technology and be subject to limitations on public disclosure or export.

Together with the University of Alberta, we are consulting with government authorities before publishing work that describes the synthesis of poxviruses, including TNX-801. Our research collaboration is dedicated not only to creating tools that better protect public health but also to safeguarding any information with broad, dual-use potential that could be inappropriately applied. "Dual use research" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to public health, agricultural crops, or national security. Because variola, the agent that causes smallpox, is a pox virus, the technology we created could be considered dual use and could be subject to export control, for example under the Wassenaar Arrangement. Further, if federal authorities determine that our research is subject to institutional oversight, we will need to implement a risk-management plan developed in collaboration with the institutional review entity. Failure to comply with the plan may result in suspension, limitation, or termination of federal funding or loss of future federal funding opportunities for any of our or the University of Alberta's research.

We face risks in connection with existing and future collaborations with respect to the development, manufacture, and commercialization of our product candidates.

We face a number of risks in connection with our current collaborations, including the University of Alberta. Our collaboration agreements are subject to termination under various circumstances. Our collaborators may change the focus of their development and commercialization efforts or may have insufficient resources to effectively assist in the development of our products. Any future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties. Further, disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays, might result in litigation or arbitration, or might result in termination of the research, development or commercialization of our products. Any such disagreements would divert management attention and resources and be time-consuming and costly.

We face risks in connection with the production and storage of the TNX-801 vaccine.

The TNX-801 vaccine candidate is a live form of HPXV. We have initiated vaccine-manufacturing activities to support further nonclinical testing of TNX-801. While it is safer than existing smallpox-preventing vaccines, the production and storage of the synthesized HPXV virus stock may carry risk of infection and harm to individuals. HPXV, an equine disease caused by a virus and characterized by eruptions in the mouth and on the skin, is believed to be eradicated. No true HPXV outbreaks have been reported since 1976, at which time the United States Department of Agriculture obtained the viral sample used for the sequence published in 2006 that allowed the synthesis of TNX-801.

RISKS RELATED TO OUR STOCK

Sales of additional shares of our common stock 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. 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 studies;
- 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.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or if we discover material weaknesses and deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

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 April 13, 2017, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 11.7% 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, 2016.

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, we executed a letter of credit, which has a remaining balance of $88,842 as of December 31, 2016, and we deposited such amount 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. In connection therewith, we paid a security deposit of $44,546. During December 2016, in an effort to reduce operating costs, we exited this facility and terminated this lease. The total costs associated with exiting this facility were $0.1 million.

On June 19, 2015, we entered into a lease for approximately 2,450 square feet of office space in Dublin, Ireland, whereby we agreed to lease premises, commencing June 1, 2015 and expiring on May 31, 2018.

On July 27, 2015, we entered into a lease for approximately 132 square feet of office space in Montreal, Canada, whereby we agreed to lease premises, commencing August 1, 2015 and expiring on July 31 on an annual renewal basis. In connection therewith, we paid a security deposit of $800.

On August 24, 2015, we entered into a lease for approximately 2,762 square feet of office space in San Diego, California, whereby we agreed to lease premises, commencing September 1, 2015 and expiring on August 31, 2019. In connection therewith, we paid a security deposit of $11,272.

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

Year Ending December 31,		
2017	$	517
2018		458
2019		181
	$	1,156

We believe that our existing facilities are suitable and adequate to meet our current business requirements.

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, operating results or cash flows.

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 is listed on The NASDAQ Global Market 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, after giving effect to the 1-for-10 reverse stock split, which was effected on March 17, 2017.

	Fiscal Year 2016	
	High	Low
First Quarter	$ 79.54	$ 22.00
Second Quarter	$ 37.70	$ 18.40
Third Quarter	$ 28.00	$ 6.90
Fourth Quarter	$ 8.50	$ 3.52

	Fiscal Year 2015	
	High	Low
First Quarter	$ 86.50	$ 56.10
Second Quarter	$ 107.20	$ 58.80
Third Quarter	$ 98.90	$ 51.40
Fourth Quarter	$ 78.40	$ 50.50

On April 12, 2017, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was $4.75 per share. On April 12, 2017, there were 110 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, 2016.

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	217,426	91.33	212,596
Equity compensation plans not approved by stockholders	—	—	—
Total	217,426	91.33	212,596

Recent Sales of Unregistered Securities

None.

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. 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: substantial competition; our possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations.

Business Overview

We are a clinical-stage pharmaceutical company dedicated to the development of innovative pharmaceutical products to address public health challenges. Our most advanced drug development program is focused on delivering an efficacious and safe long-term treatment of PTSD. PTSD is characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in the fields of PTSD and other central nervous system disorders. In September 2016, we discontinued our fibromyalgia program in order to fully focus our resources on our PTSD program.

Our lead product candidate, TNX-102 SL, a proprietary low-dose cyclobenzaprine sublingual tablet, designed for bedtime administration, is in Phase 3 clinical development as a potential treatment for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication. We hold worldwide development and commercialization rights to all of our product candidates.

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

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

In the AtEase study, TNX-102 SL was well tolerated and the patient retention rate was 73% on placebo, 79% on TNX-102 SL 2.8 mg and 84% on TNX-102 SL 5.6 mg. Four distinct serious adverse events, or SAEs, were reported in the study; three were in the placebo group, and one (proctitis/peri-rectal abscess,) in the TNX-102 SL arm, which was determined to be unrelated to TNX-102 SL. The most common non-dose related adverse events were mild and transient local administration site conditions and of these oral hypoaesthesia, or numbness, was the most frequent and occurred in 39% of patients treated with the 2.8 mg dose and 36% of the patients treated with the 5.6 mg dose, compared to 2% of the patients receiving placebo. Oral paresthesia, or tingling, occurred in 16% of patients treated with the 2.8 mg dose and 4% of patients treated with the 5.6 mg dose, compared to 3% of the patients receiving placebo. Glossodynia, or a burning or stinging sensation in the mouth, occurred in 3% of patients treated with the 2.8 mg dose and 6% of patients treated with the 5.6 mg dose, compared to 1% of patients receiving placebo.

Systemic adverse events that were potentially dose-related and occurred in greater than or equal to 5% of patients treated with the 5.6 mg dose or placebo included: somnolence in 16% versus 6% of the patients receiving placebo; dry mouth in 16% versus 11% of the patients receiving placebo; headache in 12% versus 4% of the patients receiving placebo; insomnia in 6% versus 9% of the patients receiving placebo; sedation in 12% versus 1% of the patients receiving placebo; upper respiratory tract infection in 4% versus 5% of the patients receiving placebo; abnormal dreams in 2% versus 5% of the patients receiving placebo; and weight increase in 2% versus 5% of the patients receiving placebo. For the patients treated with the 2.8 mg dose, the incidence of the most common systemic adverse events reported above were less frequent than patients treated with the 5.6 mg dose with the exception of insomnia, which was 8%.

We also have a pipeline of other drug and biologic candidates, including two pre-IND candidates, TNX-601 (tianeptine oxalate) for PTSD and TNX-801, a potential smallpox-preventing vaccine, an IND candidate, TNX-301, a potential treatment for AUD and TNX-701, a biodefense development program for protection from radiation injury.

TNX-601 is a novel oral formulation of tianeptine oxalate in the pre-IND stage of development for the treatment for PTSD. We have discovered a novel salt and polymorph, which we believe may provide improved stability, consistency, and manufacturability relative to the known forms of tianeptine. Leveraging our development expertise in PTSD, TNX-601 is being developed for daytime dosing as a first-line monotherapy for PTSD for daytime dosing. Tianeptine's reported pro-cognitive and anxiolytic effects as well as its ability to attenuate the neuropathological effects of excessive stress responses suggest that it may be used to treat PTSD by a different mechanism of action than TNX-102 SL. On April 19, 2016, we were issued US patent 9,314,469 B2 "Method for treating neurocognitive dysfunction" which includes using tianeptine for cognitive dysfunction associated with corticosteroid use. We intend to develop TNX-601 under Section 505(b)(1) of the FDCA as a potential treatment for PTSD and cognitive dysfunction associated with corticosteroid use. Pharmaceutical development work on TNX-601 has been initiated.

