As filed with the Securities and Exchange Commission on February 10, 2015

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)

Tonix Pharmaceuticals Holding Corp. 2014 Employee Stock Purchase Plan
(Full title of the plan)

Seth Lederman
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)

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	**Amount to be Registered (1)**	**Proposed Maximum Offering Price Per Share (3)**	**Proposed Maximum Aggregate Offering Price**	**Amount of Registration Fee**
Common Stock, $0.001 par value, to be issued under the Tonix Pharmaceuticals Holding Corp. 2014 Employee Stock Purchase Plan	300,000(2)	$ 4.94	$ 1,482,000	$ 172.21

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, (the "Securities Act"), this Registration Statement shall also cover any additional shares of common stock of Tonix Pharmaceuticals Holding Corp. (the "Registrant") that become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the Registrant's receipt of consideration that results in an increase in the number of the Registrant's outstanding shares of common stock.

(2) Represents shares of common stock reserved for issuance under the Tonix Pharmaceuticals Holding Corp. 2014 Employee Stock Purchase Plan (the "2014 ESPP").

(3) Estimated in accordance with Rule 457(c) and (h) under the Securities Act solely for the purpose of calculating the registration fee on the basis of 85% of $5.805 per share, which is the average of the high and low prices of the Registrant's common stock, as reported on the Nasdaq Global Market on February 6, 2015. Pursuant to the 2014 ESPP, the purchase price of the shares of the Registrant's common stock reserved for issuance thereunder will be the lower of (i) 85% of the fair market value of a share of the Registrant's common stock on the first trading day of the offering period or (ii) 85% of the fair market value of a share of the Registrant's common stock on the last trading day of the offering period.

EXPLANATORY NOTE

This registration statement on Form S-8 (the "Registration Statement") relates to 300,000 shares of the common stock of Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Registrant," the "Company," "we," "us" or "our"), $0.001 par value per share (the "Common Stock"), which are issuable pursuant to the 2014 ESPP. Under the 2014 ESPP, a total of 300,000 shares of Common Stock have been reserved for purchase by employees of the Company.

This Registration Statement also includes a reoffer prospectus prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3, which may be utilized for reofferings and resales on a continuous or a delayed basis in the future related to 13,978 unregistered shares of Common Stock previously acquired by selling shareholders pursuant to the 2014 ESPP.

The reoffer prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in schedules and exhibits to the Registration Statement, as permitted by the rules and regulations of the Securities and Exchange Commission (the "SEC" or the "Commission"). Statements contained in this reoffer prospectus as to the contents of any agreement, instrument or other document referred to herein are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

The documents containing the information specified in Part I will be sent or given to employees as specified by Rule 428(b)(1) of the Securities Act. Such documents are not being filed with the Commission either as part of this registration statement or as prospectuses or prospectus supplements pursuant to Rule 424 of the Securities Act. Such documents and the documents incorporated by reference in this registration statement pursuant to Item 3 of Part II hereof, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

REOFFER PROSPECTUS

TONIX PHARMACEUTICALS HOLDING CORP.
13,978 Shares of
Common Stock

This prospectus relates to the reoffer and resale by certain selling stockholders of shares of common stock, par value $0.001 per share ("Common Stock"), of Tonix Pharmaceuticals Holding Corp. (the "Registrant," the "Company," "we," "us" or "our") that have been acquired by the selling stockholders pursuant to the 2014 ESPP. The shares are being reoffered and resold for the account of the selling stockholders and we will not receive any of the proceeds from the resale of the shares.

The selling stockholders have advised us that the resale of their shares may be effected from time to time in one or more transactions on The NASDAQ Global Market (or on any other stock exchange on which the shares of our Common Stock may be listed at the time of sale), in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated. See "Plan of Distribution." We will bear all expenses in connection with the preparation of this prospectus.

Our Common Stock is quoted on The NASDAQ Global Market under the symbol "TNXP". On February 6, 2015, the closing price for our Common Stock as reported by The NASDAQ Global Market was $5.76.

Investing in our Common Stock involves a high degree of risk. See "Risk Factors" beginning on page P-7 for a discussion of information that should be considered in connection with an investment in our Common Stock.

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 February 10, 2015

TABLE OF CONTENTS

PROSPECTUS SUMMARY

Unless otherwise indicated or unless the context requires otherwise, this prospectus supplement includes the accounts of Tonix Pharmaceuticals Holding Corp., a Nevada corporation and its wholly-owned subsidiaries, collectively referred to as "we", "us", "Tonix" or the "Company".

