Filed Pursuant to Rule 424(b)(3)
Registration No. 333-220749

PROSPECTUS

Up to 2,100,000 Shares of Common Stock

This prospectus covers the offer and sale of up to 2,100,000 shares of common stock, $0.001 par value per share of Tonix Pharmaceuticals Holding Corp., a Nevada corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the Selling Stockholder.

The shares of common stock being offered by the Selling Stockholder have been or may be issued pursuant to the purchase agreement dated September 28, 2017, or the Purchase Agreement, that we entered into with Lincoln Park. See "The Lincoln Park Transaction" for a description of the Purchase Agreement and "Selling Stockholder" for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares of common stock will be determined by the prevailing market price for the shares of common stock or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of the shares of common stock by the Selling Stockholder.

The Selling Stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See "Plan of Distribution" for more information about how the Selling Stockholder may sell the shares of common stock being registered pursuant to this prospectus. The Selling Stockholder is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

We will pay the expenses incurred in registering the shares of common stock, including legal and accounting fees. See "Plan of Distribution".

Our common stock is currently quoted on The NASDAQ Global Market under the symbol "TNXP". On October 11, 2017, the last reported sale price of our common stock on The NASDAQ Global Market was $4.71 per share.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this Prospectus under "Risk Factors" beginning on page 10 of this Prospectus.

You should rely only on the information contained in this Prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this Prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

This Prospectus is dated October 12, 2017

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These statements include, but are not limited to, statements regarding:

- our expectations regarding clinical studies, the timing of clinical results, development timelines and regulatory filings and submissions for our product candidates;
- our intention to have one unblinded interim analysis, or IA, by an independent data monitoring committee, or IDMC, when the Phase 3 clinical study, or the HONOR study, of Tonmya ® (cyclobenzaprine HCl, or CBP, sublingual tablets), or Tonmya, in participants with military-related posttraumatic stress disorder, or PTSD, from approximately 50% efficacy-evaluable participants, or approximately 275 participants, to occur in the first half of 2018; and, if the IA results require continued enrollment, our expectation of topline results from the 550-participants available in the second half of 2018; and
- our liquidity and our expectations regarding our needs for and ability to raise additional capital.

These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown to us that could cause actual results and developments to differ materially from those expressed or implied in such statements, including the risks described under “Risk Factors” in this prospectus.

In some cases, you can identify forward-looking statements by terminology, such as “expects,” “anticipates,” “intends,” “estimates,” “plans,” “believes,” “seeks,” “may,” “should”, “could” or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and the documents that we reference herein and therein, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and the documents incorporated by reference is accurate as of their respective dates. Our business, financial condition, results of operations and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless required by law to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this prospectus, and particularly our forward-looking statements, by these cautionary statements.

ABOUT THIS PROSPECTUS

You should rely only on the information contained in this Prospectus. We have not authorized anyone to provide you with information different from that contained in this Prospectus. The selling stockholders are offering to sell and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this Prospectus is accurate only as of the date of this Prospectus, regardless of the time of delivery of this Prospectus or of any sale of our common stock. The Prospectus will be updated and updated prospectuses made available for delivery to the extent required by the federal securities laws.

No person is authorized in connection with this Prospectus to give any information or to make any representations about us, the selling stockholders, the securities or any matter discussed in this Prospectus, other than the information and representations contained in this Prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us or any selling stockholder. This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy the securities in any circumstances under which the offer or solicitation is unlawful. Neither the delivery of this Prospectus nor any distribution of securities in accordance with this Prospectus shall, under any circumstances, imply that there has been no change in our affairs since the date of this Prospectus. The Prospectus will be updated and updated prospectuses made available for delivery to the extent required by the federal securities laws.

PROSPECTUS SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider in making your investment decision. Therefore, you should read the entire prospectus carefully before investing in our securities. Investors should carefully consider the information set forth under "Risk Factors" beginning on page 10 of this prospectus. Except where the context otherwise requires, the terms, "we," "us," "our," "Tonix" or "the Company," refer to the business of Tonix Pharmaceuticals Holding Corp., a Nevada corporation and its wholly-owned subsidiaries.

Overview

We are a late 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 June 2017, the United States Food and Drug Administration, or FDA, conditionally accepted the proposed trade name Tonmya for TNX-102 SL (CBP sublingual tablets), or TNX-102 SL, for the treatment of PTSD. The FDA's final approval of Tonmya as a name for TNX-102 SL for the treatment of PTSD is subject to a new drug application, or NDA, approval. A request for review of Tonmya as the proposed name for TNX-102 SL for the management of fibromyalgia has been withdrawn at the FDA. The United States Patent and Trademark Office, or PTO, has granted the federal registration of the Tonmya mark. TNX-102 SL is an investigational new drug and has not been approved for any indication.

Our lead product candidate, Tonmya or TNX-102 SL, a proprietary low-dose CBP sublingual tablet designed for bedtime administration, is in Phase 3 development as a potential treatment for PTSD. We commenced the HONOR study, a randomized, double-blind, placebo-controlled study of Tonmya in approximately 550 participants with military-related PTSD in the first quarter of 2017. This Phase 3 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 IA and the involvement of the IDMC to review unblinded IA results. The IDMC will make a recommendation to continue as planned, to continue but increase the number of recruited participants or to stop for success. Based on the Phase 2 AtEase study results in military-related PTSD, Tonmya was granted Breakthrough Therapy designation by the FDA in December 2016, for the treatment of PTSD.

Our development pipeline includes: TNX-601 (tianeptine oxalate), a separate pre-IND, or Investigational New Drug, application candidate designed for daytime administration as a potential treatment of PTSD and for 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 our product candidates.

Our Product Pipeline

Tonmya – Posttraumatic Stress Disorder Program

Tonmya is a small, rapidly disintegrating tablet containing CBP for sublingual administration and transmucosal absorption. Tonmya is a proprietary, Protectic™ protective eutectic formulation of CBP that allows for rapid systemic exposure and increased bioavailability through the transmucosal delivery. Tonmya is in Phase 3 for the treatment of PTSD.

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.

Phase 2 AtEase Study

In the first quarter of 2015, we commenced a randomized, double-blind, placebo-controlled, 12-week Phase 2 study of Tonmya in participants with military-related PTSD, which we refer to as the AtEase study. The primary objective of this study was to evaluate the potential clinical benefit of using Tonmya to treat military-related PTSD at a dose of 2.8 mg or 5.6 mg (2 x 2.8 mg tablets). 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 of Mental Disorders-5th edition, or CAPS-5, between those treated with Tonmya and those receiving placebo. The CAPS-5 scale is a standardized structured clinical interview and is considered the gold standard in clinical research and regulatory approval for measuring the symptom severity of PTSD.

In the AtEase study, participants experienced their index trauma during military service in 2001 or later and had a baseline CAPS-5 score of 29 or higher, and were randomized in a 2:1:2 ratio to bedtime daily Tonmya 2.8 mg, Tonmya 5.6 mg, or placebo sublingual tablets for 12 weeks, respectively. The AtEase study was conducted at 24 U.S. centers and enrolled 231 participants in the modified intent-to-treat population. We reported topline results from the AtEase study in May 2016.

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 Tonmya 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 participants of the 2.8 mg and placebo arms. Tonmya 5.6 mg demonstrated a dose-effect on multiple efficacy and safety measurements in the AtEase study.

In the AtEase study, Tonmya was well tolerated and the participant retention rate was 73% on placebo, 79% on Tonmya 2.8 mg and 84% on Tonmya 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 Tonmya arm, which was determined to be unrelated to Tonmya. 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 participants treated with the 2.8 mg dose and 36% of the participants treated with the 5.6 mg dose, compared to 2% of the participants receiving placebo. Oral paresthesia, or tingling, occurred in 16% of participants treated with the 2.8 mg dose and 4% of participants treated with the 5.6 mg dose, compared to 3% of the participants receiving placebo. Glossodynia, or a burning or stinging sensation in the mouth, occurred in 3% of participants treated with the 2.8 mg dose and 6% of participants treated with the 5.6 mg dose, compared to 1% of participants receiving placebo. Systemic adverse events that were potentially dose-related and occurred in greater than or equal to 5% of participants treated with the 5.6 mg dose or placebo included: somnolence in 16% versus 6% of the participants receiving placebo; dry mouth in 16% versus 11% of the participants receiving placebo; headache in 12% versus 4% of the participants receiving placebo; insomnia in 6% versus 9% of the participants receiving placebo; sedation in 12% versus 1% of the participants receiving placebo; upper respiratory tract infection in 4% versus 5% of the participants receiving placebo; abnormal dreams in 2% versus 5% of the participants receiving placebo; and weight increase in 2% versus 5% of the participants receiving placebo. For the participants treated with the 2.8 mg dose, the incidence of the most common systemic adverse events reported above were less frequent than participants treated with the 5.6 mg dose with the exception of insomnia, which was 8%.

Retrospective analysis of the AtEase study suggested that the subset of participants with CAPS-5 score of 33 or higher was equivalent to the population of PTSD subjects studied in prior FDA registration studies of paroxetine and sertraline using older versions of the Clinician-Administered PTSD Scale. To confirm this efficacy evidence, our ongoing Phase 3 program enrolls participants with baseline CAPS-5 score of 33 or higher. The beneficial effects of Tonmya 5.6 mg were preserved in the subgroup with PTSD from combat traumas (85% of AtEase population). Also, sustained remission (i.e. satisfying remission criterion of CAPS-5 score less than 11 at both week 8 and week 12) was observed in 21% of participants receiving a 5.6 mg dose of Tonmya as compared to 5% of participants in the placebo group ($p = 0.02$, logistic regression). The AtEase study supported the hypothesized mechanism of sleep quality improvement, since additional retrospective analyses showed that in the CAPS-5 score of 33 or higher subset of participants, sleep improvement at week 4, measured by the PROMIS Sleep Disturbance instrument, predicted treatment response (by improvement in total CAPS-5 score without the sleep item) at week 12 in the Tonmya 5.6 mg group ($p = 0.01$, linear regression).

Open-label Extension Study for AtEase

Participants who completed the AtEase study were eligible to enroll into a three-month open-label extension study with Tonmya 2.8 mg. We conducted this open-label extension study to obtain additional safety information from participants in the AtEase Study. The clinical phase of this open-label extension study is complete. Tonmya 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 Tonmya in approximately 550 participants 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 IA and the involvement of the IDMC to review unblinded IA results. The IDMC will make a recommendation to continue as planned, to continue but increase the number of recruited participants 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 IA will be conducted when approximately 50% (approximately 250 – 300 participants) of the initially planned participant enrollment is evaluable for efficacy. We received FDA acceptance of the Phase 3 HONOR study design in January of 2017. The HONOR study is being conducted at approximately 45 U.S. sites. 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 Tonmya and those receiving placebo.

Open-label Extension Study for HONOR

To obtain additional safety information from participants in the HONOR study, participants who completed the HONOR study are eligible to enroll into a 12-week open-label extension study with Tonmya 5.6 mg. This open-label extension study is ongoing.

Prospective Phase 3 Study

A second, randomized, double-blind placebo-controlled Phase 3 study of Tonmya (5.6 mg administered as 2 x 2.8 mg tablets) in approximately 550 predominantly civilian PTSD participants will follow. We expect this study to be conducted at approximately 45 U.S. sites. 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 Tonmya and those receiving placebo.

Long-Term Safety Exposure Study for Tonmya

In addition to the ongoing 12-week open-label extension study for HONOR, we plan to conduct the registration-required open-label extension studies of Tonmya in participants who complete either the 12-week open-label extension study of 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 Tonmya 5.6 mg to support its registration for the treatment of PTSD, a chronic psychiatric condition.

Regulatory Update

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 Tonmya. In general, our proposed NDA CMC plan for Tonmya was acceptable to the FDA and can be applied to the PTSD NDA.

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 Tonmya 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 Tonmya for the treatment of PTSD. As described above, the first Phase 3 study will be in participants with military-related PTSD and the second Phase 3 study will study predominately civilian PTSD participants.

In December 2016, the FDA granted Breakthrough Therapy designation to Tonmya for the treatment of PTSD. The Breakthrough Therapy designation request was based on the preliminary clinical evidence of Tonmya 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 completed 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 Breakthrough Therapy 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 Tonmya 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 Tonmya, the FDA agreed that studies in assessing abuse potential of Tonmya are not required to support the Tonmya NDA.

In May 2017, the PTO issued us U.S. Patent No. 9,636,408. The patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride," claims the composition and manufacture of a unique formulation that characterizes Tonmya. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034.

In June 2017, the FDA conditionally accepted the proposed trade name Tonmya for TNX-102 SL (CBP sublingual tablets) for the treatment of PTSD.

On September 7, 2017, we had a Breakthrough Therapy CMC Guidance Meeting with the FDA to discuss the CMC plan for the Tonmya NDA filing. Formal meeting minutes from the FDA will be available by October 7, 2017.

On September 13, 2017, we were issued European patent 2501234 "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine". This patent protects the use of Tonmya for the treatment of PTSD as well as its active ingredient CBP for the treatment of PTSD. The patent is expected to provide Tonmya with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

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 Tonmya 2.8 mg tablets manufactured at two facilities: (i) the facility used to produce Tonmya 2.8 mg tablets for the Phase 2 AtEase study; and (ii) the facility used to produce Tonmya 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 Tonmya 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 Tonmya pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or 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 Tonmya 5.6 mg (administered as 2 x 2.8 mg tablets) in comparison to AMRIX 30 mg extended-release capsules in a randomized, open-label, parallel, multiple-dose bridging PK study to provide a systemic exposure bridge. If the exposures of Tonmya (2 x 2.8 mg tablets) are less than or comparable to 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 Tonmya 5.6.mg to AMRIX 30 mg extended-release capsules, and the approval of Tonmya for PTSD can thus rely on the safety findings (clinical and nonclinical) of the currently approved CBP drug products.

Food Effect and Dose-proportionality Studies

To support the Tonmya product registration, a randomized, open-label, 2-way crossover, food-effect, comparative bioavailability study of Tonmya 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 a single dose Tonmya at 2.8 mg vs. 5.6 mg in healthy subjects under fasting conditions will be completed for the Tonmya NDA submission.

Cyclobenzaprine Hydrochloride 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 the active ingredient, CBP 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 Tonmya 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 CBP. As a result, the FDA has advised that we will not have to assess the abuse and dependency potential of Tonmya to support the Tonmya 505(b)(2) NDA submission for the treatment of PTSD.

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 CBP, 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 Tonmya.

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 receiving FDA licensure. We are currently working to develop a vaccine that meets current Good Manufacturing Practice, or cGMP, quality to support an IND study.

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 the Animal Rule. We expect significant reduction in development costs and risks compared to the development of other new chemical entities, or NCEs, or new biologic candidates.

Corporate Information

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. 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*. The information on our websites is not part of this prospectus. We have included our website addresses as a factual reference and do not intend them to be active links to our websites.

The Offering

Common stock offered by the Selling Stockholder	2,100,000 shares consisting of: ● 73,039 shares of our common stock issued to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, or the Commitment Shares; and ● 2,026,961 shares we may sell to Lincoln Park under the Purchase Agreement from time to time after the date of this prospectus.
Common stock outstanding before the offering	7,581,700 shares, as of September 28, 2017.
Common stock outstanding after the offering	9,608,661 shares.
Use of proceeds	We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to $15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used for working capital and general corporate purposes. See "Use of Proceeds."
Symbol on The NASDAQ Global Market	"TNXP"
Risk factors	You should carefully consider the information set forth in this Prospectus and, in particular, the specific factors set forth in the "Risk Factors" section beginning on page 10 of this Prospectus before deciding whether or not to invest in our common stock.

