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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2018

Commission File Number 001-36019

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada		**26-1434750**
(State or other jurisdiction of incorporation or organization)		(IRS Employer Identification No.)
509 Madison Avenue, Suite 1608 **New York, New York**	**10022**	**(212) 980-9155**
(Address of principal executive office)	(Zip Code)	(Registrant's telephone number, including area code)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).Yes ☐ No ☒

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2018, based on the closing sales price of the common stock as quoted on The NASDAQ Global Market was $32,593,562. For purposes of this computation, all officers, directors, and 5 percent beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed an admission that such directors, officers, or 5 percent beneficial owners are, in fact, affiliates of the registrant.

As of March 13, 2019, there were 6,089,728 shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders to be held in 2019, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

TABLE OF CONTENTS

PART I

ITEM 1 – BUSINESS

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

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

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

Tonix Pharmaceuticals®, Tonmya®*, Protectic™, Angstro-Technology™ and other trademarks and intellectual property of ours appearing in this report are our property. This report contains additional trade names and trademarks of other companies. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for posttraumatic stress disorder, or PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

Business Overview

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Our most advanced drug development program is focused on delivering a safe and effective 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, other central nervous system disorders and biodefense.

In June 2017, the U.S. Food and Drug Administration, or 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 New Drug Application, or NDA, approval. The U.S. Patent and Trademark Office, or PTO, has granted the federal registration of the Tonmya mark.

Our lead product candidate, Tonmya, or TNX-102 SL, a proprietary low-dose cyclobenzaprine, or CBP, sublingual tablet, designed for bedtime administration, is in Phase 3 development as a potential treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for Fibromyalgia, or FM, and agitation in Alzheimer's disease, or AAD, under separate INDs to support potential pivotal efficacy studies. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but using a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication -neurocognitive dysfunction associated with corticosteroid use. Phase 1 clinical study of TNX-601 selected oral formulation will be conducted outside of the U.S. in 2019. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. TNX-701 is a biodefense development program for protection from radiation injury. We are currently not performing any activities and have no future plans related to TNX-301 an IND candidate for the treatment of alcohol use disorder. We hold worldwide development and commercialization rights to all of our product candidates.

Tonmya – Posttraumatic Stress Disorder

Tonmya is a small, rapidly disintegrating tablet containing CBP for sublingual administration. Tonmya employs a proprietary protective eutectic formulation of CBP, Protectic™, which enables rapid systemic exposure and increased bioavailability through transmucosal absorption. Based on the results of a Phase 2 study with Tonmya 2.8 mg and 5.6 mg in military-related PTSD, Tonmya 5.6 mg was studied in the first Phase 3 study which was discontinued after the results of the interim analysis, or IA, indicated a pre-defined threshold p-value for continuing enrollment was not achieved. Retrospective analysis of this Phase 3 study revealed a treatment effect in participants who experienced trauma less than or equal to 9 years prior to screening. This analysis defined an optimal treatment window for treatment with TNX-102 SL for PTSD of the first 9 years after the index trauma that resulted in PTSD and guided the design of the recently initiated new Phase 3 study.

An estimated 12 million adults annually 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 and sedative-hypnotics 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.

TNX-102 SL – Fibromyalgia

We are developing TNX-102 SL for the treatment of FM. In September 2016, we interrupted development of TNX-102 SL for the treatment of FM to focus on the treatment of PTSD. Our previous development efforts for TNX-102 SL in FM studied the 2.8 mg dose in a Phase 2 and a Phase 3 study. Based on our experience with TNX-102 SL 5.6 mg in PTSD, we are restarting the clinical program using TNX-102 SL 5.6 mg. We met with the FDA in March 2019 to discuss the clinical development plan for TNX-102 SL 5.6 mg and the next Phase 3 study to support the FM indication.

FM is a debilitating syndrome that occurs in five to 15 million U.S. adults and is associated with a substantial negative impact on social and occupational function, including disrupted relationships with family and friends, social isolation, reduced activities of daily living and leisure activities, avoidance of physical activity, and loss of career or inability to advance in careers or education. Many patients fail to adequately respond to the medications approved for FM or discontinue therapy due to poor tolerability. Prescription pain and sleep medications not approved for FM are frequently taken for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic effect.

TNX-102 SL – Agitation in Alzheimer's Disease

We are developing TNX-102 SL for the treatment of agitation in Alzheimer's disease, which has been designated as a Fast Track development program by the FDA. FDA comments on the Phase 2 potential pivotal efficacy study protocol have been received.

An estimated 5.3 million people in the U.S suffer from Alzheimer's disease, with more than half that number expected to be affected by agitation. Behavioral symptoms are a major clinical complication of Alzheimer's disease. Sleep disturbances and agitation are common and co-morbid features of Alzheimer's disease. Agitation in Alzheimer's disease is associated with significant negative consequences for both patients as well as their caregivers. Development of agitation, or its worsening, is one of the most common reasons for patients having to transition to nursing homes and other long-term care settings. Currently, there is no FDA approved treatment for behavioral symptoms such as agitation and aggression which adversely affect the quality of life of both the patients and caregivers. Off-label use of atypical anti-psychotic medications for behavioral symptoms in Alzheimer's disease is a common practice, despite the lack of evidence for their effectiveness and significant risks associated with their use in this population.

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 FM and Other Indications.*** We currently are focusing on the development of Tonmya for PTSD. Our broader development strategy is to leverage the patented formulation to explore the clinical potential of TNX-102 SL in multiple other central nervous system disorders or neuropsychiatric conditions, including agitation in Alzheimer's, that are either underserved by currently approved medications or have no approved treatment thus representing 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 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 or have no approved treatment which 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 condition 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 2012, 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 many have significant safety liabilities and dependence risk.

Fibromyalgia

FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. The peak incidence of FM occurs between 20-50 years of age, and 80-90% of diagnosed patients are female. FM may have a substantial negative impact on social and occupational function, including disrupted relationships with family and friends, social isolation, reduced activities of daily living and leisure activities, avoidance of physical activity, and loss of career or inability to advance in career or education. According to published estimates, there are approximately five to fifteen million people suffering from FM in the U.S. (Vincent et al, Arthritis Care Res 2013;65:786-792; Lawrence et al, Arthritis Rheum 2008;58:26-35). Based on our market research, last updated in 2015, we believe that sales in the U.S. of FDA-approved medications for FM were approximately $1.2 billion in 2014, representing approximately 5.6 million prescriptions.

According to a report by Frost and Sullivan that we commissioned, despite the availability of approved medications, the majority of patients fail therapy due to either insufficient efficacy or poor tolerability, or both. Prescription pain and sleep medications are frequently prescribed off-label for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic benefit, and many of these medications carry significant safety risks and risk of dependence. For example, approximately 30% of FM patients take chronic opioids, despite the lack of evidence for their effectiveness and the risk of addiction and toxicity, including overdose.

Agitation in Alzheimer's Disease

Alzheimer's is a chronic neurodegenerative disease in which behavioral symptoms are a major clinical complication. Sleep disturbances and agitation are common and co-morbid features of Alzheimer's disease. Agitation, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of these behavioral complications of Alzheimer's disease. Agitation is likely to affect more than half of the 5.3 million Americans who currently suffer from Alzheimer's disease, and this number is expected to nearly triple by 2050. The presence of agitation nearly doubles the cost of caring for patients with Alzheimer's disease, and agitation is estimated to account for more than 12 percent of the $256 billion in healthcare and societal cost of associated with Alzheimer's disease for the year 2017 in the United States.

Agitation in Alzheimer's disease is associated with significant negative consequences for both patients as well as their caregivers. Development of agitation, or its worsening, is one of the most common reasons for patients having to transition to nursing homes and other long-term care settings. Currently, there is no FDA approved treatment for behavioral symptoms such as agitation and aggression which affects the quality of life of both the patients and caregivers.

Off-label use of atypical anti-psychotic medications for behavioral symptoms in Alzheimer's disease is a common practice, despite the lack of evidence for their effectiveness and significant risks associated with their use in this population.

Our Product Candidates

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

Product Candidate	Indication	Stage of Development	Commercialization Rights
Tonmya	Posttraumatic stress disorder	Phase 3	Worldwide
TNX-102 SL	Fibromyalgia	Phase 3	Worldwide
TNX-102 SL	Agitation in Alzheimer's disease	Phase 2	Worldwide

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 as a bedtime treatment 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 sublingual tablets contain 2.8 mg of CBP. For the treatment of PTSD, Tonmya, 5.6 mg (two 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, is cyclobenzaprine or CBP, a serotonin-2A and alpha-1 adrenergic receptor antagonist as well as an inhibitor of serotonin and norepinephrine reuptake. In addition, Tonmya acts upon other receptors in the central nervous system not targeted by products approved for PTSD, including the serotonin 2A, adrenergic alpha-1, muscarinic M_1 and histaminergic 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 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 to be administered once-daily at bedtime and intended for long-term use. 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. It also showed that the sublingual route of administration, which largely bypasses the "first pass" metabolism that swallowed medications undergo, results in a higher plasma ratio of CBP to its main active metabolite, norcyclobenzaprine. In clinical studies, Tonmya 2.8 mg and Tonmya 5.6 mg were generally well-tolerated, with no drug-related serious adverse events, or SAEs, reported in these studies. Some subjects experienced transient numbness of the tongue after Tonmya administration.

We have successfully completed the pivotal exposure bridging study with TNX-102 SL using AMRIX as the reference listed drug or RLD. Results from this study support the approval of Tonmya and TNX-102 SL under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA. 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 new chemical entities, or NCEs, that have never been approved in the United States. We believe that Tonmya and TNX-102 SL have the potential to provide clinical benefit to this and possibly other CNS (central nervous system) indications that are underserved by currently marketed products or have no approved treatment.

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 or TNX-102 SL 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.

On September 13, 2017, we were issued European patent 2,501,234 "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine". This patent recites the use of CBP for the treatment of PTSD, which covers the use of Tonmya for the treatment of PTSD, since the active ingredient in Tonmya is CBP. The patent is expected to provide Tonmya with European market exclusivity until 2030.

On December 15, 2017 we were issued Japanese Patent No. 6259452, "Compositions and Methods for Transmucosal Absorption," by the Japanese Patent Office (JPO) relating to the pharmacokinetic profile of Tonmya, or TNX-102 SL.

On March 20, 2018, we were issued U.S. patent 9,918,948 “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 U.S. market exclusivity until 2030. This method of use patent for Tonmya extends upon previously granted patents related to the composition of matter (U.S. Patent No. 9,636,408) and the active ingredient in Tonmya (European Patent No. 2,501,234) as described above.

On March 23, 2018, we were issued Japanese Patent No. 6310542 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride.” This patent recites pharmaceutical compositions comprising the eutectics and methods of manufacturing these eutectic formulations.

On May 1, 2018, we were issued U.S. Patent No. 9,956,188 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”. The patent recites a eutectic of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034.

On November 6, 2018, we were issued U.S. Patent No. 10,117,936 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”. The patent recites pharmaceutical compositions of eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034.

Tonmya – Posttraumatic Stress Disorder Program

We are developing Tonmya as a bedtime treatment of PTSD under an effective IND application. The approval of Tonmya for PTSD will be under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA.

Clinical Development Plan

Phase 3 HONOR Study

In the third quarter of 2018, we announced the results of a randomized, double-blind, placebo-controlled Phase 3 study of Tonmya, planned for enrollment of approximately 550 participants with military-related PTSD, which we refer to as the HONOR study. The primary efficacy endpoint of the HONOR study was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5, or CAPS-5, between those treated with Tonmya and those receiving placebo. This study was an adaptive design study based on the results of the Phase 2 AtEase study. The study design was very similar to the Phase 2 AtEase study, except there was one planned IA and the involvement of an independent data monitoring committee, or IDMC, which reviewed the unblinded IA results. In addition, only one active dose (5.6 mg administered as 2 x 2.8 mg tablets) was investigated and the baseline severity entrance criterion was a CAPS-5 total score $\geq$ 33 in this Phase 3 study. The IA was conducted when approximately 50% of the initially planned participant enrollment was evaluable for efficacy. We received FDA acceptance of the Phase 3 HONOR study design in January of 2017. The HONOR study was conducted at approximately 40 U.S. sites. HONOR was discontinued after the results of the IA indicated a pre-defined threshold p-value for continuing enrollment was not achieved. The modified Intent-to-Treat (mITT) population analyzed at the time of the IA included 252 participants.

The HONOR study demonstrated that Tonmya was well tolerated and that the 5.6 mg (administered as 2 x 2.8 mg tablets) dose showed meaningful improvement in overall PTSD symptoms at Week 4. At Week 4, the Tonmya treated group separated from placebo in CAPS-5 ($p = 0.019$) and in the Clinical Global Impression – Improvement (CGI-I) scale ($p = 0.015$), a key secondary endpoint. A CGI-I responder analysis, with responder defined as ‘much improved’ or ‘very much improved’ on the CGI-I, demonstrated significantly greater responders in the Tonmya group (29.1% v 45.6%; $p=0.007$) at Week 4. Also, at Week 4, sleep quality improved as measured by both the PROMIS sleep disturbance scale ($p=0.015$) and the CAPS-5 sleep disturbance item ($p=0.002$), supporting the proposed mechanism of action of Tonmya. And the CAPS-5 reckless or self-destructive behavior item at Week 4 was significantly more improved ($p=0.013$). Safety data from these participants did not reveal any serious and/or unexpected adverse events. The most common adverse events were mostly related to local administration site reactions, such as oral hypoaesthesia (37.3%), abnormal product taste (11.9%), and oral paraesthesia (9.7%). The most common systemic adverse event was somnolence (15.7%).

Retrospective analysis of the HONOR study revealed a treatment effect in participants who experienced trauma less than or equal to 9 years prior to screening. In the patients who experienced trauma within 9 years, the p-value of the primary endpoint at Week 12, using mixed model repeated measures with multiple imputation (MMRM with MI), was 0.039, with a least-squares mean difference from placebo of -5.9 units. In contrast, there was no benefit in the participants who experienced trauma more than 9 years prior to screening. This analysis defined an optimal treatment window for treatment with TNX-102 SL for PTSD of the first 9 years after the index trauma that resulted in PTSD and guided the design of the recently initiated Phase 3 RECOVERY study.

Phase 2 AtEase Study

In the second quarter of 2016, we announced the results of 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 AtEase study demonstrated that Tonmya was well tolerated and that the 5.6 mg dose of Tonmya had a therapeutic effect as assessed by the CAPS-5 scale, a standardized structured clinician interview considered the gold standard in clinical research and regulatory approval for measuring the symptom severity of PTSD, which was statistically significant by MMRM with MI analysis (p-value = 0.031). The AtEase study also demonstrated that although the 2.8 mg dose trended in the direction of a therapeutic effect, it did not reach statistical significance on the primary endpoint, a 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale.

Four distinct SAEs were reported in the AtEase 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. Systemic adverse events that were potentially dose-related and occurred in greater than or equal to 5% of participants treated with the 2.8 mg or 5.6 mg dose included: somnolence (drowsiness), dry mouth, headache, insomnia, and sedation. 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 8.5% in placebo, 7.5% in Tonmya 2.8 mg, and 6.0% in Tonmya 5.6 mg.

The primary MMRM analysis of the AtEase study, which controlled for baseline severity, indicated greater response to Tonmya 5.6 mg in those with greater PTSD severity by CAPS-5 at baseline. As the first industry PTSD trial to employ the CAPS-5 (based on the DSM-5 published in 2013), it was not clear what was the ideal severity threshold for randomization into the study comparable to the standard threshold used in precedent studies that employed prior versions of the CAPS. Retrospective analysis imputing scores for all participants assuming a prior version of CAPS suggested a CAPS-5 baseline threshold for randomization of 33 or higher was equivalent to the threshold used in precedent PTSD studies on prior CAPS versions.

A retrospective analysis of the subgroup of participants in AtEase with baseline CAPS-5 score of 33 or higher supported the hypothesized mechanism of sleep quality improvement, since 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), whereas these measures were not related in placebo.

Open-label Extension Study for AtEase

Participants who completed the AtEase study were eligible to enroll into a 12-week 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. 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 RECOVERY Study

We have commenced the RECOVERY study, a randomized, double-blind, placebo-controlled Phase 3 study of Tonmya in approximately 250 participants with military-related and civilian PTSD in the first quarter of 2019. The design of this study was guided based on the results of the Phase 3 HONOR study and Phase 2 AtEase study. The RECOVERY study design is similar to the Phase 3 HONOR study, except the new trial incorporates several new design features including restricting enrollment of study participants to individuals with PTSD who experienced an index trauma within 9 years of screening, instead of 2001 or later. The RECOVERY study will also include participants who have experienced civilian traumas in addition to those with military-related traumas. The primary endpoint, mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5, is the same as that used in the Phase 3 HONOR study and the Phase 2 AtEase study, but the CAPS-5 primary endpoint will be assessed at Week 4 instead of at Week 12. CAPS-5 change at Week 12 will be the first key secondary endpoint. We received FDA acceptance of the Phase 3 RECOVERY study design in November 2018. The RECOVERY study is being conducted at approximately 30 U.S. sites.

Long-Term Safety Exposure Study for Tonmya

In addition to the completed 12-week open-label extension study for HONOR, a 40-week open label extension study (TNX-CY-P306) is ongoing and contributing long term exposure safety data required for registration of Tonmya 5.6 mg for PTSD. The goal of these 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 as it is a chronic psychiatric condition.

Regulatory Update

In May 2014, we submitted an IND for Tonmya indicated for the treatment of PTSD.

In December 2016, the FDA granted Breakthrough Therapy designation, or BTD, to Tonmya for the treatment of PTSD. The Breakthrough Therapy designation request was based on the preliminary clinical evidence of Tonmya 5.6 mg on military-related PTSD in the AtEase study. In March 2019, the BTD for Tonmya for PTSD was rescinded because the IA results of the HONOR study did not meet the criteria for the BTD granted in December 2016. The rescission of BTD of Tonmya for PTSD does not alter our plan for developing and obtaining regulatory approval for Tonmya, and we expect it will have minimum impact on our future interactions with the FDA.

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. 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 June 2017, the FDA conditionally accepted the proposed trade name Tonmya for TNX-102 SL for the treatment of PTSD.

In September 2017, we had a Breakthrough Therapy Chemistry, Manufacturing and Controls ("CMC") guidance meeting with the FDA regarding the CMC data required to support the Tonmya NDA and commercial product. We received the FDA official meeting minutes from that meeting in October 2017 that reflect our readiness to manufacture Tonmya commercial product at production scale if an NDA could have been submitted based on the HONOR study. In principle, our proposed CMC data package to support Tonmya's NDA approval and commercial manufacturing plans was acceptable to the FDA.

In April 2018, we held a Breakthrough Therapy Type B Statistical Guidance teleconference meeting with the FDA to reach an agreement on the statistical methods in the Statistical Analysis Plan (SAP) and Interim SAP (ISAP) for the Phase 3 HONOR study. The final SAP and ISAP was accepted by the FDA in June 2018.