TNX-801 is a novel potential smallpox-preventing vaccine based on a live synthetic version of HPXV grown in cell culture. TNX-801 was synthesized by Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada in collaboration with us. HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection. Vaccine manufacturing activities have been initiated to support further nonclinical testing of TNX-801. We are developing TNX-801 as a potential smallpox-preventing vaccine for widespread immunization and for the U.S. strategic national stockpile. Though it shares structural characteristics with vaccinia-based vaccines, TNX-801 has unique virulence properties that we believe may suggest lower toxicity and potential safety advantages over existing vaccinia-based vaccines, which have been associated with adverse side effects such as myopericarditis. We intend to develop TNX-801 under 21 CFR 601 Subpart H, pursuant to which the FDA may grant marketing approval for a biological product for which safety has been established in humans and for which the requirements for efficacy are met based on adequate and well-controlled animal studies, where human studies are not ethical or feasible. This approval pathway has been described as the "Animal Rule". In the 1970s, vaccination against smallpox was discontinued in the U.S.; however, smallpox remains a material threat to national security. We recently filed a patent on the novel virus vaccine. In addition, 12 years of non-patent based exclusivity is provided under the Patient Protection and Affordable Care Act. It is unknown if a replacement bill will contain the 12 year exclusivity provision. Following the recent passage of the 21st Century Cures Act, we believe TNX-801 qualifies as a medical countermeasure, and therefore should be eligible for a Priority Review Voucher upon FDA approval. We are currently working to develop a vaccine that meets current Good Manufacturing Practice, or cGMP, quality to support an IND.

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

In addition, we own rights to intellectual property on a biodefense technology relating to the development of protective agents against radiation exposure, which we refer to as TNX-701. We have begun nonclinical research and development on TNX-701. Similar to the regulatory pathway intended for TNX-801, we plan to develop TNX-701 under 21 CFR 601 Subpart H, or the "Animal Rule". We expect significant reduction in 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 for PTSD, but we also expend increasing effort on our other pipeline programs, including TNX-601, TNX-801 and 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 commenced a randomized, double-blind placebo-controlled Phase 3 study of TNX-102 SL in approximately 550 patients with military-related PTSD in the first quarter of 2017. This first Phase 3 study, the "HONOR study," is an adaptive design study based on the results of the Phase 2 AtEase study. The study design is very similar to the Phase 2 AtEase study , except there will be one planned interim analysis and the involvement of an independent data monitoring committee, or IDMC, to review unblinded interim analysis results. The IDMC will make a recommendation to continue as planned, to continue but increase the number of recruited patients or to stop for success. In addition, there will be one active dose (5.6 mg administered as 2 x 2.8 mg tablets) and the entrance criterion is CAPS-5 $\geq$ 33 in this Phase 3 study. The interim analysis will be conducted when approximately 50% (approximately 250 – 300 patients) of the initially planned patient enrollment is evaluable for efficacy. We received FDA clearance of the first Phase 3 study design in January 2017. The HONOR study involves approximately 35 U.S. centers. As in the case of the AtEase study, the primary efficacy endpoint of the HONOR study is the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale between those treated with TNX-102 SL 5.6 mg and those receiving placebo.

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

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as the progress of our research and development efforts and the timing and outcome of regulatory submissions. Due to these uncertainties, accurate predictions of future operations are difficult or impossible to make.

Fiscal year Ended December 31, 2016 Compared to Fiscal year Ended December 31, 2015

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2016 were $28.5 million, a decrease of $7.0 million, or 20%, from $35.5 million for the fiscal year ended December 31, 2015. This decrease is primarily due to decreased development work related to TNX-201 (dexisometheptene mucate) for episodic tension-type headache, including formulation development, manufacturing, human safety and efficacy trials as well as pharmacokinetic studies. This decrease is also due to decreased development work on TNX-102 SL for fibromyalgia. In 2016, we incurred $16.4 million, $1.4 million and $3.3 million in clinical, non-clinical, and manufacturing, respectively, as compared to $16.8 million, $5.3 million and $4.4 million in 2015, respectively. Costs related to product development decreased to $0.3 million for the fiscal year ended December 31, 2016 from $0.9 million for the fiscal year ended December 31, 2015, a decrease of $0.6 million, or 67%. The decrease is primarily due to the reduction in active trials.

Compensation-related expenses increased to $4.5 million for the fiscal year ended December 31, 2016, from $4.1 million for the fiscal year ended December 31, 2015, an increase of $0.4 million, or 10%. Cash compensation-related expenses were $3.6 million for the fiscal year ended December 31, 2016, an increase of $0.7 million, or 24%, from $2.9 million for the fiscal year ended December 31, 2015. The increase was primarily a result of annual salary increases and increased personnel during parts of 2016. We incurred $0.9 million in stock-based compensation in connection with the vesting of stock options in 2016, which were previously issued to officers and consultants, as compared to $1.2 million in stock-based compensation in 2015. Regulatory and legal costs decreased to $1.3 million for the fiscal year ended December 31, 2016, from $1.8 million for the fiscal year ended December 31, 2015, a decrease of $0.5 million, or 28%. The decrease in regulatory and legal costs is primarily due to a shift in personnel related to then ongoing trials.

Travel, meals and entertainment costs decreased to $0.5 million for the fiscal year ended December 31, 2016, from $1.4 million for the fiscal year ended December 31, 2015, a decrease of $0.9 million, or 64%. Travel, meals and entertainment costs include travel related to clinical development, including investigator meetings and medical-related conferences, whereas such activities decreased from 2015. Other research and development costs were $0.8 million for both reporting periods. Other research and development costs include rent, insurance and other office-related expenses.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2016 were $10.4 million, a decrease of $2.3 million, or 18%, from $12.7 million incurred in the fiscal year ended December 31, 2015. This decrease is primarily due to a reduction in activities related to compensation-related expenses and professional services.

Compensation-related expenses decreased to $5.2 million for the fiscal year ended December 31, 2016, from $5.8 million for the fiscal year ended December 31, 2015, a decrease of $0.6 million, or 10%. We incurred $2.3 million in stock-based compensation in connection with the employee stock purchase plan and the vesting of restricted stock units and stock options in 2016, which were previously issued to board members, officers, employees and a consultant, as compared to $3.2 million in stock-based compensation in 2015. Cash compensation-related expenses were $2.9 million for the fiscal year ended December 31, 2016, an increase of $0.3 million, or 12%, from $2.6 million for the fiscal year ended December 31, 2015. The increase was primarily a result of annual salary increases and increased personnel during parts of 2016.

Professional services for the fiscal year ended December 31, 2016 totaled $3.2 million, a decrease of $1.1 million, or 26%, over the $4.3 million incurred for the fiscal year ended December 31, 2015. Of professional services, legal fees totaled $1.0 million for the fiscal year ended December 31, 2016, a decrease of $0.8 million, or 44%, from $1.8 million incurred for the fiscal year ended December 31, 2015. The decrease was mainly due to a reduction in international legal work and legal fees related to patent activity. Audit and accounting fees incurred in the fiscal years ended December 31, 2016 and 2015 amounted to $0.6 million and $0.5 million, respectively, an increase of $0.1 million, or 20%. Investor and public relations fees totaled $1.0 million for the fiscal year ended December 31, 2016, a decrease of $0.3 million, or 23%, from $1.3 million incurred in the fiscal year ended December 31, 2015. The decrease is due to a reduction in non-deal roadshows and attending less investor-related conferences. Other consulting fees and other professional fees totaled $0.6 million for the fiscal year ended December 31, 2016, a decrease of $0.1 million, or 14%, from $0.7 million incurred in the fiscal year ended December 31, 2015. Other professional fees include human resources, finance and corporate consultants.

Travel, meals and entertainment costs for the fiscal year ended December 31, 2016 were $0.3 million, a decrease of $0.6 million, or 67%, from $0.9 million incurred in the fiscal year ended December 31, 2015. Travel, meals and entertainment costs include travel related to business development and investor relations activities, which were significantly reduced from 2015. Office and other administrative expenses totaled $1.7 million for both reporting periods. Office and other administrative expenses include rent, depreciation, insurance, business taxes, dues and subscriptions and other office related expenses.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2016 was $38.8 million, compared to a net loss of $48.1 million for the year ended December 31, 2015.

Liquidity and Capital Resources

As of December 31, 2016, we had working capital of $25.0 million, comprised primarily of cash and cash equivalents of $18.9 million, short-term investments of $7.2 million and prepaid expenses and other of $1.0 million, offset by $0.9 million of accounts payable and $1.2 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our phase 3 clinical trial of TNX-102 SL in PTSD. For the years ended December 31, 2016 and 2015, we used approximately $37.3 million and $42.5 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The decrease in cash outlays principally resulted from a reduction in clinical, non-clinical, manufacturing, medical research, and regulatory cost activities. For the year ended December 31, 2016, net proceeds from financing activities were $20.5 million, predominately from the sale of our common stock and warrants. In the comparable 2015 period, approximately $47.7 million was raised through the sale of shares of common stock. At December 31, 2015, we had cash of $19.2 million. Our cash and cash equivalents consisted of bank deposit accounts and money market funds.