Purchase Agreement with Lincoln Park

On September 28, 2017, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Also on September 28, 2017, we entered into a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act, the shares of common stock that have been or may be issued to Lincoln Park under the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 73,039 Commitment Shares.

We do not have the right to commence any sales of our common stock to Lincoln Park under the Purchase Agreement until certain conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park's control, have been satisfied, including that the SEC has declared effective the registration statement that includes this prospectus. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 30,000 shares on any single business day, subject to a maximum of $1,000,000 per purchase, plus an "initial amount", other "accelerated amounts" and/or "additional amounts" under certain circumstances. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock preceding the time of sale as computed under the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days' notice. There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, other than a prohibition on entering into a "Variable Rate Transaction," as defined in the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of September 28, 2017, there were 7,581,700 shares of our common stock outstanding, of which 6,304,021 shares were held by non-affiliates, excluding the 73,039 Commitment Shares that we have already issued to Lincoln Park under the Purchase Agreement. Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, only 2,100,000 shares of our common stock are being offered under this prospectus, which represents: (i) 73,039 shares that we already issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement, and (ii) an additional 2,026,961 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement. Depending on the market prices of our common stock at the time we elect to issue and sell shares to Lincoln Park under the Purchase Agreement, we may need to register for resale under the Securities Act additional shares of our common stock in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If all of the 2,100,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 22% of the total number of shares of our common stock outstanding and 25% of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. If we elect to issue and sell more than the 2,100,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Under applicable rules of The NASDAQ Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement (which is 1,500,981 shares based on 7,508,661 shares outstanding immediately prior to the execution of the Purchase Agreement), or the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds $4.5178 per share (which represents the closing consolidated bid price of our common stock on September 27, 2017, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The NASDAQ Global Market.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock, or the Beneficial Ownership Cap, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder.

Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

RISK FACTORS

This investment has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this Prospectus. If any of the following risks actually occur, our business, operating results and financial condition could be harmed and the value of our stock could go down. This means you could lose all or a part of your investment.

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, Tonmya for PTSD. We have not yet obtained regulatory approvals for Tonmya 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 Tonmya 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 Tonmya 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 REMS, or cause an approved drug to be taken off the market;
- our dependence on third party contract manufacturing organizations, or CMOs, to supply or manufacture our products;
- our dependence on third party contract research organizations, or CROs, to conduct our clinical 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, Tonmya 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, Tonmya, 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 Tonmya. If projected sales do not materialize for any reason, it would have a material adverse effect on our business and our ability to continue operations.

Tonmya 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 Tonmya 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 Tonmya 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 Tonmya 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 PTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the 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 PTO. 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 PTO 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, or IRB, 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 SAEs.

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 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 Tonmya. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of participants, 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 Tonmya 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 participants), 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 Tonmya 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 Tonmya and other product candidates we are developing.

Our product candidates may cause SAEs 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.

SAEs or undesirable side effects from Tonmya 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 Tonmya, may show that our product candidates cause SAEs 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 Tonmya or any of our other product candidates cause SAEs 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 participants 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 Tonmya or if Tonmya 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 Tonmya for PSTD Breakthrough Therapy designation based on several factors, including that Tonmya 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 Tonmya, then the FDA may rescind the designation. In addition, if Tonmya 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 Tonmya may not lead to faster development or regulatory processes nor does it increase the likelihood that Tonmya 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 Tonmya for PTSD or increase the likelihood that Tonmya will be granted marketing approval for PTSD. In some cases, the development program for the Breakthrough Therapy could be shorter than for other drugs intended to treat the disease being studied. However, the FDA notes that a compressed drug development program still must generate adequate data to demonstrate that the drug is safe, effective and meets the statutory standard for approval. Breakthrough Therapy designation does not change the standards for approval. If a clinical development program granted Breakthrough Therapy designation does not continue to meet the criteria, the FDA may rescind the designation.

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 Tonmya 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 Tonmya 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 Tonmya for the treatment of PTSD. In March 2017, we had our initial Cross-disciplinary Breakthrough Therapy meeting with the FDA to discuss ways to expedite the development and NDA submission of Tonmya. Although our interactions with the FDA have encouraged our efforts to continue to develop Tonmya 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 Tonmya 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 Tonmya 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 Tonmya, 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 Tonmya. 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 Tonmya, 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 Drug Enforcement Administration, or 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 ITB 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 Biologic License Application, or 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 CMCs. 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 CMOs 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 Tonmya 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 Modified Virus Ankara, or 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 potentially safer and possibly better tolerated 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 September 28, 2017, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 17.7% 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.

Risks Related to This Offering

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On September 28, 2017, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15,000,000 of our common stock. Upon the execution of the Purchase Agreement, we issued 73,039 Commitment Shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The remaining shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some, or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to $15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. We estimate that the net proceeds to us from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will be up to $14,900,000 over an approximately 30-month period, assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to Lincoln Park under the Purchase Agreement, and after other estimated fees and expenses. See “Plan of Distribution” elsewhere in this prospectus for more information.

We expect to use any proceeds that we receive under the Purchase Agreement for working capital and general corporate purposes.

LINCOLN PARK TRANSACTION

General

On September 28, 2017, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to $15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 73,039 Commitment Shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement.

We do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until certain conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park's control, have been satisfied, including the registration statement that includes this prospectus being declared effective by the SEC. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 30,000 shares on any single business day, which amounts may be increased to up to 70,000 shares of our common stock depending on the market price of our common stock at the time of sale but in no event greater than $1,000,000 per such purchase. The purchase price per share is based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Under applicable rules of The NASDAQ Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement shares of our common stock in excess of the Exchange Cap (which is 1,500,981 shares, or 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement), unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds $4.5178 per share (which represents the closing consolidated bid price of our common stock on September 27, 2017, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The NASDAQ Global Market.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates exceeding the Beneficial Ownership Cap.

Purchase of Shares Under the Purchase Agreement

Regular Purchases

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 30,000 shares of our common stock on any such business day, or a Regular Purchase, provided, however, that (i) the Regular Purchase may be increased to up to 40,000 shares, provided that the closing sale price is not below $5.00 on the purchase date, (ii) the Regular Purchase may be increased to up to 50,000 shares, provided that the closing sale price is not below $6.00 on the purchase date, (iii) the Regular Purchase may be increased to up to 60,000 shares, provided that the closing sale price is not below $7.50 on the purchase date, (iv) the Regular Purchase may be increased to up to 70,000 shares, provided that the closing sale price is not below $10.00 on the purchase date, and (v) we may direct Lincoln Park to purchase shares in a Regular Purchase only if at least one business day has passed since the most recent Regular Purchase, as applicable, was completed. In each case, the maximum amount of any single Regular Purchase may not exceed $1,000,000 per purchase. The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

Accelerated Purchases

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice and the closing sale price of our common stock is not below $3.00 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement), to purchase an additional amount of our common stock on the next business day, or an Accelerated Purchase, not to exceed the lesser of:

- 30% of the aggregate shares of our common stock traded during normal trading hours on the purchase date; and
- Three (3) times the number of purchase shares purchased pursuant to the corresponding Regular Purchase.

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

- 96% of the volume weighted average price during (i) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the Purchase Agreement, or (ii) the portion of the trading day of the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum; or
- the closing sale price of our common stock on the accelerated purchase date.

Initial Purchase

In addition to the Regular Purchases described above, we have the option, on the first date that we are first able to begin selling shares to Lincoln Park under the Purchase Agreement, we may direct Lincoln Park to purchase up to 300,000 shares, or the Initial Purchase, provided, however, that Lincoln Park's committed obligation under the Initial Purchase shall not exceed $1,000,000.

The purchase price for such Initial Purchase shall be equal to the lower of:

- the closing sales price for our common stock on the date immediately prior to the purchase date of such shares; or
- the arithmetic average of the closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

Additional Purchases

In addition to the Regular Purchases, Accelerated Purchases and the Initial Purchase described above, from time to time after the date that we are first able to begin selling shares to Lincoln Park under the Purchase Agreement, we may also direct Lincoln Park, on any business day that the closing price of our common stock is not below $3.00 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction), to purchase additional amounts of our common stock, or an Additional Purchase, provided, however, that (i) we may direct Lincoln Park to purchase shares in an Additional Purchase only if at least 15 business days have passed since the most recent Additional Purchase, as applicable, was completed, (ii) we may direct Lincoln Park to purchase shares in an Additional Purchase only if at least 30 business days have passed since the Initial Purchase, if exercised, was completed, (iii) Lincoln Park's committed obligation under any single Additional Purchase shall not exceed $500,000, and (iv) Lincoln Park's committed obligation under all Additional Purchases shall not exceed $2,000,000 in the aggregate.

The purchase price for each such Additional Purchase shall be equal to the lower of:

- 96% of the purchase price under a Regular Purchase on the date we give notice for the related Additional Purchase; or
- $5.50 per share.

In the case of the Regular Purchases, Accelerated Purchases, Initial Purchase and Additional Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as described above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

Events of Default

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- suspension by our principal market of our common stock from trading for a period of one business day;
- the de-listing of our common stock from The NASDAQ Global Market, our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Global Select Market, the NASDAQ Capital Market, the NYSE MK Market, the OTC Bulletin Board or OTC Markets (or nationally recognized successor thereto);
- the failure of our transfer agent to issue to Lincoln Park shares of our common stock within three business days after the applicable date on which Lincoln Park is entitled to receive such shares;
- any breach of the representations or warranties or covenants contained in the Purchase Agreement or Registration Rights Agreement that has or could have a material adverse effect on us and, in the case of a breach of a covenant that is reasonably curable, that is not cured within five business days;
- if at any time the Exchange Cap is reached, to the extent applicable;
- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or
- if at any time we are not eligible to transfer our common stock electronically.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park's control, we may not direct Lincoln Park to purchase any shares of our common stock under the Purchase Agreement.

Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Prohibitions on Variable Rate Transactions

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement other than a prohibition on entering into a "Variable Rate Transaction," as defined in the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

All 2,100,000 shares registered in this offering which have been or may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 30 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to $15,000,000 of our common stock, exclusive of the 73,039 shares issued to Lincoln Park on such date as a commitment fee. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares of our common stock, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement (i) shares of our common stock in excess of the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equal or exceed $4.5178 per share, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules, and (ii) any shares of our common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would exceed the Beneficial Ownership Cap.

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase (1)	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (2)	Proceeds from the Sale of Shares to Lincoln Park Under the $15M Purchase Agreement
$2.00	2,026,961	21%	$ 4,053,922
$4.31 (3)	2,026,961	21%	$ 8,736,202
$6.00	2,026,961	21%	$ 12,161,766
$8.00	1,875,000	20%	$ 15,000,000
$10.00	1,500,000	17%	$ 15,000,000

(1) Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, we are only registering 2,100,000 shares under this prospectus which represents: (i) 73,039 shares that we already issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement, and (ii) an additional 2,026,961 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement, and which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering. If we seek to issue shares of our common stock, including shares from other transactions that may be aggregated with the transactions contemplated by the Purchase Agreement under the applicable rules of The NASDAQ Global Market, in excess of 1,500,951 shares, or 19.99% of the total common stock outstanding immediately prior to the execution of the Purchase Agreement, we may be required to seek stockholder approval in order to be in compliance with the rules of The NASDAQ Global Market.

(2) The denominator is based on 7,581,700 shares outstanding as of September 28, 2017, adjusted to include the issuance of (i) 73,039 commitment shares issued to Lincoln Park upon the execution of the Purchase Agreement, and (ii) the number of shares set forth in the adjacent column which we would have sold to Lincoln Park, assuming the purchase price in the adjacent column. The numerator is based on the number of shares issuable under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

(3) The closing sale price of our common stock on September 27, 2017.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

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 2017	
	High	Low
First Quarter	$ 9.40	$ 3.30
Second Quarter	$ 5.81	$ 3.80
Third Quarter	$ 4.77	$ 2.85
Fourth Quarter (through October 11, 2017)	$ 4.99	$ 4.25

	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

Holders

On September 28, 2017, there were approximately 108 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Some of the information in this Form S-1 contains forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may," "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other "forward-looking" information.

We believe it is important to communicate our expectations. However, there may be events in the future that we are not able to accurately predict or over which we have no control. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors," "Business" and elsewhere in this Prospectus. See "Risk Factors."

Business Overview

We are a late 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 June 2017, the FDA conditionally accepted the proposed trade name Tonmya for TNX-102 SL for the treatment of PTSD. The FDA's final approval of Tonmya as a name for TNX-102 SL for the treatment of PTSD is subject to an NDA approval. A request for review of Tonmya as the proposed name for TNX-102 SL for the management of fibromyalgia has been withdrawn at the FDA. The U.S. Patent and Trademark Office has granted the federal registration of the Tonmya mark.

Our lead product candidate, Tonmya or TNX-102 SL, a proprietary low-dose CBP sublingual tablet designed for bedtime administration, is in Phase 3 development as a potential treatment for PTSD. The FDA has designated Tonmya a Breakthrough Therapy for the treatment of PTSD.

Our therapeutic strategy in PTSD is supported by results from a randomized, double-blind, placebo-controlled, 12-week Phase 2 study of Tonmya in participants 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, participants experienced their index trauma during military service in 2001 or later and had a baseline CAPS-5 score of 29 or higher and were randomized in a 2:1:2 ratio to Tonmya 2.8 mg, Tonmya 5.6 mg (2 x 2.8 mg tablets), or placebo sublingual tablets at bedtime daily for 12 weeks, respectively. This study was conducted at 24 U.S. centers and enrolled 231 participants in the modified intent-to-treat population. The primary objective of the AtEase study was to evaluate the efficacy and safety of Tonmya in the treatment of military-related PTSD. The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with Tonmya 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 Tonmya 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 MMRM with MI analysis (p-value = 0.031), even though this arm of the study, by design, included only approximately half the number of participants of the 2.8 mg and placebo arms. Tonmya 5.6 mg demonstrated a dose-effect on multiple efficacy and safety measurements in the AtEase study.

In the AtEase study, Tonmya was well tolerated and the participant retention rate was 73% on placebo, 79% on Tonmya 2.8 mg and 84% on Tonmya 5.6 mg. Four distinct SAEs were reported in the study; three were in the placebo group, and one (proctitis/peri-rectal abscess,) in the Tonmya arm, which was determined to be unrelated to Tonmya. 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 participants treated with the 2.8 mg dose and 36% of the participants treated with the 5.6 mg dose, compared to 2% of the participants receiving placebo. Oral paresthesia, or tingling, occurred in 16% of participants treated with the 2.8 mg dose and 4% of participants treated with the 5.6 mg dose, compared to 3% of the participants receiving placebo. Glossodynia, or a burning or stinging sensation in the mouth, occurred in 3% of participants treated with the 2.8 mg dose and 6% of participants treated with the 5.6 mg dose, compared to 1% of participants receiving placebo.

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

Retrospective analysis of the AtEase study suggested that the subset of participants with CAPS-5 score of 33 or higher was equivalent to the population of PTSD subjects studied in prior FDA registration studies of paroxetine and sertraline using older versions of the Clinician-Administered PTSD Scale. To confirm this efficacy evidence, our ongoing Phase 3 program is enrolling participants with baseline CAPS-5 score of 33 or higher. The beneficial effects of Tonmya 5.6 mg were preserved in the subgroup with PTSD from combat traumas (85% of AtEase population). Also, sustained remission (i.e. satisfying remission criterion of a CAPS-5 score less than 11 at both week 8 and week 12) was observed in 21% of participants in the Tonmya 5.6 mg group as compared to 5.2% of participants in the placebo group ($p = 0.02$, logistic regression). The AtEase study supported the hypothesized mechanism of sleep quality improvement, since additional retrospective analyses showed that in the subset of participants with CAPS-5 score of 33 or higher, sleep improvement at week 4, measured by the PROMIS Sleep Disturbance instrument, predicted treatment response (by improvement in total CAPS-5 score without the sleep item) at week 12 in the Tonmya 5.6 mg group ($p = 0.01$, linear regression).