In October 2018, subsequent to reporting the Phase 3 HONOR study IA results, we held a Type B Clinical Guidance Meeting with the FDA in October 2018 to discuss the Phase 3 HONOR study results and the proposed design of the new Phase 3 RECOVERY study to support the registration of Tonmya for the treatment of PTSD and the remaining data package for the NDA filing. Tonix received FDA's acceptance of the RECOVERY trial design in November 2018, including the expansion to study both civilian and military-related PTSD, enrollment restricted to index traumas within 9 years of screening, and primary endpoint of improvement of CAPS-5 from baseline as assessed at Week 4, with the first key secondary endpoint at Week 12. Topline data from the RECOVERY trial is expected in the first half of 2020.

In October 2018, we held a Breakthrough Therapy Type B CMC Guidance teleconference meeting with the FDA to seek acceptance of the proposed regulatory specifications for TNX-102 SL commercial product.

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 PSP once a therapeutic dose in adults is established. An acceptable Pediatric Study Plan 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 Tonmya NDA filing since the pivotal systemic exposure bridging study using AMRIX as the RLD has been successfully completed. 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.

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 a 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 Tonmya, or TNX-102 SL, 2.8 mg tablets manufactured at these two facilities were bioequivalent, supporting the use of the AtEase study to support the Phase 3 studies.

Completed Multi-dose Bridging PK Study

We intend to seek FDA marketing approval for Tonmya and TNX-102 SL pursuant to Section 505(b)(2) of the FDCA using AMRIX® extended-release, or ER, capsules (30 mg) as our reference listed drug, or RLD. We completed a study of Tonmya 5.6 mg (2 x 2.8 mg tablets) in comparison to AMRIX 30 mg ER capsules in a randomized, open-label, parallel, multiple-dose bridging PK study to provide a systemic exposure bridge. The Tonmya initial dose and at steady state exposures were less than the RLD maximum approved dose (30 mg) and the metabolic profile was similar to AMRIX. The results of this study provide the necessary systemic exposure bridge of Tonmya to AMRIX. The approval of Tonmya for PTSD can thus rely on the safety findings (clinical and nonclinical) and relevant labeling information in the approved AMRIX prescribing information.

Food Effect and Dose-proportionality Studies

To support the Tonmya product registration, a randomized, open-label, 3-way crossover, food-effect, dose-proportionality, comparative bioavailability study of Tonmya following a single dose in healthy subjects under fasting and fed conditions, and comparing Tonmya 2.8 mg to Tonmya 5.6 mg (administered as 2 x 2.8 mg tablets) in healthy subjects under fasting conditions will be completed for the Tonmya and TNX-102 SL 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 prescribing information, or labeling, which is necessary to support the Tonmya or TNX-102 SL labeling for long-term use. Due to the lack of evidence of potential abuse in clinical studies of Tonmya, the FDA agreed that nonclinical study to assess CBP abuse and dependency potential is not required to support the Tonmya NDA filing.

Manufacturing

TNX-102 SL drug product for Phase 2 was 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. FDA has accepted our proposed CMC data package to support Tonmya's NDA approval and commercial manufacturing plans, reflecting our readiness to manufacture Tonmya commercial product at production scale.

TNX 102 SL – Fibromyalgia program

We are developing TNX-102 SL as a bedtime treatment for FM under an effective IND application. The approval of TNX-102 SL for FM will be under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA.

Clinical Development Plan

Phase 3 AFFIRM Study

In the third quarter of 2016, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 3 study of TNX-102 SL in 519 participants with FM, which we refer to as the AFFIRM study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 2.8 mg, administered sublingually once daily at bedtime for 12 weeks. The primary endpoint of the AFFIRM trial was the FDA-agreed upon 30% pain responder analysis in which a responder is defined as a subject for whom pain intensity was reduced by at least 30% at Week 12 as compared to baseline. AFFIRM did not achieve statistical significance at the primary endpoint ($p=0.095$). Yet, statistical significance was achieved when pain was analyzed instead as a continuous variable, either by MMRM ($p<0.001$) or by MMRM with multiple imputation for missing data ($p=0.005$), a generally accepted approach to pain data. TNX-102 SL also showed statistically significant improvements in the declared secondary analyses of the Patient Global Impression of Change, or PGIC ($p=0.038$) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R ($p<0.001$). The study also showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, Sleep Disturbance instrument ($p<0.001$). We believe that given the consistent results of the analyses of pain as a continuous endpoint, as well as the nominal significance shown on multiple key secondary endpoints, TNX-102 SL 2.8 mg taken daily at bedtime for 12 weeks showed meaningful clinical benefit in this typical fibromyalgia population. Although, in light of improved results in PTSD with the higher TNX-102 SL 5.6 mg dose, and also better effects on pain in PTSD of 5.6 mg over 2.8 mg, it was predicted that TNX-102 SL 5.6 mg would have a stronger effect on pain in FM. Upon the re-initiation of the FM program in Fall of 2018, design of the next Phase 3 study in FM has been planned with the TNX-102 SL 5.6 mg dose.

TNX-102 SL was well tolerated in the AFFIRM trial. Among patients randomized to the active and control arms, 78% and 86%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 40% of participants on TNX-102 SL vs. 1% on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Phase 2b BESTFIT Study

In the third quarter of 2014, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 2b study of TNX-102 SL in 205 participants with FM, which we refer to as the BESTFIT study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 2.8 mg, administered sublingually once daily at bedtime for 12 weeks. The primary outcome measure of the BESTFIT trial was the mean change in week 12 average daily pain intensity from baseline on the 11-point Numeric Rating Scale (NRS), using a daily telephonic diary. BESTFIT did not achieve statistical significance in the primary outcome measure ($p=0.172$), whereas TNX-102 SL 2.8 mg did show a statistically significant effect on pain as measured by a 30% responder analysis of the primary pain data ($p=0.033$). The 30% response rate in the final analysis was 34.0% in the active treatment arm as compared to 20.6% in the control arm. The BESTFIT trial also showed statistically significant improvements with TNX-102 SL in the declared secondary analyses of the PGIC ($p=0.025$) and the FIQ-R ($p=0.015$). The study showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the PROMIS, Sleep Disturbance instrument ($p=0.004$). In addition, statistically significant improvements with TNX-102 SL were observed on several FIQ-R items (pain, sleep quality, anxiety, stiffness, and sensitivity) as well as on the overall symptom subdomain.

TNX-102 SL was well tolerated in the BESTFIT trial. Among patients randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 44% of participants on TNX-102 SL vs. 2% on placebo, and bitter taste in 8% on TNX-102 SL compared to none on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Regulatory Update

In October 2011, we filed the first IND for TNX-102 SL 2.8 mg indicated for the management of FM.

In February 2013, we had a Type B End-of-Phase 2/Pre-Phase 3 meeting with the FDA to discuss the study design of the Phase 2b BESTFIT study and the proposed 505(b)(2) NDA package to support the approval of TNX-102 SL for FM. In June 2013, we received FDA acceptance of the final Phase 2b BESTFIT study design, which was positioned as a pivotal efficacy study.

In April 2015, we received FDA acceptance on the Phase 3 AFFIRM study design and in August 2016, we reached an agreement with the FDA on the AFFIRM statistical analysis plan.

In May 2015, we received FDA conditional acceptance of the proposed proprietary name, Tonmya, for TNX-102 SL for FM.

In September 2015, we reached an agreement with the FDA on the Initial Pediatric Study Plan for FM. FDA has accepted our request to waive studies in pediatric patients from birth to 12 years of age.

In February 2016, we had a Type B End-of-Phase 2 CMC meeting with the FDA to review our proposed CMC data to support the NDA submission and discuss our plan to establish regulatory specifications for the commercial product. Based on the FDA official meeting minutes received on in March 2016, FDA accepted our NDA CMC plan and proposal to establish regulatory specifications for commercial product.

In December 2016, we notified FDA in our IND annual update that the FM development program was put on hold for business reasons after the Phase 3 AFFIRM study topline data was reported in September 2016.

In April 2017, we withdrew the proposed proprietary name, Tonmya, for TNX-102 SL for FM.

In March 2019, we had a Type C Clinical Guidance meeting with the FDA to discuss the clinical development plan for TNX-102 SL 5.6 mg and the next Phase 3 study to support the FM indication.

TNX 102 SL – Agitation in Alzheimer's Disease

Regulatory Update

In November 2017, we held a pre-IND meeting with the FDA to discuss our proposed development of TNX-102 SL for the treatment of agitation in Alzheimer's disease. We received the formal minutes from that meeting in December 2017 that reflect that Tonix has the data needed to file an IND to support a Phase 2 study which can potentially be one of the pivotal efficacy studies. In April 2018, the FDA cleared our IND to support a Phase 2 potential pivotal efficacy study

In July 2018, the FDA granted Fast Track Therapy designation to TNX-102 SL for the treatment of agitation in Alzheimer's disease.

In September 2018, we received FDA comments on our proposed Phase 2 potential pivotal efficacy study protocol.

Additional Product Candidates

We also have a pipeline of other drug and biologic candidates, including two pre-IND candidates, TNX-601, a daytime treatment for PTSD and TNX-801, a biologic vaccine product for the prevention of smallpox

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 decades of use in Europe, Asia, and Latin America, tianeptine has an established safety profile. In addition to being used to treat depression, several published studies support the potential of tianeptine as an 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.

We intend to develop TNX-601 under Section 505(b)(1) of the FDCA as a potential daytime treatment for PTSD. TNX-601 will also be developed as a treatment for a potential indication neurocognitive dysfunction associated with corticosteroid use. Pharmaceutical development work on TNX-601 has been initiated. We are planning to complete a non-IND formulation selection pharmacokinetic study in Europe by the end of 2019.

TNX-801

TNX-801 is a novel potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, or 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. An article describing the work was published (Noyce RS, Lederman S, Evans DH (2018) Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. PLoS ONE 13(1): e0188453. https://doi.org/10.1371/journal.pone.0188453). HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection. Discussions regarding 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 meet with the FDA to discuss the most efficient and appropriate investigational plan, e.g., the application of the FDA Animal Efficacy Rule, or Animal Rule, or conducting active comparator studies using ACAM2000, the current licensed live vaccinia virus vaccine, to establish the safety and effectiveness evidence to support the licensure TNX-801. 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, or PPACA. 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. However, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed. We are currently working to develop a vaccine that meets cGMP quality to support an IND study.

TNX-701

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. We plan to develop TNX-701 under the Animal Rule, which is applicable when human efficacy studies are not ethical or feasible. 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 market for therapies to treat PTSD and other CNS conditions is 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), the Multidisciplinary Association of Psychedelic Studies (methylenedioxymethamphetamine [MDMA]) and Aptinyx.

BNC-201 completed a Phase 2 for PTSD and Bionomics announced that after reformulation a new Phase 2 will be started. BNC-201 is an allosteric modulator of the alpha 7 nicotinic acetylcholine receptor. Rexulti is in Phase 3 for PTSD and is an atypical antipsychotic. Aptinyx drug (name) is Phase 2 for PTSD and is a modulator of the NMDA receptor. 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 in Phase 3 for PTSD and is a DEA schedule 1 hallucinogen that is being studied for drug-assisted psychotherapy. MDMA was granted 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 for treatment of PTSD. A number of other companies and institutions have or may be developing prescription medications for PTSD, including: Aptinyx is developing NYX-783 which is in Phase I and targets the NMDA receptor, Mt. Sinai Hospital and Medical School in New York City is developing ketamine which is in Phase 2 and targets the NMDA receptor, Azevan Pharmaceuticals is developing SRX246 which is in Phase 2 and targets the vasopressin V1A receptor, University of California, San Diego (UCSD) is developing losartan which is in Phase 2 and is an angiotensin receptor blocker (ARB), Massachusetts General Hospital (MGH), University of California, San Francisco (UCSF) are developing oxytocin which is in Phase 2 and targets the oxytocin receptor, Nobilis Therapeutics is developing NBTX-001, a noble gas, which is in Phase 2, EpiVario is developing inhibitors of Acetyl CoA synthetase, which is in Phase 1 and Seelos Therapeutics (recently merged with Apricus Biosciences) is developing an intranasal racemic ketamine to PTSD and major depressive disorder (MDD).

Several companies have clinical candidates for which PTSD is being considered as a secondary indication. Johnson and Johnson is developing CERC-501 which is in Phase 2 for depression, targeting the kappa opioid receptor, NeuroRx is developing NRX-101 which is in Phase 2 for bipolar depression and is a combination of ketamine, lurasidone, and *d*-cycloserine, Roche is developing RG7314 which is in Phase 3 for Autism and was granted Breakthrough Therapy designation by the FDA in August 2017, Rodin Therapeutics has a preclinical candidate for Alzheimer's disease that targets histone deacetylase 2 (HDAC2 gene product), SpringWorks Therapeutics is developing PF-04457845 which is in Phase 2 for osteoarthritis and targets fatty acid amide hydrolase (FAAH).

In addition, approved 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 developing prescription medicines for FM, including Aptinyx (NYX-2925) and Innovative Medical Concepts (celecoxib and famciclovir or IMC-1). NYX-2925 is in Phase 2 for the treatment of FM and painful diabetic peripheral neuropathy (DPN) and has been granted a Fast Track Designation by the FDA for DPN. IMC-1 has completed a successful phase 2 trial and has been granted a Fast Track Designation by the FDA for the treatment of fibromyalgia.

Additionally, a number of companies are developing prescription medicines for agitation in Alzheimer's, including Otsuka/Lundbeck (Rexulti® or brexpiprazole), Avanir/Otsuka (deudextromethorphan), Axsome (dextromethorphan/buproprion) and InterCellular (lumateperone). Rexulti® has completed two pivotal studies in agitation in Alzheimer's Disease. Deudextromethorphan is in Phase 3 for the treatment of agitation in patients with dementia of the Alzheimer's type. Dextromethorphan/bupropion is in Phase 3 for the treatment of resistant depression and agitation in patients with Alzheimer's disease. Lumateperone is in Phase 3 for treating behavioral disturbances associated with dementia.

Although a number of companies are marketing or developing prescription medicines for sleep disorders, including Merck & Co, Purdue Pharma, Eisai, GlaxoSmithKline, Johnson & Johnson and Sage Therapeutics, none of these sleep disorders drugs are approved for PTSD or AAD. Merck is marketing Belsomra® (suvorexant), which is a dual orexin receptor anatomist indicated for insomnia. Purdue and Eisai are developing lemborexant and GlaxoSmithKline is developing SB-649868 which are also dual orexin receptor antagonists. Johnson & Johnson and Minerva Neurosciences are developing seltorexant which is a selective orexin-2 antagonist. Sage Therapeutics is developing SAGE-217 which is a neurosteroid derivative that acts as a positive allosteric modulator of synaptic and extrasynaptic GABA receptors and was recently shown to increase sleep efficiency in a 5-hour phase advance model of insomnia.

Additionally, a number of companies are working on potential vaccines/treatments for smallpox, including Bavarian Nordic, SIGA Technologies and Chimerix. Bavarian Nordic is developing and has submitted an NDA for Imvamune® (or Modified Virus Ankara or MVA), which is a non-replicating vaccinia virus vaccine, which has been approved in other countries. SIGA received FDA approval for Arestvy®/TPOXX® (tecovirimat), which is an antiviral for smallpox. 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 or TNX-102 SL compositions and methods of use. As of March 13, 2019, the patents we are either the owner of record of or own the contractual right to include nine issued U.S. patents and 88 issued non-U.S. patents. We are actively pursuing an additional 16 U.S. patent applications, of which three are provisional and 13 are non-provisional, three international patent applications, and 60 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 or methods of making or using that 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 Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, is a federal law that encourages new drug research by restoring patent term lost to regulatory delays by permitting a patent term extension of up to five years beyond the statutory 20-year term of the patent for the approved product or its methods of manufacture or use 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 March 1, 2019 are summarized below.

TNX-102 SL — Central Nervous System Conditions

Our patent portfolio for TNX-102 SL include patent applications directed to compositions of matter of CBP, formulations containing CBP, and methods for treating CNS conditions, such as Tonmya for PTSD, and TNX-102 SL for agitation in neurodegenerative conditions, e.g. agitation in Alzheimer's disease, 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 (now U.S. Patent No. 9,636,408). 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.

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 and TNX-102 SL relating to the PK Technology includes patent applications directed to compositions of matter of CBP, formulations containing CBP, methods for treating PTSD, agitation in neurodegenerative conditions, 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.

U.S. Patent No. 9,636,408 entitled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride" issued on May 2, 2017. The patent claims recite pharmaceutical compositions comprising the eutectic. The patent claims also recite methods of manufacturing the 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.

On September 13, 2017, European patent 2,501,234, entitled "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine", issued. This patent recites the use of CBP for the treatment of PTSD, which covers the use of Tonmya for the treatment of PTSD, since the active ingredient in Tonmya is CBP and provides Tonmya with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of Tonmya for PTSD.

On December 15, 2017, Japanese Patent No. 6259452, entitled "Compositions and Methods for Transmucosal Absorption", issued. These claims relate to the pharmacokinetic profile of Tonmya or TNX-102 SL.

On March 20, 2018, U.S. Patent No. 9,918,948 entitled "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine", issued. The claims recite a method of using Tonmya's active ingredient cyclobenzaprine to treat PTSD and provides Tonmya with US market exclusivity until 2030.

On March 23, 2018, Japanese Patent No. 6310542 entitled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride", issued. The claims recite pharmaceutical compositions comprising the eutectics and methods of manufacturing these eutectic formulations.

On May 1, 2018, U.S. Patent No. 9,956,188, entitled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride", issued. The claims recite a eutectic of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics.

On November 6, 2018, U.S. Patent No. 10,117,936, entitled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride", issued. The claims recite pharmaceutical compositions of eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions.

TNX-601 — Posttraumatic Stress Disorder and Neurocognitive Dysfunction

Our patent portfolio for tianeptine oxalate includes U.S. Patent Application No. 15/856,818 and International Patent Application PCT/IB2017/001709. It includes claims directed to crystalline tianeptine oxalate and compositions of those crystal forms, and disclosures directed to methods of using those crystalline forms and their compositions.

On February 27, 2019, European Patent No. 3,246,031 entitled "Method for Treating Neurodegenerative Dysfunction", issued. The claims recite the use of TNX-601, or tianeptine oxalate and other salts, for treating neurocognitive dysfunction associated with corticosteroid treatment. This patent provides TNX-601 with European market exclusivity until April 2029 and may be extended based on the timing of the European market authorization of TNX-601 for neurocognitive disfunction associated with corticosteroid treatment.