Business Overview

We are a clinical-stage pharmaceutical company dedicated to the development of novel prescription products for challenging medical disorders. Our lead drug development programs are directed toward conditions affecting the central nervous system, or CNS. Our pipeline of product candidates is led by TNX-102 SL (cyclobenzaprine HCl sublingual tablet), which is in clinical development as a potential treatment for fibromyalgia, or FM, and represents a new class of medication for this disorder. We recently completed a Phase 2b clinical trial of TNX-102 SL in FM, and we expect to initiate a Phase 3 clinical trial in the second quarter of 2015. TNX-102 SL is also in development as a potential treatment for post-traumatic stress disorder, or PTSD, and we commenced a Phase 2 trial for this indication in January 2015. We are also developing TNX-201 ((R)-isometheptene mucate) as a potential treatment for episodic tension-type headache, or ETTH. We have completed a Phase 1 trial of TNX-201, and we expect to begin a Phase 2 trial in ETTH in the second quarter of 2015. We hold worldwide commercialization rights to TNX-102 SL and TNX-201. Our pipeline also includes preclinical programs for the treatment of alcohol abuse and dependence, and for protection from smallpox as well as from radiation and chemical exposure.

TNX-102 SL

Our lead product candidate, TNX-102 SL, is a small, rapidly disintegrating tablet containing cyclobenzaprine, or CBP, for sublingual administration. CBP is the active pharmaceutical ingredient of two widely prescribed products, or CBP products, that are approved for acute use only. We are developing TNX-102 SL as a bedtime therapy for the management of FM and PTSD, chronic indications for which CBP products are not approved. We believe that three key aspects of TNX-102 SL distinguish it from CBP products: (1) it is being developed at a dose level well below the lowest marketed doses of CBP products; (2) it is dosed daily at bedtime under the tongue for rapid sublingual absorption, whereas CBP products are swallowed and provide absorption in the small intestine; and (3) it is being developed with a safety profile suitable for chronic use, whereas CBP products are not approved for more than two to three weeks of use. We expect that any applications we submit to the Food and Drug Administration, or FDA, for approval of TNX-102 SL will be submitted under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, which we believe will allow for a shorter timeline of clinical and non-clinical development as compared to that needed to fulfill the requirements of Section 505(b)(1), under which new chemical entities, or NCEs, that have never been approved in the United States, are generally developed to meet the FDA's new drug registration requirements.

We have completed three Phase 1 clinical trials of TNX-102 sublingual formulations under Canadian clinical trial applications as well as under a U.S. investigational new drug application, or IND. These studies demonstrated TNX-102 SL to exhibit a safety and pharmacokinetic profile that we believe supports chronic bedtime administration for the treatment of FM and PTSD. These studies also demonstrated TNX-102 SL to have several potentially advantageous characteristics as compared to marketed CBP products, which are not approved for these indications. For example, our Phase 1 comparative trials showed that TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following sublingual administration relative to oral immediate-release CBP tablets. TNX-102 SL was generally well-tolerated, with no serious adverse events reported in any of these studies. Some subjects experienced transient numbness on the tongue after TNX-102 SL administration, and other side-effects reported were similar to those reported with approved CBP products.

TNX-102 SL – Fibromyalgia Program

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

In September 2013, we commenced enrollment of our BESTFIT trial, a randomized, double-blind, placebo-controlled Phase 2b clinical trial of TNX-102 SL in FM. We reported preliminary top-line results from the BESTFIT trial in September 2014. In the BESTFIT trial, 205 patients with FM were randomized at 17 U.S. centers to treatment with either TNX-102 SL 2.8 mg or placebo sublingual tablets at bedtime daily for 12 weeks. The primary outcome measure of the BESTFIT trial was the mean change in week 12 average daily pain intensity from baseline on the 11-point Numeric Rating Scale, using a daily telephonic diary. In the BESTFIT trial, TNX-102 SL did not achieve statistical significance in the primary outcome measure ($p=0.172$). However, the trial demonstrated that TNX-102 SL had a statistically significant effect on pain as measured by a 30% responder analysis of the primary pain data ($p=0.033$), in which a responder is defined as a subject for whom pain intensity was reduced by at least 30% at week 12 as compared to baseline. The 30% response rate in this analysis was 33.0% in the active treatment arm as compared to 19.6% in the control arm. The BESTFIT trial also showed statistically significant improvements with TNX-102 SL in the declared secondary analyses of the Patient Global Impression of Change ($p=0.025$) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R ($p=0.014$). The study showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the patient-reported outcomes measurement information system, or PROMIS, Sleep Disturbance instrument ($p=0.005$). In addition, statistically significant improvements with TNX-102 SL were observed on several FIQ-R items (pain, sleep quality, anxiety, stiffness, and sensitivity) as well as on the overall symptom subdomain.