On December 16, 2016, the FDA designated Tonmya a Breakthrough Therapy for the treatment of PTSD based on data derived from a population with military-related PTSD in the AtEase study.

We received FDA clearance of the first Phase 3 study design in January 2017. We commenced the HONOR study, a randomized, double-blind placebo-controlled Phase 3 study of Tonmya in approximately 550 participants with military-related PTSD in the first quarter of 2017. This 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 IA and the involvement of the IDMC to review unblinded IA results. The IDMC will make a recommendation to continue as planned, to continue but increase the number of recruited participants 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 IA will be conducted when approximately 50% of the initially planned participants (approximately 275 participants) are randomized. The HONOR study is being conducted at approximately 45 U.S. sites. 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 Tonmya 5.6 mg and those receiving placebo.

At the Initial Cross-disciplinary Breakthrough Therapy meeting on March 9, 2017, the FDA confirmed that a single-study NDA approval is possible if the topline data of the Phase 3 HONOR study is statistically persuasive and no additional abuse and dependency study is necessary to support the NDA filing.

On May 2, 2017, we were issued U.S. patent 9,636,408 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, which includes compositions of cyclobenzaprine HCl and methods of manufacturing the eutectic. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of our proprietary Tonmya composition. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034.

On September 7, 2017, we had a Breakthrough Therapy CMC Guidance meeting with the FDA to discuss the NDA CMC plan and formal meeting minutes will be available by October 7, 2017.

On September 13, 2017, we were issued European patent 2501234 “Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine”. This patent protects the use of Tonmya for the treatment of PTSD as well as its active ingredient CBP for the treatment of PTSD. The patent is expected to provide Tonmya with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

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. We hold worldwide development and commercialization rights to all of our product candidates.

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 as a first-line monotherapy for PTSD for daytime use. 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 Tonmya. On April 19, 2016, we were issued U.S. 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 daytime 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. Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada in collaboration with us, synthesized the HPVX, which demonstrated protective vaccine activity in mice, using a model of lethal vaccinia infection. 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 for the repeal of the Affordable Care Act, if enacted, would 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 cGMP quality to support an IND study.

TNX-301 is a fixed-dose CDP containing two FDA-approved drugs, disulfiram and selegiline. We intend to develop TNX-301 CDP under Section 505(b)(2) of the FDCA as a potential treatment for 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 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 Tonmya 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 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, contracts or other agreements. 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 participant 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.

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2017 were $2.8 million, a decrease of $4.7 million, or 63%, from $7.5 million for the three months ended June 30, 2016. This decrease is predominately due to the discontinuation of development work related to the fibromyalgia program. During the three months ended June 30, 2017, we incurred $1.7 million, $0.1 million and $0.4 million in clinical, non-clinical and manufacturing expenses, respectively, as compared to $4.8 million, $0.3 million, and $0.9 million for the same period last year, respectively.

Compensation-related expenses were $0.5 million for the three months ended June 30, 2017, compared to $1.0 million for the three months ended June 30, 2016, a decrease of $0.5 million, or 50%. Cash compensation-related expenses were $0.4 million for the three months ended June 30, 2017, a decrease of $0.4 million, or 50%, from $0.8 million for the three months ended June 30, 2016. The decreases were primarily a result of a reduction in personnel. We incurred $0.1 million in stock-based compensation in the three months ended June 30, 2017 in connection with the vesting of stock options, which were previously issued to officers and consultants, as compared to $0.2 million in stock-based compensation for the same period in 2016. Regulatory and legal costs for the three months ended June 30, 2017 were $0.1 million, a decrease of $0.1 million, or 50%, from $0.2 million incurred in the three months ended June 30, 2016. The decrease in regulatory and legal costs was primarily due to the decrease in active trials.

Travel, meals and entertainment costs for the three months ended June 30, 2017 and 2016 were each $0.1 million. Travel, meals and entertainment costs include travel related to clinical development and medical-related conferences. Other research and development costs totaled a credit of $0.1 million for the three months ended June 30, 2017, a decrease of $0.3 million, or 150%, from $0.2 million incurred for the three months ended June 30, 2016. Included in 2017, is an insurance refund of $0.2 million. Other research and development costs include rent, insurance and other office related expenses.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2017 were $2.0 million, a decrease of $0.3 million, or 13%, from $2.3 million incurred in the three months ended June 30, 2016. This decrease is primarily due to reduced compensation-related expenses.

Compensation-related expenses decreased to $0.8 million for the three months ended June 30, 2017, from $1.1 million for the three months ended June 30, 2016, a decrease of $0.3 million, or 27%. Cash compensation-related expenses were $0.5 million for the three months ended June 30, 2017, a decrease of $0.1 million, or 17%, from $0.6 million for the three months ended June 30, 2016. We incurred $0.3 million in stock-based compensation in connection with the 2014 employee stock purchase plan and the vesting of restricted stock units and stock options in the three months ended June 30, 2017, which were previously issued to board members, officers and consultants, as compared to $0.5 million in stock-based compensation for the same period last year. The decrease in cash compensation related costs was primarily a result of a reduction in personnel.

Professional services for the three months ended June 30, 2017 totaled $0.7 million for both reporting periods. Of professional services, legal fees totaled $0.3 million for the three months ended June 30, 2017, an increase of $0.1 million, or 50%, from $0.2 million incurred for the three months ended June 30, 2016. The increase is mainly due to an increase in legal fees related to patent activity. Audit and accounting fees incurred for the three months ended June 30, 2017 and 2016 were both $0.1 million. Investor and public relations fees incurred for the three months ended June 30, 2017 and 2016 were both $0.2 million. Other professional fees for the three months ended June 30, 2017 totaled $0.1 million, a decrease of $0.1 million, or 50%, from $0.2 million incurred for the three months ended June 30, 2016. Other professional fees include human resources and corporate consultants.

Travel, meals and entertainment costs for the three months ended June 30, 2017 were $0.1 million for both reporting periods. Office and other administrative expenses were $0.4 million for both reporting periods. Office and other administrative expenses include rent, insurance and other office related expenses.

Net Loss. As a result of the foregoing, the net loss for the three months ended June 30, 2017 was $4.8 million, compared to a net loss of $9.8 million for the three months ended June 30, 2016.

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2017 were $5.8 million, a decrease of $12.4 million, or 68%, from $18.2 million for the six months ended June 30, 2016. This decrease is predominately due to the discontinuation of development work related to the episodic tension-type headache and fibromyalgia programs. During the six months ended June 30, 2017, we incurred $3.1 million, $0.1 million and $0.7 million in clinical, non-clinical and manufacturing expenses, respectively, as compared to $11.0 million, $1.2 million and $2.2 million for the same period last year, respectively.

Compensation-related expenses were $1.1 million for the six months ended June 30, 2017, compared to $2.0 million for the six months ended June 30, 2016, a decrease of $0.9 million, or 45%. Cash compensation-related expenses were $0.9 million for the six months ended June 30, 2017, a decrease of $0.7 million, or 44%, from $1.6 million for the six months ended June 30, 2016. The decreases were primarily a result of a reduction in personnel. We incurred $0.2 million in stock-based compensation in connection with the vesting of stock options in the six months ended June 30, 2017 that were previously issued to officers and consultants as compared to $0.4 million in stock-based compensation for the same period last year. Regulatory and legal costs for the six months ended June 30, 2017 were $0.4 million, a decrease of $0.3 million, or 43%, from $0.7 million incurred in the six months ended June 30, 2016. The decrease in regulatory and legal costs was primarily due to the decrease in active trials.

Travel, meals and entertainment costs for the six months ended June 30, 2017 and 2016 were both $0.4 million. Travel, meals and entertainment costs include travel related to clinical development and medical-related conferences. Other research and development costs totaled $0 for the six months ended June 30, 2017 after offsetting an insurance refund received of $0.2 million, compared to $0.7 million for the six months ended June 30, 2016. Other research and development costs include rent, insurance and other office related expenses.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2017 were $4.1 million, a decrease of $1.6 million, or 28%, from $5.7 million incurred in the six months ended June 30, 2016. This decrease is primarily due to reduced compensation-related expenses.

Compensation-related expenses decreased to $1.8 million for the six months ended June 30, 2017 from $3.0 million for the six months ended June 30, 2016, a decrease of $1.2 million, or 40%. Cash compensation-related expenses were $1.0 million for the six months ended June 30, 2017, a decrease of $0.7 million, or 41%, from $1.7 million for the six months ended June 30, 2016. We incurred $0.8 million in stock-based compensation in connection with the 2014 employee stock purchase plan and the vesting of restricted stock units and stock options in the six months ended June 30, 2017 that were previously issued to board members, officers and consultants as compared to $1.3 million in stock-based compensation for the same period last year. The decrease in cash compensation-related costs was primarily a result of a reduction in personnel.

Professional services for the six months ended June 30, 2017 totaled $1.5 million, a decrease of $0.1 million, or 6%, from the $1.6 million incurred for the six months ended June 30, 2016. Of professional services, legal fees totaled $0.5 million for both reporting periods. Audit and accounting fees incurred for the six months ended June 30, 2017 and 2016 were both $0.2 million. Investor and public relations fees totaled $0.4 million for the six months ended June 30, 2017, a decrease of $0.1 million, or 20%, from $0.5 million incurred for the six months ended June 30, 2016. Other professional fees incurred for the six months ended June 30, 2017 and 2016 were both $0.4 million. Other professional fees include human resources and corporate consultants.

Travel, meals and entertainment costs for the six months ended June 30, 2017 were $0.1 million, a decrease of $0.1 million, or 50%, from $0.2 million incurred in the six months ended June 30, 2016. Travel, meals and entertainment costs include travel related to business development and investor relations activities, which were reduced from 2016. Office and other administrative expenses totaled $0.7 million, a decrease of $0.2 million, or 22%, from $0.9 million incurred in the six months ended June 30, 2016. Office and other administrative expenses include rent, insurance and other office related expenses.

Net Loss. As a result of the foregoing, the net loss for the six months ended June 30, 2017 was $9.8 million, compared to a net loss of $23.8 million for the six months ended June 30, 2016.

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 Tonmya 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 June 30, 2017, we had working capital of $33.7 million, comprised primarily of cash and cash equivalents of $34.4 million and prepaid expenses and other of $1.1 million, which was offset by $1.2 million of accounts payable and $0.6 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our ongoing HONOR study. For the six months ended June 30, 2017 and 2016, we used approximately $9.2 million and $23.5 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. Decreases in cash outlays principally resulted from reduced spending on manufacturing, non-clinical and clinical cost and activities, regulatory cost, and payroll. For the six months ended June 30, 2017, net proceeds from financing activities were from the sale of our common stock of approximately $17.4 million. In the comparable 2016 period, approximately $11.8 million was raised through the sale of shares of common stock.

Cash provided by investing activities for the six months ended June 30, 2017 was approximately $7.2 million, related to the maturity of marketable securities. Investing activities for the six months ended June 30, 2016 related to the maturity of marketable securities of $7.5 million offset by the purchase of equipment and leasehold improvements of $0.1 million.

April 2017 Financing

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

The April 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 incurred offering expenses of approximately $0.2 million. We received 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).

At-the-Market Offering

On April 28, 2016, we entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, as sales agent, pursuant to which we could have, from time to time, issued and sold common stock with an aggregate value of up to $15.0 million in at-the-market, or ATM, sales. On the same day, we filed a prospectus supplement under our existing shelf registration relating to the Sales Agreement. Cowen acted as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. Our common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied. During the six months ended June 30, 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 of approximately $0.3 million of Cowen's commission. With these sales, we sold all $15 million of shares under the Sales Agreement, and the Sales Agreement was terminated.

Lincoln Park Equity Offering

On September 28, 2017, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement, we issued 73,039 Commitment Shares to Lincoln Park.

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 activities through at least the end of the ongoing Phase 3 HONOR study in military-related PTSD. Our existing cash and marketable securities are sufficient to fund our operating expenses and planned clinical trial through at least 12 months from the date of this filing.

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

We have issued awards under our 2012 Incentive Stock Option Plan, 2014 Stock Incentive Plan and 2016 Stock Incentive Plan, or collectively, the Prior Plans, and under the 2017 Stock Incentive Plan, or the 2017 Plan, and together with the Prior Plans, the Plans. No future awards are issuable under the Prior Plans.

On June 16, 2017, our stockholders approved the 2017 Plan. As a result of adoption of the 2017 Plan by the stockholders, no further grants may be made under the Prior Plans. Under the terms of the 2017 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 2017 Plan provides for the issuance of up to 1,280,000 shares of common stock, which amount will be (a) reduced by awards granted under the Prior Plans after March 31, 2017, 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 2017 Plan).

In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after March 31, 2017, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.15 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 2017 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 750,000 shares of our common stock, (ii) earn more than 500,000 shares of our common stock under restricted stock awards, restricted stock unit awards, performance awards and/or other stock-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 2017 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 2017 Plan may not be more than five years and expiration period not more than ten years. We reserved 1,280,000 shares of our common stock for future issuance under the terms of the 2017 Plan. As of June 30, 2017, 1,153,968 shares were available for future grants under the 2017 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 September 12, 2017, 20,000 options were granted to our new non-employee director for board services for the one year term of the director's board appointment, in lieu of cash, exercisable for ten years with a one year vesting from the grant date and a fair value of $4.25 at the date of grant.

On June 20, 2017, 150,000 options were granted to our non-employee directors for board services for the one year term of the director's board appointment, in lieu of cash, exercisable for ten years with a one year vesting from the grant date and a fair value of $2.73 at the date of grant.

On March 1, 2017, 61,750 options were granted to employees with an exercise price of $5.50, exercisable for a period of ten years and a grant date fair value of $3.36. 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 participants in the ongoing HONOR study by December 31, 2017, and the remaining 50% vesting 1% for each participant 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.

Stock-based compensation expense relating to options granted of $0.5 million and $1.0 million was recognized for the three and six month periods ended June 30, 2017, respectively, and $0.7 million and $1.5 million was recognized for the three and six month periods ended June 30, 2016, respectively.

As of June 30, 2017, we had approximately $1.5 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 1.23 years.

Employee Stock Purchase Plan

On June 9, 2014, we approved the Tonix Pharmaceuticals Holdings Corp. 2014 Employee Stock Purchase Plan, or 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 June 30, 2017, after giving effect to shares purchased, as described below, there were 1,689 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 six months ended June 30, 2017 and 2016 was $36,000 and $59,000, respectively. As of June 30, 2017, approximately $76,000 of employee payroll deductions, which had been withheld since January 1, 2017, the commencement of the offering period ending June 30, 2017, are included in accrued expenses in the accompanying balance sheet. In July 2017, 17,760 shares that were purchased as of June 30, 2017, were issued under the 2014 ESPP, and approximately $64,000 of employee payroll deductions accumulated at June 30, 2017, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. 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

In February 2017, 5,625 RSUs that were granted to our non-employee directors for board services in 2016, in lieu of cash, with a one year vesting from the grant date and a fair value of $38.10 at the date of grant vested, and 5,625 shares of our common stock were issued during the six months ended June 30, 2017.