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 being developed as a new smallpox preventing vaccine, 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. non-provisional Patent Application No. 15/802,189 and International Patent Application No. PCT/US2017/059782. We also own the rights to develop other vaccine candidates against smallpox. With respect to these vaccine candidates, we own U.S. 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-701 — Radioprotection Biodefense Technology

We own the rights to develop a potential biodefense technology, which is a potential radioprotective therapy. For protection of our 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 CBP/Amitriptyline

Patent No.	Title	Country / Region	Expiration Date
6259452	Compositions and Methods for Transmucosal Absorption	Japan	June 14, 2033
631144	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033
I590820	Compositions and Methods for Transmucosal Absorption	Taiwan	June 14, 2033
2013274003	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
I642429	Compositions and Methods for Transmucosal Absorption	Taiwan	June 14, 2033
726488	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033

CBP - Depression

Patent No.	Title	Country / Region	Expiration Date
2012225548	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia	March 6, 2032
2016222412	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
714294	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand	March 6, 2032

Low Dose CBP

Patent No.	Title	Country / Region	Expiration Date
6,395,788	Methods for Treating Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	U.S.A.	August 11, 2020
6,541,523	Methods for Treating or Preventing Fibromyalgia Using Very Low Doses of Cyclobenzaprine	U.S.A.	August 11, 2020
1202722; ATE299369T1 in Austria; 60021266.1 in Germany; ES 2245944 T3 in Spain	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	European Patent Office – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	August 11, 2020
1047691	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Hong Kong	August 11, 2020
516749	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	New Zealand	August 11, 2020

Low Dose CBP - GAD

Patent No.	Title	Country / Region	Expiration Date
6,358,944	Methods and Compositions for Treating Generalized Anxiety Disorder	U.S.A.	August 23, 2020

CBP - PTSD

Patent No.	Title	Country / Region	Expiration Date
9,918,948	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	U.S.A.	November 18, 2030
2501234 (602010045270.0 in Germany; 502017000142469 in Italy; 56634 in Serbia; 201717905 in Turkey)	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	European Patent Office – Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, Turkey	November 16, 2030
HK1176235	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	Hong Kong	November 16, 2030

CBP Fatigue

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

Tianeptine - Neurocognitive Dysfunction

Patent No.	Title	Country / Region	Expiration Date
9,314,469	Method for Treating Neurocognitive Dysfunction	U.S.A.	September 24, 2030
2723688	Method for Treating Neurodegenerative Dysfunction	Canada	April 30, 2029
2299822 (602009047361.1 in Germany)	Method for Treating Neurodegenerative Dysfunction	Europe – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	April 30, 2029
3246031	Method for Treating Neurodegenerative Dysfunction	Europe – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	April 30, 2029

Eutectic CBP/Amitriptyline

Patent No.	Title	Country / Region	Expiration Date
631152	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand	March 14, 2034
9,636,408	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
9,956,188	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
10,117,936	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
6310542	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan	March 14, 2034
6088	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Saudi Arabia	March 14, 2034
IDP000055516	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia	March 14, 2034

Pending Patent Applications

Our current pending patent applications are as follows:

CBP/Amitriptyline Eutectic Formulations

Application No.	Title	Country / Region
15/941,484	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
15/511,287	Eutectic Formulations of Cyclobenzaprine Hydrochloride (Allowed)	U.S.A.
16/140,090	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
16/140,105	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	Pharmaceutical Composition, Method of Fabrication, Eutectic Composition and Use of Compositions Containing Cyclobenzaprine HCl and Mannitol	Brazil
BR112017005231-8	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 (Allowed)	China
201580050140.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China
14762323.5	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride (Allowed)	European Patent Office
15841528.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride	European Patent Office
16106690.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
18101200.4	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Hong Kong
P00201702438	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Indonesia
P00201808623	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia
241353	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Israel
251218	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Methods of Producing Same	Israel
3392/KOLNP/2015	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	India
201717013182	Eutectic Formulations of Cyclobenzaprine Hydrochloride	India
2017-535609	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan
2018-27899	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan

Application No.	Title	Country / Region
2018-173466	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
730379	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand
747040	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand
517381123	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Saudi Arabia
11201701995P	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Singapore
10201707528W	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Singapore
2015/07443	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride (Allowed)	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

Sublingual CBP/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
2018241128	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
2013/37088	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
2017-192713	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
10201605407T	Compositions and Methods for Transmucosal Absorption	Singapore
107117266	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

CBP - PTSD

Application No.	Title	Country / Region
15/915,688	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	

CBP - Sleep Disorder

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.

CBP - Agitation in Neurodegenerative Condition

Application No.	Title	Country / Region
16/215,952	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	U.S.A.
PCT/IB2018/001509	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	PCT

CBP - Depression

Application No.	Title	Country / Region
13/412,571	Methods and Compositions for Treating Depression Using Cyclobenzaprine	U.S.A.
2018204633	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 (Allowed)	European Patent Office

Tianeptine - Oxalate - Salts and Crystalline Forms

Application No.	Title	Country / Region
15/856,818	Tianeptine Oxalate Salts and Polymorphs	U.S.A.
PCT/IB2017/001709	Tianeptine Oxalate Salts and Polymorphs	PCT

Tianeptine Neurocognitive Dysfunction

Application No.	Title	Country / Region
15/064,196	Method for Treating Neurocognitive Dysfunction	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
15/802,189	Synthetic Chimeric Poxviruses	U.S.A.
P 20170103043	Synthetic Chimeric Poxviruses	Argentina
2017/34209	Synthetic Chimeric Poxviruses	Gulf Cooperation
106137976	Synthetic Chimeric Poxviruses	Council Taiwan
2017-000418	Synthetic Chimeric Poxviruses	Venezuela
PCT/US2017/059782	Synthetic Chimeric Poxviruses	PCT

Synthetic Vaccinia Virus

Application No.	Title	Country / Region
62/665,973	Synthetic Chimeric Vaccinia Virus	U.S.A.

Stem Cells-scPV Treatment

Application No.	Title	Country / Region
62/666,013	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	U.S.A.

CBP - ASD and PTSD

Application No.	Title	Country / Region
62/720,063	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	U.S.A.

Trademarks and Service Marks

We seek trademark and service mark protection in the United States and outside of the United States where available and when appropriate. 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 7 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.

Manufacturing

We have contracted with third-party cGMP-compliant contract manufacturer organization, or CMOs, for the manufacture of Tonmya and TNX-102 SL drug substances and drug products for investigational purposes, including nonclinical and clinical testing. For Tonmya and TNX-102 SL, we have engaged a cGMP facility for manufacturing of to-be-marketed product for Phase 3 clinical and commercial. Our manufacturing operations are managed and controlled in Dublin, Ireland.

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

Our smallpox-preventing vaccine candidate is a biologic 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 Biologics License Application, or BLA, for biologic products;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with cGMP regulations; and

- FDA review and approval of the NDA or BLA prior to any commercial marketing, sale or shipment of the drug.

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

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

Clinical Trials

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

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

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

- Phase 2 clinical trials are generally conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks. Phase 2 clinical trials, in particular Phase 2b trials, can be undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites.

- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

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

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

New Drug Applications

Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA (or BLA, in the case of a biologic product). An NDA or BLA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA or BLA 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 and BLAs 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 or BLA 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 or BLA 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 or BLA 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 or BLA. 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 or BLA 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 a safety 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, or BTD, to Tonmya for the treatment of PTSD. The Breakthrough Therapy designation was granted based on the preliminary clinical evidence of Tonmya on military-related PTSD in the Phase 2 AtEase study.

In March 2019, the BTD for Tonmya for PTSD was rescinded because the IA results of the HONOR study did not meet the criteria for the BTD granted in December 2016. The rescission of BTD of Tonmya for PTSD does not alter our plan for developing and obtaining regulatory approval for Tonmya, and we expect it will have minimum impact on our future interactions with the FDA.

Fast Track Designation

A Fast Track is a designation by the FDA of an investigational drug which:

- intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and
- non-clinical or clinical data demonstrate the potential to address an unmet medical need

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The benefits of a Fast Track designation include rolling submission of portions of the NDA for the drug candidate and eligibility for priority review of the NDA. Additionally, more frequent meetings and written communication with the FDA regarding the development plan and trial design for the drug candidate are encouraged throughout the entire drug development and review process, with the goal of having earlier drug approval and access for patients.

In April 2018, FDA cleared our IND for TNX-102 SL for treatment of AAD to support a Phase 2, potential pivotal efficacy study, and granted TNX-102 SL for the treatment of AAD Fast Track development program in July 2018.

Material Threat Medical Countermeasures

In 2016, the 21st Century Cures Act, or 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 application; it shortens the FDA review timeline for a new application from 10-12 months to 6 months. The recipient of a priority review voucher may transfer it. We intend to seek a priority review voucher for TNX-801 licensure as a material threat medical countermeasure. However, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed.

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.

Coverage and Reimbursement

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

Other Healthcare Laws

Because of our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors, we will also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both. The U.S. laws that may affect our ability to operate, among others, include: the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; certain state laws governing the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

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 expired 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.

We expect that additional federal and state, as well as foreign, healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or additional pricing pressure.

Employees

As of March 13, 2019, we had 12 full-time employees, of whom three hold M.D. or Ph.D. degrees. We have seven employees dedicated to research and development. Our research and development operations are located in New York, NY, San Diego, CA, Dublin, Ireland and Montreal, Canada. We have used, and expect to continue to use, third parties to conduct our nonclinical and clinical studies as well as part-time employees. None of our employees are represented by a collective bargaining agreement, and we believe that our relations with our employees are good.

Corporate Information

We lease the space for our principal executive offices, which are located at 509 Madison Avenue, Suite 1608, New York, New York 10022, and our telephone number is (212) 980-9155. Our website addresses are www.tonixpharma.com, www.tonix.com, and www.krele.com. We do not incorporate the information on our websites into this annual report, and you should not consider such information part of this annual report.

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

Item 1A. Risk Factors

RISKS RELATED TO OUR BUSINESS

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

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

We and our prospects should be examined in light of the risks and difficulties frequently encountered by new and early-stage companies in new and rapidly evolving markets. These risks include, among other things, the speed at which we can scale up operations, our complete dependence upon development of our product candidates 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.

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; successfully commercializing our products; establishing a favorable competitive position; and raising sufficient funds to finance our activities. Many of these factors will depend on circumstances beyond our control. 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, among other things:

- 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 ability to establish or maintain collaborations, licensing or other arrangements;

- market acceptance of our product candidates;

- 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; and

- potential product liability claims;

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

RISKS RELATED TO PRODUCT DEVELOPMENT, REGULATORY APPROVAL, MANUFACTURING AND COMMERCILAIZATION

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.

Further, 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 one product candidate, TNX-102 SL, ready to resume Phase 3 FM clinical development, 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.

As we have no approved products on the market, we 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.

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.

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 pharmaceutical 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 the Phase 3 AFFIRM trial for a product candidate for fibromyalgia, we were not able replicate the results we had in the Phase 2b BESTFIT trial using TNX-102 SL 2.8 mg dose in September 2016, and as a result temporarily discontinued this program but subsequently resumed the clinical development using the 5.6 mg dose in March 2019. 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.

We 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 civilian and military-related PTSD in the first quarter of 2019. 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 and clinical testing of drug candidates and the commercialization of drug, we have conducted only two pivotal clinical study before (the HONOR study in PTSD participants and 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 serious adverse events, or 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 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 notwithstanding the FDA's BTD rescission in March 2019 of its previously granted Breakthrough Therapy designation for Tonmya, 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.

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.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for TNX-102 SL for the treatment of agitation in Alzheimer's disease and may seek fast track designation for other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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.

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.

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.

RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS; COMPETITION

We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2018 with respect to our ability to continue as a going concern.

In their report dated March 18, 2019, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern as we have incurred losses since inception, have a negative cash flow from operations, and require additional financing to fund future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities

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 drug product candidate, Tonmya, 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 or similar 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.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY RIGHTS AND REGULATORY EXCLUSIVITY

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.

GENERAL COMPANY-RELATED RISKS

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 contract research organizations, or 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 RECOVERY study, will require a sufficiently large number of participants to evaluate the effectiveness and safety of Tonmya in PTSD. 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 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, Phase 3 HONOR study and is directing the Phase 3 RECOVERY 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 or TNX-102 SL, we may not be successful in negotiating acceptable terms with any of them.

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

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

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

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

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 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.

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.

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other health care laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers, and their respective business associates;

- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and

- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Coverage and adequate reimbursement may not be available for our current or any future drug candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any drug candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future drug candidates that we develop.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the PPACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. The Budget Resolution is not a law, however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The PPACA remains subject to legislative efforts to repeal, modify or delay the implementation of the law. Recent efforts to repeal, modify or delay implementation of the ACA have resulted in some level of success. If the PPACA is repealed or further modified, or if implementation of certain aspects of the PPACA are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the PPACA on us at this time. Due to the substantial regulatory changes that will need to be implemented by CMS and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

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 $1,000,000 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 review 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 10-12 months to 6 months. The recipient of a priority review voucher may transfer it.

We intend to seek a priority review 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. Moreover, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed. As such, the market for the TNX-801 will be limited if we are successful in obtaining a priority review voucher, assuming that the Priority Review Voucher Program is in effect at the time TNX-801 is available for licensing.

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 under the tradename Imvamune®, which may compete with TNX-801. As such, even if TNX-801 were to receive FDA licensure, 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.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the NASDAQ Global Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

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, disapproval or delay of approval 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 March 13, 2019, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 26% 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.

Other companies may have difficulty acquiring us, even if doing so would benefit our stockholders, due to provisions under our corporate charter and bylaws, as well as Nevada law.

Provisions in our articles of incorporation, our bylaws, and under Nevada law could make it more difficult for other companies to acquire us, even if doing so would benefit our stockholders. Our articles of incorporation and bylaws contain the following provisions, among others, which may inhibit an acquisition of our company by a third party:

- advance notification procedures for matters to be brought before stockholder meetings

- a limitation on who may call stockholder meetings
- a limitation on the removal of directors
- the ability of our board of directors to issue up to 5,000,000 shares of preferred stock without a stockholder vote

We are also subject to provisions of Nevada law that prohibit us from engaging in any business combination with any "interested stockholder," meaning generally that a stockholder who beneficially owns 10 percent or more of our stock cannot acquire us for a period of time after the date this person became an interested stockholder, unless various conditions are met, such as approval of the transaction by our board of directors and stockholders.

ITEM 1B – UNRESOLVED STAFF COMMENTS

There are no unresolved staff comments at December 31, 2018.

ITEM 2 – PROPERTIES

We maintain our principal office at 509 Madison Avenue, Suite 1608, New York, New York 10022. Our telephone number at that office is (212) 980-9155 and our fax number is (212) 923-5700. On December 6, 2018, we entered into a lease amendment, whereby we agreed to lease new office space, commencing January 15, 2019 and expiring on November 30, 2020. In connection therewith, we maintain a letter of credit, which has a remaining balance of $99,479 as of December 31, 2018, and such amount is deposited into the restricted cash account maintained at the bank that issued the letter of credit. The total square footage of our principal office space is approximately 2,658.

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. In November 2018, we signed a one-year extension, expiring on November 30, 2019.

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

Year Ending December 31,	
2019	$ 341
2020	200
	$ 541

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

ITEM 3 – LEGAL PROCEEDINGS

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

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Price Range of Common Stock

Our common stock is listed on The NASDAQ Global Market under the symbol "TNXP". The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported by The NASDAQ Stock Market, after giving effect to the 1-for-10 reverse stock split, which was effected on November 28, 2018.

	Fiscal Year 2018	
	High	Low
First Quarter	$ 43.50	$ 29.00
Second Quarter	$ 51.10	$ 27.00
Third Quarter	$ 48.00	$ 5.80
Fourth Quarter	$ 9.88	$ 1.70

	Fiscal Year 2017	
	High	Low
First Quarter	$ 94.00	$ 33.01
Second Quarter	$ 58.10	$ 38.00
Third Quarter	$ 47.70	$ 28.50
Fourth Quarter	$ 49.90	$ 33.10

On March 13, 2019, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was $2.58 per share. On March 13, 2019, there were 104 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

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

Equity Compensation Information

The following table summarizes information about our equity compensation plans as of December 31, 2018.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders	137,145	$ 143.09	118,496
Equity compensation plans not approved by stockholders	—	—	—
Total	137,145	$ 143.09	118,496

Recent Sales of Unregistered Securities

None.

Repurchases of Equity Securities by the Issuer and Affiliated Purchasers

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

ITEM 6 – SELECTED FINANCIAL DATA

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

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a number of forward-looking statements that reflect Management's current views with respect to future events and financial performance. You can identify these statements by forward-looking words such as "may" "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. Those statements include statements regarding the intent, belief or current expectations of us and members of its management team as well as the assumptions on which such statements are based and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report and in other reports we file with the Securities and Exchange Commission, particularly those under "Risk Factors.".

Business Overview

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Our most advanced drug development program is focused on delivering a safe and effective long-term treatment for posttraumatic stress disorder, or PTSD. PTSD is characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in the fields of PTSD, other central nervous system disorders and biodefense.

In June 2017, the U.S. Food and Drug Administration, or 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 a New Drug Application, or NDA, approval. The U.S. Patent and Trademark Office, or PTO, has granted the federal registration of the Tonmya mark.

Our lead product candidate, Tonmya, or TNX-102 SL, a proprietary low-dose cyclobenzaprine, or CBP, sublingual tablet, designed for bedtime administration, is in Phase 3 development as a potential treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for Fibromyalgia, or FM, and agitation in Alzheimer's disease, or AAD, under separate INDs to support potential pivotal efficacy studies. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but using a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication: neurocognitive dysfunction associated with corticosteroid use. Phase 1 clinical study of TNX-601 selected oral formulation will be conducted outside of the U.S. in 2019. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. TNX-701 is a biodefense development program for protection from radiation injury. We are currently not performing any activities and have no future plans related to TNX-301 an IND candidate for the treatment of alcohol use disorder. We hold worldwide development and commercialization rights to all of our product candidates.

Posttraumatic Stress Disorder Program

Clinical Development Plan

Phase 3 HONOR Study

In the third quarter of 2018, we announced the results of a randomized, double-blind, placebo-controlled Phase 3 study of Tonmya, planned for enrollment of approximately 550 participants with military-related PTSD, which we refer to as the HONOR study. The primary efficacy endpoint of the HONOR study was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5, or CAPS-5, between those treated with Tonmya and those receiving placebo. This study was an adaptive design study based on the results of the Phase 2 AtEase study. The study design was very similar to the Phase 2 AtEase study, except there was one planned interim analysis, or IA, and the involvement of an independent data monitoring committee, or IDMC, which reviewed the unblinded IA results. In addition, only one active dose (5.6 mg administered as 2 x 2.8 mg tablets) was investigated and the baseline severity entrance criterion was a CAPS-5 total score $\geq$ 33 in this Phase 3 study. The IA was conducted when approximately 50% of the initially planned participant enrollment was evaluable for efficacy. The HONOR study was conducted at approximately 40 U.S. sites. The HONOR study was discontinued after the results of the IA indicated a pre-defined threshold p-value for continuing enrollment was not achieved. The modified Intent-to-Treat (mITT) population analyzed at the time of the IA included 252 participants.

