As filed with the Securities and Exchange Commission on August 11, 2017
Registration No. 333-_____

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

FORM S-8
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Tonix Pharmaceuticals Holding Corp.
(Exact name of registrant as specified in its charter)

Nevada	**26-1434750**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

509 Madison Avenue, Suite 306
New York, New York 10022
(Address of principal executive offices) (Zip Code)

2017 Stock Incentive Plan
(Full title of the plan)

Seth Lederman, MD, Chief Executive Officer
Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 306
New York, New York 10022
(Name and Address of agent for service)

(212) 980-9155
(Telephone number, including area code, of agent for service)

With a copy to:

Marc J. Ross, Esq.
James M. Turner, Esq.
Sichenzia Ross Ference Kesner LLP
61 Broadway, 32nd Floor
New York, NY 10006
Phone (212) 930-9700
Fax (212) 930-9725

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if smaller reporting company)	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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $0.001 par value	150,000(2)	$ 4.18(3)	$ 627,000	$ 72.67
Common Stock, $0.001 par value	1,130,000(4)	$ 3.305(5)	$ 3,734,650	$ 432.85
TOTAL	**1,280,000**		**$ 4,361,650**	**$ 505.52**

(1) This Registration Statement also registers an indeterminable number of additional securities to be offered or issued upon adjustments or changes made to registered securities by reason of any stock splits, stock dividends or similar transactions as permitted by Rule 416(a) and Rule 416(b) under the Securities Act of 1933, as amended, or the Securities Act.

(2) Represents shares of common stock issuable pursuant to stock option awards outstanding under the 2017 Stock Incentive Plan (the "Plan").

(3) Estimated pursuant to Rule 457(h) solely for purposes of calculating the aggregate offering price and the amount of the registration fee based upon a weighted average of the exercise prices of outstanding options previously granted.

(4) Represents shares of common stock reserved for future issuance pursuant to the Plan.

(5) Estimated pursuant to Rule 457(c) and (h) solely for purposes of calculating the aggregate offering price and the amount of the registration fee based upon the average of the high and low prices reported for the shares on the NASDAQ Global Market on August 10, 2017.

EXPLANATORY NOTE

This Registration Statement contains two parts. The first part contains a reoffer prospectus pursuant to Form S-3 (in accordance with Section C of the General Instructions to the Form S-8), which covers reoffers and resales of "restricted securities" and/or "control securities" (as such terms are defined in Section C of the General Instructions to Form S-8). This reoffer prospectus relates to offers and resales by directors of shares of common stock, par value $0.001 per share (the "Common Stock") that are issuable upon the exercise of options granted by Tonix Pharmaceuticals Holding Corp. (the "Company") pursuant to the Plan. This reoffer prospectus may be used by the Selling Securityholders for reoffers and resales on a continuous or delayed basis in the future of up to 150,000 shares of Common Stock issued pursuant to the Plan. The second part of this Registration Statement contains information required in the Registration Statement pursuant to Part II of Form S-8.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.

The Company will provide each recipient of a grant under the Plan (the "Recipients") with documents that contain information related to the Plan, and other information including, but not limited to, the disclosure required by Item 1 of Form S-8, which information is not required to be and are not being filed as a part of this Registration Statement on Form S-8 (the "Registration Statement") or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. The foregoing information and the documents incorporated by reference in response to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act. A Section 10(a) prospectus will be given to each Recipient who receives common stock covered by this Registration Statement, in accordance with Rule 428(b)(1) under the Securities Act.

Item 2. Registrant Information and Employee Plan Annual Information.

We will provide to each Recipient a written statement advising of the availability of documents incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in this Section 10(a) prospectus) and of documents required to be delivered pursuant to Rule 428(b) under the Securities Act without charge and upon written or oral request by contacting:

Jessica Morris
Executive Vice President – Operations
Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 306
New York, New York 10022

REOFFER PROSPECTUS

150,000 Shares

Common Stock

Issued or issuable under certain awards granted under the Plan

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This reoffer prospectus relates to the public resale, from time to time, of an aggregate of 150,000 shares (the "Shares") of our common stock, $0.001 par value per share by certain securityholders identified herein in the section entitled ''Selling Securityholders''. Such shares have been or may be acquired in connection with awards granted under the Tonix Pharmaceuticals Holding Corp. (the "Company") 2017 Stock Incentive Plan (the "Plan"). You should read this prospectus carefully before you invest in our common stock.