Cash provided by investing activities for the year ended December 31, 2016 was approximately $16.6 million, predominately from the maturity of marketable securities, as compared to cash used for the year ended December 31, 2015 of approximately $24.2 million, of which $28.6 million related to the purchase of marketable securities, $0.1 million related to the purchase of equipment and leasehold improvements and $0.1 million related to the purchase of an intangible asset, offset by maturities of marketable securities of $4.7 million.

March 2017 Financing

On March 30, 2017, we entered into an underwriting agreement with Aegis Capital Corp., as representative of the several underwriters (collectively, the "2017 Underwriters"), relating to the issuance and sale of 1,800,000 shares of our common stock, in an underwritten public offering (the "March 2017 Financing"). The public offering price for each share of common stock was $4.45. We granted the 2017 Underwriters a 45-day (or as otherwise specified in the underwriting agreement) option to purchase up to an additional 270,000 shares of common stock to cover over-allotments, if any.

The March 2017 Financing closed on April 4, 2017. The 2017 Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of $0.6 million (or $0.31 per share). We also expect to incur offering expenses of approximately $0.3 million. We expect to receive net proceeds of approximately $7.2 million. On April 13, 2017, the 2017 Underwriters fully exercised the over-allotment option and purchased 270,000 shares of common stock for net proceeds of approximately $1.1 million, net of an aggregate discount of $0.1 million (or $0.31 per share).

October 2016 Financing

On October 26, 2016, we entered into an underwriting agreement with Dawson James Securities, Inc. ("Dawson") relating to the issuance and sale of an aggregate of 950,000 units ("Unit", and collectively, the "Units") at a public offering price of $5.50 per Unit in an underwritten public offering (the "October 2016 Financing"). Each Unit consisted of one share of our common stock, par value $0.001 per share, and a warrant to purchase one-half share of common stock. Because we are prohibited from issuing fractional shares, the warrants can only be exercised in lots of two, which means that each holder must exercise two warrants to receive one share of common stock, or an aggregate of 475,000 shares of common stock. The warrants have an initial exercise price of $6.30 per share and have a term of five years. The exercise price and number of shares of common stock issuable upon exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, as described in the warrants.

We also granted Dawson a 45-day option to purchase up to 142,500 additional shares of common stock and/or warrants to purchase up to 71,250 shares of common stock, to cover over-allotments, if any.

The October 2016 Financing closed on October 31, 2016. Dawson purchased the Units at an eight-percent discount to the public offering price, for an aggregate discount of approximately $0.4 million (or $0.40 per Unit). Dawson also received warrants to purchase up to an aggregate of 47,361 shares of common stock, or approximately five percent of the total number of shares included in the Units. We received net proceeds from the October 2016 Financing of approximately $4.6 million, after deducting the underwriting discount and other offering expenses of approximately $0.6 million. Additionally, Dawson fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 71,250 shares of common stock for net proceeds of approximately $700.

June 2016 Financing

On June 15, 2016, we entered into an underwriting agreement with Roth Capital Partners, LLC and National Securities Corporation (collectively, the "Underwriters"), relating to the issuance and sale of 500,000 shares of our common stock, in an underwritten public offering (the "June 2016 Financing"). The public offering price for each share of common stock was $20.00. We granted the Underwriters a 45-day option to purchase up to an additional 75,000 shares of common stock to cover over-allotments, if any.

The June 2016 Financing closed on June 21, 2016. The Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of $0.7 million (or $1.40 per share). We also paid offering expenses of approximately $0.2 million. We received net proceeds of approximately $9.1 million. On July 12, 2016, the Underwriters fully exercised the over-allotment option and purchased 75,000 shares of common stock for net proceeds of approximately $1.4 million, net of an aggregate discount of $0.1 million (or $1.40 per share).

At-the-Market Offering

On April 28, 2016, we entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $15.0 million in at-the-market ("ATM") sales. On the same day, we filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. Our common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. During the year ended December 31, 2016, we sold an aggregate of 500,889 shares of common stock using the ATM, resulting in net proceeds of $5.4 million, net of expenses of $0.3 million, which included Cowen's commission of $0.2 million. During February and March 2017, we sold an aggregate of 1,486,474 shares of common stock using the ATM, resulting in net proceeds of $9.1 million, net of expenses, which included Cowen's commission of approximately $0.3 million. As of the date of this annual report, we have sold all $15 million of shares under the Sales Agreement, and the Sales Agreement has been terminated.

July 2015 Financing

On July 14, 2015, we entered into an underwriting agreement with Roth and Oppenheimer & Co Inc. (collectively, the "Representatives"), as representatives of several underwriters (collectively, the "2015 Underwriters"), relating to the issuance and sale of 232,500 shares of our common stock, in an underwritten public offering (the "July 2015 Financing"). The public offering price for each share of common stock was $75.00. We granted the 2015 Underwriters a 45-day option to purchase up to an additional 34,875 shares of common stock to cover over-allotments, if any.

The July 2015 Financing closed on July 17, 2015. The 2015 Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of $1.0 million (or $4.50 per share). We also paid offering expenses of approximately $0.2 million. We received net proceeds of approximately $16.2 million. On July 17, 2015, the 2015 Underwriters fully exercised the over-allotment option and purchased 34,875 shares of common stock for net proceeds of approximately $2.5 million, net of an aggregate discount of $0.2 million (or $4.50 per share).

February 2015 Financing

On February 4, 2015, we entered into an underwriting agreement with the Representatives, as representatives of the 2015 Underwriters, relating to the issuance and sale of 490,000 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 $58.50. We granted the 2015 Underwriters a 45-day option to purchase up to an additional 73,500 shares of common stock to cover over-allotments, if any.

The February 2015 Financing closed on February 9, 2015. The 2015 Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of $1.7 million (or $3.50 per share). We also paid offering expenses of approximately $0.3 million. We received net proceeds of approximately $26.7 million. On February 24, 2015, the 2015 Underwriters partially exercised the over-allotment option and purchased 41,870 shares of common stock for net proceeds of approximately $2.3 million, net of an aggregate discount of $0.1 million (or $3.50 per share).

Future Liquidity Requirements

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

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

We will need to obtain additional capital in order to fund future research and development activities. Future financing may include the issuance of equity or debt securities, obtaining credit facilities, or other financing mechanisms. Even if we are able to raise the funds required, it is possible that we could incur unexpected costs and expenses, fail to collect significant amounts owed to us, or experience unexpected cash requirements that would force us to seek alternative financing. Furthermore, if we issue additional equity or debt securities, shareholders may experience additional dilution or the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock.

If additional financing is not available or is not available on acceptable terms, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Stock Compensation

Stock Options

In February 2012, we approved the 2012 Incentive Stock Options Plan, which was amended and restated in February 2013 ("2012 Plan"). The 2012 Plan provided for the issuance of options to purchase up to 55,000 shares of our common stock to officers, directors, employees and consultants. Under the terms of the 2012 Plan, we may have issued Incentive Stock Options, as defined by the Internal Revenue Code, and nonstatutory options. The Board of Directors determined 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 have been at least 100% of fair value of the common stock at the date of the grant (or 110% for any shareholder that owned 10% or more of our common stock). The fair market value of the common stock was 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 were not more than five years and the expiration period not more than ten years. We reserved 55,000 shares of our common stock for future issuance under the terms of the 2012 Plan. All reserved shares under the 2012 Plan were subject to granted awards outstanding. With the adoption of the 2016 Plan (as defined below), no further grants may be made under the 2012 Plan, and the only current activity relates to the administration of existing options under the 2012 Plan.

On June 9, 2014, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan (the "2014 Plan" and together with the 2012 Plan, the "Prior Plans"). Under the terms of the 2014 Plan, we may have issued (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 provided for the issuance of up to 180,000 shares of common stock, provided, however, that, of the aggregate number of 2014 Plan shares authorized, no more than 20,000 of such shares may have been 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 determined 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 have been 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 was not a 10% shareholder. The fair value of the common stock was 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 have been more than five years and the expiration period not more than ten years. We reserved 180,000 shares of our common stock for future issuance under the terms of the 2014 Plan. With the adoption of the 2016 Plan, no further grants may be made under the 2014 Plan, and the only current activity relates to the administration of existing options under the 2014 Plan.

On May 11, 2016, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2016 Stock Incentive Plan (the "2016 Plan" and together with the Prior Plans, the "Plans"). As a result of adoption of the 2016 Plan, no further grants may be made under the Prior Plans. Under the terms of the 2016 Plan, we may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2016 Plan provides for the issuance of up to 278,500 shares of common stock, which amount will be (a) reduced by awards granted under the 2014 Plan after December 31, 2015, and (b) increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2016 Plan).