The HONOR study demonstrated that Tonmya was well tolerated and that the 5.6 mg dose (administered as 2 x 2.8 mg tablets) showed meaningful improvement in overall PTSD symptoms at Week 4. At Week 4, the Tonmya treated group separated from placebo in CAPS-5 (p = 0.019) and in the Clinical Global Impression – Improvement (CGI-I) scale (p = 0.015), a key secondary endpoint. A CGI-I responder analysis, with responder defined as 'much improved' or 'very much improved' on the CGI-I, demonstrated significantly greater responders in the Tonmya group (29.1% v 45.6%; p=0.007) at week 4. Also, at Week 4, sleep quality improved as measured by both the PROMIS sleep disturbance scale (p=0.015) and the CAPS-5 sleep disturbance item (p=0.002), supporting the proposed mechanism of action of Tonmya. And the CAPS-5 reckless or self-destructive behavior item at week 4 was significantly more improved (p=0.013). Safety data from these participants did not reveal any serious and/or unexpected adverse events. The most common adverse events were mostly related to local administration site reactions, such as oral hypoaesthesia (37.3%), abnormal product taste (11.9%), and oral paraesthesia (9.7%). The most common systemic adverse event was somnolence (15.7%).

Retrospective analysis of the HONOR study revealed a treatment effect in participants who experienced trauma less than or equal to 9 years prior to screening. In the patients who experienced trauma within 9 years, the p-value of the primary endpoint at Week 12, using mixed model repeated measures with multiple imputation (MMRM with MI), was 0.039, with a least-squares mean difference from placebo of -5.9 units. In contrast, there was no benefit in the participants who experienced trauma more than 9 years prior to screening. This analysis defined an optimal treatment window for treatment with TNX-102 SL for PTSD of the first 9 years after the index trauma.

Phase 2 AtEase Study

In the second quarter of 2016, we announced the results of 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 AtEase study demonstrated that Tonmya was well tolerated and that the 5.6 mg dose of Tonmya had a therapeutic effect as assessed by the CAPS-5 scale, a standardized structured clinician interview considered the gold standard in clinical research and regulatory approval for measuring the symptom severity of PTSD, which was statistically significant by MMRM with MI analysis (p-value = 0.031). AtEase also demonstrated that although the 2.8 mg dose trended in the direction of a therapeutic effect, it did not reach statistical significance on the primary endpoint, a 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale.

Four distinct SAEs were reported in the AtEase 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. Systemic adverse events that were potentially dose-related and occurred in greater than or equal to 5% of participants treated with the Tonmya 2.8 mg or 5.6 mg dose included: somnolence (drowsiness), dry mouth, headache, insomnia, and sedation. 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 8.5% in placebo, 7.5% in Tonmya 2.8 mg, and 6.0% in Tonmya 5.6 mg.

The primary MMRM analysis of the AtEase study, which controlled for baseline severity, indicated greater response to Tonmya 5.6 mg in those with greater PTSD severity by CAPS-5 at baseline. As the first industry PTSD trial to employ the CAPS-5 (based on the DSM-5 published in 2013), it was not clear what was the ideal severity threshold for randomization into the study comparable to the standard threshold used in precedent studies that employed prior versions of the CAPS. Retrospective analysis imputing scores for all participants assuming a prior version of CAPS suggested a CAPS-5 baseline threshold for randomization of 33 or higher was equivalent to the threshold used in precedent PTSD studies on prior CAPS versions.

A retrospective analysis of the subgroup of participants in AtEase with baseline CAPS-5 score of 33 or higher supported the hypothesized mechanism of sleep quality improvement, since 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), whereas these measures were not related in placebo.

Ongoing Phase 3 RECOVERY Study

We recently commenced the RECOVERY study, a randomized, double-blind, placebo-controlled Phase 3 study of Tonmya in approximately 250 participants with military-related and civilian PTSD in the first quarter of 2019. The design of this study was guided based on the results of the Phase 3 HONOR study and Phase 2 AtEase study. The RECOVERY study design is similar to the Phase 3 HONOR study, except the new trial incorporates several new design features including restricting enrollment of study participants to individuals with PTSD who experienced an index trauma within 9 years of screening, instead of 2001 or later. The RECOVERY study will also include participants who have experienced civilian traumas in addition to those with military-related traumas. The primary endpoint, mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5, is the same as that used in the Phase 3 HONOR study and the Phase 2 AtEase study, but the CAPS-5 primary endpoint will be assessed at Week 4 instead of at Week 12. CAPS-5 change at Week 12 will be the first key secondary endpoint. We received FDA acceptance of the Phase 3 RECOVERY study design in November 2018. The RECOVERY study is being conducted at approximately 30 U.S. sites with topline data expected in the first half of 2020.

Regulatory Update

Subsequent to reporting the Phase 2 AtEase study topline result, we held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in August 2016 to review the Phase 2 AtEase study results and discuss the Phase 3 study required to support the registration of Tonmya for the treatment of PTSD and the remaining data package for the NDA filing.

In December 2016, Tonmya for the treatment of PTSD was designated as a Breakthrough Therapy by the FDA based on the preliminary clinical evidence of Tonmya on military-related PTSD in the Phase 2 AtEase study. In March 2019, the BTD for Tonmya for PTSD was rescinded because the IA results of the HONOR study did not meet the criteria for the BTD granted in December 2016. The rescission of BTD of Tonmya for PTSD does not alter our plan for developing and obtaining regulatory approval for Tonmya.

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. 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 September 2017, we had a Breakthrough Therapy Chemistry, Manufacturing and Controls ("CMC") guidance meeting with the FDA regarding the CMC data required to support the Tonmya NDA and commercial product. In principle, our proposed CMC data package to support Tonmya's NDA approval and commercial manufacturing plans was acceptable to the FDA.

Subsequent to reporting the Phase 3 HONOR study IA results, we held a Type B Clinical Guidance Meeting with the FDA in October 2018 to discuss the Phase 3 HONOR study results and the proposed design of the new Phase 3 RECOVERY study to support the registration of Tonmya for the treatment of PTSD and the remaining data package for the NDA filing. We received FDA's acceptance of the RECOVERY trial design in November 2018.

In October 2018, we held a Breakthrough Type B CMC Guidance teleconference meeting with the FDA to seek acceptance of the proposed regulatory specifications for TNX-102 SL commercial product.

Fibromyalgia program

We are developing TNX-102 SL as a bedtime treatment of FM. FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. The peak incidence of FM occurs between 20 to 50 years of age, and 80 to 90% of diagnosed patients are female. FM may have a substantial negative impact on social and occupational function. TNX-102 SL 2.8 mg for FM has been in Phase 3 development since 2015. However, based on the more promising efficacy results in PTSD with the higher TNX-102 SL 5.6 mg dose in the Phase 2 AtEase study, especially on pain in PTSD with the 5.6 mg (2 x 2.8 mg tablets) dose over the 2.8 mg dose, we temporary discontinued the FM clinical development with the 2.8 mg dose in September 2016 for business reasons.

Supported by the encouraging pain data with TNX-102 SL 5.6 mg in PTSD, we are continuing the TNX-102 SL FM clinical development with the 5.6 mg dose.

Clinical Development Plan

Phase 3 AFFIRM Study

In the third quarter of 2016, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 3 study of TNX-102 SL in 519 participants with FM, which we refer to as the AFFIRM study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 2.8 mg, administered sublingually once daily at bedtime for 12 weeks. The primary endpoint of the AFFIRM trial was the FDA-agreed upon 30% pain responder analysis in which a responder is defined as a subject for whom pain intensity was reduced by at least 30% at week 12 as compared to baseline. AFFIRM did not achieve statistical significance at the primary endpoint ($p=0.095$). Yet, statistical significance was achieved when pain was analyzed instead as a continuous variable, either by MMRM ($p<0.001$) or by MMRM with multiple imputation for missing data ($p=0.005$), a generally accepted approach to pain data. TNX-102 SL also showed statistically significant improvements in the declared secondary analyses of the Patient Global Impression of Change, or PGIC ($p=0.038$) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R ($p<0.001$). The study also showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, Sleep Disturbance instrument ($p<0.001$). TNX-102 SL was well tolerated in the AFFIRM study. Among patients randomized to the active and control groups, 78% and 86%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 40% of participants on TNX-102 SL vs. 1% on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

We believe that given the consistent results of the analyses of pain as a continuous endpoint, as well as the nominal significance shown on multiple key secondary endpoints, TNX-102 SL 2.8 mg taken daily at bedtime for 12 weeks can be beneficial in this typical fibromyalgia population. However, based on the more promising efficacy results in PTSD with the higher TNX-102 SL 5.6 mg dose in the Phase 2 AtEase study, especially on pain in PTSD with the 5.6 mg (2 x 2.8 mg tablets) dose over the 2.8 mg dose, we temporary discontinued the FM clinical development with the 2.8 mg dose in September 2016 for business reasons.

TNX-102 SL was well tolerated in the AFFIRM trial. Among patients randomized to the active and control arms, 78% and 86%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 40% of participants on TNX-102 SL vs. 1% on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Phase 2b BESTFIT Study

In the third quarter of 2014, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 2b study of TNX-102 SL in 205 participants with FM, which we refer to as the BESTFIT study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 2.8 mg, administered sublingually once daily at bedtime for 12 weeks. The primary outcome measure of the BESTFIT trial was the mean change in week 12 average daily pain intensity from baseline on the 11-point Numeric Rating Scale (NRS), using a daily telephonic diary. BESTFIT did not achieve statistical significance in the primary outcome measure (p=0.172), whereas TNX-102 SL 2.8 mg did show a statistically significant effect on pain as measured by a 30% responder analysis of the primary pain data (p=0.033). The 30% response rate in the final analysis was 34.0% in the active treatment arm as compared to 20.6% in the control arm. The BESTFIT trial also showed statistically significant improvements with TNX-102 SL in the declared secondary analyses of the PGIC (p=0.025) and the FIQ-R (p=0.015). The study showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the PROMIS, Sleep Disturbance instrument (p=0.004). In addition, statistically significant improvements with TNX-102 SL were observed on several FIQ-R items (pain, sleep quality, anxiety, stiffness, and sensitivity) as well as on the overall symptom subdomain.

TNX-102 SL was well tolerated in the BESTFIT trial. Among patients randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 44% of participants on TNX-102 SL vs. 2% on placebo, and bitter taste in 8% on TNX-102 SL compared to none on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Regulatory Update

In December 2016, we notified FDA in our IND annual update that the FM development program was put on hold for business reasons after the Phase 3 AFFIRM study topline data was reported in September 2016.

In April 2017, we withdrew the proposed proprietary name, Tonmya, for TNX-102 SL for FM.

In March 2019, we had a Type C Clinical Guidance meeting with the FDA to discuss our plan to resume the clinical development of the TNX-102 SL 5.6 mg dose for the treatment of FM. The design of the planned Phase 3 study was discussed with the FDA.

Agitation in Alzheimer's Disease Program

TNX-102 SL is also being developed as a bedtime treatment for agitation in Alzheimer's disease, or AAD, under a separate Investigational New Drug application or IND.

Regulatory Update

In November 2017, we held a pre-IND meeting with the FDA to discuss our proposed development of TNX-102 SL for the treatment of agitation in Alzheimer's disease. In April 2018, the FDA cleared our IND to support a Phase 2 potential pivotal efficacy study.

In July 2018, the FDA granted Fast Track Therapy designation to TNX-102 SL for the treatment of agitation in Alzheimer's disease.

In September 2018, we received FDA comments on our proposed Phase 2 potential pivotal efficacy study protocol.

Patent update

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 or TNX-102 SL 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.

On September 13, 2017, we were issued European patent 2,501,234 "Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine". This patent recites the use of CBP for the treatment of PTSD, which covers the use of Tonmya for the treatment of PTSD, since the active ingredient in Tonmya is CBP. The patent is expected to provide Tonmya with European market exclusivity until 2030.

On December 15, 2017 we were issued Japanese Patent No. 6259452, "Compositions and Methods for Transmucosal Absorption," by the Japanese Patent Office (JPO) relating to the pharmacokinetic profile of Tonmya, or TNX-102 SL.

On March 20, 2018, we were issued U.S. patent 9,918,948 "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. A The patent is expected to provide Tonmya with U.S. market exclusivity until 2030 for the allowed claims when the patent is issued. This method of use patent for Tonmya extends upon previously granted patents related to the composition of matter (U.S. Patent No. 9,636,408) and the active ingredient in Tonmya (European Patent No. 2,501,234) as described above.

On March 23, 2018, we were issued Japanese Patent No. 6310542 "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride. This patent recites pharmaceutical compositions comprising the eutectics and methods of manufacturing these eutectic formulations.

On May 1, 2018, we were issued U.S. Patent No. 9,956,188 "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride". The patent recites a eutectic of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034.

On November 6, 2018, we were issued U.S. Patent No. 10,117,936 "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride". The patent recites pharmaceutical compositions of eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions. The patent is expected to provide Tonmya with U.S. market exclusivity until 2034.

On February 27, 2019, European Patent No. 3,246,031 entitled "Method for Treating Neurodegenerative Dysfunction", issued. The claims recite the use of TNX-601, or tianeptine oxalate and other salts, for treating neurocognitive dysfunction associated with corticosteroid treatment. This patent provides TNX-601 with European market exclusivity until April 2029 and may be extended based on the timing of the European market authorization of TNX-601 for neurocognitive disfunction associated with corticosteroid treatment.

Additional Product Candidates

We also have a pipeline of other drug and biologic candidates, including two pre-IND candidates, TNX-601 (tianeptine oxalate) for PTSD and neurocognitive dysfunction, and TNX-801, a potential smallpox-preventing vaccine, an IND candidate, and TNX-701, a biodefense development program for protection from radiation injury. We are currently not performing any activities and have no future plans related to TNX-301 an IND candidate for the treatment of alcohol use disorder. 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 daytime treatment for PTSD and neurocognitive dysfunction. 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 (Noyce RS, et. al. 2018 PLoS ONE 13(1)). 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 meet with the FDA to discuss the most efficient and appropriate investigational plan, e.g., the application of the Animal Rule, or conducting active comparator study using ACAM2000, to establish the safety and effectiveness evidence to support the licensure TNX-801. 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, or PPACA. 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. However, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed. We are currently working to develop a vaccine that meets cGMP quality to support an IND study.

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. 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 effort on our other pipeline programs, including TNX-601, and TNX-801. 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.

Fiscal year Ended December 31, 2018 Compared to Fiscal year Ended December 31, 2017

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2018 were $17.6 million, an increase of $4.3 million, or 32%, from $13.3 million for the fiscal year ended December 31, 2017. This increase is predominately due to the continued development work related to the PTSD program which resulted in a $3.9 million and $0.2 million increase in clinical and manufacturing expenses, respectively.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2018 were $8.8 million, an increase of $0.8 million, or 10%, from $8.0 million incurred in the fiscal year ended December 31, 2017. This increase is primarily due to an increase in legal fees of $0.6 million predominately due to increased patent prosecution costs and an increase in investor and public relations expenses of $0.2 million due to increased investor meetings.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2018 was $26.1 million, compared to a net loss of $21.1 million for the year ended December 31, 2017.

Liquidity and Capital Resources

As of December 31, 2018, we had working capital of $23.4 million, comprised primarily of cash and cash equivalents of $25.0 million and prepaid expenses and other of $1.0 million, offset by $1.4 million of accounts payable and $1.3 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our Phase 3 clinical trial of Tonmya in PTSD. For the years ended December 31, 2018 and 2017, we used approximately $24.0 million and $19.1 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The decrease in cash outlays principally resulted from a reduction in clinical, non-clinical, manufacturing and regulatory cost activities. For the year ended December 31, 2018, net proceeds from financing activities were $23.5 million, predominately from the sale of our common stock and warrants. In the comparable 2017 period, approximately $18.5 million was raised through the sale of shares of common stock.

Cash used by investing activities for the year ended December 31, 2018 was approximately $6,000, related to the purchase of furniture and fixtures. Cash provided by investing activities for the year ended December 31, 2017 was $7.2 million which was predominately related to the maturity of marketable securities.

We believe that our cash resources will be sufficient to meet our projected operating requirements through the end of 2019, but we do not have enough resources to meet our operating requirements for the one-year period from the date of filing of this Form 10-K.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes we may make in our research and development spending plans. These factors raise substantial doubt about our ability to continue as a going concern for the one year period from the date of filing of this Form 10-K. We have the ability to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

December 2018 Financing

On December 7, 2018, we entered into an underwriting agreement with Alliance Global Partners ("AGP") and Dawson James Securities, Inc. ("Dawson") (collectively "the Underwriters") pursuant to which we sold securities consisting of 861,710 Class A Units at a public offering price of $3.50 per unit, with each unit consisting of one share of Common Stock and a Warrant to purchase one share of Common Stock, and 11,984 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of $3.50 per share, and Warrants to purchase 285.7143 shares of Common Stock. The Warrants have an exercise price of $3.50, are exercisable upon issuance and expire five years from the date of issuance.

We also granted the underwriters a 45-day option to purchase up to 642,856 shares of common stock and/or additional Warrants to purchase up to 642,856 additional shares of common stock.

The December 2018 Financing closed on December 11, 2018. The Underwriters purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately $1.1 million. We received net proceeds from the December 2018 Financing of approximately $13.6 million, after deducting the underwriting discount and other offering expenses of approximately $0.4 million. Additionally, the Underwriters fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 640,000 shares of common stock for net proceeds of approximately $6,000.

On December 13, 2018, the 2018 Underwriters partially exercised the over-allotment option and purchased 250,000 shares of common stock for net proceeds of approximately $0.8 million, net of an aggregate discount of $0.1 million (or $0.24 per share).

After allocating proceeds to the warrants issued with the Series A convertible preferred stock, the effective conversion price of the Series A convertible preferred Stock, after the bifurcation of the warrants, was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature ("BCF") at that date. Since the Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF was charged to additional paid in capital as a "deemed dividend" and impacted earnings per share. We recognized a one-time non-cash deemed dividend of $3.3 million for the beneficial conversion feature resulting from the intrinsic value of the conversion options of the preferred stock.

During the year ended December 31, 2018, 2,128 shares of Series A convertible preferred stock were converted into 608,000 shares of common stock. As of March 13, 2019, all Series A convertible preferred stock has been converted into common stock.

2018 At-the-Market Offering

On May 1, 2018, we entered into a sales agreement (the "Sales Agreement"), with Cowen and Company, LLC., ("Cowen"), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $9.5 million in at-the-market offerings ("ATM") sales. On the same day, we filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen acted as sales agent and was paid a 3% commission on each sale under the Sales Agreement. Our common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied.

During the year ended December 31, 2018, we sold an aggregate of approximately 593,000 shares of common stock using the ATM, resulting in net proceeds of $6.9 million, net of expenses of approximately $0.2 million of Cowen's commission.

2018 Lincoln Park Transaction

On October 18, 2018, we entered into a purchase agreement (the "2018 Purchase Agreement") and a registration rights agreement (the "2018 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2018 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 2018 Purchase Agreement. Pursuant to the terms of the 2018 Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2018 Purchase Agreement.

Pursuant to the terms of the 2018 Purchase Agreement, at the time we signed the 2018 Purchase Agreement and the 2018 Registration Rights Agreement, we issued 35,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2018 Purchase Agreement. The commitment shares were valued at $245,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2018 Purchase Agreement.

Regular Purchases

Under the 2018 Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 7,500 shares of our common stock on any such business day (a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 10,000 shares, provided that the closing sale price is not below $7.50 on the purchase date, (ii) the Regular Purchase may be increased to up to 12,500 shares, provided that the closing sale price is not below $10.00 on the purchase date, (iii) the Regular Purchase may be increased to up to 15,000 shares, provided that the closing sale price is not below $12.50 on the purchase date, (iv) the Regular Purchase may be increased to up to 17,500 shares, provided that the closing sale price is not below $20.00 on the purchase date. In each case, the maximum amount of any single Regular Purchase may not exceed $1,000,000 per purchase.