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

Following our report of the results of the BESTFIT trial, we requested guidance from the FDA on our proposed use of a 30% pain responder analysis as the primary efficacy endpoint in our prospective Phase 3 clinical trials. In January 2015, we announced receipt of the written guidance, whereby the FDA accepted our proposal to use a 30% pain responder analysis as the primary efficacy endpoint in our Phase 3 trials to support the approval of TNX-102 SL for the management of FM. We expect to initiate a randomized, double-blind, placebo-controlled, 12-week Phase 3 trial of TNX-102 SL in 500 patients with FM in the second quarter of 2015. We expect to report top line results from this trial in the third quarter of 2016.

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

FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. According to published estimates, there are approximately five to fifteen million people suffering from FM in the U.S. (Vincent et al, Arthritis Care Res 2013;65:786-792; Lawrence et al, Arthritis Rheum 2008;58:26-35). The peak incidence of FM occurs at 20 – 50 years of age, and 80-90% of diagnosed patients are female. FM may have a substantial negative impact on social and occupational function, including disrupted relationships with family and friends, social isolation, reduced activities of daily living and leisure activities, avoidance of physical activity, and loss of career or inability to advance in careers or education.

Although the disordered brain processes that underlie FM are yet to be fully understood, the mechanisms of drugs that treat central pain are believed to target certain aspects of nerve signaling. Three drugs, pregabalin (Lyrica®), duloxetine (Cymbalta®), and milnacipran (Savella®), are approved by the FDA for the management of FM and are believed to act upon molecular pathways involved in central pain. Pregabalin is believed to affect nerve signaling by blocking calcium channels on nerve cells, and is considered a nerve membrane stabilizer. Duloxetine and milnacipran are believed to directly inhibit the reuptake of serotonin and norepinephrine by nerves, and are referred to as Serotonin and Norepinephrine Reuptake Inhibitors, or SNRIs. CBP, the active ingredient of TNX-102 SL, is a selective antagonist of serotonin and norepinephrine receptors as well as an inhibitor of serotonin and norepinephrine reuptake, and we refer to it as a Serotonin and Norepinephrine receptor Antagonist and Reuptake Inhibitor, or SNARI.

Despite the availability and use of a variety of pharmacologic and non-pharmacologic interventions, FM remains a significant unmet medical need. Many patients fail to adequately respond to the approved medications, or discontinue therapy due to poor tolerability. Prescription pain and sleep medications are frequently prescribed for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic effect. An important goal of FM treatment is to reduce the use of opiate analgesics as well as of benzodiazepine and non-benzodiazepine sedative-hypnotic medications by FM patients. CBP has no recognized addictive potential. We believe that TNX-102 SL, if approved, could reduce the exposure of FM patients to medications that have not been shown to be effective in treating FM and are associated with significant safety risks.

TNX-102 SL – Post-Traumatic Stress Disorder Program

We are developing TNX-102 SL for the management of PTSD under a separate IND allowed by the FDA in June 2014. In January 2015, we commenced the AtEase trial, a 220-patient, randomized, double-blind, placebo-controlled, 12-week Phase 2 trial of TNX-102 SL in subjects with military-related PTSD. This trial will be conducted at approximately 25 U.S. centers. The AtEase trial is designed to study the efficacy and safety of two doses of TNX-102 SL (2.8 mg and 5.6 mg) administered once daily at bedtime. The primary objective of the AtEase trial is to evaluate the efficacy of TNX-102 SL 2.8 mg as compared to placebo sublingual tablet following eight weeks of treatment using the Clinician-Administered PTSD Scale.