In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after December 31, 2015, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.25 shares for every one share that was subject to an award other than an option or SAR. With respect to awards intended to qualify as performance-based compensation under Section 162(m) of the Code, the 2016 Plan provides that, subject to adjustment as provided in the plan, no participant may, in any 12-month period (i) be granted options or SARs with respect to more than 75,000 shares of our common stock, (ii) earn more than 50,000 shares of our common stock under restricted stock awards, restricted stock unit awards, performance awards and/or other share-based awards, or (iii) earn more than $5,000,000 under an award; provided, however, that each of these limitations shall be multiplied by two (2) with respect to awards granted to a participant during the first calendar year in which the participant commences employment with us or any of our subsidiaries. The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2016 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the 2016 Plan may not be more than five years and the expiration period not more than ten years. We reserved 278,500 shares of our common stock for future issuance under the terms of the 2016 Plan. As of December 31, 2016, 212,596 shares were available for future grants under the 2016 Plan.

We measure the fair value of stock options on the date of grant, based on a Binomial option pricing model using certain assumptions discussed in the following paragraph, and the closing market price of our common stock on the date of the grant. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. Most stock options granted pursuant to the Plans typically vest 1/3rd 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, we also issue performance-based options to executive officers, which options vest when the target parameters are met, subject to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

On March 1, 2017, 61,750 options were granted to employees with an exercise price of $5.50 and exercisable for a period of ten years. Additionally, we granted options to purchase 28,250 shares of our common stock to employees with an exercise price of $5.50, exercisable for a period of ten years and vesting 50% upon our achieving enrollment of 250 patients in the HONOR study by December 31, 2017, and the remaining 50% vesting 1% for each patient that is enrolled in the HONOR study by December 31, 2017 in excess of 250, subject to a one year minimum service period prior to vesting.

On May 27, 2016, 3,500 options were granted to employees with an exercise price of $24.20 and exercisable for a period of ten years. Additionally, we granted options to purchase 6,000 shares of our common stock to an employee with an exercise price of $24.20, exercisable for a period of ten years, and vesting 1/3 each upon our common stock having an average closing sale price equal to or exceeding each of $60.00, $70.00 and $80.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

On February 9, 2016, 40,300 options were granted to employees with an exercise price of $50.30 and exercisable for a period of ten years. Additionally, we granted options to purchase 20,000 shares of our common stock to employees with an exercise price of $50.30, exercisable for a period of ten years, and vesting 1/3 each upon our common stock having an average closing sale price equal to or exceeding each of $60.00, $70.00 and $80.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

During the year ended December 31, 2016, 1,430, 2,611, 3,781, 9,216 and 1,000 unvested options with exercise prices of $98.65, $66.80, $59.50, $50.30 and $24.20, respectively, were forfeited.

On February 25, 2015, 41,950 and 3,000 options were granted to employees/directors and consultants, respectively, under the 2014 Plan with an exercise price of $59.50 and exercisable for a period of ten years. Additionally, we granted options to purchase 714 shares of our common stock to Seth Lederman, our Chief Executive Officer, as a non-cash bonus which vested immediately, with an exercise price of $59.50 and exercisable for a period of ten years. As of December 31, 2016, the fair value related to consultant grants was $1.66.

During the year ended December 31, 2015, 380, 3,980 and 3,980 unvested options with exercise prices of $59.50, $98.70 and $66.80, respectively, were forfeited.

The weighted-average grant-date fair value of stock options granted was $46.58 in 2016 and $47.40 in 2015.

Stock-based compensation expense relating to options granted of $2.9 million and $4.1 million was recognized for the years ended December 31, 2016 and 2015, respectively.

As of December 31, 2016, we had approximately $1.8 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 1.32 years.

Restricted Stock Units

On February 25, 2015, we granted an aggregate of 4,200 RSUs with a fair value of $62.40 per unit to its non-employee directors for board services in 2015, in lieu of cash, which vest one year from the grant date. In February 2016, these RSU's vested and 4,200 shares of our common stock were issued in settlement of those RSUs during the first quarter of 2016.

On February 9, 2016, we granted an aggregate of 5,625 RSU's to our non-employee directors for board services in 2016, in lieu of cash, which vest one year from the grant date with a fair value of $38.10. In February 2017, these RSU's vested and 5,625 shares of our common stock were issued in settlement of those RSUs during the first quarter of 2017.

On May 27, 2016, we granted an aggregate of 5,625 RSU's to our non-employee directors for board services through the first half of 2017, in lieu of cash, which vest one year from the grant date with a fair value of $22.90.

Stock-based compensation expense related to RSU grants was $315,000 and $218,000 for the year ended December 31, 2016 and 2015, respectively. As of December 31, 2016, the stock-based compensation relating to RSU's of $0.1 million remains unamortized and is expected to be amortized over a weighted average period of three months.

Employee Stock Purchase Plan

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 30,000 shares of our common stock. Under the 2014 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of our common stock at the end of the offering period. Each offering period under the 2014 ESPP is for six months, which can be modified from time-to-time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee's accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2014 ESPP, subject to the statutory limit under the Code. As of December 31, 2016, there were 19,449 shares available for future issuance under the 2014 ESPP.

The 2014 ESPP is considered a compensatory plan with the related compensation cost written off over the six month offering period. The compensation expense related to the 2014 ESPP for the years ended December 31, 2016 and 2015 was $69,000 and $98,000, respectively. In February 2015, 1,398 shares that were purchased as of December 31, 2014, were issued under the 2014 ESPP, and approximately $0.1 million of employee payroll deductions accumulated at December 31, 2014, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital. In January 2016, 1,760 shares that were purchased as of December 31, 2015, were issued under the 2014 ESPP, and the employee payroll deductions accumulated at December 31, 2015, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital.

As of December 31, 2016, approximately $10,000 of employee payroll deductions, which had been withheld since July 1, 2016, the commencement of the offering period ended December 31, 2016, are included in accrued expenses in the accompanying balance sheet. In January 2017, 2,496 shares that were purchased as of December 31, 2016, were issued under the 2014 ESPP, and approximately $10,000 of employee payroll deductions accumulated at December 31, 2016, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital.

Lease Commitments

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

Year Ending December 31,		
2017	$	517
2018		458
2019		181
	$	1,156

Critical Accounting Policies and Estimates

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

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

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

We estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants and clinical research organizations and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We account for trial expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us at that time. Our clinical trial accruals and prepaid assets are dependent upon the timely and accurate reporting of CROs and other third-party vendors.

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

Income Taxes. Deferred income tax assets and liabilities are determined based on the estimated future tax effects of net operating loss and credit carryforwards and temporary differences between the tax basis of assets and liabilities and their respective financial reporting amounts measured at the current enacted tax rates. We record an estimated valuation allowance on its deferred income tax assets if it is not more likely than not that these deferred income tax assets will be realized. We recognized a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

Recent Accounting Pronouncements

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

In December 2016, we adopted FASB ASU No. 2016-09, issued in March 2016, related to stock-based compensation. The new guidance simplifies the accounting for stock-based compensation transactions, including tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows.

In December 2016, we adopted FASB ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to continue as a Going Concern, issued in August 2014. ASU 2014-15 explicitly requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosure in certain circumstances.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To 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, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended. The 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
April 13, 2017

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2016 AND 2015
(In Thousands, Except Par Value and Share Amounts)

	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,941	$ 19,175
Marketable securities-available for sale, at fair value	7,180	23,841
Prepaid expenses and other	1,019	3,343
Total current assets	27,140	46,359
Property and equipment, net	150	350
Restricted cash	89	132
Intangible asset	120	120
Security deposits	11	57
Total assets	$ 27,510	$ 47,018
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 872	$ 3,049
Accrued expenses	1,244	3,601
Total current liabilities	2,116	6,650
Deferred rent payable	33	106
Total liabilities	2,149	6,756
Commitments (See Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, none issued or outstanding	-	-
Common stock, $0.001 par value; 15,000,000 shares authorized; 3,918,111 and 1,883,167 shares issued and outstanding as of December 31, 2016 and 2015, respectively, 2,496 and 1,760 shares to be issued as of December 31, 2016 and 2015, respectively	4	2
Additional paid in capital	166,604	142,675
Accumulated deficit	(141,240)	(102,398)
Accumulated other comprehensive income loss	(7)	(17)
Total stockholders' equity	25,361	40,262
Total liabilities and stockholders' equity	$ 27,510	$ 47,018

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2016	2015
COSTS AND EXPENSES:		
Research and development	$ 28,533	$ 35,504
General and administrative	10,436	12,658
	38,969	48,162
Operating loss	(38,969)	(48,162)
Interest income, net	127	108
NET LOSS	$ (38,842)	$ (48,054)
Net loss per common share, basic and diluted	$ (15.41)	$ (28.62)
Weighted average common shares outstanding, basic and diluted	2,521,016	1,679,106