Such resales shall take place on The NASDAQ Global Market, or such other stock market or exchange on which our common stock may be listed or quoted, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated (see "Plan of Distribution" starting on page 31 of this prospectus). We will receive no part of the proceeds from sales made under this reoffer prospectus. The Selling Securityholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the Selling Securityholders will be borne by us.

This reoffer prospectus has been prepared for the purposes of registering the Shares under the Securities Act to allow for future sales by the Selling Securityholders on a continuous or delayed basis to the public without restriction. We have not entered into any underwriting arrangements in connection with the sale of the Shares covered by this reoffer prospectus. The Selling Securityholders identified in this reoffer prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the Shares covered by this reoffer prospectus from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 7 of this reoffer prospectus. These are speculative securities.

Our common stock is quoted on The NASDAQ Global Market under the symbol "TNXP" and the last reported sale price of our common stock on August 10, 2017 was $3.29 per share.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is August 11, 2017

TONIX PHARMACEUTICALS HOLDING CORP.

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Except where the context otherwise requires, the terms, "we," "us," "our" or "the Company," refer to the business of Tonix Pharmaceuticals Holding Corp., a Nevada corporation and its wholly-owned subsidiaries.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

PROSPECTUS SUMMARY

The Commission allows us to ''incorporate by reference'' certain information that we file with the Commission, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the Commission will update automatically, supplement and/or supersede the information disclosed in this prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other document that also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should read the following summary together with the more detailed information regarding our company, our common stock and our financial statements and notes to those statements appearing elsewhere in this prospectus or incorporated herein by reference.

Overview

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

In July 2017, the United States Food and Drug Administration, or FDA, conditionally accepted the proposed trade name Tonmya for TNX-102 SL (cyclobenzaprine HCl sublingual tablets), or TNX-102 SL, for the treatment of PTSD. The FDA's final approval of Tonmya as a name for TNX-102 SL for the treatment of PTSD is subject to a new drug application, or NDA, approval. The United States Patent and Trademark Office, or PTO, has granted the federal registration of the Tonmya mark. TNX-102 SL is an investigational new drug and has not been approved for any indication.

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

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

Our Product Pipeline

Tonmya – Posttraumatic Stress Disorder Program

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

An estimated 8.6 million adults in the U.S. suffer from PTSD, a chronic disorder that is characterized by hyperarousal, avoidance, emotional numbing, and sleep disturbances. People with PTSD suffer significant impairment in their functioning, including occupational activities and social relations, and are at elevated risk for impulsive, violent behaviors toward others and themselves, including suicide. Many patients fail to adequately respond to the medications approved for PTSD. Antidepressants, sedative-hypnotics and antipsychotics not approved for PTSD are commonly prescribed despite generally weak evidence in support of their use. Antianxiety drugs, also called anxiolytics, are not approved for PTSD, but are commonly prescribed despite the recommendations against their use by many experts. Anxiolytics are comprised of benzodiazepine and non-benzodiazepine drugs, which carry risks of tolerance and addiction and are also associated with potential serious side-effects, such as retrograde amnesia.

Phase 2 AtEase Study

In the first quarter of 2015, we commenced a randomized, double-blind, placebo-controlled, 12-week Phase 2 study of Tonmya in participants with military-related PTSD, which we refer to as the AtEase study. The primary objective of this study was to evaluate the potential clinical benefit of using Tonmya to treat military-related PTSD at a dose of 2.8 mg or 5.6 mg. The primary efficacy endpoint was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual-5, or CAPS-5, between those treated with Tonmya and those receiving placebo. The CAPS-5 scale is a standardized structured clinician interview and is considered the gold standard in clinical research and regulatory approval for measuring the symptom severity of PTSD.