In May 2017, 5,625 RSUs vested that were granted to our non-employee directors for board services in 2016, in lieu of cash, with a one year vesting from the grant date and a fair value of $22.90 at the date of grant, and 4,125 shares of our common stock were issued during the six months ended June 30, 2017.

Stock-based compensation expense related to RSU grants was $21,000 and $72,000 for the three and six months ended June 30, 2017, respectively, and $64,000 and $144,000 for the three and six months ended June 30, 2016, respectively.

Lease Commitments

As of September 28, 2017, future minimum lease payments under operating leases for office space were as follows (in thousands):

Year Ending December 31,		
2017	$	136
2018		458
2019		181
	$	775

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 participant progression and the timing of various aspects of the trial. We determine accrual estimates that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us at that time. Our clinical trial accruals and prepaid assets are dependent upon the timely and accurate reporting of 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, or FASB, issued Accounting Standards Update, or 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 November 2016, FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, to provide guidance on the presentation of restricted cash or restricted cash equivalents in the statement of cash flows, thereby reducing the diversity in presentation. This update is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. This update may have an effect on our future classification of certain transactions on our consolidated statement of cash flows and related disclosures.

BUSINESS

Business Overview

Tonix 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.

In June 2017, the FDA conditionally accepted the proposed trade name Tonmya for TNX-102 SL, for the treatment of PTSD. The FDA's final approval of Tonmya as a name for TNX-102 SL for the treatment of PTSD is subject to an NDA approval. A request for review of Tonmya as the proposed name for TNX-102 SL for the management of fibromyalgia has been withdrawn at the FDA. The PTO has granted the federal registration of the Tonmya mark.

Our lead product candidate, Tonmya, a proprietary low-dose CBP 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 candidate designed for daytime administration as a potential treatment of PTSD and for cognitive dysfunction associated with steroid use; TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of HPXV; TNX-301 an IND candidate for the treatment of 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.

Tonmya – Posttraumatic Stress Disorder Program

Tonmya is a small, rapidly disintegrating tablet containing CBP for sublingual administration and transmucosal absorption. Tonmya has a proprietary, Protectic™ protective eutectic formulation of CBP that allows for rapid systemic exposure and increased bioavailability through the transmucosal delivery. We are developing Tonmya for the management of PTSD under an IND cleared by the 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 Tonmya for PTSD and TNX-102 SL for Other Indications***. We currently are focusing on the development of Tonmya 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 Tonmya***. We plan to commercialize Tonmya for PTSD, either on our own or through collaboration with partners. We believe Tonmya 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 Tonmya;

- ***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 cases of Tonmya and 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 PTO, for patent claims that will protect the pharmaceutical eutectic composition of Tonmya or TNX-102 SL until 2034. We were issued U.S Patent No. 9,636,408 for patent claims that will protect the composition and manufacture of a unique formulation that characterizes Tonmya and 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 Tonmya, 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 Tonmya 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.

Tonmya

Overview

Tonmya or 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 Tonmya for PTSD. We own all rights to Tonmya in all geographies, and we bear no obligations to third-parties for any future development or commercialization. Excipients used in Tonmya 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 Tonmya or TNX-102 SL sublingual tablets contain 2.8 mg of CBP. For the treatment of PTSD, 5.6 mg of Tonmya, comprised of two Tonmya 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.

The active ingredient in Tonmya or TNX-102 SL, CBP, is a serotonin 2A and alpha-1 adrenergic receptor antagonist as well as an inhibitor of serotonin and norepinephrine reuptake. In PTSD, both paroxetine and sertraline are believed to exert their clinical benefit primarily by blocking serotonin reuptake. As such, Tonmya acts upon cellular receptors that play important roles in the treatment of PTSD, including the transporters that mediate serotonin and norepinephrine reuptake. In addition, Tonmya 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 ® (5 mg and 10 mg oral immediate-release, or IR, tablet) and AMRIX® (15 mg and 30 mg oral extended-release capsule). The FLEXERIL brand of CBP IR tablet has been discontinued since May 2013. There are numerous generic versions of CBP IR 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. 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 IR CBP tablets.

We designed Tonmya and TNX-102 SL to be administered once-daily at bedtime and intended for long-term dosing regimen. We believe the selected dose of Tonmya 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, Tonmya results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following sublingual administration relative to oral IR CBP tablets. In clinical studies, Tonmya 2.8 mg and Tonmya 5.6 mg were generally well-tolerated, with no SAEs reported in these studies. Some subjects experienced transient numbness of the tongue after Tonmya administration.

We expect that any applications we submit to the FDA for approval of Tonmya for the treatment of PTSD will be submitted under Section 505(b)(2) of the 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) NDA is shorter and less expensive than an NDA developed under Section 505(b)(1), which is for NCEs that have never been approved in the United States. Currently, we are pursuing the development of Tonmya for PTSD, for which Tonmya is in Phase 3 development. We believe that Tonmya and TNX-102 SL have the potential to provide clinical benefit to this and possibly other CNS indications that are underserved by currently marketed products.

On May 2, 2017, we were issued U.S. patent 9,636,408 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, which includes compositions of CBP and methods of manufacturing the eutectic. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of our proprietary Tonmya or TNX-102 SL composition. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034. Eutectic tablets containing CBP 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.

On September 13, 2017, we were issued European patent 2501234 “Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine”. This patent protects the use of Tonmya for the treatment of PTSD as well as its active ingredient CBP for the treatment of PTSD. The patent is expected to provide Tonmya with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

Tonmya – PTSD Program

We are developing Tonmya 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 Tonmya in participants with military-related PTSD, which we refer to as the AtEase study. The primary objective of this study was to evaluate the potential clinical benefit of using Tonmya to treat military-related PTSD at a dose of 2.8 mg or 5.6 mg (2 x 2.8 mg tablets). The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 between those treated with Tonmya 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.

In the AtEase study, participants experienced their index trauma during military service in 2001 or later and had a baseline CAPS-5 score of 29 or higher, and were randomized in a 2:1:2 ratio to bedtime daily Tonmya 2.8 mg, Tonmya 5.6 mg, or placebo sublingual tablets for 12 weeks, respectively. The AtEase study was conducted at 24 U.S. centers and enrolled 231 participants in the modified intent-to-treat population. We reported topline results from the AtEase study in May 2016.

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 Tonmya 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 MMRM with MI analysis (p-value = 0.031), even though this arm of the study, by design, included only approximately half the number of participants of the 2.8 mg and placebo arms. Tonmya 5.6 mg demonstrated a dose-effect on multiple efficacy and safety measurements in the AtEase study.

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

Retrospective analysis of the AtEase study suggested that the subset of participants with CAPS-5 score of 33 or higher was equivalent to the population of PTSD subjects studied in prior FDA registration studies of paroxetine and sertraline using older versions of the Clinician-Administered PTSD Scale. To confirm this efficacy evidence, our ongoing Phase 3 program enrolls participants with baseline CAPS-5 score of 33 or higher. The beneficial effects of Tonmya 5.6 mg were preserved in the subgroup with PTSD from combat traumas (85% of AtEase population). Also, sustained remission (i.e. satisfying remission criterion of CAPS-5 score less than 11 at both week 8 and week 12) was observed in 21% of participants receiving a 5.6 mg dose of Tonmya as compared to 5% of participants in the placebo group (p = 0.02, logistic regression). The AtEase study supported the hypothesized mechanism of sleep quality improvement, since additional retrospective analyses showed that in the CAPS-5 score of 33 or higher subset of participants, sleep improvement at week 4, measured by the PROMIS Sleep Disturbance instrument, predicted treatment response (by improvement in total CAPS-5 score without the sleep item) at week 12 in the Tonmya 5.6 mg group (p = 0.01, linear regression).

Open-label Extension Study for AtEase

Participants who completed the AtEase study were eligible to enroll into a three-month open-label extension study with Tonmya 2.8 mg. We conducted this open-label extension study to obtain additional safety information from participants in the AtEase Study. The clinical phase of this open-label extension study is complete. Tonmya 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 the HONOR study, a randomized, double-blind, placebo-controlled Phase 3 study of Tonmya in approximately 550 participants with military-related PTSD in the first quarter of 2017. This 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 IA and the involvement of the IDMC to review unblinded IA results. The IDMC will make a recommendation to continue as planned, to continue but increase the number of recruited participants 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 IA will be conducted when approximately 50% (approximately 250 – 300 participants) of the initially planned participant enrollment is evaluable for efficacy. We received FDA acceptance of the Phase 3 HONOR study design in January of 2017. The HONOR study is being conducted at approximately 45 U.S. sites. 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 Tonmya and those receiving placebo.

Open-label Extension Study for HONOR

To obtain additional safety information from participants in the HONOR study, participants who completed the HONOR study are eligible to enroll into a 12-week open-label extension study with Tonmya 5.6 mg. This open-label extension study is ongoing.

Prospective Phase 3 Study

A second, randomized, double-blind placebo-controlled Phase 3 study of Tonmya (5.6 mg administered as 2 x 2.8 mg tablets) in approximately 550 predominantly civilian PTSD participants will follow. We expect this study to be conducted at approximately 45 U.S. sites. 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 Tonmya and those receiving placebo.

Long-Term Safety Exposure Study for Tonmya

In addition to the ongoing 12-week open-label extension study for HONOR, we plan to conduct the registration-required open-label extension studies of Tonmya in participants who complete either the 12-week open-label extension study of 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 Tonmya 5.6 mg to support its registration for the treatment of PTSD, a chronic psychiatric condition.

Regulatory Update

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

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 Tonmya 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 Tonmya for the treatment of PTSD. As described below, the first Phase 3 study will be in participants with military-related PTSD and the second Phase 3 study will study predominately civilian PTSD participants.

In December 2016, the FDA granted Breakthrough Therapy designation to Tonmya for the treatment of PTSD. The Breakthrough Therapy designation request was based on the preliminary clinical evidence of Tonmya 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 completed 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 Breakthrough Therapy 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 Tonmya 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 statistically persuasive topline data from the ongoing HONOR study. Additionally, due to the lack of evidence of potential abuse in clinical studies of Tonmya, the FDA agreed that studies in assessing abuse and dependency potential of Tonmya are not required to support the Tonmya NDA filing.

In May 2017, the PTO issued us U.S. Patent No. 9,636,408. The patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride," claims the composition and manufacture of a unique formulation that characterizes Tonmya. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034 upon NDA approval.

In June 2017, the FDA conditionally accepted the proposed trade name Tonmya for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD.

On September 7, 2017, we had a Breakthrough Therapy CMC Guidance Meeting with the FDA to discuss the CMC plan for the Tonmya NDA filing. Formal meeting minutes from the FDA will be available in October.

On September 13, 2017, we were issued European patent 2501234 "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine". This patent protects the use of Tonmya for the treatment of PTSD as well as its active ingredient CBP for the treatment of PTSD. The patent is expected to provide Tonmya with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

Other NDA Requirements

An Agreed Initial Pediatric Study Plan, or Agreed iPSP, is required for the initial NDA submission. We submitted a revised iPSP in the first quarter of 2017, which incorporated the FDA comments received on our iPSP submitted in the third quarter of 2016. Additional comments from the FDA were received in second quarter of 2017 on our revised iPSP. We plan to submit an Agreed iPSP in the first quarter of 2018. 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 Tonmya 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 Tonmya 2.8 mg tablets manufactured at two facilities: (i) the facility used to produce Tonmya 2.8 mg tablets for the Phase 2 AtEase study; and (ii) the facility used to produce Tonmya 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 Tonmya 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 Tonmya pursuant to Section 505(b)(2) of the FDCA using AMRIX ® extended-release capsules (30 mg) as our RLD. As agreed upon by the FDA, we plan to study Tonmya 5.6 mg (administered as 2 x 2.8 mg tablets) in comparison to AMRIX 30 mg extended-release capsules in a randomized, open-label, parallel, multiple-dose bridging PK study to provide a systemic exposure bridge. If the exposures of Tonmya 5.6 mg are less than or comparable to 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 Tonmya 5.6.mg to AMRIX 30 mg extended-release capsules and the approval of Tonmya for PTSD NDA can thus rely on the safety findings (clinical and nonclinical) of the currently approved CBP drug products.

Food Effect and Dose-proportionality Studies

To support the Tonmya product registration, a randomized, open-label, 2-way crossover, food-effect, comparative bioavailability study of Tonmya 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 a single dose Tonmya 2.8 mg vs 5.6 mg in healthy subjects under fasting conditions will be completed for the Tonmya NDA submission.

Cyclobenzaprine Hydrochloride 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 the active ingredient, CBP 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 Tonmya 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 CBP. As a result, the FDA has advised that we will not have to assess the abuse and dependency potential of Tonmya to support the Tonmya 505(b)(2) NDA submission for the treatment of PTSD.

Manufacturing

The Tonmya and TNX-102 SL drug products were manufactured in a small-scale cGMP facility that is licensed to manufacture clinical trial materials, but not equipped for large-scale commercial production. For the clinical trial materials for Phase 3 clinical and NDA required Phase 1 studies, 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 CBP, 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 Tonmya.

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 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 receiving FDA licensure. We are currently working to develop a vaccine that meets cGMP quality to support an IND study.

TNX-301

TNX-301 is a fixed-dose CDP containing two FDA-approved drugs, disulfiram and selegiline. We intend to develop TNX-301 CDP under Section 505(b)(2) of the FDCA as a potential treatment for 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 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 DEA schedule 1 hallucinogen that is being studied for drug-assisted psychotherapy. MDMA was awarded Breakthrough Therapy designation by the FDA in August 2017. 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 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 Tonmya or TNX-102 SL and our other product candidates. Our patent portfolio, described more fully below, includes claims directed to Tonmya compositions and methods of use. As of September 28, 2017, the patents we are either the owner of record of or own the contractual right to include five issued U.S. patents and 26 issued non-U.S. patents. We are actively pursuing an additional 16 U.S. patent applications, of which five are provisional and 11 are non-provisional, one international patent application, and 68 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 an 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 five most advanced product candidates as of September 28, 2017 are summarized below.

Tonmya — CNS

Our patent portfolio for Tonmya and TNX-102 SL includes patent applications directed to compositions of matter of CBP, formulations containing CBP, and methods for treating CNS conditions, such as PTSD, utilizing these compositions and formulations.

Certain eutectic compositions were discovered by development partners and are termed the "Eutectic Technology." The patent portfolio for Tonmya and 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 CBP and methods of manufacturing the eutectic. The U.S. eutectic patent was issued on May 2, 2017. 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 CBP 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 Tonmya and TNX-102 SL, or the PK Technology, was discovered by Tonix and its development partners. The patent portfolio for Tonmya 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.