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2016	2015
Net loss	$ (38,842)	$ (48,054)
Other comprehensive loss:		
Foreign currency translation (loss) gain	(17)	8
Unrealized gain (loss) on available for sale securities	27	(27)
Total other comprehensive gain (loss)	10	(19)
Comprehensive loss	$ (38,832)	$ (48,073)

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In Thousands, Except Share and Per Share Amounts)

	Preferred stock		Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance, December 31, 2014	-	$ -	1,080,522	$ 1	$ 90,433	$ 2	$ (54,344)	$ 36,092
Issuance of common stock in February 2015 ($58.50 per share) net of transaction expenses of $2,115	-	-	531,870	1	28,999	-	-	29,000
Issuance of common stock in July 2015 ($75.00 per share), net of transaction expenses of $1,369	-	-	267,375	-	18,685	-	-	18,685
Issuance of common stock in exchange for exercise of warrants ($42.50 per share)	-	-	200	-	9	-	-	9
Employee stock purchase plan	-	-	3,200	-	160	-	-	160
Stock-based compensation	-	-	-	-	4,389	-	-	4,389
Foreign currency translation adjustment	-	-	-	-	-	8	-	8
Unrealized loss on available for sale securities	-	-	-	-	-	(27)	-	(27)
Net loss	-	-	-	-	-	-	(48,054)	(48,054)
Balance, December 31, 2015	-	$ -	1,883,167	$ 2	$ 142,675	$ (17)	$ (102,398)	$ 40,262

	Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2015	-	$ -	1,883,167	$ 2	$ 142,675	$ (17)	$ (102,398)	$ 40,262
Employee stock purchase plan	-	-	4,855	-	167	-	-	167
Issuance of common stock related to restricted stock units	-	-	4,200	-	-	-	-	-
Issuance of common stock in May and June 2016 ($24.00 per share), September 2016 ($7.40 per share), and October 2016 ($6.50 per share), net of transaction expenses of $280	-	-	500,889	-	5,377	-	-	5,377
Issuance of common stock in June 2016 ($20.00 per share), net of transaction expenses of $916	-	-	500,000	1	9,083	-	-	9,084
Issuance of common stock in July 2016 ($20.00 per share), net of transaction expenses of $105	-	-	75,000	-	1,395	-	-	1,395
Issuance of common stock in October 2016 ($5.50 per share), net of transaction costs of $585			950,000	1	4,641		-	4,642
Stock-based compensation					3,266	-	-	3,266
Foreign currency translation loss	-	-	-	-	-	(17)	-	(17)
Unrealized gain on available for sale securities	-	-	-	-	-	27	-	27
Net loss	-	-	-	-	-	-	(38,842)	(38,842)
Balance, December 31, 2016	-	$ -	3,918,111	$ 4	$ 166,604	$ (7)	$ (141,240)	$ 25,361

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31, 2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (38,842)	$ (48,054)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	206	161
Stock-based compensation	3,266	4,389
Loss on disposal of property and equipment	133	-
Changes in operating assets and liabilities:		
Prepaid expenses	2,370	(2,524)
Accounts payable	(2,185)	1,583
Accrued expenses	(2,190)	1,874
Security deposit	-	(11)
Other long term liabilities	(73)	54
Net cash used in operating activities	(37,315)	(42,528)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(66)	(118)
Purchase of intangible asset	-	(120)
Purchase of marketable securities	-	(28,643)
Proceeds from restricted cash	45	-
Maturities of marketable securities	16,615	4,710
Net cash provided by (used in) investing activities	16,594	(24,171)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	-	9
Proceeds, net of expenses of $1,866 and $3,484, from sale of common stock	20,498	47,685
Net cash provided by financing activities	20,498	47,694
Effect of currency rate change on cash	(11)	(4)
Net decrease in cash and cash equivalents	(234)	(19,009)
Cash and cash equivalents, beginning of the year	19,175	38,184
Cash and cash equivalents, end of year	$ 18,941	$ 19,175
Supplemental disclosures of cash flow information:		
Non cash financing activities:		
Issuance of common stock under employee stock purchase plan	$ 167	$ 160

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. ("Tonix Sub"), is a clinical-stage pharmaceutical company dedicated to the development of innovative pharmaceutical products to address public health challenges. All drug product candidates are still in development.

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

On October 29, 2014, Tonix Sub formed Tonix Pharma Holdings Limited ("Tonix International Holding"), which was incorporated under the laws of Ireland and is a tax resident in Bermuda, for the purpose of acquiring the rights to develop and commercialize Tonix products. Tonix International Holding formed Tonix Pharma Limited ("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 for non-U.S. markets. Tonix Barbados was liquidated and dissolved during the year ended December 31, 2015. All assets have been transferred to, and liabilities were assumed by, 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 Sub 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 pronouncements

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

In December 2016, the Company adopted FASB ASU No. 2016-09, issued in March 2016, related to stock-based compensation. The new guidance simplifies the accounting for stock-based compensation transactions, including tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows.

In December 2016, the Company adopted FASB ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to continue as a Going Concern issued in August 2014. ASU 2014-15 explicitly requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosure in certain circumstances.

Risks and uncertainties

The Company's primary efforts are devoted to conducting research and development of innovative pharmaceutical products to address public health challenges. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. Further, the Company does not have any commercial products available for sale and has not generated revenues and there is no assurance that if its products are approved for sale, that the Company will be able to generate cash flow to fund operations. In addition, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable.

At December 31, 2016, the Company had working capital of approximately $25.0 million, after raising approximately $10.5 million, net of expenses, through the sale of common stock in an underwritten public offering in June 2016 and from the exercise of the underwriter's overallotment option in July 2016, and approximately $5.4 million, net of expenses, through the at-the-market ("ATM") offering during the year ended December 31, 2016. In addition, in October 2016, the Company raised approximately $4.6 million, net of expenses, through the sale of common stock and warrants in an underwritten public offering.

At December 31, 2016, the Company had cash and marketable securities of approximately $26.1 million, which together with approximately $17.4 million of net proceeds from the sales of common stock subsequent to December 31, 2016 (see Note 12), constitutes sufficient funds for the Company to meet its research and development and other funding requirements for at least the next 12 months.

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 expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets, assumptions used in the fair value of stock-based compensation and other equity instruments, and the percent of completion of research and development contracts.

Cash equivalents

The Company considers cash equivalents to be those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased. At December 31, 2016 and 2015, cash equivalents, which consisted of money market funds, amounted to $10.0 million and $7.6 million, respectively.

Marketable securities

Marketable securities consist primarily of certificates of deposit, U.S. agency, and U.S. treasury bonds with maturities greater than three months and up to two years at the time of purchase. These securities, which are classified as available for sale, are carried at fair value, with unrealized gains and losses, net of any tax effect, reported in stockholders' equity as accumulated other comprehensive (loss) income. As investments are available for current operations, they are classified as current irrespective of their maturities. Amortization of premiums is included in interest income. For the years ended December 31, 2016 and 2015, the amortization of bond premiums totaled $73,000 and $65,000, respectively. As of December 31, 2016 and 2015, amortized cost basis of the securities approximated their fair value. The values of these securities may fluctuate as a result of changes in market interest rates and credit risk. Marketable securities with a principal balance aggregating $16.6 million and $0 matured during the years ended December 31, 2016 and 2015, respectively.

Marketable securities owned at December 31, 2016, all of which have maturities of 1 year or less as of such date, were as follows (in thousands):

	1 Year or Less
U.S. treasury bonds	$ 2,752
U.S. agency bonds	1,254
Certificates of deposit	3,174
Total	$ 7,180

The schedule of maturities at December 31, 2015 was as follows (in thousands):

	1 Year or Less	1 to 2 Years
U.S. Treasury bond	$ -	$ 2,750
U.S agency bonds	1,248	2,531
Corporate bonds	6,142	-
Certificates of deposit	7,994	3,176
Total	$ 15,384	$ 8,457

Intangible asset with indefinite lives

During the year ended December 31, 2015, the Company purchased certain internet domain rights, which were determined to have an indefinite life. Identifiable intangibles with indefinite lives are not amortized but are reviewed for impairment annually or whenever events or changes in circumstances indicate that its carrying amount may be less than fair value. As of December 31, 2016 and 2015, the Company believed that no impairment existed.

Research and development costs

The Company outsources certain of its research and development efforts and expenses these costs as incurred, including the cost of manufacturing products for testing, as well as licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired has been expensed as research and development costs, as such property related to particular research and development projects and had no alternative future uses.

The Company estimates its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company accounts for trial expenses according to the timing of various aspects of the trial. The Company determines accrual estimates taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed.

During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life, which is three years for computer assets, five years for furniture and all other equipment and term of lease for leasehold improvements. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization expense for the years ended December 31, 2016 and 2015 was $133,000 and $96,000, respectively. During December 2016, in an effort to reduce operating costs, the Company exited the San Jose, CA facility. This resulted in the disposal of property and equipment in the amount of $133,000. All remaining property and equipment is located in the United States.