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 $7.50 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the 2018 Purchase Agreement), to purchase an additional amount of our common stock on the next business day (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.

Additional Purchases

In addition to the Regular Purchases and Accelerated Purchases described above, from time to time we may also direct Lincoln Park, on any business day that the closing price of our common stock is not below $7.50 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the 2018 Purchase Agreement), to purchase additional amounts of our common stock (an "Additional Accelerated Purchase"), not to exceed the lesser of:

- 96% of the volume weighted average price of our common stock during the applicable Additional Accelerated Purchase Measurement Period on the applicable Additional Accelerated Purchase date; and
- the closing sale price of our common stock on the applicable Additional Accelerated Purchase date.

Tranche Purchases

In addition to the Regular Purchases, Accelerated Purchases and the Additional Accelerated Purchases described above, from time to time we may also direct Lincoln Park, on any business day that the closing price of ours common stock is not below $1.00, to purchase additional amounts of its common stock (a "Tranche Purchase"), provided, however, that any single Tranche Purchase shall not exceed $400,000, and shall not exceed $2,000,000 in the aggregate, not to exceed the lesser of:

- $55.00 and
- 96% of the lower of (i) the lowest sale price of our common stock on the Tranche Purchase date and (ii) the arithmetic average of the three (3) lowest closing sale prices for our common stock during the ten consecutive business days ending on the day immediately preceding the Tranche Purchase date (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of this Agreement).

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 will not have enough resources to meet our operating requirements for the one-year period from the date of this report.

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, 2016 Stock Incentive Plan and 2017 Stock Incentive Plan (collectively, the "Prior Plans"). No future awards are issuable under these Prior Plans.

On June 8, 2018, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2018 Stock Incentive Plan (the "2018 Plan" and together with the Prior Plans, the "Plans"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the Prior Plans.

Under the terms of the 2018 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 2018 Plan provides for the issuance of up to 132,000 shares of common stock, which amount was (a) reduced by awards granted under the Prior Plans after March 1, 2018, and (b) will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2018 Plan). In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after March 1, 2018, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.23 shares for every one share that was subject to an award other than an option or SAR. The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2018 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 expiration period of grants under the 2018 Plan may not more than ten years. We reserved 132,000 shares of our common stock for future issuance under the terms of the 2018 Plan. As of December 31, 2018, 118,496 shares were available for future grants under the 2018 Plan.

We measure the fair value of stock options on the date of grant, based on the Black Scholes 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 issue options to directors which vest over a one-year period. 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.

The weighted-average grant-date fair value of stock options granted was $27.78 in 2018 and $29.20 in 2017.

Stock-based compensation expense relating to options granted of $1.6 million and $1.7 million was recognized for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, we had approximately $1.8 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 1.87 years.

Employee Stock Purchase Plan

We have issued awards under our 2014 Employee Stock Purchase Plan (the "2014 ESPP").

On June 8, 2018, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2018 Employee Stock Purchase Plan (the "2018 ESPP"). As a result of adoption of the 2018 ESPP by the stockholders, no further grants may be made under the 2014 ESPP.

The 2018 ESPP allows eligible employees to purchase up to an aggregate of 30,000 shares of our common stock. Under the 2018 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 2018 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 2018 ESPP, subject to the statutory limit under the Code.

As of December 31, 2018, there were 28,242 shares available for future issuance under the 2018 ESPP after taking into account the shares issued below.

The 2018 ESPP and 2014 ESPP are considered compensatory plans with the related compensation cost written off over the six-month offering period. The compensation expense related to the 2018 ESPP for the year ended December 31, 2018 was $32,000. The compensation expense related to the 2014 ESPP for the year ended December 31, 2017 was $36,000. As of December 31, 2018, approximately $38,000 of employee payroll deductions, which have been withheld since July 1, 2018, the commencement of the offering period ending December 31, 2018, are included in accrued expenses in the accompanying balance sheet. In January 2019, 1,758 shares that were purchased as of December 31, 2018, were issued under the 2018 ESPP, and approximately $3,000 of employee payroll deductions accumulated at December 31, 2018, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $35,000 was returned to the employees. In July 2017, 1,776 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. No employee deductions were withheld during 2017.

Restricted Stock Units

In February 2017, a total of 563 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 $38.10 at the date of grant. 563 shares of our common stock were issued upon the vesting of such RSU's during the quarter ended March 31, 2017.

In May 2017, a total of 563 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. 488 shares of our common stock were issued upon the vesting of such RSU's during the year ended December 31, 2017. The remaining 75 shares of common stock were issued during the three months ended March 31, 2018.

Stock-based compensation expense related to RSU grants was $0 and $72,000 for the three and twelve months ended December 31, 2017, respectively. There is no stock-based compensation related to RSU's in 2018.

Commitments

Research and Development Contracts

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $5.5 million at December 31, 2018 for future work to be performed.

Operating Leases

Future minimum lease payments under operating leases were as follows (in thousands):

Year Ending December 31,		
2019	$	413
2020		212
2021		6
	$	631

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 contract research organizations and other third-party vendors.

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

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

On December 22, 2017, the United States enacted tax reform legislation through the Tax Cuts and Jobs Act, which significantly changes the existing U.S. tax laws, including a reduction in the corporate tax rate from 35% to 21%, a move from a worldwide tax system to a territorial system, a change in the treatment of operating loss carryforwards as well as other changes. As a result of enactment of the legislation, the Company anticipates a one-time change to its deferred tax assets and related valuation allowance. As the Company has a full valuation allowance such change is not expected to impact the Company's results of operations or financial position. All impacts of the Tax Act have been measured in the Company's income tax provision.

Accounting for sale of Class B Units in December 2018 including beneficial conversion feature. In connection with the December 2018 underwritten offering, we issued warrants to purchase our common stock and convertible preferred stock. To account for the transaction, we had to calculate the relative fair value of each instrument issued in the financing. We also had to determine if a beneficial conversion feature existed. A beneficial conversion feature is defined as a nondetachable conversion feature that is in the money at the commitment date. A conversion feature is in the money if its conversion price is less than the current fair value of the share. For purposes of measuring a beneficial conversion feature, the effective conversion price should be based on the proceeds allocated to the convertible instrument.

We determine the fair value of the warrant, using a Monte Carlo simulation, which is a statistical method used to generate a defined number of share price paths to develop a reasonable estimate of the range of future expected share prices. Estimates and assumptions impacting the fair value measurement include the warrant's callable feature, the number of shares for which the warrants are exercisable, remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying common shares. We estimate expected share volatility based on our historical volatility for a term equal to the contractual term of the warrants adjusted for a discount that a market participant would have taken when pricing the instrument. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We estimated a 0% expected dividend yield based on the fact that we have never paid or declared dividends and do not intend to do so in the foreseeable future. In general, the assumptions used in calculating the fair value of the warrant represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment. We determine the fair value of the convertible preferred stock utilizing the price of the common stock on the commitment date. We then allocated the relative fair value between the preferred shares and the warrants. Since the effective conversion price of the Preferred Stock is less than the fair value of the underlying common stock at the date of commitment, there is a beneficial conversion feature at the commitment date. Since the Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the beneficial conversion feature was charged to additional paid in capital as a "deemed dividend" and impacted earnings per share.

Recently Issued Accounting Pronouncements

In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. We adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. We have elected the 'package of practical expedients', which permit us not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. We do not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to us.

The new standard will have a material effect on our financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

Upon adoption, we will recognize operating lease liabilities of approximately $0.3 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. We expect to recognize corresponding ROU assets of approximately $0.3 million.

The new standard also provides practical expedients for an entity's ongoing accounting. We will elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Beginning in 2019, we expect changes to our disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. These revised disclosures will be made in our first quarterly report in 2019.

Off-Balance Sheet Arrangements

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retain or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. and subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has continuing losses and negative cash flows from operating activities which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2010.

EISNERAMPER LLP
New York, New York
March 18, 2019

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2018 AND 2017
(In Thousands, Except Par Value and Share Amounts)

	2018	2017
ASSETS		
Current assets:		
Cash	$ 25,034	$ 25,496
Prepaid expenses and other	1,022	947
Total current assets	26,056	26,443
Property and equipment, net	43	91
Restricted cash	100	89
Intangible Asset	120	120
Security deposits	—	11
Total assets	$ 26,319	$ 26,754
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,404	$ 1,296
Accrued expenses	1,251	830
Total current liabilities	2,655	2,126
Deferred rent payable	—	12
Total liabilities	2,655	2,138
Commitments (See Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized		
Series A Convertible Preferred stock, $0.001 par value; 11,984 shares designated; 9,856 and 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	—
Common stock, $0.001 par value; 15,000,000 shares authorized; 3,251,970 and 785,874 shares issued and outstanding as of December 31, 2018 and 2017, respectively, and 1,758 shares to be issued as of December 31, 2018	3	1
Additional paid in capital	212,154	186,990
Accumulated deficit	(188,452)	(162,363)
Accumulated other comprehensive loss	(41)	(12)
Total stockholders' equity	23,664	24,616
Total liabilities and stockholders' equity	$ 26,319	$ 26,754

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2018	**2017**
COSTS AND EXPENSES:		
Research and development	$ 17,558	$ 13,342
General and administrative	8,764	7,949
	26,322	21,291
Operating Loss	(26,322)	(21,291)
Interest income, net	233	168
Net loss	(26,089)	(21,123)
Preferred stock deemed dividend	3,266	—
Net loss available to common stockholders	$ (29,355)	$ (21,123)
Net loss per common share, basic and diluted	$ (26.81)	$ (31.69)
Weighted average common shares outstanding, basic and diluted	1,094,867	666,509

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2018	**2017**
Net loss	$ (26,089)	$ (21,123)
Other comprehensive loss:		
Foreign currency translation loss	(29)	(5)
Comprehensive loss	$ (26,118)	$ (21,128)

See the accompanying notes to the consolidated financial statements

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

	Series A Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2016	—	$ —	394,787	$ 1	$ 166,607	$ (7)	$ (141,240)	$ 25,361
Employee stock purchase plan	—	—	2,026	—	74	—	—	74
Issuance of common stock related to restricted stock units	—	—	1,050	—	—	—	—	—
Issuance of common stock in February 2017 ($50.90 per share), March 2017 ($45.00 per share) and April 2017 ($65.50 per share), net of transaction expenses of $280	—	—	148,648	—	9,062	—		9,062
Issuance of common stock in April 2017 ($44.50 per share, net of transaction expenses of $888)	—	—	207,000	—	8,325	—	—	8,325
Issuance of commitment shares in September 2017 ($41.10 per share)	—	—	7,304	—	—	—	—	—
Issuance of common stock in exchange for exercise of warrants in April 2017 ($63.00 per share)	—	—	225	—	14	—	—	14
Issuance of common stock in October 2017 ($45.60 per share, net of transaction expenses of $15)	—	—	24,834		1,118	—	—	1,118
Stock-based compensation	—	—	—	—	1,790	—	—	1,790
Foreign currency translation loss	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(21,123)	(21,123)
Balance, December 31, 2017	—	$ —	785,874	$ 1	$ 186,990	$ (12)	$ (162,363)	$ 24,616

See the accompanying notes to the consolidated financial statements

	Series A Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2017	—	$ —	785,874	$ 1	$ 186,990	$ (12)	$ (162,363)	$ 24,616
Issuance of common stock related to restricted stock units	—	—	75	—	—	—	—	—
Issuance of commitment shares in October 2018 ($7.00 per share)	—	—	35,000	—	—	—	—	—
Issuance of common stock under 2017 Purchase Agreement, net of transactional expenses of $45	—	—	117,961	—	2,315	—	—	2,315
Issuance of common stock under At-the-market offering, net of transactional expenses of $212	—	—	593,350	1	6,856	—	—	6,857
Issuance of Series A Convertible preferred stock and common stock warrants in December 2018 ($1,000.00 per unit, net of transactional expenses of $1,159)	11,984	—	—	—	10,825	—	—	10,825
Issuance of common stock and common stock warrants in December 2018 ($3.50 per unit, net of transaction expenses of $353)	—	—	1,111,710	1	3,541	—	—	3,542
Beneficial conversion feature in connection with issuance of Series A Convertible preferred stock	—	—	—	—	3,266	—	—	3,266
Preferred stock deemed dividend	—	—	—	—	(3,266)	—	—	(3,266)
Issuance of common stock upon conversion of Series A Convertible preferred stock	(2,128)	—	608,000	—		—	—	—
Stock-based								

compensation	—	—	—	—	1,627	—	—	1,627
Foreign currency transaction loss	—	—	—	—	—	(29)	—	(29)
Net loss	—	—	—	—	—	—	(26,089)	(26,089)
Balance, December 31, 2018	9,856	$ —	3,251,970	$ 3	$ 212,154	$ (41)	$ (188,452)	$ 23,664

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (26,089)	$ (21,123)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54	70
Stock-based compensation	1,627	1,790
Changes in operating assets and liabilities:	—	
Prepaid expenses	(79)	72
Accounts payable	106	424
Accrued expenses and deferred rent	410	(361)
Net cash used in operating activities	(23,971)	(19,128)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(6)	(5)
Maturities of marketable securities	—	7,174
Net cash provided by investing activities	(6)	7,169
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	—	14
Proceeds, net of $1,159 expenses, from sale of preferred stock	10,825	—
Proceeds, net of $610 and $1,183 expenses, from sale of common stock	12,714	18,505
Net cash provided by financing activities	23,539	18,519
Effect of currency rate change on cash	(13)	(5)
Net (decrease) increase in cash, cash equivalents and restricted cash	(451)	6,555
Cash, cash equivalents and restricted cash beginning of the year	25,585	19,030
Cash, cash equivalents and restricted cash end of year	$ 25,134	$ 25,585
Supplemental disclosures of cash flow information:		
Taxes paid	$ 82	$ 65
Non cash financing activities:		
Issuance of common stock under employee benefit plan	$ —	$ 74
Beneficial conversion feature in connection with sale of Series A Convertible preferred stock and deemed dividend	$ 3,266	$ —

See the accompanying notes to consolidated financial statements

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. ("Tonix Sub"), is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. All drug product candidates are still in development.

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

Going Concern

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At December 31, 2018, the Company had working capital of approximately $23.4 million. At December 31, 2018, the Company had an accumulated deficit of approximately $188.5 million. The Company held cash and cash equivalents of approximately $25.0 million as of December 31, 2018. The Company does not have enough resources to meet its operating requirements through March 2020. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company continues to face significant challenges and uncertainties and, as a result, the Company's available capital resources may be consumed more rapidly than currently expected due to changes the Company may make in its research and development spending plans. The Company has the ability to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. However, the Company may not be able to raise capital with terms acceptable to the company. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Consolidation

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its direct and indirect wholly owned subsidiaries.

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

Recently Issued Accounting Pronouncements

In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company has elected the ‘package of practical expedients’, which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

The new standard will have a material effect on the Company’s financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

Upon adoption, the Company will recognize additional operating lease liabilities of approximately $0.3 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company expects to recognize corresponding ROU assets of approximately $0.3 million.

The new standard also provides practical expedients for an entity’s ongoing accounting. The Company will elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Beginning in 2019, the Company expects changes to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. These revised disclosures will be made in the Company’s first quarterly report in 2019.

Risks and Uncertainties

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

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets, assumptions used in the fair value of stock-based compensation and other equity instruments, and the percent of completion of research and development contracts.

Cash Equivalents and Restricted Cash

The Company considers cash equivalents to be those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased. At December 31, 2018 and December 31, 2017, cash equivalents, which consisted of money market funds, amounted to $10.1 million and $17.3 million, respectively. Restricted cash at December 31, 2018 and December 31, 2017 of approximately $100,000 and $89,000, respectively, collateralizes a letter of credit issued in connection with the lease of office space in New York City (see Note 8).

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statement of cash flow:

	December 31, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$ 25,034	$ 25,496
Restricted cash	100	89
Total	$ 25,134	$ 25,585

Intangible Asset with Indefinite Lives

During the year ended December 31, 2015, the Company purchased certain internet domain rights, which were determined to have an indefinite life. Identifiable intangibles with indefinite lives are not amortized but are tested for impairment annually or whenever events or changes in circumstances indicate that its carrying amount may be less than fair value. As of December 31, 2018, and 2017, the Company believed that no impairment existed.

Research and Development Costs

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

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

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

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life, which is three years for computer assets, five years for furniture and all other equipment and term of lease for leasehold improvements. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was $54,000 and $64,000, respectively. All remaining property and equipment is located in the United States.

Income Taxes

Deferred income tax assets and liabilities are determined based on the estimated future tax effects of net operating loss and credit carryforwards and temporary differences between the tax basis of assets and liabilities and their respective financial reporting amounts measured at the current enacted tax rates. The Company records a valuation allowance on its deferred income tax assets if it is not more likely than not that these deferred income tax assets will be realized.

The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2018, the Company has not recorded any unrecognized tax benefits.

Stock-Based Compensation

All stock-based payments to employees and to nonemployee directors for their services as directors, including grants of restricted stock units ("RSUs"), and stock options, are measured at fair value on the grant date and recognized in the condensed consolidated statements of operations as compensation or other expense over the relevant service period.

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

Foreign Currency Translation

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

Comprehensive Income (Loss)

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

Per Share Data

Basic and diluted net loss per common share is calculated by dividing net loss, by the weighted average number of outstanding shares of common stock, adjusted to give effect to the 1-for-10 reverse stock split, which was effected on November 28, 2018 (see Note 6).

As of December 31, 2018, and 2017, there were outstanding warrants to purchase an aggregate of 4,985,079 and 68,668 shares, respectively, of the Company's common stock (see Note 8). The Company has issued to employees, directors and consultants, options to acquire shares of the Company's common stock, of which 137,145 and 40,174 were outstanding at December 31, 2018 and 2017, respectively. For the year ended December 31, 2018, net loss attributable to common stockholders included preferred stock dividends of $3.3 million, related to the beneficial conversion feature of the issuance of the Series A convertible preferred stock. The number of preferred shares convertible to common stock that were excluded from the computations of net loss per common share for the year ended December 31, 2018 were 2,816,000. In computing diluted net loss per share for the years ended December 31, 2018 and 2017, no effect has been given to such convertible preferred stock, options and warrants as their effect would be anti-dilutive.

NOTE 3 – OTHER BALANCE SHEET INFORMATION

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

	December 31,	
	2018	2017
	(in thousands)	
Property, plant and equipment, net:		
Office furniture and equipment	$ 317	$ 311
Leasehold improvements	23	23
	340	334
Less: Accumulated depreciation and amortization	(297)	(243)
	$ 43	$ 91
Prepaid expenses and other:		
Contract-related	$ 525	$ 494
Other	497	453
	$ 1,022	$ 947
Accrued expenses:		
Contract-related	$ 475	$ 519
Compensation and compensation-related	614	65
Professional fees and other	162	246
	$ 1,251	$ 830

NOTE 4 – FAIR VALUE MEASUREMENTS

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

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

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

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

As of December 31, 2018, and December 31, 2017, the Company used Level 1 quoted prices in active markets to value cash equivalents of $10.1 million and $17.3 million, respectively.