On September 13, 2017, we were issued European patent 2501234 "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine". This patent protects the use of Tonmya for the treatment of PTSD as well as its active ingredient CBP for the treatment of PTSD. The patent is expected to provide Tonmya with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

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
I590820	Compositions and Methods for Transmucosal Absorption	Taiwan	June 14, 2033

PTSD Treatment

Patent No.	Title	Country / Region	Expiration Date
2501234	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	Europe	November 16, 2030

Sleep Disorder Treatment

Patent No.	Title	Country / Region	Expiration Date
9,474,728	Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine	U.S.A.	June 9, 2031

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

Cyclobenzaprine/Amitriptyline Eutectics

Patent No.	Title	Country / Region	Expiration Date
9,636,408	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
631152	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand	March 14, 2034

Neurocognitive Dysfunction Treatment

Patent No.	Title	Country / Region	Expiration Date
9,314,469	Method for Treating Neurocognitive Dysfunction	U.S.A.	September 24, 2030
2299822	Method for Treating Neurocognitive Dysfunction	Europe	April 30, 2029

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

Cocaine Addiction Treatment

Patent No.	Title	Country / Region	Expiration Date
2011314358	Treatment for Cocaine Addiction	Australia	Aug. 31, 2031
2611440	Treatment for Cocaine Addiction	Austria, Belgium, Portugal, Denmark, Switzerland	Aug. 31, 2031

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
2015317336	Eutectic Formulations of Cyclobenzaprine 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
2,961,822	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Canada
201480024011.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	China
201580050140.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China
14762323.5	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Europe
15841528.1	Eutectic Formulations of Cyclobenzaprine 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
P00201702438	Eutectic Formulations of Cyclobenzaprine 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
201717013182	Eutectic Formulations of Cyclobenzaprine Hydrochloride	India
2016-503239	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan
2017-535609	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan
MX/a/2015/012622	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico
MX/a/2017/003644	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
Not Yet Assigned	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline 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
15110186.6	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
106117185	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.
13103530.6	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	Hong Kong
62/532,353	Analogs of Cyclobenzaprine	U.S.A

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
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.
17176372.5	Method for Treating Neurodegenerative Dysfunction	Europe
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 eight 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 Tonmya 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 CMOs for the manufacture of Tonmya drug substances and drug products for investigational purposes, including nonclinical and clinical testing. For Tonmya, 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 and uses live form of HPXV. Both the drug substance (HPVX 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 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 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 Tonmya 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 Tonmya 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 Tonmya, the time and financial resources required to obtain FDA approval for Tonmya could substantially and materially increase, and Tonmya might be less likely to be approved. If the FDA requires a full NDA for Tonmya, 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 Tonmya 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 Tonmya 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 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 FDA Reauthorization Act of 2017 or the FDASIA 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. 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 September 28, 2017, we had 13 full-time employees, of whom five hold M.D. or Ph.D. degrees. We have eight 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.

DESCRIPTION OF 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. During August 2017, in an effort to reduce operating costs, we terminated this lease and will exit the premises in November 2017.

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.

On August 22, 2017, we entered into a lease for approximately 450 square feet of office space in Dublin, Ireland, whereby we agreed to lease premises, commencing November 20, 2017 and expiring on November 30, 2018. In connection therewith, we paid a security deposit of $7,067.

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

Year Ending December 31,	
2017	$ 136
2018	458
2019	181
	$ 775

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

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.

MANAGEMENT

The Board of Directors elects our executive officers annually. A majority vote of the directors who are in office is required to fill vacancies. Each director shall be elected for the term of one year and until his successor is elected and qualified or until his earlier resignation or removal. Our directors and executive officers are as follows:

NAME	AGE	CURRENT POSITION
Seth Lederman	60	President, CEO and Chairman of the Board of Directors
Margaret Smith Bell	57	Director
Stuart Davidson	60	Director
Patrick Grace	61	Director
Donald W. Landry	63	Director
Ernest Mario	79	Director
Charles E. Mather IV	57	Director
John Rhodes	61	Lead Director
Samuel Saks	62	Director
Bradley Saenger	44	Chief Financial Officer and Treasurer
Gregory Sullivan	52	Chief Medical Officer and Secretary

The following information with respect to the principal occupation or employment of each nominee for director, the principal business of the corporation or other organization in which such occupation or employment is carried on, and such nominee's business experience during the past five years, as well as the specific experiences, qualifications, attributes and skills that have led the Board to determine that such Board members should serve on our Board, has been furnished to the Company by the respective director nominees:

Seth Lederman, MD became our President, Chief Executive Officer, Chairman of the Board and a Director in October 2011. Dr. Lederman founded Tonix Pharmaceuticals, Inc., a wholly-owned subsidiary of the Company, or Tonix Sub, in June of 2007 and has acted as its Chairman of the Board of Directors since its inception and as President since June 2010. Dr. Lederman is an inventor on key patents and patent applications underlying our programs including: TNX-102 SL's eutectic composition; Tonmya's pharmacokinetic profile and related therapeutic properties, and Tonmya for PTSD. Dr. Lederman has been the Chairman of Krele since its inception in August 2010. Dr. Lederman has also been the President and a director of Tonix Pharmaceuticals (Canada), Inc. since its inception in April 2013, a director of Tonix Pharmaceuticals (Barbados), Ltd. from December 2013 until it was dissolved in 2015. Lederman served as a director of Tonix Pharma Limited between December 2014 and September 2015 and Tonix Pharma Holdings Limited between December 2014 and November 2015. Since 1996, Dr. Lederman served as an Associate Professor at Columbia University, and retired on April 13, 2017. As an Assistant Professor at Columbia, Dr. Lederman discovered and characterized the CD40-ligand and invented therapeutic candidates to treat autoimmune diseases and transplant rejection. Dr. Lederman has been a Manager of L&L Technologies LLC, or L&L, since 1996. In addition, Dr. Lederman has been the Managing Member of Seth Lederman Co, LLC since January 2007 and the Managing Member of Lederman & Co, LLC, or Lederman & Co, since 2002, both of which are biopharmaceutical consulting and investing companies. Dr. Lederman has also been the Managing Member of Targent Pharmaceuticals, LLC, or Targent, since 2000, and Managing Member of Plumbline LLC since 2002. Targent was a founder of Targent Pharmaceuticals Inc. on which Board of Directors Dr. Lederman served from inception in 2001 until the sale of its assets to Spectrum Pharmaceuticals Inc. in 2006. Between January 2007 and November 2008, Dr. Lederman was a Managing Partner of Konanda Pharma Partners, LLC, a Director of Konanda Pharma Fund I, LP, and a Managing Partner of Konanda General Partner, LLC, which were related private growth equity fund entities. As well, between January 2007 and November 2008, Dr. Lederman was Chairman of Validus Pharmaceuticals, Inc. and Fontus Pharmaceuticals, Inc., which were portfolio companies of the Konanda private growth equity funds. Since December 2011, Dr. Lederman has served as CEO and Chairman of Leder Laboratories Inc., or Leder Labs, and Starling Pharmaceuticals Inc., or Starling, which are biopharmaceutical development companies. Since March 2013, Dr. Lederman has been the chairman of Leder Laboratories, Ltd., a wholly-owned subsidiary of Leder Labs. In 2015, Dr. Lederman served as a member of the US – Japan Business Council. Between 2006 and 2011, Dr. Lederman was a director of Research Corporation, a New York-based non-profit organization. Dr. Lederman received his BA degree in Chemistry from Princeton University in 1979 and his MD from Columbia University in 1983. Dr. Lederman has been a New York State licensed physician since 1985. Dr. Lederman's significant experience with our patent portfolio and his experience as an entrepreneur, seed capital investor, fund manager, and director of start-up biopharmaceutical companies were instrumental in his selection as a member of the Board.

Margaret Smith Bell became a Director in September 2017. For the last five years, Ms. Bell has been a homemaker. Previously, Ms. Bell was a Vice President at Standard Life Investments where she was a portfolio manager and health care equity analyst. Ms. Bell was also a Managing Director at Putnam Investments, and served as a senior health care analyst and a portfolio manager of the Putnam Health Sciences Trust. Ms. Bell was an analyst and vice president at State Street Research and a research analyst at Alex. Brown & Sons, Inc. Ms. Bell is a past member of the Board of Overseers at Beth Israel Deaconess Medical Center. Ms. Bell holds a B.A. from Wesleyan University and an M.B.A. from the Wharton School at the University of Pennsylvania. Ms. Bell's extensive healthcare and investment banking experience was instrumental in her selection as a member of our Board.

Stuart Davidson became a Director in October 2011. Between July 2010 and October 2011, Mr. Davidson served as a director of Tonix Sub. Since 2011, Mr. Davidson has been a Managing Director of Sonen Capital. Since 1994, Mr. Davidson has been a Managing Partner of Labrador Ventures. Prior to Labrador, Mr. Davidson founded and served as CEO of Combion, Inc., which was acquired by Incyte. He also served as President of Alkermes, Inc., a biotechnology company focused on drug delivery. Mr. Davidson received his Bachelor's Degree from Harvard College in 1978 and his MBA from Harvard Business School in 1984. Mr. Davidson's prior experience as a venture capital investor, entrepreneur, and biotechnology industry executive experience in the leadership of pharmaceutical companies was instrumental in his selection as a member of our Board.

Patrick Grace became a Director in October 2011. Between June 2007 and October 2011, Mr. Grace served as a director of Tonix Sub. Since January 2017, Mr. Grace has been the President and CEO of Grace Institute Foundation. From 1996 to September 2016, he served as Chairman of the Grace Institute, New York, New York (workforce development for women). Mr. Grace was the co-founder of and served as the Managing Partner of Apollo Philanthropy Partners, L.L.C. from October 2008 until October 2012. He was President of MLP Capital, Inc., an investment holding company, from 1996 to 2016. Mr. Grace served in various senior management roles with W. R. Grace & Co. from 1977 to 1995, and was last President and CEO of Grace Logistics Services, Inc. From January 2000 to August 2002, Mr. Grace was also President and Chief Executive Officer of Kingdom Group, LLC, or Kingdom, a provider of turnkey compressed natural gas fueling systems, and he was Executive Vice President of Kingdom from August 1999 to December 2000. Since 1996, he has been a director of Chemed Corporation. Mr. Grace was a liberal arts major at the University of Notre Dame and earned a MBA in finance from Columbia University. Mr. Grace's extensive executive experience, along with his membership on the board of directors of a public company, was instrumental in his selection as a member of our Board.

Donald W. Landry, MD, PhD became a Director in October 2011. Between June 2007 and October 2011, Dr. Landry served as a director of Tonix Sub. Dr. Landry has been a member of the faculty of Columbia University since 1985, and has served as the Samuel Bard Professor of Medicine, Chair of the Department of Medicine and Physician-in-Chief at New York Presbyterian Hospital/Columbia University Medical Center since 2008. Since November 2015, he has been a director of Sensient Technologies Corp. Dr. Landry was a co-founder and has been a member of L&L since 1996. Dr. Landry received his BS degree in Chemistry from Lafayette College in 1975, his PhD in Organic Chemistry from Harvard University in 1979 and his M.D. from Columbia University in 1983. Dr. Landry has been a New York State licensed physician since 1985. In 2008, Dr. Landry was awarded the Presidential Citizens Medal, the second-highest award that the President can confer upon a civilian. Dr. Landry's significant medical and scientific background was instrumental in his selection as a member of the Board.

Ernest Mario, PhD became a Director in October 2011. Between September 2010 and October 2011, Dr. Mario served as a director of Tonix Sub. Dr. Mario is a former Deputy Chairman and Chief Executive of Glaxo Holdings plc and a former Chairman and Chief Executive Officer of ALZA Corporation. Since April 2014, Dr. Mario has served as Chairman of Soleno Therapeutics, Inc. (formerly Capnia, Inc.), a specialty pharmaceutical company in Palo Alto, CA. Between August 2007 and February 2014, Dr. Mario served as the Chief Executive Officer and Chairman of Soleno Therapeutics, Inc. and between February 2014 and April 2014, Dr. Mario served as Executive Chairman. From 2003 to 2007, he was Chairman and Chief Executive of Reliant Pharmaceuticals, Inc. Dr. Mario is currently a director of Soleno Therapeutics, Inc. (since 2007), Celgene Corp. (since 2007) and Chimerix, Inc. (since February 2013). Dr. Mario is also Chairman of Chimerix. Dr. Mario served as a director of Boston Scientific Corp. (2001 – 2016), Kindred Biosciences, Inc. (2013 – 2016), VIVUS Inc. (2012 – 2013), XenoPort Inc. (2012 – 2015), and Maxygen Inc. (2001 – 2013). He serves as an advisor to The Ernest Mario School of Pharmacy at Rutgers University. In 2007, Dr. Mario was awarded the Remington Medal by the American Pharmacists' Association, pharmacy's highest honor. Dr. Mario received a PhD and an MS in physical sciences from the University of Rhode Island and a BS in pharmacy from Rutgers University. Dr. Mario brings to his service as a director his significant executive leadership experience, including his experience leading several pharmaceutical companies, as well as his membership on public company boards and foundations. He also has extensive experience in financial and operations management, risk oversight, and quality and business strategy.

Charles E. Mather IV became a Director in October 2011. Between April and October 2011, Mr. Mather served as a director of Tonix Sub. Mr. Mather has been a Managing Director of Equity Capital Markets at BTIG since March 2015 and served as its co-head of Capital Markets since March 2017. From December 2009 to February 2015 he was the Head of Private and Alternative Capital and Co-Head of Equity Capital Markets at Janney Montgomery Scott. Between May 2007 and September 2008, Mr. Mather was the head of the Structured Equity Group at Jefferies Group Inc. Prior to that, Mr. Mather held various senior investment banking positions at Cowen and Company, including as Co-Head of the Private Equity Group. From July 2015 until August 2017, Mr. Mather served as a director of the Finance Company of Pennsylvania. Mr. Mather received a BA in History from Brown University and an MBA in Finance from The Wharton School, University of Pennsylvania. Mr. Mather's extensive experience advising life science companies as an investment banker was instrumental in his selection as a member of our Board.

John Rhodes became a Director in October 2011 and Lead Director in February 2014. Mr. Rhodes has served as Chair of the New York State Public Service Commission and Chief Executive Officer of the Department of Public Services since June 2017. Mr. Rhodes served as President and CEO of the New York State Energy Research and Development Authority between September 2013 and June 2017. Between October 2010 and October 2011, Mr. Rhodes served as a director of Tonix Sub. Between 2005 and 2013, Mr. Rhodes was a director of Dewey Electronics Company, a manufacturer of electronic and electromechanical systems for the military and commercial markets. Between January 2013 and September 2013, he served as director of the Center for Market Innovation at Natural Resources Defense Council. Between April 2007 and June 2010, Mr. Rhodes was a Senior Advisor to Good Energies, Inc., a renewable energy company. Mr. Rhodes is a former Vice President of Booz Allen Hamilton, Inc. Mr. Rhodes is a graduate of Princeton University and the Yale School of Management. Mr. Rhodes' extensive business and consulting experience, along with his membership on the board of directors of a public company was instrumental in his selection as a member of our Board.

Samuel Saks, MD became a Director in May 2012. Between 2003 and April 2009, Dr. Saks was the chief executive officer and a director of Jazz Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, which he co-founded in 2003. From April 2011 until February 2012, Dr. Saks served as interim Chief Medical Officer of Threshold Pharmaceuticals, a publicly-held biopharmaceutical company. Between November 2013 and May 2015, Dr. Saks served as the Chief Development Officer of Auspex Pharmaceuticals, Inc., a publicly-held biopharmaceutical company. From 2001 until 2003, Dr. Saks was company group chairman of ALZA Corporation and a member of the Johnson & Johnson Pharmaceuticals Operating Committee. From 1992 until 2001, Dr. Saks held various positions at ALZA, including Chief Medical Officer and Group Vice President, where he was responsible for clinical, regulatory and commercial activities. Previously, Dr. Saks held clinical research and development management positions with Schering-Plough, Xoma and Genentech. Dr. Saks formerly served as a scientific advisor to ArQule Pharmaceuticals, CMEA Ventures and ProQuest Investments. Dr. Saks is currently a director of Velocity Pharmaceutical Development LLC (since 2011), Bullet Biotechnology, Inc. (since 2012), NuMedii (since 2013) and PDL BioPharma, Inc. (since September 2015). Dr. Saks served as a director of Depomed, Inc. (2012 – 2017), Auspex Pharmaceuticals, Inc. (2009 – 2015), Trubion Pharmaceuticals, Inc. (2005 – 2010), Corixa Corporation, Cougar Biotechnology, Inc., Coulter Pharmaceuticals, Inc., Ilypsa, Inc. and Sirna Therapeutics Inc. (formerly, Ribozyme Pharmaceuticals, Inc.). Dr. Saks is board certified in oncology and received a B.S. and an M.D. from the University of Illinois. Mr. Saks' extensive scientific and medical expertise and experience in formulating partnering and business development strategies, including those involving larger pharmaceutical companies, was instrumental in his selection as a member of our Board.