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, 2016, 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 units ("RSUs"), and stock options, are measured at fair value on the grant date and recognized in the consolidated statements of operations as compensation or other expense over the relevant service period.

Stock-based payments to nonemployees are recognized as an expense over the period of performance. Such payments are measured at fair value at the earlier of the date a performance commitment is reached or the date performance is completed. In addition, for awards that vest immediately and are non-forfeitable, the measurement date is the date the award is issued.

Foreign currency translation

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

Comprehensive income (loss)

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

The following table summarizes the changes in accumulated other comprehensive income by component:

	Foreign Currency Translation Adjustment	Unrealized Gains (Losses) on available for sale securities	Total
Balance at December 31, 2014	2	-	2
Other Comprehensive Gain (Loss)	8	(27)	(19)
Balance at December 31, 2015	10	(27)	(17)
Other Comprehensive Loss (Gain)	(17)	27	10
Balance at December 31, 2016	(7)	-	(7)

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 1-for-10 reverse stock split, which was effected on March 17, 2017 (see Note 7).

As of December 31, 2016 and 2015, there were outstanding warrants to purchase an aggregate of 766,533 and 172,922 shares, respectively, of the Company's common stock (see Note 9). The Company has issued to employees, directors and consultants, options to acquire shares of the Company's common stock, of which 217,426 and 165,664 were outstanding at December 31, 2016 and 2015, respectively. In addition at December 31, 2016 and 2015, there were outstanding 11,250 and 4,200, respectively, unvested RSUs. In computing diluted net loss per share for the years ended December 31, 2016 and 2015, no effect has been given to such options, warrants and RSUs as their effect would be anti-dilutive.

NOTE 3 – RESTRICTED CASH

Restricted cash at December 31, 2016 and 2015 of approximately $89,000 and $132,000, respectively, collateralizes a letter of credit issued in connection with the lease of office space in New York City (see Note 10).

NOTE 4 – OTHER BALANCE SHEET INFORMATION

Components of selected captions in the consolidated balance sheets consist of:

	December 31, 2016	December 31, 2015
	(in thousands)	
Property, plant and equipment, net:		
Office furniture and equipment	$ 306	$ 351
Leasehold improvements	23	179
	329	530
Less: Accumulated depreciation and amortization	(179)	(180)
	$ 150	$ 350
Prepaid expenses and other:		
Contract-related	$ 392	$ 2,826
Professional fees and other	627	517
	$ 1,019	$ 3,343
Accrued expenses:		
Contract-related	$ 504	$ 2,246
Compensation and compensation-related	484	1,128
Professional fees and other	256	227
	$ 1,244	$ 3,601

NOTE 5 – FAIR VALUE MEASUREMENTS

Fair value measurements affect the Company's accounting for certain of its financial assets. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured according to a hierarchy that includes:

Level 1: Observable inputs, such as quoted prices in active markets.

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly. Level 2 assets and liabilities include debt securities with quoted market prices that are traded less frequently than exchange-traded instruments. This category includes U.S. government agency-backed debt securities.

Level 3: Unobservable inputs in which there is little or no market data.

The following table summarizes the Company's financial assets measured at fair value on a recurring basis as of December 31, 2016 (in thousands):

Description	December 31, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents	$ 10,006	$ 10,006	$ —
Marketable securities – available for sale	7,180	5,926	1,254
Total assets	$ 17,186	$ 15,932	$ 1,254

The following table summarizes the Company's financial assets measured at fair value on a recurring basis as of December 31, 2015 (in thousands):

Description	December 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents	$ 7,649	$ 7,649	$ —
Marketable securities – available for sale	23,841	13,920	9,921
Total assets	$ 31,490	$ 21,569	$ 9,921

NOTE 6 – SALE OF COMMON STOCK

June 2016 public offering

On June 15, 2016, the Company entered into an underwriting agreement with Roth Capital Partners, LLC and National Securities Corporation as underwriters (collectively, the "2016 Underwriters"), relating to the issuance and sale of 500,000 shares of the Company's common stock, in an underwritten public offering (the "June 2016 Financing"). The public offering price for each share of common stock was $20.00. The Company granted the 2016 Underwriters a 45-day option to purchase up to an additional 75,000 shares of common stock to cover over-allotments, if any.

The June 2016 Financing closed on June 21, 2016. The 2016 Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of $0.7 million (or $1.40 per share). The Company also paid offering expenses of approximately $0.2 million. The Company received net proceeds of approximately $9.1 million. On July 12, 2016, the 2016 Underwriters fully exercised the over-allotment option and purchased 75,000 shares of common stock for net proceeds of approximately $1.4 million, net of an aggregate discount of $0.1 million (or $1.40 per share).

October 2016 public offering

On October 26, 2016, the Company entered into an underwriting agreement with Dawson James Securities, Inc. ("Dawson") relating to the issuance and sale of an aggregate of 950,000 units ("Unit", and collectively, the "Units") at a public offering price of $5.50 per Unit in an underwritten public offering (the "October 2016 Financing"). Each Unit consisted of one share of the Company's common stock, par value $0.001 per share, and a warrant to purchase one-half share of common stock. Because the Company is prohibited from issuing fractional shares, the warrants can only be exercised in lots of two, which means that each holder must exercise two warrants to receive one share of common stock, or an aggregate of 475,000 shares of common stock. The warrants have an initial exercise price of $6.30 per share and have a term of five years. The exercise price and number of shares of common stock issuable upon exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, as described in the warrants.

The Company also granted Dawson a 45-day option to purchase up to 142,500 additional shares of common stock and/or warrants to purchase up to 71,250 shares of common stock, to cover over-allotments, if any.

The October 2016 Financing closed on October 31, 2016. Dawson purchased the Units at an eight-percent discount to the public offering price, for an aggregate discount of approximately $0.4 million (or $0.40 per Unit). Dawson also received warrants to purchase up to an aggregate of 47,361 shares of common stock, or approximately five percent of the total number of shares included in the Units. The Company received net proceeds from the October 2016 Financing of approximately $4.6 million, after deducting the underwriting discount and other offering expenses of approximately $0.6 million. Additionally, Dawson fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 71,250 shares of common stock for net proceeds of approximately $700.

At-the-market offering

On April 28, 2016, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), as sales agent, pursuant to which the Company may, from time to time, issue and sell common stock with an aggregate value of up to $15.0 million in ATM sales. On the same day, the Company filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. During the year ended December 31, 2016, the Company sold an aggregate of 500,889 shares of common stock using the ATM, resulting in net proceeds of $5.4 million, net of expenses of $0.3 million, which included Cowen's commission of $0.2 million.

February 2015 financing

On February 4, 2015, the Company entered into an underwriting agreement with Roth Capital Partners, LLC ("Roth"), and Oppenheimer & Co Inc. (collectively, the "Representatives"), as representatives of several underwriters (collectively, the "Underwriters"), relating to the issuance and sale of 490,000 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 $58.50. The Company granted the Underwriters a 45-day option to purchase up to an additional 73,500 shares of common stock to cover over-allotments, if any.

The February 2015 Financing closed on February 9, 2015. The Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of $1.7 million (or $3.50 per share). The Company also paid offering expenses of approximately $0.3 million. The Company received net proceeds of approximately $26.7 million. On February 24, 2015, the Underwriters partially exercised the over-allotment option and purchased 41,870 shares of common stock for net proceeds of approximately $2.3 million, net of an aggregate discount of $0.1 million (or $3.50 per share).

July 2015 financing

On July 14, 2015, the Company entered into an underwriting agreement with the Representatives of the Underwriters, relating to the issuance and sale of 232,500 shares of the Company's common stock, in an underwritten public offering (the "July 2015 Financing"). The public offering price for each share of common stock was $75.00. The Company granted the Underwriters a 45-day option to purchase up to an additional 34,875 shares of common stock to cover over-allotments, if any.

The July 2015 Financing closed on July 17, 2015. The Underwriters purchased the shares at a six percent discount to the public offering price, for an aggregate discount of $1.0 million (or $4.50 per share). The Company also paid offering expenses of approximately $0.2 million. The Company received net proceeds of approximately $16.2 million. On July 17, 2015, the Underwriters fully exercised the over-allotment option and purchased 34,875 shares of common stock for net proceeds of approximately $2.5 million, net of an aggregate discount of $0.2 million (or $4.50 per share).

NOTE 7 – STOCKHOLDERS' EQUITY

On March 13, 2017, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective March 17, 2017. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value, whereby 41,010,720 outstanding shares of the Company's common stock were exchanged for 4,101,072 shares of the Company's common stock. In addition, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 150 million to 15 million. 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.