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

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

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

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

Open-label Extension Study for AtEase

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

Ongoing Phase 3 Study

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

Prospective Phase 3 Study

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

Long-Term Safety Exposure Study for Tonmya

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

Regulatory Update

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

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

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

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

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

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

In July 2017, the FDA conditionally accepted the proposed trade name Tonmya for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD. A request for review of Tonmya as the proposed name for TNX-102 SL for the management of fibromyalgia has been withdrawn at the FDA.

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

Completed Bioequivalence Study

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

Planned Multi-dose Bridging PK Study

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

Food Effect and Dose-proportionality Studies

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

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

Additional Product Candidates

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

TNX-601

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

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

TNX-801

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

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

TNX-301

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

TNX-701

In addition, we own rights to intellectual property on a biodefense technology relating to the development of protective agents against radiation exposure, which we refer to as TNX-701. We have begun nonclinical research and development on TNX-701. Similar to the regulatory pathway intended for TNX-801, we plan to develop TNX-701 under 21 CFR 601 Subpart H, or the "Animal Rule". We expect significant reduction in development costs and risks compared to the development of other new chemical entities, or NCEs, or new biologic candidates.

Corporate Information

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp. Our principal executive offices are located at 509 Madison Avenue, Suite 306, New York, New York 10022, and our telephone number is (212) 980-9155. Our website addresses are *www.tonixpharma.com, www.tonix.com,* and *www.krele.com*. The information on our websites is not part of this prospectus. We have included our website addresses as a factual reference and do not intend them to be active links to our websites.

The Offering	
Outstanding Common Stock:	7,508,661 shares of our common stock are outstanding as of August 10, 2017.
Common Stock Offered:	Up to 150,000 shares of common stock for sale by the selling stockholders (which include our directors) for their own account pursuant to the Plan.
Selling Securityholders:	The selling securityholders are set forth in the section entitled "Selling Securityholders" of this reoffer prospectus on page 25.
Use of proceeds:	We will not receive any proceeds from the sale of our common stock by the selling stockholders. We would, however, receive proceeds upon the exercise of the stock options by those who receive options under the Plan and exercise such options for cash. Any cash proceeds will be used by us for general corporate purposes.
Risk Factors:	The securities offered hereby involve a high degree of risk. See "Risk Factors."
NASDAQ Global Market trading symbol:	TNXP

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus, including our financial statements and related notes.

RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

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

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

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

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

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

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

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

We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

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

We are largely dependent on the success of our clinical-stage product candidate, Tonmya for PTSD, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical studies, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have one product candidate, Tonmya, in Phase 3 development for the treatment of PTSD, and the success of our business currently depends on its successful development, approval and commercialization. Any projected sales or future revenue predictions are predicated upon FDA approval and market acceptance of Tonmya. If projected sales do not materialize for any reason, it would have a material adverse effect on our business and our ability to continue operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

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

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

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

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

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

- obtaining institutional review board approval to conduct a clinical study at a prospective site.

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

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

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

We rely on third parties to conduct, supervise and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

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

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

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

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

We have limited experience in completing a Phase 3 clinical study and have never submitted an NDA before, and may be unable to do so for Tonmya or other product candidates we are developing.

We initiated a Phase 3 study in military-related PTSD in the first quarter of 2017. As this study is intended to provide efficacy and safety evidence to support marketing approval by the FDA, it is considered a pivotal, confirmatory or registration, study. The conduct of pivotal clinical studies and the submission of a successful NDA is a complicated process. Although members of our management team have extensive industry experience, including in the development, clinical testing and commercialization of drug candidates, we have conducted only one pivotal clinical study before (the AFFIRM study in fibromyalgia participants), have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete this planned clinical study in a way that leads to NDA submission and approval of Tonmya and other product candidates we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical studies would prevent or delay commercialization of Tonmya and other product candidates we are developing.