Bradley Saenger, CPA became our Chief Financial Officer in February 2016. Mr. Saenger has worked for Tonix since May 2014, as the Director of Accounting (May 2014 – December 2015) and VP of Accounting (January 2016 – February 2016). Between June 2013 and March 2014, Mr. Saenger worked for Shire Pharmaceuticals as a consultant in the financial analyst research and development group. Since November 2015, Mr. Saenger has been a director of Tonix Pharma Holdings Limited. Between February 2013 and May 2013, Mr. Saenger worked for Stewart Health Care System as a financial consultant. Between October 2011 and December 2012, Mr. Saenger was an Associate Director of Accounting at Vertex Pharmaceuticals, Inc. Between January 2005 and September 2011, Mr. Saenger worked for Alere Inc., as a Manager of Corporate Accounting and Consolidations (2007 – 2011) and Manager of Financial Reporting (2005 – 2006). Mr. Saenger also worked for PricewaterhouseCoopers LLP, Shifren Hirsowitz, public accountants and auditors in Johannesburg, South Africa, Investec Bank in Johannesburg, South Africa and Norman Sifris and Company, public accountants and auditors in Johannesburg, South Africa. Mr. Saenger received his Bachelor's and Honors' degrees in Accounting Science from the University of South Africa. Mr. Saenger is a Chartered Accountant in South Africa and a Certified Public Accountant in the Commonwealth of Massachusetts.

Gregory Sullivan, MD became our Chief Medical Officer on June 3, 2014 and our Secretary in March 2017. Prior to becoming our Chief Medical Officer, he served on our Scientific Advisory Board since October 2010, and had also provided *ad hoc* consulting services. Previously, Dr. Sullivan had been a member of the faculty of Columbia University since July 1999, where he served as an Assistant Professor of Psychiatry in the Department of Psychiatry at Columbia University Medical Center (CUMC) until June 2014. Between June 1997 and August 2014, Dr. Sullivan maintained a part-time psychiatry practice. He served as a Research Scientist at the New York State Psychiatric Institute (NYSPI) from December 2006 to June 2014. He also served as a member of the Institutional Review Board of the NYSPI from January 2009 to June 2014. As Principal Investigator and Co-Investigator on several human studies of PTSD, Dr. Sullivan has administered the recruitment, biological assessments, treatment, and safety of participants with PTSD in clinical trials of the disorder. He has published more than 50 articles and chapters on research topics ranging from stress and anxiety disorders to abnormal serotonin receptor expression in depression, PTSD and panic disorder. He is a recipient of grants from the National Institute of Mental Health (NIMH), the Anxiety Disorders Association of America, NARSAD, the Dana Foundation, and the American Foundation for Suicide Prevention. Dr. Sullivan received a BA in Biology from the University of California, Berkeley, and received his MD from the College of Physicians & Surgeons at Columbia University. He completed his residency training in psychiatry at CUMC, and then a two-year NIMH-sponsored research fellowship in anxiety and affective disorders before joining the faculty at Columbia.

Directors serve until the next annual meeting of shareholders or until their successors are elected and qualified. Officers serve at the discretion of the Board.

Board Independence

The Board has determined that (i) Seth Lederman has a relationship which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and is not an "independent director" as defined in the Marketplace Rules of The NASDAQ Stock Market and (ii) Margaret Smith Bell, Stuart Davidson, Patrick Grace, Donald Landry, Ernest Mario, Charles Mather, John Rhodes, and Samuel Saks are each an independent director as defined in the Marketplace Rules of The NASDAQ Stock Market.

Board Leadership Structure

Our CEO also serves as the chairman of the Board. An independent director serves as the Board's lead director. This structure allows one person to speak for and lead both the Company and the Board, while also providing for effective independent board oversight through an independent lead director. Having Dr. Lederman, our CEO, serve as Chairman creates clear and unambiguous authority, which is essential to effective management. Our Board and management can respond more effectively to a clearer line of authority. By designating our CEO as its Chairman, our Board also sends as an important signal to our employees and shareholders about who is accountable. Further, since Dr. Lederman is the founder of our Company and is an inventor on key patents and patent applications underlying our programs, we believe that Dr. Lederman is best-positioned to set our Board's agenda and provide leadership.

We have established the position of lead director, which is filled by Mr. Rhodes. The lead director has the following responsibilities, as detailed in the Lead Director charter, adopted by the Board (and also performs any other functions the Board may request):

- **Board leadership** — provides leadership to the Board in any situation where the chairman's role may be, or may be perceived to be, in conflict, and also chairs meetings when the chairman is absent;
- **Leadership of independent director meetings** — leads independent director meetings, which take place without any management directors or Tonix employees present;
- **Additional meetings** — calls additional independent director meetings as needed;
- **Chairman-independent director liaison** — regularly meets with the chairman and serves as liaison between the chairman and the independent directors;
- **Stockholder communications** — makes himself available for direct communication with our stockholders;
- **Board agenda, schedule & information** — works with the chairman regarding meeting agendas, meeting schedules and information sent to directors for Board meetings, including the quality, quantity, appropriateness and timeliness of such information; and
- **Advisors and consultants** — recommends to the Board the retention of outside advisors and consultants who report directly to the Board on Board-wide issues.

Board Role in Risk Oversight

Risk is an integral part of the Board and Board committee deliberations throughout the year. While the Board has the ultimate oversight responsibility for the risk management process, various committees of the Board also have responsibility for risk management. In particular, the Audit Committee focuses on financial risk, including internal controls, and receives financial risk assessment reports from management. Risks related to the compensation programs are reviewed by the Compensation Committee. The Board is advised by these committees of significant risks and management's response through periodic updates.

Stockholder Communications with the Board

The Company's stockholders may communicate with the Board, including non-executive directors or officers, by sending written communications addressed to such person or persons in care of Tonix Pharmaceuticals Holding Corp., Attention: Secretary, 509 Madison Avenue, Suite 306, New York, New York 10022. All communications will be compiled by the Secretary and submitted to the addressee. If the Board modifies this process, the revised process will be posted on the Company's website.

Meetings and Committees of the Board

During the fiscal year ended December 31, 2016, the Board held 13 meetings, the Audit Committee held six meetings, the Compensation Committee held four meetings and the Nominating and Corporate Governance Committee held three meetings. The Board and Board committees also approved certain actions by unanimous written consent.

Board Committees

The Board has standing Audit, Compensation, and Nominating and Corporate Governance Committees. Information concerning the membership and function of each committee is as follows:

Board Committee Membership

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Seth Lederman			
Margaret Smith Bell			
Stuart Davidson		**	
Patrick Grace	**		*
Donald W. Landry			
Ernest Mario		*	
Charles E. Mather IV	*		*
John Rhodes	*		**
Samuel Saks		*	

* Member of Committee
** Chairman of Committee

Audit Committee

Our Audit Committee consists of Patrick Grace, Charles Mather and John Rhodes, with Mr. Grace elected as Chairman of the Committee. Our Board has determined that each of Messrs. Grace, Mather and Rhodes are "independent" as that term is defined under applicable SEC rules and under the current listing standards of the NASDAQ Stock Market. Mr. Grace is our audit committee financial expert.

Our Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent auditors, (ii) appointing, replacing and discharging the independent auditor, (iii) pre-approving the professional services provided by the independent auditor, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditor, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditor. The Audit Committee reviewed and discussed with management the Company's audited financial statements for the year ended December 31, 2016.

Compensation Committee

Our Compensation Committee consists of Stuart Davidson, Ernest Mario and Samuel Saks, with Mr. Davidson elected as Chairman of the Committee. Our Board has determined that all of the members are "independent" under the current listing standards of the NASDAQ Stock Market. Our Board has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee.

Our Compensation Committee has responsibility for, among other things, evaluating and making decisions regarding the compensation of our executive officers, assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy, producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC and periodically evaluating and administering the terms and administration of our incentive plans and benefit programs. In addition, our Compensation Committee reviews and makes recommendations to the Board regarding incentive compensation plans that require shareholder approval, director compensation, the Company's compensation discussion and analysis and the related executive compensation information for inclusion in the Company's 10-K and proxy statement, and employment and severance agreements relating to the chief executive officer.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Patrick Grace, Charles Mather and John Rhodes, with Mr. Rhodes elected as Chairman of the Committee. The Board has determined that all of the members are "independent" under the current listing standards of the NASDAQ Stock Market.

Our Nominating and Corporate Governance Committee has responsibility for assisting the Board in, among other things, effecting the organization, membership and function of the Board and its committees. The Nominating and Corporate Governance Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors. In addition, the Nominating and Corporate Governance Committee is responsible for developing, recommending and evaluating corporate governance standards and a code of business conduct and ethics.

Nomination of Directors

As provided in its charter and our Company's corporate governance principles, the Nominating and Corporate Governance Committee is responsible for identifying individuals qualified to become directors. The Nominating and Corporate Governance Committee seeks to identify director candidates based on input provided by a number of sources, including (1) the Nominating and Corporate Governance Committee members, (2) our other directors, (3) our shareholders, (4) our Chief Executive Officer or Chairman, and (5) third parties such as professional search firms. In evaluating potential candidates for director, the Nominating and Corporate Governance Committee considers the entirety of each candidate's credentials.

Qualifications for consideration as a director nominee may vary according to the particular areas of expertise being sought as a complement to the existing composition of the Board. However, at a minimum, candidates for director must possess:

- high personal and professional ethics and integrity;
- the ability to exercise sound judgment;
- the ability to make independent analytical inquiries;
- a willingness and ability to devote adequate time and resources to diligently perform Board and committee duties; and
- the appropriate and relevant business experience and acumen.

In addition to these minimum qualifications, the Nominating and Corporate Governance Committee also takes into account when considering whether to nominate a potential director candidate the following factors:

- whether the person possesses specific industry expertise and familiarity with general issues affecting our business;
- whether the person's nomination and election would enable the Board to have a member that qualifies as an "audit committee financial expert" as such term is defined by the SEC in Item 401 of Regulation S-K;
- whether the person would qualify as an "independent" director under the listing standards of the Nasdaq Stock Market;
- the importance of continuity of the existing composition of the Board to provide long term stability and experienced oversight; and
- the importance of diversified Board membership, in terms of both the individuals involved and their various experiences and areas of expertise.

The Nominating and Corporate Governance Committee will consider director candidates recommended by shareholders provided such recommendations are submitted in accordance with the procedures set forth below. In order to provide for an orderly and informed review and selection process for director candidates, the Board has determined that shareholders who wish to recommend director candidates for consideration by the Nominating and Corporate Governance Committee must comply with the following:

- The recommendation must be made in writing to the Corporate Secretary at Tonix Pharmaceuticals Holding Corp.;
- The recommendation must include the candidate's name, home and business contact information, detailed biographical data and qualifications, information regarding any relationships between the candidate and the Company within the last three years and evidence of the recommending person's ownership of the Company's common stock;
- The recommendation shall also contain a statement from the recommending shareholder in support of the candidate; professional references, particularly within the context of those relevant to board membership, including issues of character, judgment, diversity, age, independence, expertise, corporate experience, length of service, other commitments and the like; and personal references; and
- A statement from the shareholder nominee indicating that such nominee wants to serve on the Board and could be considered "independent" under the Rules and Regulations of the Nasdaq Stock Market and the SEC, as in effect at that time.

All candidates submitted by shareholders will be evaluated by the Nominating and Corporate Governance Committee according to the criteria discussed above and in the same manner as all other director candidates.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC reports regarding their ownership and changes in ownership of our securities. We believe that, during fiscal 2016, our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements.

Involvement in Certain Legal Proceedings

Our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;

4. being found by a court of competent jurisdiction in a civil action, the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a Federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

5. being subject of, or a party to, any Federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any Federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

6. being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

EXECUTIVE COMPENSATION

Compensation Philosophy and Practices

We believe that the performance of our executive officers significantly impacts our ability to achieve our corporate goals. We, therefore, place considerable importance on the design and administration of our executive officer compensation program. This program is intended to enhance stockholder value by attracting, motivating and retaining qualified individuals to perform at the highest levels and to contribute to our growth and success. Our executive officer compensation program is designed to provide compensation opportunities that are tied to individual and corporate performance.

Our compensation packages are also designed to be competitive in our industry. The Compensation Committee from time-to-time consults with compensation consultants, legal counsel and other advisors in designing our compensation program, including in evaluating the competitiveness of individual compensation packages and in relation to our corporate goals.

Our overall compensation philosophy has been to pay our executive officers an annual base salary and to provide opportunities, through cash and equity incentives, to provide higher compensation if certain key performance goals are satisfied. We believe that many of our key practices and programs demonstrate good governance. The main principles of our fiscal year 2016 compensation strategy included the following:

- *An emphasis on pay for performance.* A significant portion of our executive officers' total compensation is variable and at risk and tied directly to measurable performance, which aligns the interests of our executives with those of our stockholders;

- *Performance results are linked to Company and individual performance*. When looking at performance over the year, we equally weigh individual performance as well as that of the Company as a whole. Target annual compensation is positioned to allow for above-median compensation to be earned through an executive officer's and the Company's extraordinary performance;

- *Equity as a key component to align the interests of our executives with those of our stockholders.* Our Compensation Committee continues to believe that keeping executives interests aligned with those of our stockholders is critical to driving toward achievement of long-term goals of both our stockholders and the Company; and

- *Peer group positioning*. While the Compensation Committee considers the level of compensation paid by the companies in our peer group as a reference point that provides a framework for its compensation decisions, in order to maintain competiveness and flexibility, the Compensation Committee does not target compensation at a particular level relative to the peer group; nor does the Compensation Committee employ a formal benchmarking strategy or rely upon specific peer–derived targets.

In 2016, we also continued practices that demonstrate good governance and careful stewardship of corporate assets, including:

- *Limited personal benefits*. Our executive officers are eligible for the same benefits as our non-executive salaried employees, and they do not receive any additional perquisites.

- *No retirement benefits*. We do not provide our executive officers with a traditional retirement plan, or with any supplemental deferred compensation or retirement benefits.

- *No tax gross-ups*. We do not provide our executive officers with any tax gross-ups.

- *No single-trigger cash change in control benefits*. We do not provide cash benefits to our executives upon a change in control, absent an actual termination of employment.

At our annual meeting in May 2016, we conducted our tri-annual advisory vote on executive compensation, commonly referred to as a "say-on-pay" vote. At that time, approximately 95% of the votes affirmatively cast on the advisory say-on-pay proposal were voted in favor of the compensation of our named executive officers. The Compensation Committee understood this level of approval to indicate strong stockholder support for our executive compensation policies and programs generally, and as a result, our Compensation Committee made no fundamental changes to our executive compensation programs. We will hold our next say-on-pay vote at the 2019 annual meeting. Our Compensation Committee and our Board will consider shareholder feedback through the say-on-pay vote and remains committed to engaging with shareholders and are open to feedback from shareholders.

Summary Compensation Table

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Chief Executive Officer and the two highest paid executive officers and up to two other highest paid individuals whose total annual salary and bonus exceeded $100,000 for fiscal years 2016 and 2015.