NOTE 5 – STOCKHOLDERS' EQUITY

On November 26, 2018, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective November 28, 2018. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value, whereby 15,293,782 outstanding shares of the Company's common stock were exchanged for 1,529,427 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 2,833 shares of the Company's common stock due to rounding. Furthermore, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 150 million to 15 million. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

NOTE 6 – SALE OF COMMON STOCK

December 2018 Financing

On December 7, 2018, the Company entered into an underwriting agreement with Alliance Global Partners ("AGP") and Dawson James Securities, Inc. ("Dawson") (collectively "the Underwriters") pursuant to which the Company sold securities consisting of 861,710 Class A Units at a public offering price of $3.50 per unit, with each unit consisting of one share of Common Stock and a Warrant to purchase one share of Common Stock, and 11,984 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of $3.50 per share, and Warrants to purchase 285.7143 shares of Common Stock. The Warrants have an exercise price of $3.50, are exercisable and expire five years from the date of issuance.

The Company also granted the underwriters a 45-day option to purchase up to 642,856 shares of common stock and/or additional Warrants to purchase up to 642,856 additional shares of common stock.

The December 2018 Financing closed on December 11, 2018. The Underwriters purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately $1.1 million (or $0.24 per share). The Company received net proceeds from the December 2018 Financing of approximately $13.6 million, after deducting the underwriting discount and other offering expenses of approximately $0.4 million. Additionally, the Underwriters fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 640,000 shares of common stock for net proceeds of approximately $6,000.

On December 13, 2018, the 2018 Underwriters partially exercised the over-allotment option and purchased 250,000 shares of common stock for net proceeds of approximately $0.8 million, net of an aggregate discount of $0.1 million (or $0.24 per share).

After allocating proceeds to the warrants issued with the Series A convertible preferred stock, the effective conversion price of the Series A convertible preferred Stock, after the bifurcation of the warrants, was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature ("BCF") at that date. Since the Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF was charged to additional paid in capital as a "deemed dividend" and impacted earnings per share. The Company recognized a one-time non-cash deemed dividend of $3.3 million for the beneficial conversion feature resulting from the intrinsic value of the conversion options of the preferred stock.

During the year ended December 31, 2018, 2,128 shares of Series A convertible preferred stock were converted into 608,000 shares of common stock. As of March 13, 2019, all Series A convertible preferred stock has been converted into common stock.

2018 At-the-Market Offering

On May 1, 2018, the Company entered into a sales agreement ("the Sales Agreement"), with Cowen and Company, LLC., ("Cowen"), pursuant to which the Company may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $9.5 million in at-the-market offerings ("ATM") sales. On the same day, the Company filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen acted as sales agent and was paid a 3% commission on each sale under the Sales Agreement. The Company's common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied.

During the year ended December 31, 2018, the Company sold an aggregate of approximately 593,000 shares of common stock using the ATM, resulting in net proceeds of $6.9 million, net of expenses of approximately $0.2 million of Cowen's commission.

2018 Lincoln Park Transaction

On October 18, 2018, the Company entered into a purchase agreement (the "2018 Purchase Agreement") and a registration rights agreement (the "2018 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2018 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 2018 Purchase Agreement. Pursuant to the terms of the 2018 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2018 Purchase Agreement.

Pursuant to the terms of the 2018 Purchase Agreement, at the time the Company signed the 2018 Purchase Agreement and the 2018 Registration Rights Agreement, the Company issued 35,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2018 Purchase Agreement. The commitment shares were valued at $245,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2018 Purchase Agreement.

As of December 31, 2018, no shares of common stock were sold under this agreement.

2017 Lincoln Park Transaction

On September 28, 2017, the Company entered into a purchase agreement (the "2017 Purchase Agreement") and a registration rights agreement (the "2017 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2017 Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to $15,000,000 of its common stock (subject to certain limitations) from time to time during the term of the 2017 Purchase Agreement. Pursuant to the terms of the 2017 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2017 Purchase Agreement.

Pursuant to the terms of the 2017 Purchase Agreement, at the time the Company signed the 2017 Purchase Agreement and the 2017 Registration Rights Agreement, the Company issued 7,304 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of its common stock under the 2017 Purchase Agreement. The commitment shares were valued at $300,000, recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2017 Purchase Agreement.

During the year ended December 31, 2018, the Company sold an aggregate of approximately 118,000 shares of common stock under the 2017 Purchase Agreement, for gross proceeds of $2.4 million, and from inception of the 2017 Purchase Agreement, the Company has sold an aggregate of approximately 143,000 shares of common stock, for gross proceeds of approximately $3.5 million.

Under applicable rules of the NASDAQ Global Market, the Company could not issue or sell more than 19.99% of the shares of its common stock outstanding immediately prior to the execution of the 2017 Purchase Agreement (approximately 150,000 shares) to Lincoln Park under the 2017 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 2017 Purchase Agreement equals or exceeds a threshold amount. As the Company has issued approximately 150,000 shares to Lincoln Park under the 2017 Purchase Agreement at less than the threshold amount, the Company will not sell any additional shares under the 2017 Purchase Agreement without shareholder approval.

April 2017 Financing

On March 30, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp., as representative of the several underwriters (collectively, the "2017 Underwriters"), relating to the issuance and sale of 180,000 shares of our common stock, in an underwritten public offering (the "April 2017 Financing"). The public offering price for each share of common stock was $44.50. We granted the 2017 Underwriters an option to purchase up to an additional 27,000 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 $3.12 per share). The Company 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 27,000 shares of common stock for net proceeds of approximately $1.1 million, net of an aggregate discount of $0.1 million (or $3.12 per share).

2016 At-the-Market Offering

During the year ended December 31, 2017, the Company sold an aggregate of approximately 149,000 shares of common stock using the at 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, the Company sold all $15 million of shares under the 2016 Sales Agreement, and the 2016 Sales Agreement was terminated.

NOTE 7 – STOCK-BASED COMPENSATION

2017 Stock Incentive Plan

On June 16, 2017, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2017 Stock Incentive Plan (the "2017 Plan" and together with the 2012 Incentive Stock Option Plan, 2014 Incentive Stock Option Plan and the 2016 Stock Incentive Plan, the "Prior Plans"). Under the terms of the 2017 Plan, the Company could have issued (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 provided for the issuance of up to 128,000 shares of common stock. With the adoption of the 2018 Plan (as defined below), no further grants may be made under the Prior Plans.

2018 Stock Incentive Plan

On June 8, 2018, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2018 Stock Incentive Plan (the "2018 Plan" and together with the Prior Plans, the "Plans"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the Prior Plans.

Under the terms of the 2018 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2018 Plan provides for the issuance of up to 132,000 shares of common stock, which amount was (a) reduced by awards granted under the Prior Plans after March 1, 2018, and (b) will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2018 Plan). In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after March 1, 2018, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.23 shares for every one share that was subject to an award other than an option or SAR. The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2018 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 expiration period of grants under the 2018 Plan may not more than ten years. The Company reserved 132,000 shares of its common stock for future issuance under the terms of the 2018 Plan. As of December 31, 2018, 118,496 shares were available for future grants under the 2018 Plan.

General

A summary of the stock option activity and related information for the Plans for the years ended December 31, 2018, and 2017 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	21,745	$ 913.29	7.82	$ —
Grants	26,000	$ 46.34		—
Exercised	—			
Forfeitures or expirations	(7,571)	670.36		
Outstanding at January 1, 2018	40,174	$ 398.06	8.35	$ —
Grants	101,968	$ 37.52		$ —
Exercised	—			
Forfeitures or expirations	(4,997)	$ 38.75		
Outstanding at December 31, 2018	137,145	$ 143.09	8.14	$ —
Vested and expected to vest at December 31, 2017	137,145	$ 143.09	8.14	$ —
Exercisable at December 31, 2018	39,860	$ 375.05	5.84	$ —

General

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

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

The assumptions used in the valuation of stock options granted during the years ended December 31, 2018 and 2017 were as follows:

	2018	2017
Risk-free interest rate	2.54% to 2.81%	1.75% to 2.33%
Expected term of option	4.5 to 7.00 years	5.0 to 7.91 years
Expected stock price volatility	99.65% to 109.22%	76.28% to 77.59%
Expected dividend yield	0%	0%

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

The weighted-average grant-date fair value of stock options granted was $27.78 in 2018 and $29.20 in 2017.

Stock-based compensation expense relating to options granted of $1.6 million and $1.7 million was recognized for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company had approximately $1.8 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.87 years.

2014 Employee Stock Purchase Plan

On June 9, 2014, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2014 Employee Stock Purchase Plan (the "2014 ESPP"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the 2014 ESPP.

2018 Employee Stock Purchase Plan

On June 8, 2018, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2018 Employee Stock Purchase Plan (the "2018 ESPP"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the Prior Plan.

The 2018 ESPP allows eligible employees to purchase up to an aggregate of 30,000 shares of the Company's common stock. Under the 2018 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of the Company's common stock at the end of the offering period. Each offering period under the 2018 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 2018 ESPP, subject to the statutory limit under the Code. As of December 31, 2018, there were 28,242 shares available for future issuance under the 2018 ESPP, after taking into account the shares issued below.

The 2018 ESPP and 2014 ESPP are considered compensatory plans with the related compensation cost written off over the six-month offering period. The compensation expense related to the 2018 ESPP for the year ended December 31, 2018 was $32,000. The compensation expense related to the 2014 ESPP for the year ended December 31, 2017 was $36,000. As of December 31, 2018, approximately $38,000 of employee payroll deductions, which have been withheld since July 1, 2018, the commencement of the offering period ending December 31, 2018, are included in accrued expenses in the accompanying balance sheet. In January 2019, 1,758 shares that were purchased as of December 31, 2018, were issued under the 2018 ESPP, and approximately $3,000 of employee payroll deductions accumulated at December 31, 2018, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $35,000 was returned to the employees. In July 2017, 1,776 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, 250 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. No employee deductions were withheld during 2017.

Restricted Stock Units

In February 2017, a total of 563 RSUs vested that were granted to the Company's 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 $381.00 at the date of grant. 563 shares of the Company's common stock were issued upon the vesting of such RSUs during the year ended December 31, 2017.

In May 2017, a total of 563 RSUs vested that were granted to the Company's 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 $229.00 at the date of grant. 488 shares of the Company's common stock were issued upon the vesting of such RSU's during the year ended December 31, 2017. The remaining 75 shares of common stock were issued during the year ended December 31, 2018.

The following table summarizes the RSU activity for the years ended December 31, 2018 and 2017:

Unvested restricted stock units as of January 1, 2017	1,126
Granted	—
Forfeited	—
Vested	(1,126)
Unvested restricted stock units as of January 1, 2018	—
Granted	—
Forfeited	—
Vested	—
Unvested restricted stock units as of December 31, 2018	—

Stock-based compensation expense related to RSU grants was $0 and $0.1 million for the year ended December 31, 2018 and 2017, respectively.

NOTE 8 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company, all of which were vested and exercisable, at December 31, 2018:

Exercise Price	Number Outstanding	Expiration Date
$ 3.50	4,925,710	December 2023
$ 63.00	54,400	October 2021
$ 69.00	4,736	October 2021
$ 2,500.00	233	January 2019 to February 2019
	4,985,079	

During the year ended December 31, 2017, 225 warrants with an exercise price of $63.00 were exercised. During the year ended December 31, 2018, 108 warrants with an exercise price of $1,200.00 and 9,190 warrants with an exercise price of $425.00 expired. During the year ended December 31, 2017, 3,309 and 4,452 warrants with exercise prices of $2,500.00 and $1,200.00, respectively, expired.

NOTE 9 – COMMITMENTS

Research and Development Contracts

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $5.5 million at December 31, 2018 for future work to be performed.

Operating Leases

As of December 31, 2018, future minimum lease payments are as follows (in thousands):

Year Ending December 31,	
2019	$ 413
2020	212
2021	6
	$ 631

Rent expense charged to operations, which differs from rent paid due to rent credits and to increasing amounts of base rent, is calculated by allocating total rental payments on a straight-line basis over the term of the lease. During the years ended December 31, 2018 and 2017, rent expense was $0.5 million and $0.6 million, respectively, and as of December 31, 2018 and 2017, deferred rent payable was $12,000 and $32,000, respectively, including the current portion, which at December 31, 2018 and 2017, was $12,000 and $20,000, respectively, which is included in accrued expenses in 2018 and 2017.

Defined Contribution Plan

Effective April 1, 2014, the Company established a qualified defined contribution plan (the "401(k) Plan") pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 100 percent of each participant's pretax contributions of up to six percent of his or her eligible compensation, and the Company is also required to make a contribution equal to three percent of each participant's salary, on an annual basis, subject to limitations under the Code. For the years ended December 31, 2018 and 2017, the Company charged operations $0.2 million and $0.1 million, respectively, for contributions under the 401(k) Plan.

NOTE 10 – INCOME TAXES

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

	Year ended December 31,	
	2018	2017
Foreign	$ (21,502)	$ (20,490)
Domestic	(4,587)	(633)
Total	$ (26,089)	$ (21,123)

In 2018, the foreign losses are comprised of $20.9 million related to the Bermudan operations of Tonix International Holding. In 2017, the foreign losses were primarily comprised of $18.9 million related to the Bermudan operations of Tonix International Holding, which included a licensing fee of $2.0 million charged by Tonix subsidiary pursuant to a licensing agreement with Tonix subsidiary.

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

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

	Year Ended December 31,	
	2018	2017
Statutory federal income tax	(21.0)%	(34.0)%
State income tax, net of federal tax effect	0.0%	0.0%
Permanent difference	0.1%	0.1%
Change in valuation allowance	1.7%	(65.3)%
Foreign loss not subject to income tax	17.0%	32.1%
Return to provision true-ups	(0.1)%	(2.6)%
Tax rate change	0.0%	22.8%
Attribute reduction from control Change	3.9%	43.8%
Forfeiture of stock options	0.0%	4.8%
Other	(1.6)%	(1.7)%
Income Tax Provision	0.0%	0.0%

Deferred tax assets and related valuation allowance as of December 31, 2018 and 2017 were as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforward	$ 763	$ 724
Stock-based compensation	2,659	2,424
Other	226	176
Total deferred assets	3,648	3,324
Valuation allowance	(3,648)	(3,324)
Net deferred tax assets	$ —	$ —

The Company has incurred research and development ("R&D") expenses, a portion of which qualifies for tax credits. The Company conducted an R&D credit study to quantify the amount of credits and has claimed an R&D credit on its 2014-2017 tax returns. A portion of these R&D credit carryforwards are subject to annual limitations in their use in accordance with Internal Revenue Service Code ("IRC") section 383. The R&D credit carryforwards at December 31, 2018 have been reduced to $0 to reflect IRC section 383 ownership changes through December 31, 2018 and the resulting inability to utilize a portion of the R&D credit prior to its expiration.

At December 31, 2018, the Company had available unused federal net operating loss ("NOL") carryforwards of approximately $0.1 million of which do not expire. Additionally, the Company has $4.7 million of Ireland NOL carryforwards that do not expire, $0.1 million of Canada NOL which expires between 2036 and 2038 and $0.1 million of Quebec NOL which expires between 2036 and 2038. A portion of the federal, New York State, and New York City NOL carryforwards is subject to annual limitations in their use in accordance with IRC section 382. The NOL carryforwards at December 31, 2018 have been reduced to reflect IRC section 382 ownership changes through December 31, 2018 and the resultant inability due to annual limitations, to utilize a portion of the NOL prior to its expiration.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2018. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth. As such, the Company has determined that it is not more likely than not that the deferred tax assets will be realized and accordingly, has provided a full valuation allowance against its gross deferred tax assets. The increase/ (decrease) in the valuation allowance for the years ended December 31, 2018 and 2017 were $0.3 million, and ($13.9) million respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2018 there are no unrecognized tax benefits recorded. The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of December 31, 2018, the Company's tax returns remain open and subject to examination by the tax authorities for the tax years 2015 and after.

The Tax Act also includes a provision to tax global intangible low-taxed income of foreign subsidiaries, a special tax deduction for foreign-derived intangible income ("GILTI"), and a base erosion anti-abuse tax measure that may tax certain payments between a U.S. corporation and its subsidiaries. These additional provisions of the Tax Act are effective for the Company beginning after December 31, 2107. The Company has elected to account for GILTI as a period cost in the year the tax is incurred.

NOTE 11 – SUBSEQUENT EVENTS

On February 14, 2019, the Company granted options to purchase an aggregate of 10,000 shares of the Company's common stock to a director with an exercise price of $1.86, with a term of ten years, vesting on the date of the Corporation's 2019 annual meeting of shareholders.

On February 26, 2019, the Company granted options to purchase an aggregate of 62,040 shares of the Company's common stock to employees with an exercise price of $1.89, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months. Additionally, the Company granted options to purchase 41,360 shares of the Company's common stock to employees with an exercise price of $2.36, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months.

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

None.

ITEM 9A – CONTROLS AND PROCEDURES

Management's evaluation of disclosure controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Exchange Act. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on management's evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for the implementation of controls to account for leases as a result of ASU 2016-02. The modified controls have been designed to address risks associated with accounting for leases and liabilities and the related income and expenses under ASC 842.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's principal executive and principal financial officer and effected by the our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

We conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our principal executive officer and principal financial officer conclude that, at December 31, 2018, our internal control over financial reporting was effective.

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

ITEM 9B – OTHER INFORMATION

None.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The 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	61	President, CEO and Chairman of the Board of Directors
Margaret Smith Bell	59	Director
Patrick Grace	63	Director
David Grange	71	Director
Donald W. Landry	64	Director
Adeoye Olukotun	74	Director
John Rhodes	62	Lead Director
James Treco	63	Director
Jessica Morris	41	Chief Operating Officer
Bradley Saenger	45	Chief Financial Officer and Treasurer
Gregory Sullivan	53	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 ("Tonix Sub") in 2007 and has acted as its Chairman of the Board of Directors since its inception and as President since 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 posttraumatic stress disorder (PTSD). Dr. Lederman served as an Associate Professor at Columbia University, between 1996 and 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 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 2007 and 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 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. Dr. Lederman was the chairman of Leder Laboratories, Ltd., a wholly-owned subsidiary of Leder Laboratories Inc., between 2013 and 2018, when the entity was dissolved. 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'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. Ms. Bell has been retired for the last ten years. 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 were instrumental in her selection as a member of the 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 ("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.