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

Serious adverse events or undesirable side effects from 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 serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical studies, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

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

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

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

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

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

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

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

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

Our current plans for filing NDAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for our product candidates and therefore reduce the development time. We held a pre-IND meeting with the FDA in October 2012 to discuss the development of Tonmya in PTSD. Following the results of the AtEase Study, we held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in August 2016 to discuss the Phase 3 study design and NDA filing requirement. In December 2016, Tonmya for the treatment of PTSD was granted Breakthrough Therapy designation by the FDA and in March 2017, an Initial Cross-disciplinary Breakthrough Therapy meeting was held with the FDA to discuss the possibility to accelerate the development and approval of Tonmya for PTSD. Although our interactions with the FDA have encouraged our efforts to continue to develop Tonmya for PTSD, there is no assurance that we will satisfy the FDA's requirements for approval in this indication. The timeline for filing and review of our NDA for Tonmya for PTSD is based on our plan to submit this NDA under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any of our product candidates. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us. In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to realize a shortened development timeline for Tonmya for PTSD, and the FDA may not approve our NDA based on their review of the submitted data. If CBP-containing products are withdrawn from the market by the FDA for any safety reason, we may not be able to reference such products to support a 505(b)(2) NDA for Tonmya, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our lead product candidate.

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

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

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

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

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

Our success depends to a significant extent upon the continued services of Dr. Seth Lederman, our President and Chief Executive Officer and Dr. Gregory M. Sullivan, our Chief Medical Officer. Dr. Lederman has overseen Tonix Pharmaceuticals, Inc., a wholly-owned subsidiary, since inception and provides leadership for our growth and operations strategy as well as being an inventor on many of our patents. Dr. Sullivan has served as our Chief Medical Officer since 2014 and directed the Phase 2 AtEase study and is directing the Phase 3 HONOR study. Loss of the services of Drs. Lederman or Sullivan would have a material adverse effect on our growth, revenues, and prospective business. The loss of any of our key personnel, or the inability to attract and retain qualified personnel, may significantly delay or prevent the achievement of our research, development or business objectives and could materially adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates are novel and still in development.

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

Successful development of our products is uncertain.

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

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

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

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

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

Our clinical studies may be conducted in participants 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 participants could suffer adverse medical events or die for reasons that may or may not be related to our product candidates. We cannot ensure that safety issues will not arise with respect to our product candidates in clinical development.

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

We are subject to extensive and costly government regulation.

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

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

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

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

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

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

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

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

Our product candidates may face competition sooner than expected.

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

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

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

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

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

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

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

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

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

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects (including drowsiness and dry mouth), as compared to alternative products or treatment methods;
- the timing of market entry as compared to competitive products;
- the rate of adoption of our products by doctors and nurses;
- product labeling or product insert required by the FDA for each of our products;
- reimbursement policies of government and third-party payors;
- effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and
- unfavorable publicity concerning our products or any similar products.

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

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

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

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

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

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

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

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

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

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

We cannot predict the availability of reimbursement for health care products to be approved in the future. Third-party payors, including Medicare and Medicaid, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs whether approved under Section 505(b)(1), 505(b)(2), or 505(j) of the FDCA, through direct payment mechanisms and through cost containment programs such as the Medicaid Drug Rebate Program. Third-party insurance coverage may not be available to patients for any of our products.

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

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

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

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, hurricanes, floods and fires; and
- difficulty in importing and exporting clinical study materials and study samples.

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

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

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

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

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

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

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

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

We carry insurance for most categories of risk that our business may encounter, however, we may not have adequate levels of coverage. We currently maintain general liability, clinical study, property, workers’ compensation, products liability and directors’ and officers’ insurance, along with an umbrella policy, which collectively costs approximately $600,000 per annum. We cannot provide any assurances that we will be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

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

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

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

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

There may not be market interest in TNX-801.

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

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

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

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

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

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

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

RISKS RELATED TO OUR STOCK

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

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

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

- changes in accounting principles;
- the loss of any of our key scientific or management personnel; and
- if a clinical development program granted Breakthrough Therapy designation does not continue to meet the criteria, the FDA may rescind the designation.

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 August 10, 2017, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 17.6% 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.