Name & Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Seth Lederman	2016	472,500	—	—	292,763	—	—	—	765,263
Chief Executive Officer	2015	450,000	225,000	—	887,098	—	—	—	1,562,098
Gregory Sullivan	2016	335,000	—	—	79,844	—	—	—	414,844
Chief Medical Officer	2015	238,110	47,000	—	124,382	—	—	—	409,492
Bradley Saenger	2016	301,361	—	—	71,760	—	—	—	373,121
Chief Financial Officer	2015	215,000	64,500	—	61,017	—	—	—	340,517
Leland Gershell (2)	2016	33,056	—	—	—	—	—	392,000(3)	425,056
Former Chief Financial Officer	2015	350,000		—	234,682	—	—	—	584,682
Bruce Daugherty (4) Former Chief Scientific Officer	2015	238,110	62,275	—	168,971	—	—	—	469,356

(1) Represents the aggregate grant date fair value of options granted in accordance with FASB Accounting Standards Codification, or ASC, Topic 718, "Stock Compensation." For the relevant assumptions used in determining these amounts, refer to Note 8 to our audited financial statements.
(2) Dr. Gershell resigned effective January 8, 2016.
(3) Represents severance payment and consulting fees.
(4) Dr. Daugherty's employment was terminated, effective December 31, 2016.

Grants of Plan-Based Awards in Fiscal 2016

The following table provides information with regard to each grant of plan-based award made to a named executive officer under any plan during the fiscal year ended December 31, 2016.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Share)	Grant Date Fair Value of Stock and Option Awards ($) (1)
Seth Lederman	2/9/2016	11,000	$ 50.30	$ $2.49
	2/9/2016	11,000	$ 50.30	$ $0.17
Bradley Saenger	2/9/2016	1,500	$ 50.30	$ $2.49
	5/27/2016	6,000	$ 24.20	$ $0.08
	5/27/2016	2,000	$ 24.20	$ $1.47
Gregory Sullivan	2/9/2016	3,000	$ 50.30	$ $2.49
	2/9/2016	3,000	$ 50.30	$ $0.17

(1) Represents the aggregate grant date fair value of options granted in accordance with FASB ASC Topic 718.

Outstanding Equity Awards at December 31, 2016

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2016.

Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($/Sh)	Option Expiration Date
Seth Lederman	3,500	—	$ 300.00	5/9/2022
	6,750	—	$ 102.00	2/12/2023
	6,708	392 (1)	$ 158.80	2/11/2024
	8,334	1,666 (2)	$ 98.70	6/17/2024
	7,223	2,777 (3)	$ 66.80	10/29/2024
	11,550	7,350 (4)	$ 59.50	2/25/2025
	715	—	$ 59.50	2/25/2025
	—	11,000 (5)	$ 50.30	2/9/2026
	—	11,000 (6)	$ 50.30	2/9/2026
Bradley Saenger	918	182 (2)	$ 98.70	6/17/2024
	796	304 (3)	$ 66.80	10/29/2024
	796	504 (4)	$ 59.50	2/25/2025
	—	1,500 (5)	$ 50.30	2/9/2026
	—	6,000 (6)	$ 24.20	5/27/2026
	—	2,000 (7)	$ 24.20	5/27/2026
Gregory Sullivan	2,209	441 (2)	$ 98.70	6/17/2024
	1,916	734 (3)	$ 66.80	10/29/2024
	1,621	1,029 (4)	$ 59.50	2/25/2025
	—	3,000 (5)	$ 50.30	2/9/2026
	—	3,000 (6)	$ 50.30	2/9/2026

(1) The shares subject to this stock option vested as to 1/3 of the shares on February 11, 2015, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(2) The shares subject to this stock option vested as to 1/3 of the shares on June 17, 2015, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(3) The shares subject to this stock option vested as to 1/3 of the shares on October 29, 2015, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(4) The shares subject to this stock option vested as to 1/3 of the shares on February 25, 2016, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(5) The shares subject to this stock option vested as to 1/3 of the shares on February 9, 2017, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(6) The shares subject to this stock option vest 1/3rd upon the date(s) that certain stock price goals are achieved. The stock price goals are such date(s) when the Company's common stock has an average closing sales 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.

(7) The shares subject to this stock option vested as to 1/3 of the shares on May 27, 2017, with the remaining shares vesting on an equal monthly basis over the following 24 months.

Option Exercises and Stock Vested

No options were exercised by any of the named executive officers and no named executive officers held restricted stock units during the fiscal year ended December 31, 2016.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2016.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (A)	Weighted-average exercise price of outstanding options, warrants and rights (B)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column A)[2] (C)
Equity compensation plans approved by security holders[1]	228,676	$ $88.34	232,045
Equity compensation plans not approved by security holders	—	$ —	—
Total	228,676		232,045

(1) Consists of the Prior Plans and the 2014 ESPP.

(2) Consists of shares available for future issuance under the 2016 Plan and the 2014 ESPP. As of December 31, 2016, 212,596 shares of common stock were available for issuance under the 2016 Plan and 19,449 shares of common stock were available for issuance under the 2014 ESPP.

Employment Contracts and Termination of Employment and Change-In-Control Arrangements

Employment Agreement with Seth Lederman

On February 11, 2014, the Company entered into an employment agreement, or the Lederman Agreement, with Dr. Seth Lederman, or Lederman, to continue to serve as our President, Chief Executive Officer and Chairman of the Board.

The base salary for Lederman under the Lederman Agreement was $425,000 per annum. The Lederman Agreement has an initial term of one year and automatically renew for successive one year terms unless either party delivers written notice not to renew at least 60 days prior to the end of the current term.

Pursuant to the Lederman Agreement, if the Company terminates Lederman's employment without Cause (as defined in the Lederman Agreement) or Lederman resigns for Good Reason (as defined in the Lederman Agreement), Lederman is entitled to the following payments and benefits: (1) his fully earned but unpaid base salary through the date of termination at the rate then in effect, plus all other benefits, if any, under any group retirement plan, nonqualified deferred compensation plan, equity award plan or agreement, health benefits plan or other group benefit plan to which Lederman may be entitled to under the terms of such plans or agreements; (2) a lump sum cash payment in an amount equal to 12 months of his base salary as in effect immediately prior to the date of termination; (3) continuation of health benefits for Lederman and his eligible dependents for a period of 12 months following the date of termination; and (4) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards as to the number of stock awards that would have vested over the 12-month period following termination had Lederman remained continuously employed by the Company during such period.

Pursuant to the Lederman Agreement, if Lederman's employment is terminated as a result of death or permanent disability, Lederman or his estate, as applicable, is entitled to the following payments and benefits: (1) his fully earned but unpaid base salary through the date of termination at the rate then in effect; (2) a lump sum cash payment in an amount equal to six months of his base salary as in effect immediately prior to the date of termination; and (3) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards.

If Lederman is terminated without Cause or resigns for Good Reason during the period commencing 90 days prior to a Change in Control (as defined below) or 12 months following a Change in Control, Lederman shall be entitled to receive, in lieu of the severance benefits described above, the following payments and benefits: (1) a lump sum cash payment in an amount equal to 36 months of his base salary as in effect immediately prior to the date of termination, except that, if and while Lederman is still entitled to the Sale Bonus (as defined below), it will only be 18 months; (2) continuation of health benefits for Lederman and his eligible dependents for a period of 24 months following the date of termination, except that, if and while Lederman is still entitled to the Sale Bonus it will only be 12 months; and (3) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards.

If during the term of the Lederman Agreement or within 120 days after Lederman is terminated without Cause or resigns for Good Reason, following a Change in Control, the Company consummates a Change in Control transaction in which the Enterprise Value (as defined below) equals or exceeds $50 million, Lederman shall be entitled to receive a lump sum payment equal to 4.4% of the Enterprise Value, or the Sale Bonus. The Sale Bonus provision of the Lederman Agreement will terminate upon the Company granting Lederman long-term incentive compensation mutually agreed to by the Board and Lederman.

For purposes of the Lederman Agreement, "Cause" generally means (1) commission of an act of fraud, embezzlement or dishonesty or some other illegal act that has a demonstrable material adverse impact on the Company or any successor or affiliate of the Company, (2) conviction of, or entry into a plea of "guilty" or "no contest" to, a felony, (3) unauthorized use or disclosure of the Company's confidential information or trade secrets or any successor or affiliate of the Company that has, or may reasonably be expected to have, a material adverse impact on any such entity; (4) gross negligence, failure to follow a material, lawful and reasonable request of the Board or material violation of any duty of loyalty to the Company or any successor or affiliate of the Company, or any other demonstrable material willful misconduct by Lederman, (5) ongoing and repeated failure or refusal to perform or neglect of his duties as required by his employment agreement, which failure, refusal or neglect continues for 30 days following Lederman's receipt of written notice from the Board stating with specificity the nature of such failure, refusal or neglect, provided that such failure to perform is not as a result of illness, injury or medical incapacity, or (6) material breach of any Company policy or any material provision of the Lederman Agreement.

For purposes of the Lederman Agreement, "Good Reason" generally means (1) a material diminution in Lederman's title, authority, duties or responsibilities, (2) a material diminution in Lederman's base compensation, unless such a reduction is imposed across-the-board to the Company's senior management, and such reduction is not greater than 15%, (3) a material change in the geographic location at which Lederman must perform his duties, (4) any other action or inaction that constitutes a material breach by the Company or any successor or affiliate of the Company's obligations to Lederman under the Lederman Agreement, or (5) the Company elects not to renew the Lederman Agreement for another term.

For purposes of the Lederman Agreement, "Change in Control" generally means:

- A transaction or series of transactions (other than public offerings) that results in any person or entity or related group of persons or entities (other than the Company, its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a person or entity that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of more than 40% of the total combined voting power of the Company's securities outstanding immediately after such acquisition;

- (1) a merger, consolidation, reorganization, or business combination or (2) the sale, exchange or transfer of all or substantially all of the Company's assets in any single transaction or series of transactions or (3) the acquisition of assets or stock of another entity, in each case other than a transaction:

    - which results in the Company's voting securities outstanding immediately before the transaction continuing to represent, directly or indirectly, at least 60% of the combined voting power of the successor entity's outstanding voting securities immediately after the transaction, and

    - after which no person or group beneficially owns voting securities representing 40% or more of the combined voting power of the Company or its successor; provided, however, that no person or group is treated as beneficially owning 40% or more of combined voting power of the Company or its successor solely as a result of the voting power held in the Company prior to the consummation of the transaction.

For purposes of the Lederman Agreement, "Enterprise Value" generally means (1) in a Change in Control in which consideration is received by the Company, the total cash and non-cash consideration, including debt assumed, received by the Company, net of any fees and expenses in connection with the transaction and (2) in a Change in Control in which consideration is payable to the stockholders of the Company, the total cash and non-cash consideration, including debt assumed, payable to the Company's stockholders net of any fees and expenses in connection with the transaction. Enterprise Value also includes any cash or non-cash consideration payable to the Company or to the Company's stockholders on a contingent, earnout or deferred basis.

Employment Agreement with Gregory Sullivan

On June 3, 2014, the Company entered into an employment agreement, or the Sullivan Agreement, with Dr. Gregory Sullivan, or Sullivan, to serve as our Chief Medical Officer. The base salary for Sullivan under the Sullivan Agreement was $225,000 per annum. The Sullivan Agreement had an initial term of one year and automatically renews for successive one year terms unless either party delivers written notice not to renew at least 60 days prior to the end of the current term.

Pursuant to the Sullivan Agreement, if the Company terminates Sullivan's employment without Cause (as defined below) or Executive resigns for Good Reason (as defined below), Sullivan is entitled to the following payments and benefits: (1) his fully earned but unpaid base salary through the date of termination at the rate then in effect, plus all other benefits, if any, under any group retirement plan, nonqualified deferred compensation plan, equity award plan or agreement, health benefits plan or other group benefit plan to which Sullivan may be entitled to under the terms of such plans or agreements; (2) a lump sum cash payment in an amount equal to 12 months of his base salary as in effect immediately prior to the date of termination; (3) continuation of health benefits for Sullivan and his eligible dependents for a period of 12 months following the date of termination; and (4) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards as to the number of stock awards that would have vested over the 12-month period following termination had Sullivan remained continuously employed by the Company during such period.

Pursuant to the Sullivan Agreement, if Sullivan's employment is terminated as a result of death or permanent disability, Sullivan or his estate, as applicable, is entitled to his fully earned but unpaid base salary through the end of the month in which termination occurs at the rate then in effect.

For purposes of the Sullivan Agreement, "Cause" generally means (1) commission of an act of fraud, embezzlement or dishonesty or some other illegal act that has a demonstrable material adverse impact on the Company or any successor or affiliate of the Company, (2) conviction of, or entry into a plea of "guilty" or "no contest" to, a felony, (3) unauthorized use or disclosure of the Company's confidential information or trade secrets or any successor or affiliate of the Company that has, or may reasonably be expected to have, a material adverse impact on any such entity, (4) gross negligence, failure to follow a material, lawful and reasonable request of the Company or material violation of any duty of loyalty to the Company or any successor or affiliate of the Company, or any other demonstrable material misconduct by Sullivan, (5) ongoing and repeated failure or refusal to perform or neglect of his duties as required by his employment agreement, which failure, refusal or neglect continues for 30 days following Sullivan's receipt of written notice from the Company stating with specificity the nature of such failure, refusal or neglect, or (6) material breach of any Company policy or any material provision of the Sullivan Agreement.

For purposes of the Sullivan Agreement, "Good Reason" generally means (1) a material diminution in Executive's title, authority, duties or responsibilities, (2) a material diminution in the executive officer's base compensation, unless such a reduction is imposed across-the-board to the Company's senior management and such reduction is not greater than 15%, (3) a material change in the geographic location at which the executive officer must perform his duties, (4) any other action or inaction that constitutes a material breach by the Company or any successor or affiliate of the Company's obligations to Sullivan under the Sullivan Agreement, or (5) the Company elects not to renew the Sullivan Agreement for another term.

Directors Compensation Table

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2016 for services to our Company.

Name	Stock Awards ($)[1]	Option Awards ($)	Total ($)
Stuart Davidson	$ 45,750	$ —	$ 45,750
Patrick Grace	$ 45,750	$ —	$ 45,750
Donald Landry	$ 45,750	$ —	$ 45,750
Ernest Mario	$ 45,750	$ —	$ 45,750
Charles Mather IV	$ 45,750	$ —	$ 45,750
John Rhodes[2]	$ 68,625	$ —	$ 68,625
Samuel Saks	$ 45,750	$ —	$ 45,750
Total:	$ 343,125	$ —	$ 343,125

(1) Represents the aggregate grant date fair value of restricted stock units granted in accordance with FASB ASC Topic 718. For the relevant assumptions used in determining these amounts, refer to Note 8 to our audited financial statements included in our Annual Report on Form 10-K. These amounts do not necessarily correspond to the actual value that may be recognized from the restricted stock unit grant.

(2) Mr. Rhodes received additional restricted stock units for serving as lead director.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-party transactions." For purposes of our policy only, a "related-party transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related party" are participants involving an amount that exceeds $120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related party is any executive officer, director or a holder of more than five percent of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-party transaction, our Chief Compliance Officer must present information regarding the proposed related-party transaction to our Nominating and Corporate Governance Committee for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related parties, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-party transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-party transactions, our Nominating and Corporate Governance Committee will take into account the relevant available facts and circumstances including, but not limited to:

- whether the transaction was undertaken in the ordinary course of our business;
- whether the related party transaction was initiated by us or the related party;
- whether the transaction with the related party is proposed to be, or was, entered into on terms no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us from the related party transaction;
- the approximate dollar value of the amount involved in the related party transaction, particularly as it relates to the related party;
- the related party's interest in the related party transaction, and
- any other information regarding the related party transaction or the related party that would be material to investors in light of the circumstances of the particular transaction.