NOTE 8 – STOCK-BASED COMPENSATION

2012 incentive stock option plan

In April 2012, the Company's stockholders approved the 2012 Incentive Stock Option Plan (the "2012 Plan"). The 2012 Plan provides for the issuance of options to purchase up to 20,000 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.

On February 12, 2013, the 2012 Plan was amended and restated to increase the number of shares reserved under the plan to 55,000. At December 31, 2016, all reserved shares under the 2012 Plan were subject to granted awards outstanding. With the adoption of the 2016 Plan (as defined below), no further grants may be made under the 2012 Plan.

2014 stock incentive plan

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

Under the terms of the 2014 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights ("SARs"), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2014 Plan provides for the issuance of up to 180,000 shares of common stock, provided, however, that, of the aggregate number of 2014 Plan shares authorized, no more than 20,000 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 180,000 shares of its common stock for future issuance under the terms of the 2014 Plan. With the adoption of the 2016 Plan, no further grants may be made under the 2014 Plan.

2016 stock incentive plan

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

Under the terms of the 2016 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2016 Plan provides for the issuance of up to 278,500 shares of common stock, which amount will be (a) reduced by awards granted under the 2014 Plan after December 31, 2015, and (b) increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2016 Plan). In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after December 31, 2015, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.25 shares for every one share that was subject to an award other than an option or SAR. With respect to awards intended to qualify as performance-based compensation under Section 162(m) of the Code, the 2016 Plan provides that, subject to adjustment as provided in the plan, no participant may, in any 12-month period (i) be granted options or SARs with respect to more than 75,000 shares of the Company's common stock, (ii) earn more than 50,000 shares of the Company's common stock under restricted stock awards, restricted stock unit awards, performance awards and/or other share-based awards, or (iii) earn more than $5,000,000 under an award; provided, however, that each of these limitations shall be multiplied by two (2) with respect to awards granted to a participant during the first calendar year in which the participant commences employment with the Company or any of its subsidiaries. The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2016 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the 2016 Plan may not be more than five years and expiration period not more than ten years. The Company reserved 278,500 shares of its common stock for future issuance under the terms of the 2016 Plan. As of December 31, 2016, 212,596 shares were available for future grants under the 2016 Plan.

General

A summary of the stock option activity and related information for the Plans for the years ended December 31, 2016, and 2015 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2015	122,680	$ 124.04		$ -
Grants	51,324	$ 60.13		-
Exercised	-			
Forfeitures or expirations	(8,340)	81.67		
Outstanding at January 1, 2016	165,664	$ 106.38	8.35	$ 1,125,299
Grants	69,800	$ 46.58		$ -
Exercised	-			
Forfeitures or expirations	(18,038)	57.00		
Outstanding at December 31, 2016	217,426	$ 91.33	7.82	$ -
Vested and expected to vest at December 31, 2016	217,426	$ 91.33	7.82	$ -
Exercisable at December 31, 2016	131,277	$ 115.51	7.19	$ -

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

The Company measures the fair value of stock options on the date of grant, based on a Binomial option pricing model using certain assumptions discussed below, and the closing market price of the Company's common stock on the date of the grant. 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. Most stock options granted pursuant to the Plans typically vest 1/3rd 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, the Company also issues performance-based options to executive officers, which options vest when the target parameters are met, subject to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

The assumptions used in the valuation of stock options granted during the years ended December 31, 2016 and 2015 were as follows:

	2016	2015
Risk-free interest rate	0.85% to 2.25%	1.47% to 2.35%
Expected term of option	6.0 to 9.06 years	6.0 to 9.91 years
Expected stock price volatility	73.46% to 81.59%	80.91% to 92.13%

The risk-free interest rate is based on the yield of Daily U.S. Treasury Yield Curve Rates with terms equal to the expected term of the options as of the grant date. The expected term of options is determined using the simplified method, as provided in an SEC Staff Accounting Bulletin, and the expected stock price volatility is based on comparable companies' historical stock price volatility since the Company does not have sufficient historical exercise or volatility data because its equity shares have been publicly traded for only a limited period of time.

Stock-based compensation expense relating to options granted of $2.9 million and $4.1 million was recognized for the years ended December 31, 2016 and 2015, respectively.

As of December 31, 2016, the Company had approximately $1.8 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.32 years.

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 30,000 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, 2016, there were 19,449 shares available for future issuance under the 2014 ESPP.

The 2014 ESPP is considered a compensatory plan with the related compensation cost written off over the six month offering period. The compensation expense related to the 2014 ESPP for the years ended December 31, 2016 and 2015 was $69,000 and $98,000, respectively.

In February 2015, 1,398 shares that were purchased as of December 31, 2014, were issued under the 2014 ESPP, and approximately $0.1 million of employee payroll deductions accumulated at December 31, 2014, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital. In July 2015, 1,802 shares that were purchased as of June 30, 2015, were issued under the 2014 ESPP, and approximately $0.1 million of employee payroll deductions accumulated at June 30, 2015, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. In January 2016, 1,760 shares that were purchased as of December 31, 2015, were issued under the 2014 ESPP, and approximately $113,000 of employee payroll deductions accumulated at December 31, 2015, related to acquiring such shares, were transferred from accrued expenses to additional paid in capital.

As of December 31, 2016, approximately $10,000 of employee payroll deductions, which had been withheld since July 1, 2016, the commencement of the offering period ended December 31, 2016, are included in accrued expenses in the accompanying consolidated balance sheet. In January 2017, 2,496 shares that were purchased as of December 31, 2016, were issued under the 2014 ESPP, and approximately $10,000 of employee payroll deductions accumulated at December 31, 2016, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital.

Restricted stock units

On February 25, 2015, the Company granted an aggregate of 4,200 RSUs with a fair value of $62.40 per unit to its non-employee directors for board services in 2015, in lieu of cash, which vest one year from the grant date. In February 2016, these RSU's vested and 4,200 shares of the Company's common stock were issued in settlement of those RSUs during the first quarter of 2016.

On February 9, 2016, the Company granted an aggregate of 5,625 RSU's to its non-employee directors for board services in 2016, in lieu of cash, which vest one year from the grant date with a fair value of $38.10. In February 2017, these RSU's vested and 5,625 shares of the Company's common stock were issued in settlement of those RSUs during the first quarter of 2017.

On May 27, 2016, the Company granted an aggregate of 5,625 RSU's to its non-employee directors for board services through the first half of 2017, in lieu of cash, which vest one year from the grant date with a fair value of $22.90.

The following table summarizes the RSU activity for the years ended December 31, 2016 and 2015:

Unvested restricted stock units as of January 1, 2015	-
Granted	4,200
Forfeited	-
Vested	-
Unvested restricted stock units as of January 1, 2016	4,200
Granted	11,250
Forfeited	-
Vested	(4,200)
Unvested restricted stock units as of December 31, 2016	11,250

Stock-based compensation expense related to RSU grants was $315,000 and $218,000 for the year ended December 31, 2016 and 2015, respectively. As of December 31, 2016, the stock-based compensation relating to RSU's of $0.1 million remained unamortized and is expected to be amortized over a weighted average period of three months.

NOTE 9 – 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, 2016:

Exercise Price	Number Outstanding	Expiration Date
$ 6.30	546,250	October 2021
$ 6.90	47,361	October 2021
$ 42.50	91,898	August 2018
$ 120.00	45,601	December 2017 to February 2018
$ 250.00	35,423	January 2017 to February 2019
	766,533	

In connection with the October 2016 Financing, the Company issued to Dawson warrants to purchase up to an aggregate of 47,361 shares of the Company's common stock. The Warrants are exercisable at $6.90 per share, expire five years from the date of issuance and have a fair value of $2.65. The Company measures the fair value 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 issued to Dawson were as follows:

Risk-free interest rate	1.30%
Life of warrant	5 years
Expected stock price volatility	78.04%
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.

In January 2015, 1,454 warrants with an exercise price of $200.00 expired.

During the year ended December 31, 2015, the Company issued an aggregate of 200 shares of its common stock upon the exercise of warrants at $42.50 per share.

NOTE 10 – COMMITMENTS

Operating leases

As of December 31, 2016, future minimum lease payments for office space are as follows (in thousands):

Year Ending December 31,	
2017	$ 517
2018	458
2019	181
	$ 1,156

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, 2016 and 2015, rent expense was $0.7 million and $0.6 million, respectively, and as of December 31, 2016 and 2015, deferred rent payable was $44,000 and $112,000, respectively, including the current portion, which at December 31, 2016 and 2015, was $11,000 and $6,000, respectively, which is included in accrued expenses in 2016 and 2015. In December 2016, the Company terminated the lease of the San Jose office. The costs related to the termination of the lease totaled $72,000 and are included in general and administrative expenses in the accompanied consolidated statement of operations for the year ended December 31, 2016.