General David Grange (retired) became a director in February 2018. Gen. Grange has been Chief Executive Officer of Pharm-Olam International, Ltd. ("Pharm-Olam"), a contract research organization, since April 2017. Prior to joining Pharm-Olam, Gen. Grange was President and founder of Osprey Global Solutions, LLC ("OGS"), a Service Disabled Veterans Organization, from 2009 to 2017. Prior to founding OGS, Gen. Grange held various positions with Pharmaceutical Product Development, Inc. (PPDI), a contract research organization, from 2003 to 2009, including as a member of the Board of Directors and Chief Executive Officer. Prior to PPDI he served in the McCormick Tribune Foundation for 10 years most recently as Chief Executive Officer and President, where he also oversaw the support of Veteran Programs. Gen. Grange served 30 years in the U.S. Army as a Ranger, Green Beret, Aviator, Infantryman and a member of special operating units. At the Pentagon, he was Director of Army Current Operations, Readiness, and Mobilization. Gen. Grange commanded the Ranger Regiment and the First Infantry Division (the Big Red One). Gen. Grange holds a master's degree in Public Service from Western Kentucky University. Gen. Grange's extensive experience in the pharmaceutical industry and service with the U.S. military 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.

Adeoye Olukotun, MD became a Director in September 2018. Dr. Olukotun has been the Chief Executive Officer of CR Strategies, LLC, a medical products consulting company, since 2000, and was the Chief Executive Officer of EpiGen Pharmaceuticals, Inc., a pharmaceutical company, from 2014 to January of 2018. Dr. Olukotun served as Vice Chairman of CardoVax, Inc., a pharmaceutical company, from 2012 to 2016, and as its Chief Executive Officer from 2006 to 2012. He is also co-founder of VIA Pharmaceuticals, Inc., a pharmaceutical company, and served as the company's Chief Medical Officer from 2004 to 2008.

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.

James Treco became a director in February 2019. Mr. Treco has been a Managing Partner at First Chicago Advisors, Inc., a boutique financial advisory firm where he advises executives and boards of directors of a wide range of companies, from global, large-cap companies to emerging companies, from 2009 to 2012 and from 2014 to the present. From 2012 to 2013 Mr. Treco was an investment banker with Gleacher & Company, a company that previously operated an investment banking business, providing corporate and institutional clients with strategic and financial advisory services. Mr. Treco held various positions of increasing responsibility at Salomon Brothers/Citigroup from 1984 to 2008, where he used his extensive experience in the global capital markets to advise a wide range of clients. Mr. Treco holds a B.A. from Yale University and an M.B.A. from the Stanford University Graduate School of Business. Mr. Treco's extensive healthcare and investment banking experience were instrumental in his selection as a member of the Board.

Jessica Morris is our Chief Operations Officer and has worked for the Company since April 2013, first as a consultant (April 2013 – September 2013), then as SVP of Finance (September 2013 – October 2015), followed by Chief Administrative Officer (October 2015 – January 2016), Acting Chief Financial Officer (January 2016 – February 2016), and Executive Vice President, Operations (February 2016 – January 2018). Prior to joining the Company, Ms. Morris was a Vice President in investment management at Zhong Rong Group. Previously, Ms. Morris was a Senior Associate in the Sponsor Finance Group at American Capital, a Vice President of the mezzanine debt fund at Calvert Street Capital Partners, an Associate in the commercial finance department of Silicon Valley Bank, and a Financial Analyst in the investment banking group at Deutsche Bank. Ms. Morris earned a B.S. in Commerce and a B.A. in Music from the University of Virginia, where she was an Echols Scholar.

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, Patrick Grace, David Grange, Donald Landry, Adeoye Olukotun, John Rhodes and James Treco are each an independent director as defined in the Marketplace Rules of The NASDAQ Stock Market. Prior to his resignation in February 2019, the Board found that Mr. Mather was also an independent director.

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 1608, 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, 2018, the Board held six meetings, the Audit Committee held eight meetings, the Compensation Committee held six meetings and the Nominating and Corporate Governance Committee held five 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		**	
Patrick Grace	**		*
David Grange		*	*
Donald W. Landry			
Adeoye Olukotun		*	
John Rhodes	*		**
James Treco	*		

* Member of Committee
** Chairman of Committee

Audit Committee

Our Audit Committee consists of Patrick Grace, John Rhodes and James Treco, with Mr. Grace elected as Chairman of the Committee. Our Board has determined that each of Messrs. Grace, Rhodes and Treco 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, 2018.

Compensation Committee

Our Compensation Committee consists of Margaret Smith Bell, David Grange and Adeoye Olukotun, with Ms. Bell 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 ("CD&A") 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, David Grange 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 Securities Exchange Act of 1934, as amended, 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 2018, our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements.

Involvement in Certain Legal Proceedings

Except as disclosed below, 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.

In January 2013, the Chief Operating Officer filed for bankruptcy protection under Chapter 7 of Title 11 under the United States Code in the U. S. Bankruptcy Court in New York, New York. The petition was discharged in April 2013.

ITEM 11 – 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 2018 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 competitiveness 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 2018, 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 next most highly paid executive officers for fiscal years 2018 and 2017.

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	2018	472,500	160,000	—	844,945	—	—	—	1,477,445
Chief Executive Officer	2017	472,500	—	—	103,344	—	—	—	575,844
Gregory Sullivan	2018	335,000	70,000	—	316,855	—	—	—	721,855
Chief Medical Officer	2017	335,000	—	—	48,443	—	—	—	383,443
Bradley Saenger	2018	335,000	70,000	—	211,235	—	—	—	616,235
Chief Financial Officer	2017	335,000	—	—	30,680	—	—	—	365,680

(1) Represents the aggregate grant date fair value of options granted in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, "Stock Compensation." For the relevant assumptions used in determining these amounts, refer to Note 7 to our audited financial statements.

Grants of Plan-Based Awards in Fiscal 2018

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, 2018.

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	2/13/2018	15,661	$ 34.00	$ 27.36
	2/13/2018	15,661	$ 42.50 [2]	$ 26.60
Bradley Saenger	2/13/2018	3,915	$ 34.00	$ 27.36
	2/13/2018	3,915	$ 42.50 [2]	$ 26.60
Gregory Sullivan	2/13/2018	5,873	$ 34.00	$ 27.36
	2/13/2018	5,873	$ 42.50 [2]	$ 26.60

(1) Represents the aggregate grant date fair value of options granted in accordance with FASB ASC Topic 718.
(2) Represents an exercise price at a 125% premium of the closing price of the Company's common stock on the grant date.

Outstanding Equity Awards at December 31, 2018

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2018.

Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($/Sh)	Option Expiration Date
Seth Lederman	350	—	$ 3000.00	5/9/2022
	675	—	$ 1020.00	2/12/2023
	710	—	$ 1588.00	2/11/2024
	1,000	—	$ 987.00	6/17/2024
	1,000	—	$ 668.00	10/29/2024
	1,890	—	$ 595.00	2/25/2025
	72	—	$ 595.00	2/25/2025
	1,049	51 [1]	$ 503.00	2/9/2026
	—	1,100 [2]	$ 503.00	2/9/2026
	933	667 [4]	$ 55.00	3/1/2027
	—	15,661 [5]	$ 34.00	2/13/2028
	—	15,661 [5]	$ 42.50	2/13/2028
Bradley Saenger	110	—	$ 987.00	6/17/2024
	110	—	$ 668.00	10/29/2024
	130	—	$ 595.00	2/25/2025
	142	8 [1]	$ 503.00	2/9/2026
	—	600 [2]	$ 242.00	5/27/2026
	172	28 [3]	$ 242.00	5/27/2026
	275	200 [4]	$ 55.00	3/1/2027
	—	3,915 [5]	$ 34.00	2/13/2028
	—	3,915 [5]	$ 42.50	2/13/2028
Gregory Sullivan	265	—	$ 987.00	6/17/2024
	265	—	$ 668.00	10/29/2024
	265	—	$ 595.00	2/25/2025
	283	17 [1]	$ 503.00	2/9/2026
	—	300 [2]	$ 503.00	2/9/2026
	438	312 [4]	$ 55.00	3/1/2027
	—	5,873 [5]	$ 34.00	2/13/2028
	—	5,873 [5]	$ 42.50	2/13/2028

(1) 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.
(2) 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 $600.00, $700.00 and $800.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.
(3) 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.

(4) The shares subject to this stock option vested as to 1/3 of the shares on March 1, 2018, 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 13, 2019, 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, 2018.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2018.

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]	137,145	$ 143.09	146,738
Equity compensation plans not approved by security holders	—	—	—
Total	137,145	$ 143.09	146,738

(1) Consists of the 2012 Plan, the 2014 Plan, the 2016 Plan, the 2017 Plan, the 2018 Plan and the 2014 employee stock purchase plan ("ESPP").

(2) Consists of shares available for future issuance under the 2018 Plan and our ESPP. As of December 31, 2018, 118,496 shares of common stock were available for issuance under the 2018 Plan and 28,242 shares of common stock were available for issuance under the 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 (the "Lederman Agreement") with Dr. Seth Lederman ("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 and as of January 1, 2019, the base salary is $585,000. 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 (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 (the "Sullivan Agreement") with Dr. Gregory Sullivan ("Sullivan") to serve as our Chief Medical Officer. The base salary for Sullivan under the Sullivan Agreement was $225,000 per annum and as of January 1, 2019, the base salary is $400,000. 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 Agreement, or (5) the Company elects not to renew the 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 2018 for services to our Company.

Name	Stock Awards ($)	Option Awards ($)[1]	Total ($)
Margaret Smith Bell	$ —	$ 65,869	$ 65,869
Patrick Grace	$ —	$ 65,869	$ 65,869
David Grange	$ —	$ 83,979	$ 83,979
Donald Landry	$ —	$ 65,869	$ 65,869
Ernest Mario*	$ —	$ 12,416	$ 12,416
Charles Mather IV*	$ —	$ 65,869	$ 65,869
Adeoye Olukotun	$ —	$ 12,396	$ 12,396
John Rhodes [2]	$ —	$ 98,803	$ 98,803
Samuel Saks*	$ —	$ 12,416	$ 12,416
Total:	$ —	$ 483,486	$ 483,486

(1) Represents the aggregate grant date fair value of stock options granted in accordance with FASB ASC Topic 718. For the relevant assumptions used in determining these amounts, refer to Note 7 to our audited financial statements. These amounts do not necessarily correspond to the actual value that may be recognized from the stock option grant.

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

* Dr. Saks resigned from the Board August 21, 2018

* Dr. Mario resigned from the Board September 5, 2018

* Mr. Mather resigned from the Board February 16, 2019

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 13, 2019:

- 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 1608, 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	32,666 [3]	*
Jessica Morris	Common Stock	4,602 [4]	*
Bradley Saenger	Common Stock	4,977 [5]	*
Gregory Sullivan	Common Stock	8,840 [6]	*
Margaret Smith Bell	Common Stock	2,000 [7]	*
Patrick Grace	Common Stock	2,701 [8]	*
David Grange	Common Stock	700 [9]	*
Donald Landry	Common Stock	3,332 [10]	*
Adeoye Olukotun	Common Stock	—	*
John Rhodes	Common Stock	5,965 [11]	*
James Treco	Common Stock	—	*
Officers and Directors as a Group (11 persons)	Common Stock	65,458 [12]	1.07%
Iroquois Capital Management LLC	Common Stock	1,980,634 [13]	24.95%

* 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 March 13, 2019 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 6,089,728 shares of common stock issued and outstanding as of March 13, 2019.

(3) Includes 20,133 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 50 shares of common stock underlying warrants, 2,047 shares of common stock owned by Lederman & Co, 325 shares of common stock owned by L&L, 590 shares of common stock owned by Targent, 292 shares of common stock owned by Leder Laboratories, Inc. (Leder Labs), 292 shares of common stock owned by Starling, 2,270 shares owned through a 401(k) account, 4,590 shares owned through an IRA account and 310 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 4,415 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, and 23 shares of common stock underlying warrants.

(5) Includes 4,083 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(6) Includes 6,205 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(7) Includes 2,000 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(8) Includes 2,425 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(9) Includes 700 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(10) Includes 2,410 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 325 shares of common stock owned by L&L. Donald Landry, as a Member of L&L, has investment and voting control over the shares held by this entity.

(11) Includes 3,493 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days and 125 shares of common stock underlying warrants.

(12) Includes 45,864 shares of common stock underlying options which are currently exercisable or vested or become exercisable within 60 days, 2,047 shares of common stock owned by Lederman & Co, 325 shares of common stock owned by L&L, 590 shares of common stock owned by Targent, 292 shares of common stock owned by Leder Labs, 292 shares of common stock owned by Starling, 2,270 shares owned through a 401(k) account of Dr. Lederman, 4,590 shares owned through an IRA account of Dr. Lederman, 310 shares owned by Dr. Lederman's spouse and 198 shares of common stock underlying warrants owned directly by the executive officers and directors.

(13) Based upon a Schedule 13G filed with the SEC on February 14, 2019 by Iroquois Capital Management L.L.C., Richard Abbe and Kimberly Page, . Iroquois Master Fund Ltd. held 51,584 shares of Common Stock, 1,062 shares preferred stock convertible into 303,429 shares of Common Stock and warrants to purchase 356,975 shares of Common Stock; and Iroquois Capital Investment Group LLC held 79,050 shares of Common Stock, 1,913 shares of preferred stock convertible into 546,571 shares of Common Stock and warrants to purchase 643,025 shares of Common Stock. Mr. Abbe shares authority and responsibility for the investments made on behalf of Iroquois Master Fund with Ms. Kimberly Page, each of whom is a director of the Iroquois Master Fund Ltd. As such, Mr. Abbe and Ms. Page may each be deemed to be the beneficial owner of all shares of Common Stock held by, and underlying the preferred stock and warrants held by, Iroquois Master Fund. Iroquois Capital is the investment advisor for Iroquois Master Fund and Mr. Abbe is the President of Iroquois Capital. Mr. Abbe has the sole authority and responsibility for the investments made on behalf of Iroquois Capital Investment Group LLC. As such, Mr. Abbe may be deemed to be the beneficial owner of all shares of Common Stock held by, and underlying the preferred stock and warrants held by, Iroquois Master Fund and Iroquois Capital Investment Group LLC. Each of the Reporting Persons disclaims any beneficial ownership of any shares of Common Stock except to the extent of their pecuniary interest therein. As of March 13, 2019, all shares of preferred stock held by Iroquois Capital Management L.L.C., Iroquois Master Fund Ltd., Richard Abbe, Kimberly Page, Iroquois Capital Investment Group LLC had been converted into common stock. The mailing address for each beneficial owner is 125 Park Ave, 25th floor, NY, NY 10017.

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

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.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees billed by our independent registered public accounting firm, for professional services rendered for the audit of our annual financial statements for the years ended December 31, 2018 and 2017, including review of our interim financial statements as well as registration statement filings with the SEC and comfort letters issued to underwriters were $424,380 and $386,790, respectively.

Audit-Related Fees

We did not incur fees to our independent registered public accounting firm for audit related fees during the fiscal years ended December 31, 2018 and 2017.

Tax and Other Fees

We incurred fees to our independent registered public accounting firm for tax services during the fiscal years ended December 31, 2018 and 2017, of $7,500 and $12,000, respectively, related to a net operating loss study.

Pre-Approval Policies and Procedures

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(c) Index to Exhibits

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

Exhibit No.	Description
3.01	Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "Commission") on April 9, 2008 and incorporated herein by reference.
3.02	Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.

3.03	Third Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 3, 2016 and incorporated herein by reference.
3.04	Certificate of Change of Tonix Pharmaceuticals Holding Corp., dated March 13, 2017 and effective March 17, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 16, 2017 and incorporated herein by reference.
3.05	Certificate of Amendment to Articles of Incorporation, effective June 16, 2017, filed as an exhibit to the Current report on Form 8-K, filed with the Commission on June 16, 2017 and incorporated herein by reference.
3.06	Specimen Common Stock Certificate, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 24, 2018 and incorporated herein by reference.
3.07	Certificate of Change of Tonix Pharmaceuticals Holding Corp., dated November 26, 2018 and effective November 28, 2018, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on November 27, 2018 and incorporated herein by reference.
3.08	Certificate of Designation of Series A Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 11, 2018 and incorporated herein by reference.
10.01	Lease Agreement, dated as of September 28, 2010, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the amended Current Report on Form 8-K/A, filed with the Commission on February 3, 2012 and incorporated herein by reference.
10.02	Tonix Pharmaceuticals Holding Corp. 2012 Amended and Restated Incentive Stock Option Plan, incorporated herein by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A (File No. 000-54879), filed with the Commission on April 3, 2013.
10.03	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Seth Lederman, dated February 11, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 14, 2014 and incorporated herein by reference.
10.04	Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on May 2, 2014.
10.05	Lease Amendment and Expansion Agreement, dated February 11, 2014, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on February 27, 2015 and incorporated herein by reference.
10.06	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Gregory Sullivan, dated June 3, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on June 3, 2014 and incorporated herein by reference.
10.07	Tonix Pharmaceuticals Holding Corp. 2016 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 25, 2016.
10.08	Tonix Pharmaceuticals Holding Corp. 2017 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on May 2, 2017.
10.09	Sales Agreement, dated August 1, 2017, by and between Tonix Pharmaceuticals Holding Corp. and Cowen and Company, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on August 1, 2017 and incorporated herein by reference.
10.10	Registration Rights Agreement, dated September 28, 2017, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on September 29, 2017 and incorporated herein by reference.

10.11	Purchase Agreement, dated September 28, 2017, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on September 29, 2017 and incorporated herein by reference.
10.12	Sales Agreement, dated May 1, 2018, by and between Tonix Pharmaceuticals Holding Corp. and Cowen and Company, LLC, filed as an exhibit to the Registration Statement on Form S-3 filed with the Commission on May 1, 2018 and incorporated herein by reference.
10.13	Tonix Pharmaceuticals Holding Corp. 2018 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A, filed with the Commission on April 19, 2018.
10.14	Tonix Pharmaceuticals Holding Corp. 2018 Employee Stock Purchase Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A, filed with the Commission on April 19, 2018.
10.15	Purchase Agreement, dated October 18, 2018, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 24, 2018 and incorporated herein by reference.
10.16	Registration Rights Agreement, dated October 18, 2018, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 24, 2018 and incorporated herein by reference.
10.17	Second Amendment of Lease and Assignment of Lease (this "Amendment") made as of December 6, 2018, by and between 509 Madison Avenue Associates, LP, and Tonix Pharmaceuticals, Inc.
10.18	Underwriting Agreement, dated December 7, 2018, by and between Tonix Pharmaceuticals Holding Corp. and A.G.P./Alliance Global Partners, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 11, 2018 and incorporated herein by reference.
10.19	Form of Warrant, dated December 11, 2018, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 11, 2018 and incorporated herein by reference.
14.01	Code of Business Conduct and Ethics for Employees, Executive Officers and Directors, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on February 16, 2016 and incorporated herein by reference.
21.01	List of Subsidiaries.
23.01	Consent of Independent Registered Public Accounting Firm, filed herewith.
31.01	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Tonix Pharmaceuticals Holding Corp.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: March 18, 2019

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

Date: March 18, 2019

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

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ SETH LEDERMAN Seth Lederman	Chief Executive Officer, President and Director (Principal Executive Officer)	March 18, 2019
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2019
/s/ MARGARET SMITH BELL Margaret Smith Bell	Director	March 18, 2019
/s/ DAVID GRANGE David Grange	Director	March 18, 2019
/s/ PATRICK GRACE Patrick Grace	Director	March 18, 2019
/s/ DONALD W. LANDRY Donald W. Landry	Director	March 18, 2019
/s/ ADEOYE OLUKOTUN Adeoye Olukotun	Director	March 18, 2019
/s/ JOHN RHODES John Rhodes	Director	March 18, 2019
/s/ JAMES TRECO James Treco	Director	March 18, 2019

Exhibit 10.17

SECOND AMENDMENT OF LEASE AND ASSIGNMENT OF LEASE

SECOND AMENDMENT OF LEASE AND ASSIGNMENT OF LEASE (this "Amendment") made as of the 6 day of December, 2018 (the "Effective Date"), by and between **509 MADISON AVENUE ASSOCIATES, LP** , a New York limited partnership, having an office c/o Kensico Management, Inc., 509 Madison Avenue, New York, New York 10022 ("Landlord"), **TONIX PHARMACEUTICALS, INC.**, a Delaware corporation having an office at 509 Madison Avenue, Suite 306, New York, New York 10022 ("Assignor"), and **TONIX PHARMACEUTICALS HOLDINGS CORP.**, a Nevada corporation having an office at 509 Madison Avenue, Suite 306, New York, New York 10022 ("Tenant").