The Nominating and Corporate Governance Committee shall then make a recommendation to the Board, who will determine whether or not to approve of the related party transaction, and if so, upon what terms and conditions. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Other than as disclosed below, during the last two fiscal years, there have been no related party transactions.

On February 3, 2015, we entered into an underwriting agreement for an offering of common stock with a group of underwriters, including Janney Montgomery Scott LLC. Charles Mather, one of our directors, was a Managing Director of Janney until February 2015.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of our common stock as of September 28, 2017:

- by each person who is known by us to beneficially own more than 5% of our common stock;
- by each of our officers and directors; and
- by all of our officers and directors as a group.

Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o Tonix Pharmaceuticals Holding Corp., 509 Madison Avenue, Suite 306, New York New York 10022.

NAME OF OWNER	TITLE OF CLASS	NUMBER OF SHARES OWNED (1)		PERCENTAGE OF COMMON STOCK (2)
Seth Lederman	Common Stock	182,871	(3)	2.39%
Bradley Saenger	Common Stock	8,071	(4)	*
Gregory Sullivan	Common Stock	19,093	(5)	*
Margaret Smith Bell	Common Stock	0		*
Stuart Davidson	Common Stock	15,429	(6)	*
Patrick Grace	Common Stock	6,966	(7)	*
Donald Landry	Common Stock	14,663	(8)	*
Ernest Mario	Common Stock	79,863	(9)	1.05%
Charles Mather IV	Common Stock	7,644	(10)	*
John Rhodes	Common Stock	24,763	(11)	*
Samuel Saks	Common Stock	12,088	(12)	*
Officers and Directors as a Group (11 persons)	Common Stock	316,938	(13)	4.11%
Rosalind Advisors, Inc. (14)	Common Stock	594,077	(15)	7.79%
Opaleye, L.P. (16)	Common Stock	413,593		5.46%

* Denotes less than 1%

(1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of September 28, 2017 are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person.

(2) Percentage based upon 7,581,700 shares of common stock issued and outstanding as of September 28, 2017.

(3) Includes 61,811 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, days, 1,677 shares of common stock underlying warrants, 18,463 shares of common stock and 5,450 shares of common stock underlying warrants owned by Lederman & Co, 3,246 shares of common stock and 1,267 shares of common stock underlying warrants owned by L&L, 5,898 shares of common stock and 825 shares of common stock underlying warrants owned by Targent, 2,917 shares of common stock and 417 shares of common stock underlying warrants owned by Leder Labs, 2,917 shares of common stock and 417 shares of common stock underlying warrants owned by Starling, 13,300 shares owned through a 401(k) account, 50,000 shares owned through an IRA account and 3,100 shares owned by Dr. Lederman's spouse. Seth Lederman, as the Managing Member of Lederman & Co and Targent, the Manager of L&L and the Chairman of Leder Labs and Starling, has investment and voting control over the shares held by these entities.

(4) Includes 5,292 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(5) Includes 9,494 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(6) Includes 4,136 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days, 7,454 shares of common stock and 1,084 shares of common stock underlying warrants owned by Lysander, LLC and 655 shares owned by Oystercatcher Trust. Stuart Davidson, as the Member of Lysander, LLC and Trustee of Oystercatcher Trust, has investment and voting control over the shares held by these entities.

(7) Includes 4,211 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(8) Includes 4,061 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 125 shares of common stock underlying warrants, 3,246 shares of common stock and 1,267 shares of common stock underlying warrants owned by L&L. Donald Landry, as a Member of L&L, has investment and voting control over the shares held by this entity.

(9) Includes 4,061 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 6,084 shares of common stock underlying warrants and 5,895 shares owned by Ernest and Mildred Mario Revocable Trust. Ernest Mario, as a Trustee of Ernest and Mildred Mario Revocable Trust, has investment and voting control over the shares held by this entity.

(10) Includes 4,811 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days and 300 shares of common stock underlying warrants.

(11) Includes 4,866 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days and 3,927 shares of common stock underlying warrants.

(12) Includes 4,061 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days and 1,422 shares of common stock underlying warrants.

(13) Includes 106,804 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days, 18,463 shares of common stock and 5,450 shares of common stock underlying warrants owned by Lederman & Co, 3,246 shares of common stock and 1,267 shares of common stock underlying warrants owned by L&L, 5,898 shares of common stock and 825 shares of common stock underlying warrants owned by Targent, 2,917 shares of common stock and 417 shares of common stock underlying warrants owned by Leder Labs, 2,917 shares of common stock and 417 shares of common stock underlying warrants owned by Starling, 13,300 shares owned through a 401(k) account of Dr. Lederman, 50,000 shares owned through an IRA account of Dr. Lederman, 3,100 shares owned by Dr. Lederman's spouse, 7,454 shares of common stock and 1,084 shares of common stock underlying warrants owned by Lysander, LLC, 655 shares owned by Oystercatcher Trust, 5,895 shares owned by Ernest and Mildred Mario Revocable Trust and 13,535 shares of common stock underlying warrants owned directly by the executive officers and directors.

(14) Based upon a Schedule 13G/A filed with the SEC on April 7, 2017. The mailing address for this beneficial owner is 175 Bloor Street East, Suite 1316, North Tower, Toronto, Ontario, M4W 3R8 Canada . Steven Salamon is the portfolio manager of this entity and may be deemed to beneficially own the securities held by this entity.

(15) Includes 40,169 shares of common stock underlying warrants.

(16) Based upon a Schedule 13G filed with the SEC on April 17, 2017. The mailing address for this beneficial owner is One Boston Place, 26th Floor, Boston, Massachusetts 02108. James Silverman is the president of Opaleye Management Inc., the investment manager of Opaleye, L.P., and may be deemed to beneficially own the securities held by this entity.

DESCRIPTION OF SECURITIES

Common Stock

We are authorized to issue up to 150,000,000 shares of our common stock, par value $0.001 per share. As of September 28, 2017, there were 7,581,700 shares of our common stock issued and outstanding. The outstanding shares of our common stock are validly issued, fully paid and nonassessable.

Holders of our common stock are entitled to one vote for each share on all matters submitted to a stockholder vote. Holders of our common stock do not have cumulative voting rights. Therefore, holders of a majority of the shares of our common stock voting for the election of directors can elect all of the directors. Holders of our common stock representing a majority of the voting power of our capital stock issued, outstanding and entitled to vote, represented in person or by proxy, are necessary to constitute a quorum at any meeting of stockholders. A vote by the holders of a majority of our outstanding shares is required to effectuate certain fundamental corporate changes such as liquidation, merger or an amendment to our articles of incorporation.

Holders of our common stock are entitled to share in all dividends that our Board of Directors, in its discretion, declares from legally available funds. In the event of a liquidation, dissolution or winding up, each outstanding share entitles its holder to participate pro rata in all assets that remain after payment of liabilities and after providing for each class of stock, if any, having preference over our common stock. Our common stock has no pre-emptive, subscription or conversion rights and there are no redemption provisions applicable to our common stock.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, par value $.001 per share, none of which are currently outstanding. The shares of preferred stock may be issued in series, and shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the resolution or resolutions providing for the issuance of such stock adopted from time to time by the board of directors. The board of directors is expressly vested with the authority to determine and fix in the resolution or resolutions providing for the issuances of preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Nevada.

Convertible Securities

None.

Warrants

As of September 28, 2017, we had outstanding warrants to purchase 731,194 shares of common stock at a weighted-average exercise price of $18.76 per share, which expire between December 2017 and October 2021.

Anti-Takeover Effects of Provisions of the Articles of Incorporation and Bylaws

Articles of Incorporation and Bylaw Provisions. Our articles of incorporation and bylaws include a number of provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. They are intended to enhance long-term value to our stockholders by increasing the likelihood of continued stability in the composition of our board of directors and its policies and discouraging certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. These provisions include the items described below.

Filling Vacancies. Any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board of directors, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

Meetings of Stockholders. Our bylaws provide that only our president or our board of directors may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements. Our bylaws include advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in the amended and restated bylaws.

Amendment to Bylaws and Articles of Incorporation. As required by Nevada law, any amendment of our articles of incorporation must first be approved by a majority of our board of directors and, if required by law or our articles of incorporation, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the bylaws, or by the holders of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding voting power of our company, voting together as a single class.

Blank Check Preferred Stock. Our articles of incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our company or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring, or preventing a change of control of us.

Exchange Listing

Our common stock is listed on The NASDAQ Global Market under the trading symbol “TNXP.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is vStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Nevada Revised Statutes, or NRS, Sections 78.7502 and 78.751 provide us with the power to indemnify any of our directors and officers. The director or officer must have conducted himself/herself in good faith and reasonably believe that his/her conduct was in, or not opposed to, our best interests. In a criminal action, the director, officer, employee or agent must not have had reasonable cause to believe his/her conduct was unlawful.

Under NRS Section 78.751, advances for expenses may be made by agreement if the director or officer affirms in writing that he/she believes he/she has met the standards and will personally repay the expenses if it is determined such officer or director did not meet the standards.

We are also permitted to apply for insurance on behalf of any director, officer, employee or other agent for liability arising out of his actions, whether or not the NRS would permit indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Our Articles of Incorporation, as amended, provides a limitation of liability such that no director or officer shall be personally liable to us or any of our stockholders for damages for breach of fiduciary duty as a director or officer, involving any act or omission of any such director or officer, provided there was no intentional misconduct, fraud or a knowing violation of the law, or payment of dividends in violation of NRS Section 78.300.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the Selling Stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the Selling Stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the Selling Stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive.

We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the Selling Stockholder, and any other required information.

We will pay the expenses incident to the registration, offering, and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Lincoln Park.

Our common stock is quoted on The NASDAQ Global Market under the symbol “TNXP”.

SELLING STOCKHOLDERS

This prospectus relates to the possible resale by the Selling Stockholder, Lincoln Park, of shares of our common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on September 28, 2017 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the Selling Stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have issued or may issue to Lincoln Park under the Purchase Agreement. The Selling Stockholder may sell some, all or none of its shares. We do not know how long the Selling Stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the Selling Stockholder regarding the sale of any of the shares.

The following table presents information regarding the Selling Stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the Selling Stockholder, and reflects its holdings as of September 28, 2017. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Section 13(d) of the Exchange Act and Rule 13d-3 thereunder. The percentage of shares beneficially owned prior to the offering is based on 7,581,700 shares of our common stock actually outstanding as of September 28, 2017.

Selling Stockholder	Shares Beneficially Owned Before this Offering	Percentage of Outstanding Shares Beneficially Owned Before this Offering	Shares to be Sold in this Offering	Percentage of Outstanding Shares Beneficially Owned After this Offering
Lincoln Park Capital Fund, LLC (1)	82,039(2)	1.08% (3)	2,100,000(4)	* (5)

* Represents less than 1%

(1) Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Cope and Scheinfeld have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Lincoln Park Capital, LLC is not a licensed broker dealer or an affiliate of a licensed broker dealer.

(2) Represents (i) 73,039 Commitment Shares of our common stock issued to Lincoln Park upon our execution of the Purchase Agreement as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement, all of which shares are covered by the registration statement that includes this prospectus, and (ii) 9,000 shares of common stock issuable upon exercise of outstanding warrants. We have excluded from the number of shares beneficially owned by Lincoln Park prior to the offering all of the additional shares of common stock that Lincoln Park may be required to purchase pursuant to the Purchase Agreement, because the issuance of such shares is solely at our discretion and is subject to certain conditions, the satisfaction of all of which are outside of Lincoln Park's control, including the registration statement of which this prospectus is a part becoming and remaining effective. Furthermore, under the terms of the Purchase Agreement, issuances and sales of shares of our common stock to Lincoln Park are subject to certain limitations on the amounts we may sell to Lincoln Park at any time, including the Exchange Cap and the Beneficial Ownership Cap. See the description under the heading "The Lincoln Park Transaction" for more information about the Purchase Agreement.

(3) Based on 7,581,700 outstanding shares of our common stock as of September 28, 2017, which includes the 73,039 Commitment Shares we issued to Lincoln Park on September 28, 2017.

(4) Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, only 2,100,000 shares of our common stock are being offered under this prospectus, which represents: (i) 73,039 Commitment Shares issued to Lincoln Park upon our execution of the Purchase Agreement as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement; and (ii) an aggregate of 2,026,961 shares of our common stock that may be sold by us to Lincoln Park at our discretion from time to time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

(5) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling stockholder is under no obligation to sell any shares of common stock at this time.

LEGAL MATTERS

Sichenzia Ross Ference Kesner LLP, New York, New York will issue an opinion with respect to the validity of the shares of common stock being offered hereby.

EXPERTS

The consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. and subsidiaries 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 have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are required to file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document filed by us at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our filings with the SEC are also available to the public at the SEC's Internet web site at *http://www.sec.gov*.

We have filed a registration statement, of which this prospectus is a part, covering the securities offered hereby. As allowed by SEC rules, this prospectus does not include all of the information contained in the Registration Statement and the included exhibits, financial statements and schedules. You are referred to the Registration Statement, the included exhibits, financial statements and schedules for further information. This prospectus is qualified in its entirety by such other information.

We are subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at *www.tonixpharma.com*. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we have filed with them, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. The documents we are incorporating by reference are:

- Annual Report on Form 10-K for the year ended December 31, 2016, filed on April 13, 2017, as amended by our Annual Report on Form 10-K/A filed on September 1, 2017;
- Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed on May 12, 2017;

- Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed on August 11, 2017;
- Current Reports on Form 8-K, filed on January 10, 2017 (as to Item 8.01 only), January 31, 2017 (as to Item 8.01 only), March 2, 2017 (as to Item 8.01 only), March 14, 2017, March 16, 2017, March 28, 2017, March 30, 2017, April 3, 2017, April 4, 2017, April 11, 2017, April 13, 2017, May 22, 2017, May 30, 2017, June 15, 2017, June 16, 2017, July 6, 2017 (as to Item 8.01 only), August 1, 2017, August 29, 2017, September 14, 2017 (as to Items 5.02 and 8.01 only) and September 29, 2017; and
- The description of our common stock contained in our Form 8-A, filed on July 23, 2013.

All documents we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any report or documents that is not deemed filed under such provisions, (1) on or after the date of filing of the Registration Statement containing this prospectus and prior to the effectiveness of the Registration Statement and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the Registration Statement of which this prospectus is a part has been withdrawn, shall be deemed incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of those documents and will be automatically updated and, to the extent described above, supersede information contained or incorporated by reference in this prospectus and previously filed documents that are incorporated by reference in this prospectus.

Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC pursuant to Item 2.02, 7.01 or 9.01 of Form 8-K.

Upon written or oral request, we will provide without charge to each person to whom a copy of the prospectus is delivered a copy of the documents incorporated by reference herein (other than exhibits to such documents, unless such exhibits are specifically incorporated by reference herein). You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Tonix Pharmaceuticals Holding Corp., 509 Madison Avenue, Suite 306, New York, NY 10022 Attention: Investor Relations, telephone: (212) 9809155. We maintain a website at http://www.tonixpharma.com. You may access our definitive proxy statements on Schedule 14A, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and periodic amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus. We have not authorized any one to provide you with any information that differs from that contained in this prospectus. Accordingly, you should not rely on any information that is not contained in this prospectus. You should not assume that the information in this prospectus is accurate as of any date other than the date of the front cover of this prospectus.

Tonix Pharmaceuticals Holding Corp.

PROSPECTUS

Up to 2,100,000 shares of
Common Stock, par value $0.001 per share

PROSPECTUS

October 12, 2017