USE OF PROCEEDS

The shares which may be sold under this reoffer prospectus will be sold for the respective accounts of each of the Selling Securityholders listed herein (which includes our directors). Accordingly, we will not realize any proceeds from the sale of the shares of our common stock. We will receive proceeds from the exercise of the options; however, no assurance can be given as to when or if any or all of the options will be exercised. If any options are exercised, the proceeds derived therefrom will be used for working capital and general corporate purposes. All expenses of the registration of the shares will be paid by us. See “Selling Securityholders” and “Plan of Distribution.”

SELLING SECURITYHOLDERS

We are registering for resale the Shares covered by this prospectus to permit the Selling Securityholders identified below and their pledgees, donees, transferees and other successors-in-interest that receive their securities from a Selling Securityholder as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus to resell the Shares when and as they deem appropriate. The Selling Securityholders may acquire these Shares from us pursuant to the Plan. The Shares may not be sold or otherwise transferred by the Selling Securityholders unless and until the applicable awards vest and are exercised, as applicable, in accordance with the terms and conditions of the Plan.

The following table sets forth:

- the name of each Selling Securityholder;
- the position(s), office or other material relationship with our company and its predecessors or affiliates, over the last three years of each Selling Securityholder;
- the number and percentage of shares of our common stock that each Selling Securityholder beneficially owned as of August 10, 2017 prior to the offering for resale of the Shares under this prospectus;
- the number of shares of our common stock that may be offered for resale for the account of each Selling Securityholder under this prospectus; and
- the number and percentage of shares of our common stock to be beneficially owned by each Selling Securityholder after the offering of the resale shares (assuming all of the offered resale shares are sold by such Selling Securityholder).

Information with respect to beneficial ownership is based upon information obtained from the Selling Securityholders. Because the Selling Securityholders may offer all or part of the shares of common stock, which they own pursuant to the offering contemplated by this reoffer prospectus, and because its offering is not being underwritten on a firm commitment basis, no estimate can be given as to the amount of shares that will be held upon termination of this offering.

The number of shares in the column "Number of Shares Being Offered" represents all of the shares of our common stock that each Selling Securityholder may offer under this prospectus. We do not know how long the Selling Securityholders will hold the shares before selling them or how many shares they will sell. The shares of our common stock offered by this prospectus may be offered from time to time by the Selling Securityholders listed below. We cannot assure you that any of the Selling Securityholders will offer for sale or sell any or all of the shares of common stock offered by them by this prospectus.

	Number of Shares Beneficially Owned Prior to Offering (1)		Number of Shares Being Offered	Number of Shares Beneficially Owned After Offering (2)	
Securityholders	**Number**	**Percent (%)**		**Number**	**Percent (%)**
Stuart Davidson (3)	15,390	*	20,000	15,390	*
Patrick Grace (4)	6,927	*	20,000	6,927	*
Donald Landry (5)	14,624	*	20,000	14,624	*
Ernest Mario (6)	79,824	1.06%	20,000	79,824	1.06%
Charles Mather, IV (7)	7,605	*	20,000	7,605	*
John Rhodes (8)	24,704	*	30,000	24,704	*
Samuel Saks (9)	12,049	*	20,000	12,049	*

*less than 1%

(1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any shares as to which the Selling Securityholder has sole or shared voting power or investment power and also any shares which the Selling Securityholder has the right to acquire within 60 days. Applicable percentage ownership is based on 7,508,661 shares of common stock outstanding as of August 10, 2017.

(2) Assumes that all shares of common stock to be offered, as set forth above, are sold pursuant to this offering and that no other shares of common stock are acquired or disposed of by the Selling Securityholders prior to the termination of this offering. Because the Selling Securityholders may sell all, some or none of their shares of common stock or may acquire or dispose of other shares of common stock, no reliable estimate can be made of the aggregate number of shares of common stock that will be sold pursuant to this offering or the number or percentage of shares of common stock that each Selling Securityholder will own upon completion of this offering.