W I T N E S S E T H:

WHEREAS, by Agreement of Lease dated (the "Original Lease") as of September 28, 2010, Landlord did demise and let unto Tenant and Tenant did hire and take space on the third floor (also known as Suite 306) as more particularly identified in the Original Lease in the building known by the street address 509 Madison Avenue, New York, New York (the "Building");

WHEREAS, Landlord and Tenant entered into that certain Lease Amendment and Expansion Agreement dated as of February 11, 2014 (the "First Amendment") pursuant to which Tenant also hired and took space on the third floor (known as Suite 310) (Suite 306 and Suite 310 shall collectively be referred to herein as "(the "Original Demised Premises");

WHEREAS, Landlord and Tenant desires to modify the Original Lease to (i) extend the term of the Original Lease, (ii) substitute for the Original Demised Premises other space in the Building located on the sixteenth (16^{th}) floor, being more particularly shown on Exhibit A annexed hereto (and also known as Suite 1608) (the "New Demised Premises"), and (iii) surrender to Landlord the Original Demised Premises and to modify the Original Lease in connection therewith, all as hereinafter set forth (the Original Lease, as modified by the First Amendment and this Amendment, the "Lease").

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

1. Lease of New Demised Premises. Commencing on the later to occur of (i) January 15, 2019 or (ii) the day after Landlord delivers written notice to Tenant of the substantial completion of Landlord's Work (as defined in Section 3(B) hereof) (the "Extended Term Commencement Date"), Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the New Demised Premises upon all of the terms and conditions of the Original Lease, except as follows:

(A) The term of the Lease is extended through and including the last day of the twenty second (22^{nd}) full month following the Extended Term Commencement Date, or on such earlier date upon which said term may be terminated pursuant to any other conditions in the Lease or pursuant to law, upon all of the terms, covenants and conditions contained in the Lease, except as otherwise expressly set forth in this Amendment (the "Extended Term Expiration Date");

(B) The "demised premises" shall mean the New Demised Premises; provided, however, that from the Extended Term Commencement Date until the Surrender Date (as defined in Section 4 hereof), the demised premises shall be deemed to include both the Original Demised Premises and the New Demised Premises, subject to the terms herein;

(C) The annual Base Rent for the New Demised Premises, payable in equal monthly installments (including the Electrical Inclusion Factor), shall be as follows:

a. $195,363.00 per annum for the period commencing on the Extended Term Commencement Date and ending on the day immediately preceding the first anniversary of the Extended Term Commencement Date;

b. $200,944.80 per annum for the period commencing on the first anniversary of the Extended Term Commencement Date and ending on the Extended Term Expiration Date.

(D) "Base Tax Year" as defined in Article 43(A)(2) of the Original Lease shall mean the real estate taxes payable with respect to the Building for the New York City fiscal year beginning on July 1, 2018 and ending on June 30, 2019;

(E) "Tenant's Percentage" as defined in Article 43(A)(4) of the Original lease (as amended by Section 4(B) of the First Amendment) shall mean 1.84%;

(F) The "Electrical Inclusion Factor" as defined in Article 46(2) and (5) of the Original Lease (as amended by Section 4(C) of the First Amendment) shall be "NINE THOUSAND THREE HUNDRED AND THREE DOLLARS AND 00/100 ($9,303.00)"; and

(G) The rentable square footage for the New Demised Premises for purposes of Article 46(C)(6) only (as amended by Section 4(D) of the First Amendment) shall be 2,658 square feet.

2. Original Demised Premises. Landlord and Tenant hereby acknowledge and agree that Tenant shall continue leasing the Original Demised Premises until the Surrender Date (as defined in Section 4 hereof) (the "Original Demised Premises Term"). During the Original Demised Premises Term, and subject to Section 4(B) hereof, Tenant shall lease the Original Demised Premises upon all of the terms and conditions of the Original Lease, as modified by this Amendment, including, without limitation, the continued payment of Base Rent and additional rent with respect to the Original Demised Premises.

3. Condition of New Demised Premises. (A) Tenant covenants and agrees that it shall accept the New Demised Premises in its condition "AS IS" as of the Effective Date, subject to any and all defects therein but subject to Landlord's repair and maintenance obligations as explicitly set forth in the Lease, and that Landlord shall have no obligation to do any work or make any installation, repair or alteration of any kind to or in respect of the New Demised Premises other than using Building standard materials to perform the work described on Exhibit B annexed hereto ("Landlord's Work").

(B) For purposes of this Section 3, "substantial completion" of Landlord's Work shall mean Landlord's Work then remaining to be done, if any, shall have reached that stage of completion such that Tenant could use and occupy the New Demised Premises and operate its business therein without substantial interference by reason of those items still required to be done to complete Landlord's Work. In any event, Tenant will at all times cooperate with Landlord so as not to impede Landlord's ability to complete Landlord's Work as expeditiously as possible. Additionally, Tenant understands and confirms that Landlord's Work shall be deemed substantially completed even though certain details, adjustments or other matters which do not materially impede Tenant's access to the New Demised Premises and use thereof for the conduct of Tenant's business remain to be completed (collectively, "Punch List Items"). Landlord shall complete all Punch List Items within thirty (30) days of substantial completion of Landlord's Work. In the event that any requests for changes and/or additions in Landlord's Work are made by Tenant and approved by Landlord, and such requests extend the estimated time for substantial completion of Landlord's Work, such estimate to be reasonably determined by Landlord or Landlord's contractors or subcontractors hired to perform said required work, then, for the purposes hereof, Landlord's Work shall be deemed to have been substantially completed except for the delay caused by or in any manner related to the requests of Tenant made as aforesaid. Nothing in the preceding sentence shall be construed as requiring Landlord to grant, approve or comply with any such requests for changes and/or additions.

(C) Landlord shall cause substantial completion of Landlord's Work to occur by no later than January 30, 2019 (the "Intended Completion Date") which date shall be further delayed on a day-for-day basis for each day of any Tenant Delay (as hereinafter defined) or delays caused by force majeure or other events beyond Landlord's reasonable control. If for any reason substantial completion does not occur by the Intended Completion Date, then Base Rent with respect to the Original Demised Premises shall be abated during the period commencing on the Intended Completion Date and ending on the date upon which Landlord causes substantial completion to occur. A "Tenant Delay" will be deemed to have occurred if the completion of Landlord's Work is delayed due to any act or omission by Tenant (or Tenant's agents, servants, employees, subtenants, contractors, invitees, licensees and all other persons invited by Tenant into the New Demised Premises as guests or doing lawful business with Tenant), including, but not limited to, delays due to changes in or additions to Landlord's Work requested by Tenant, delays in submission of information or estimates, delays in giving authorizations or approvals, or delays due to the postponement of any work at the request of Tenant.

4. Surrender of Original Demised Premises.

(A) On the later to occur of (i) the Extended Term Commencement Date, and (ii) the date upon which Tenant shall remove all of Tenant's movable personal property and movable trade fixtures from the Original Demised Premises and vacate same and deliver vacant possession thereof to Landlord (such date, as applicable, the "Surrender Date"), Tenant shall surrender possession of the Original Demised Premises to Landlord and Tenant shall give, grant and surrender all of its right, title and interest to the Original Demised Premises to Landlord. Tenant covenants and agrees on behalf of itself, its successors and assigns, that it has not done or suffered (and will not do or suffer) anything whereby the Original Demised Space has (or will) become encumbered in any way whatsoever. Through and including the Surrender Date, Tenant shall continue to pay Landlord any and all payments, sums or charges due or to become due relating to the Original Demised Premises pursuant to the terms of the Original Lease. On or before the Surrender Date, Tenant shall deliver the Original Demised Premises to Landlord broom clean, in good order and condition, except wear and tear, and otherwise in the condition required under the Lease. Tenant shall deliver the Original Demised Premises to Landlord broom clean, in good order and condition Effective as of the Surrender Date (and provided Tenant delivers possession of the Original Demised Premises to Landlord in the condition required by the Original Lease), (i) all references to the "demised premises" in the Original Lease shall mean the New Demised Premises and (ii) Tenant shall have no further obligation to Landlord under the Original Lease (or any amendment thereto) with respect to the Original Demised Premises except with respect to obligations that survive the termination of the Lease.

(B) If Tenant shall fail to surrender possession of the Original Demised Premises to Landlord by the date which is thirty (30) days after the Extended Term Commencement Date, then Tenant shall be deemed to be a holdover in respect thereof and shall be subject to all of Landlord's rights and remedies set forth in the Original Lease and this Amendment by reason of such holdover. Notwithstanding anything to the contrary contained herein, in the event of a holdover hereunder, Tenant shall be required to pay Landlord holdover rent for the Original Demised Premises as required under Article 52 of the Original Lease for each month (or portion thereof) during which Tenant holds over in the Original Demised Premises after the Outside Surrender Date, in addition to any Base Rent and additional rent for the New Demised Premises required hereunder.

5. Broker. Landlord and Tenant each represent and warrant that it has dealt with no broker in connection with this Agreement other than Circle Group Realty LLC (the "Broker") each agree to indemnify and hold the other party harmless from any and all loss, costs, damage or expense (including, without limitation, reasonable attorneys' fees and disbursements) incurred by the other party by reason of any claim or liability to any broker, finder or like agent other than Broker, who shall claim to have dealt with the indemnifying party in connection with this Agreement. This Section shall survive the expiration or earlier termination of the Lease and this Amendment.

6. Assignment and Assumption of Lease.

(A) Assignor hereby assigns, sells, and transfers to and for the exclusive benefit of Tenant, all right, title, interest, claim and demand of Assignor in and to the Lease, including, without limitation, the security deposit. Tenant hereby accepts the foregoing assignment and assumes and agrees to pay, perform, discharge and otherwise be and remain responsible for all covenants, obligations, and liabilities of Assignor as tenant under the Lease.

(B) Landlord hereby grants its consent (the "Consent") to the assignment by Assignor to Assignee, subject to the following terms and conditions:

i. Nothing herein contained shall be construed to modify, waive, impair or affect any of the provisions, covenants, agreements, terms or conditions in the Lease, or to waive any breach thereof, or any right of Landlord against any person, firm, association or corporation liable or responsible for the performance thereof, or to enlarge or increase Landlord's obligations under the Lease, and all provisions, covenants, agreements, terms and conditions of the Lease are hereby mutually declared to be in full force and effect.

ii. This Consent shall not be assignable and shall not be construed as a consent by Landlord to, or as permitting, any other assignment of the Lease without Landlord's prior written consent.

iii. Tenant and Assignee covenant and agree to indemnify and hold Landlord harmless against any and all claims (including, without limitation, reasonable attorneys' fees and disbursements) for brokerage commissions in connection with the Assignment and/or this Consent.

iv. Assignee shall not use or permit the use of the demised premises or any part thereof in any way which might or would violate any of the provisions, covenants, agreements, terms and conditions of the Lease, or for any unlawful purposes or in any unlawful manner and Assignee shall not suffer or permit anything to be done therein or suffer or permit anything to be brought into or kept in the premises which, in the judgment of Landlord, might or shall in any way reasonably impair or tend to impair the character, appearance or reputation of the Building, impair or interfere with or tend to impair or interfere with any of the Building services or the proper and economic heating, cleaning, air conditioning or other servicing of the Building or the demised premises or impair or interfere with or tend to impair or interfere with the use of any of the other areas of the Building by, or occasion discomfort, inconvenience or annoyance to, any of the other tenants of the Building. Assignee shall not install or permit to be installed in the demised premises or any part thereof any electrical or other similar or dissimilar equipment of any kind which, in the judgment of Landlord, might cause any such impairment, interference, discomfort, inconvenience or annoyance.

v. Assignor shall be and remain liable and responsible for the due keeping, performance and observance of all the provisions, covenants, agreements, terms and conditions set forth in the Lease on the part of the tenant under the Lease to be kept, performed and observed and for the payment of the rent, additional rent and all other sums now and/or hereafter becoming payable thereunder, expressly including as such (but not limited to) additional rent, adjustments of rent, and any and all charges for any property, material, labor, utility or other similar or dissimilar services rendered or supplied or furnished by Landlord in, or in connection with, the demised premises under the Lease.

7. Miscellaneous.

(A) As modified and amended by this Agreement, all of the terms, covenants and conditions of the Lease are hereby ratified and confirmed and shall continue to be and remain in full force and effect throughout the remainder of the term thereof.

(B) Unless otherwise set forth herein, capitalized terms shall have the meanings set forth in the Lease.

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

[Signature Page Follows]

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

LANDLORD:

509 MADISON AVENUE ASSOCIATES, LP

By: /s/ Marilyn Cafone
Name: Marilyn Cafone
Title: Corporate Controller

ASSIGNOR:

TONIX PHARMACEUTICALS, INC.

By: /s/ Seth Lederman
Name: Seth Lederman
Title: CEO

TENANT:

TONIX PHARMACEUTICALS HOLDINGS CORP.

By: /s/ Jessica Morris
Name: Jessica Morris
Title: COO

EXHIBIT A

New Demised Premises

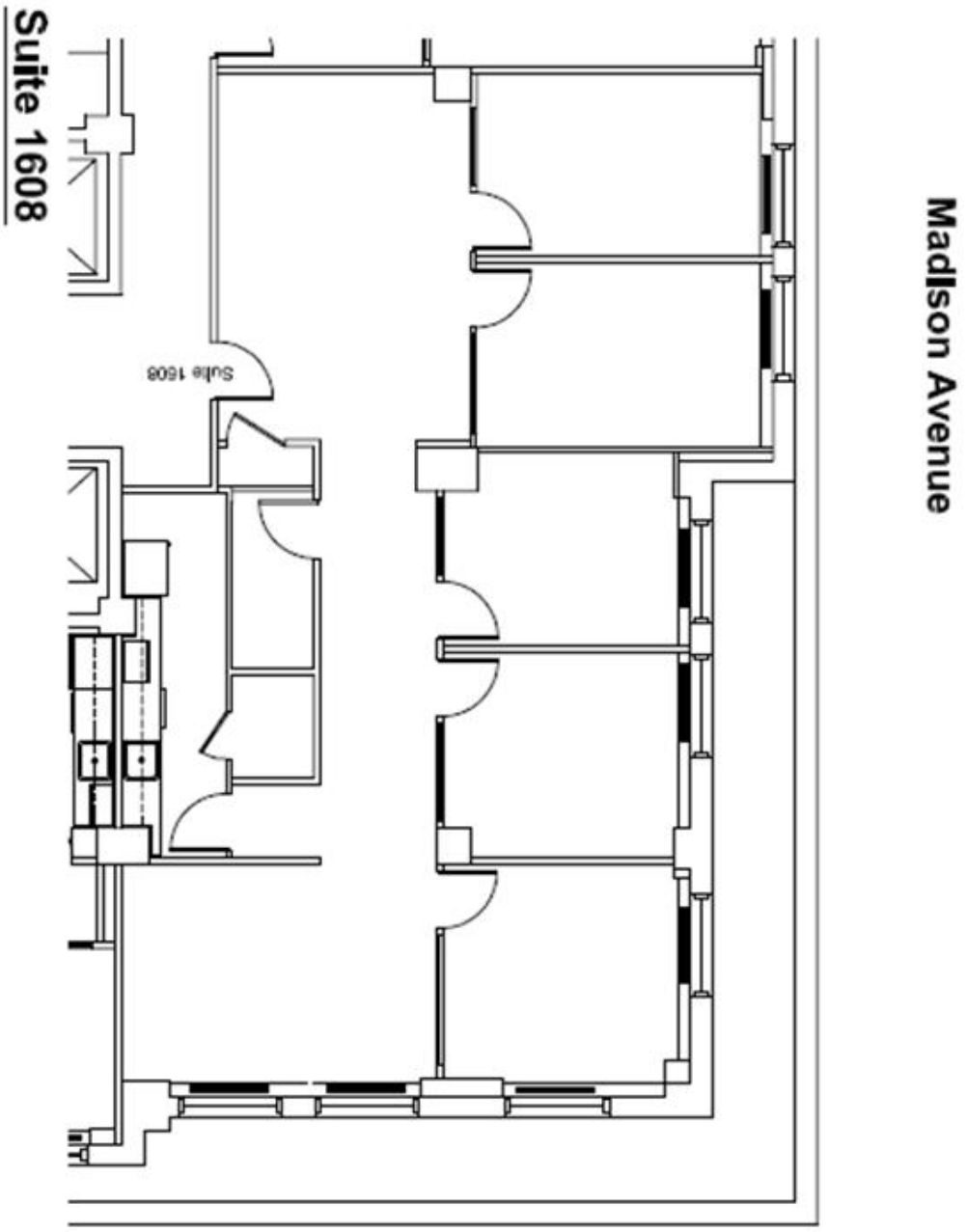

EXHIBIT B

Landlord's Work

Suite 1608

1. Install Floor Power and Data Outlet in location to be specified by Tenant. Power outlet to be 115V/15A separate branch circuit. Data cabling excluded.

2. Paint entire office, except office fronts and doors, Chantilly Lace (off white).

3. Carpet entire area with building standard nylon, 20 oz. broadloom carpet. Carpet to be double adhesive installation with rubber cushion. Carpet choice made by Tenant from building standard selection.

4. Replace wooden entry door.

Exhibit 21.01

SUBSIDIARIES OF THE COMPANY

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

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Tonix Pharmaceuticals Holding Corp. on Form S-1 (Nos. 333-220749, 333-227967, and 333-220749), Form S-3 (Nos. 333-197824 and 333-224586) and Form S-8 (Nos. 333-219928, 333-212300 and 333-202006, and 333-226776) of our report dated March 18, 2019, on our audit of the consolidated financial statements as of December 31, 2018 and 2017 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 18, 2019. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
New York, New York
March 18, 2019

Exhibit 31.01

CERTIFICATION

I, Seth Lederman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 18, 2019

/s/ SETH LEDERMAN

Seth Lederman
Chief Executive Officer

Exhibit 31.02

CERTIFICATION

I, Bradley Saenger, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 18, 2019

/s/ BRADLEY SAENGER

Bradley Saenger
Chief Financial Officer

Exhibit 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2018 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: March 18, 2019

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

I, Bradley Saenger, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2018 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: March 18, 2019

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