Research and development agreements

The Company has contracts with various contract research organizations for which there are outstanding commitments aggregating approximately $7.1 million at December 31, 2016 for future work to be performed.

Defined contribution plan

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. In 2017, the Company reduced the annual contribution to 3%. For the years ended December 31, 2016 and 2015, the Company charged operations $0.3 million and $0.4 million, respectively, for contributions under the 401(k) Plan.

NOTE 11 – INCOME TAXES

Components of the net loss consist of the following (in thousands):

	Year ended December 31, 2016	2015
Foreign	$ (34,124)	$ (45,303)
Domestic	(4,718)	(2,751)
Other	$ (38,842)	$ (48,054)

In 2016, the foreign losses were primarily comprised of $32.4 million related to the Bermudan operations of Tonix International Holding, which included a licensing fee of $2.0 million charged by Tonix Sub pursuant to a licensing agreement with Tonix Sub. In 2015, the foreign losses were comprised of $43.9 million related to the Bermudan operations of Tonix International Holding, which included a licensing fee of $4.0 million charged by Tonix Sub pursuant to a licensing agreement with Tonix Sub.

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 are not subject to income tax in Bermuda.

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,	
	2016	2015
Statutory federal income tax	(35.0)%	(35.0)%
State income tax, net of federal tax effect	0.0%	(0.6)%
Permanent difference	0.1%	0.2%
Change in valuation allowance	4.0%	4.6%
Foreign loss not subject to income tax	30.9%	32.7%
Other	0.0%	(1.9)%
Income Tax Provision	0.0%	0.0%

Deferred tax assets and related valuation allowance as of December 31, 2016 and 2015 were as follows (in thousands):

	December 31,	
	2016	2015
Deferred tax assets:		
Research and development credit carryforward	$ 1,610	$ 6
Net operating loss carryforward	11,038	11,645
Stock-based compensation	4,379	3,186
Accrued bonuses	-	388
Other	180	224
Total deferred assets	17,207	15,449
Valuation allowance	(17,207)	(15,449)
Net deferred tax assets	$ -	$ -

The Company has incurred research and development (“R&D”) expenses, a portion of which qualifies for tax credits. The Company conducted an R&D credit study to quantify the amount of credits and has claimed an R&D credit on its 2013, 2014, and 2015 tax returns. As of December 31, 2016, the Company has a credit carryforward of $1.6 million, which will begin to expire in 2033.

At December 31, 2016, the Company had available unused net operating loss (“NOL”) carryforwards of approximately $21.1 million that expire from 2027 to 2036 for federal tax purposes. The Company also has approximately $32.5 million of NOL carryforwards for New York State and $27.8 million for New York City purposes expiring from 2030 to 2036. Additionally, the Company has $1.8 million of foreign NOL balances in various jurisdictions with various expiration periods. A portion of these NOL carryforwards are subject to annual limitations in their use in accordance with Internal Revenue Code (“IRC”) section 382. At December 31, 2016, the NOL carryforward balance has been reduced to reflect IRC section 382 limitation.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2016. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future growth. As such, 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 full valuation allowance against its gross deferred tax assets. The increases in the valuation allowance for the years ended December 31, 2016 and 2015 were $1.8 million and 2.2 million, respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2016 there were no unrecognized tax benefits recorded. The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of December 31, 2016, the Company's tax returns remained open and subject to examination by the tax authorities for the tax years 2013 and after.

NOTE 12 – SUBSEQUENT EVENTS

On March 1, 2017, the Company granted options to purchase an aggregate of 61,750 shares of the Company's common stock to employees with an exercise price of $5.50, 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 28,250 shares of the Company's common stock to employees with an exercise price of $5.50, exercisable for a period of ten years, fully vesting based on the number of patients that are enrolled in the upcoming HONOR Study at December 31, 2017, subject to a one year minimum service period prior to vesting.

On March 13, 2017, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective March 17, 2017. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value, whereby 41,010,720 outstanding shares of the Company's common stock were exchanged for 4,101,072 shares of the Company's common stock. In addition, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 150 million to 15 million.

Between February and April 2017, the Company sold an aggregate of 1,486,474 shares of common stock using the ATM, resulting in net proceeds of $9.1 million, net of expenses, which included Cowen's commission of approximately $0.3 million.

On March 30, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp., as representative of the several underwriters (collectively, the "2017 Underwriters"), relating to the issuance and sale of 1,800,000 shares of the Company's common stock, in an underwritten public offering (the "March 2017 Financing"). The public offering price for each share of common stock was $4.45. The Company granted the 2017 Underwriters a 45-day (or as otherwise specified in the underwriting agreement) option to purchase up to an additional 270,000 shares of common stock to cover over-allotments, if any.

The March 2017 Financing closed on April 4, 2017. The 2017 Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of $0.6 million (or $0.31 per share). The Company also expects to incur offering expenses of approximately $0.3 million. The Company expects to receive net proceeds of approximately $7.2 million. On April 13, 2017, the 2017 Underwriters fully exercised the over-allotment option and purchased 270,000 shares of common stock for net proceeds of approximately $1.1 million, net of an aggregate discount of $0.1 million (or $0.31 per share).

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.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's principal executive and principal financial officer and effected by the our board of directors, management and other personnel, 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 and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) 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 in accordance with authorizations of management and directors of the company; and

(3) 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. 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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

We conducted an evaluation of the effectiveness of 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, our principal executive officer and principal financial officer conclude that, at December 31, 2016, our internal control over financial reporting was effective.

This annual report does not include an attestation report by EisnerAmper LLP, our independent registered public accounting firm regarding internal control over financial reporting. As a smaller reporting company, our management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2016.

ITEM 11 - EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2016.

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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2016.

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 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2016.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (SEC) within 120 days of the fiscal year ended December 31, 2016.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) List of Documents Filed as a Part of This Report:

(b) Index to Financial Statement Schedules:

All schedules have been omitted because the required information is included in the consolidated financial statements or the notes thereto, or is not applicable or required.

(c) Index to Exhibits

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by an asterisk (*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15.

Exhibit No.	Description
3.01	Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "Commission") on April 9, 2008 and incorporated herein by reference.
3.02	Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.
3.03	Third Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 3, 2016 and incorporated herein by reference.
3.03	Certificate of Change of Tonix Pharmaceuticals Holding Corp., dated March 13, 2017 and effective March 17, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 16, 2017 and incorporated herein by reference.
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	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.

10.04	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.
10.05	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.*
10.06	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.*
10.07	Lease Amendment and Expansion Agreement, dated February 11, 2014, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on February 27, 2015 and incorporated herein by reference.
10.08	Sales Agreement, dated April 28, 2016, by and between Tonix Pharmaceuticals Holding Corp. and Cowen and Company, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on April 28, 2016 and incorporated herein by reference.
14.01	Code of Business Conduct and Ethics for Employees, Executive Officers and Directors, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on February 16, 2016 and incorporated herein by reference.
21.01	List of Subsidiaries, filed as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 3, 2016 and incorporated herein by reference.
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	The following materials from Tonix Pharmaceuticals Holding Corp.'s Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

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: April 13, 2017

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

Date: April 13, 2017

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Seth Lederman and Bradley Saenger, jointly and severally, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K 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	Chief Executive Officer, President and Director (Principal Executive Officer)	April 13, 2017
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 13, 2017
/s/ STUART DAVIDSON Stuart Davidson	Director	April 13, 2017
/s/ PATRICK GRACE Patrick Grace	Director	April 13, 2017
/s/ DONALD W. LANDRY Donald W. Landry	Director	April 13, 2017
/s/ ERNEST MARIO Ernest Mario	Director	April 13, 2017
/s/ CHARLES MATHER IV Charles Mather IV	Director	April 13, 2017
/s/ JOHN RHODES John Rhodes	Director	April 13, 2017
/s/ SAMUEL SAKS Samuel Saks	Director	April 13, 2017

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Tonix Pharmaceuticals Holding Corp. on Form S-3 (No. 333-197824) and Form S-8 (Nos. 333-202006 and 333-212300) of our report dated April 13, 2017, on our audits of the consolidated financial statements as of December 31, 2016 and 2015 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about April 13, 2017.

/s/ EisnerAmper LLP

New York, New York
April 13, 2017

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: April 13, 2017

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

Exhibit 31.02

CERTIFICATION

I, Bradley Saenger, 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: April 13, 2017

/s/ BRADLEY SAENGER
Bradley Saenger
Chief Financial Officer

Exhibit 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

By: /s/ SETH LEDERMAN
Date: April 13, 2017 Name: Seth Lederman
Title: *Chief Executive Officer*

I, Bradley Saenger, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

By: /s/ BRADLEY SAENGER
Date: April 13, 2017 Name: Bradley Saenger
Title: *Chief Financial Officer*