(3) Mr. Davidson is a member of the Board. The shares of common stock beneficially owned prior to this offering include 4,097 shares of common stock issuable upon exercise of options which are currently exercisable or become exercisable within 60 days, 7,454 shares of common stock and 1,084 shares of common stock underlying warrants owned by Lysander, LLC and 655 shares owned by Oystercatcher Trust. Stuart Davidson, as the Member of Lysander, LLC and Trustee of Oystercatcher Trust, has investment and voting control over the shares held by these entities. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

(4) Mr. Grace is a member of the Board. The shares of common stock beneficially owned prior to this offering include 4,172 shares of common stock issuable upon exercise of options which are currently exercisable or become exercisable within 60 days. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

(5) Dr. Landry is a member of the Board. The shares of common stock beneficially owned prior to this offering include 4,022 shares of common stock issuable upon exercise of options which are currently exercisable or become exercisable within 60 days, 125 shares of common stock underlying warrants, and 3,246 shares of common stock and 1,267 shares of common stock issuable upon exercise of outstanding warrants owned by L&L. Donald Landry, as a Member of L&L, has investment and voting control over the shares held by this entity. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

(6) Dr. Mario is a member of the Board. The shares of common stock beneficially owned prior to this offering include 4,022 shares of common stock issuable upon exercise of options which are currently exercisable or become exercisable within 60 days, 6,084 shares of common stock issuable upon exercise of outstanding warrants and 5,895 shares of common stock owned by the Ernest and Mildred Mario Revocable Trust. Dr. Mario, as Trustee of the Ernest and Mildred Mario Revocable Trust, has investment and voting control over the shares held by this entity. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

(7) Mr. Mather is a member of the Board. The shares of common stock beneficially owned prior to this offering include 4,772 shares of common stock issuable upon settlement of previously issued and vested RSUs and exercise of options which are currently exercisable or become exercisable within 60 days and 300 shares of common stock issuable upon exercise of outstanding warrants. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

(8) Mr. Rhodes is a member of the Board and our Lead Director. The shares of common stock beneficially owned prior to this offering include 4,807 shares of common stock issuable upon exercise of options which are currently exercisable or become exercisable within 60 days and 3,927 shares of common stock issuable upon exercise of outstanding warrants. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

(9) Dr. Saks is a member of the Board. The shares of common stock beneficially owned prior to this offering include 4,022 shares of common stock issuable upon exercise of options which are currently exercisable or become exercisable within 60 days and 1,422 shares of common stock issuable upon exercise of outstanding warrants. The shares of common stock registered for resale hereunder represent shares issuable upon exercise of unvested stock options.

PLAN OF DISTRIBUTION

The Selling Securityholders and any of their respective pledgees, donees, assignees and other successors-in-interest may, from time to time, sell any or all of their shares of our common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Securityholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales after this registration statement becomes effective;
- broker-dealers may agree with the Selling Securityholders to sell a specified number of such shares at a stipulated price per share;
- through the writing of options on the shares;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Securityholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus. The Selling Securityholders will have the sole and absolute discretion not to accept any purchase offer or make any sale of shares if they deem the purchase price to be unsatisfactory at any particular time.

The Selling Securityholders may also engage in short sales against the box after this registration statement becomes effective, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades.

The Selling Securityholders or their respective pledges, donees, transferees or other successors in interest, may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. Such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the Selling Securityholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principal or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then market price. The Selling Securityholders cannot assure that all or any of the shares offered in this prospectus will be issued to, or sold by, the Selling Securityholders. The Selling Securityholders and any brokers, dealers or agents, upon effecting the sale of any of the shares offered in this prospectus, may be deemed to be ‘‘underwriters’’ as that term is defined under the Securities Act or the Securities Exchange Act of 1934, as amended, or the rules and regulations under such acts. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the Selling Securityholders. The Selling Securityholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The Selling Securityholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledge or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or any other applicable provision of the Securities Act amending the list of Selling Securityholders to include the pledge, transferee or other successors in interest as Selling Securityholders under this prospectus.

The Selling Securityholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledges or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of Selling Securityholders to include the pledge, transferee or other successors in interest as Selling Securityholders under this prospectus.

Each of the Selling Securityholders acquired the securities offered hereby in the ordinary course of business and have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any Selling Securityholder. If we are notified by any Selling Securityholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the

Selling Securityholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of our common stock and activities of the Selling Securityholders.

We will bear all costs, expenses and fees in connection with the registration of the common stock offered hereby. However, the Selling Securityholders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of common stock offered pursuant to this reoffer prospectus. We have agreed to indemnify certain of the Selling Securityholders against certain liabilities, including liabilities under the Act, or to contribute to payments to which any of those security holders may be required to make in respect thereof.

There can be no assurance that the Selling Securityholders will sell any or all of the securities offered by them hereby.

LEGAL MATTERS

The validity of the issuance of the securities offered by this prospectus will be passed upon for us by Sichenzia Ross Ference Kesner LLP, New York, New York.

EXPERTS

The consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. and subsidiaries as of December 31, 2016 and 2015 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (unless otherwise noted, the SEC file number for each of the documents listed below is 001-36019):

- Annual Report on Form 10-K for the year ended December 31, 2016, filed on April 13, 2017;
- Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed on May 12, 2017;
- Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed on August 11, 2017;
- Definitive Proxy Statement on Schedule 14A, filed on May 2, 2017;
- Current Reports on Form 8-K, filed on January 10, 2017 (as to Item 8.01 only), January 31, 2017 (as to Item 8.01 only), March 2, 2017 (as to Item 8.01 only), March 14, 2017, March 16, 2017, March 28, 2017, March 30, 2017, April 3, 2017, April 4, 2017, April 11, 2017, April 13, 2017, May 22, 2017, May 30, 2017, June 15, 2017, June 16, 2017, July 6, 2017 (as to Item 8.01 only) and August 1, 2017 and
- The description of our common stock contained in our Form 8-A, filed on July 23, 2013.

We also incorporate by reference into this prospectus additional documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits on such form that are related to such items) that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the completion or termination of the offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information deemed furnished and not filed with the SEC. Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus, or the date of the documents incorporated by reference in this prospectus.

We will provide to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, at no cost to the requester, a copy of any and all of the information that is incorporated by reference in this prospectus.

You may request, and we will provide you with, a copy of these filings, at no cost, by contacting us at:

Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 306
New York, New York 10022
Attention: Investor Relations
Telephone (212) 980-9155

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant, the registrant has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this reoffer prospectus. This reoffer prospectus is part of that registration statement and does not contain all the information included in the registration statement. For further information with respect to our common stock and us, you should refer to the registration statement, its exhibits and the material incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this reoffer prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document. The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission's Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at http://www.sec.gov.

You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission's public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

TONIX PHARMACEUTICALS HOLDING CORP.

150,000 SHARES OF COMMON STOCK

REOFFER PROSPECTUS

August 11, 2017

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 3. Incorporation of Documents by Reference.

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (unless otherwise noted, the SEC file number for each of the documents listed below is 001-36019):

- Annual Report on Form 10-K for the year ended December 31, 2016 filed on April 13, 2017;
- Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 filed on May 12, 2017;
- Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 filed on August 11, 2017;
- Definitive Proxy Statement on Schedule 14A filed on May 2, 2017;
- Current Reports on Form 8-K filed on January 10, 2017 (as to Item 8.01 only), January 31, 2017 (as to Item 8.01 only), March 2, 2017 (as to Item 8.01 only), March 14, 2017, March 16, 2017, March 28, 2017, March 30, 2017, April 3, 2017, April 4, 2017, April 11, 2017, April 13, 2017, May 22, 2017, May 30, 2017, June 15, 2017, June 16, 2017, July 6, 2017 (as to Item 8.01 only) and August 1, 2017 and
- The description of our common stock contained in our Form 8-A filed on July 23, 2013.

We also incorporate by reference into this prospectus additional documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits on such form that are related to such items) that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the completion or termination of the offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information deemed furnished and not filed with the SEC. Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus, or the date of the documents incorporated by reference in this prospectus.

We will provide to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, at no cost to the requester, a copy of any and all of the information that is incorporated by reference in this prospectus.

You may request, and we will provide you with, a copy of these filings, at no cost, by contacting us at:

Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 306
New York, New York 10022
Attention: Investor Relations
Telephone (212) 980-9155

Item 4. Description of Securities.

Not applicable.

Item 5. Interests of Named Experts and Counsel.

Not applicable.

Item 6. Indemnification of Directors and Officers.

Our bylaws, as amended, provide to the fullest extent permitted by Nevada law, our directors or officers shall not be personally liable to us or our shareholders for damages for breach of such director's or officer's fiduciary duty. The effect of this provision of our bylaws, as amended, is to eliminate our right and our shareholders (through shareholders' derivative suits on behalf of our company) to recover damages against a director or officer for breach of the fiduciary duty of care as a director or officer (including breaches resulting from negligent or grossly negligent behavior), except under certain situations defined by statute. We believe that the indemnification provisions in our bylaws, as amended, are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Item 7. Exemption from Registration Claimed.

Not applicable.

Item 8. Exhibits.

Exhibit Number	Description
4.1	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
5.1	Opinion of Sichenzia Ross Ference Kesner LLP
23.1	Consent of EisnerAmper LLP
23.2	Consent of Sichenzia Ross Ference Kesner LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)

Item 9. Undertakings.

A. The undersigned Registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

Provided, however, that paragraphs (A)(1)(i) and (A)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

B. The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

C. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on August 11, 2017.

TONIX PHARMACEUTICALS HOLDING CORP.

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

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Seth Lederman and Bradley Saenger, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution, for him in any and all capacities, to sign any or all amendments to this Registration Statement on Form S-8 (including post-effective amendments), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agent, proxy and agent, or his substitute, may lawfully do or cause to be done by virtue hereof

Pursuant to the requirements of the Securities Act of 1933, as amended, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

Signature	Title	Date
/s/ SETH LEDERMAN Seth Lederman	Chief Executive Officer (Principal Executive Officer) and Director	August 11, 2017
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	August 11, 2017
/s/ STUART DAVIDSON Stuart Davidson	Director	August 11, 2017
/s/ PATRICK GRACE Patrick Grace	Director	August 11, 2017
/s/ DONALD W. LANDRY Donald W. Landry	Director	August 11, 2017
/s/ ERNEST MARIO Ernest Mario	Director	August 11, 2017
/s/ CHARLES MATHER IV Charles Mather IV	Director	August 11, 2017
/s/ JOHN RHODES John Rhodes	Director	August 11, 2017
/s/ SAMUEL SAKS Samuel Saks	Director	August 11, 2017

EXHIBIT 5.1

SICHENZIA ROSS FERENCE KESNER LLP

August 11, 2017

VIA ELECTRONIC TRANSMISSION

Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Re: Tonix Pharmaceuticals Holding Corp.
Form S-8 Registration Statement

Ladies and Gentlemen:

We refer to the above-captioned registration statement on Form S-8 (the "Registration Statement") under the Securities Act of 1933, as amended (the "Act"), filed by Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Company"), with the Securities and Exchange Commission.

We have examined the originals, photocopies, certified copies or other evidence of such records of the Company, certificates of officers of the Company and public officials, and other documents as we have deemed relevant and necessary as a basis for the opinion hereinafter expressed. In such examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as certified copies or photocopies and the authenticity of the originals of such latter documents.

Based on our examination mentioned above, we are of the opinion that the securities being registered to be sold pursuant to the Registration Statement are duly authorized and will be, when sold in the manner described in the Registration Statement, legally and validly issued, and fully paid and non-assessable.

We hereby consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement. In giving the foregoing consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Act, or the rules and regulations of the Securities and Exchange Commission.

Very truly yours,

/s/ Sichenzia Ross Ference Kesner LLP
Sichenzia Ross Ference Kesner LLP

61 Broadway | New York, NY | 10006
T (212) 930 9700 | F (212) 930 9725 | WWW.SRFKLLP.COM

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of Tonix Pharmaceuticals Holding Corp. on Form S-8 to be filed on or about August 11, 2017, of our report dated April 13, 2017, on our audits of the consolidated financial statements as of December 31, 2016 and 2015 and for each of the years then ended, which report was included in the Annual Report on Form 10-K. We also consent to the reference of our firm under the caption "Experts" in the Registration Statement on Form S-8.

/s/EISNERAMPER LLP

New York, New York
August 11, 2017