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

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

The treatment of PTSD typically involves a multidimensional approach that includes pharmacologic and psychosocial interventions. Two antidepressant drugs, paroxetine (Paxil®) and sertraline (Zoloft®), are FDA-approved for the treatment of PTSD. Other antidepressants, as well as sedative-hypnotics and antipsychotics, are commonly prescribed off-label despite generally weak clinical evidence in support of their use. With the exception of certain antidepressants, there is also little evidence to support relapse prevention in the chronic setting for those who initially improve with acute pharmacotherapy. Patients often take several medications concurrently to address multiple symptoms. Sleep disturbances play a central role in PTSD, and present a difficult therapeutic challenge. For example, in 2009, although 30% of veterans with PTSD were prescribed benzodiazepines, a class of sedative-hypnotic medication (Lund et al, J Clin Psych 2012;73:292-296), evidence suggests that these drugs interfere with recovery from, and increase the incidence of, PTSD (van Minnen et al, Behav Res Ther 2002;40:439-57) and are not recommended per current guidelines (Department of Veterans Affairs, 2010). Co-morbid alcohol and substance abuse and dependence, which occur frequently in the PTSD population, generally complicate the use of sedative-hypnotics in these patients. Given TNX-102 SL's pharmacological mode of action, its ability to significantly improve sleep quality as demonstrated in a Phase 2b trial in FM, and its lack of Drug Enforcement Agency scheduling, we believe TNX-102 SL, if approved, has the potential to serve as an important and differentiated new option for the management of PTSD.

TNX-201 – Episodic Tension-Type Headache Program

We are developing TNX-201 for the treatment of ETTH under an IND cleared by the FDA in October 2014. TNX-201 is (R)-isometheptene mucate, a single isomer of isometheptene mucate, or IMH. Although currently not approved for any indication, IMH has an extensive history of use as a prescription pharmaceutical in the U.S. as a racemic mixture, which consists of two mirror-image isomers, or IMH enantiomers. Racemic IMH has been marketed as Octin® for conditions including tension and vascular headache. In addition, racemic IMH has been marketed in combination products for the relief of tension and vascular headaches (examples include Midrin®, MigraTen® and Prodrin®). Between 1990 and 1998, Midrin was the second most-widely prescribed headache medication in the U.S. (Gibbs et al, Headache 2003;43:330-335)

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

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

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

We are preparing to commence a 150-patient Phase 2 study in ETTH in the second quarter of 2015, in which patients will be randomized at approximately 10 U.S. centers to receive TNX-201 140 mg (4 x 35 mg) or placebo capsules. The primary efficacy endpoint will be the difference between the two study arms in the number of subjects who report complete relief from their headache pain at two hours following a dose of study medication. We expect to report top line results from this study in the fourth quarter of 2015. Although the clinical development of TNX-201 can be accelerated based on the available information on racemic IMH, approval of any NDA will be as a new chemical entity pursuant to Section 505(b)(1) of the FDCA.

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

Many people who suffer ETTH are able to adequately manage their symptoms through the use of over-the-counter products containing aspirin, acetaminophen, or non-steroidal anti-inflammatory drugs (NSAIDs). However, an analysis of IMS data indicates that approximately 10 million prescriptions for medications intended to treat non-migraine headaches are issued each year in the U.S., excluding those issued for NSAIDs, indicating that many people who suffer ETTH seek prescription options. All of the products that are FDA-approved for the treatment of ETTH contain butalbital, a barbiturate that is a Drug Enforcement Agency Schedule III substance. Due to its potential for addiction and abuse, extended use of butalbital is not recommended, and this agent is banned in several European countries. Although butalbital-containing products may have initial therapeutic value in treating the primary headache condition, they pose a significant risk of inducing analgesic-overuse headache over time due to their tendency for overuse, driven by tolerance and physical and psychological dependence (Young et al, Curr Pain Headache Rep 2002;6:151-155). We are developing TNX-201 with the goal of introducing a safe, effective, and non-addictive treatment option for ETTH.

Additional Product Candidates

We also have a pipeline of other product candidates, including TNX-301. TNX-301 is a fixed dose combination drug product, or CDP, containing two FDA-approved drugs, disulfiram and selegiline. We intend to develop TNX-301 CDP under Section 505(b)(2) of the FDCA as a potential treatment for alcohol abuse and dependence, and we have commenced development work on TNX-301 formulations. In addition, we own rights to intellectual property on two biodefense technologies: one relating to the development of novel smallpox vaccines; and the other to the development of protective agents against radiation exposure. We have begun non-clinical research and development on these programs. The FDA Animal Efficacy Rule provides a mechanism for product licensure when human efficacy studies are not feasible or ethical. As a result, the licensure of these biodefense products in the U.S. may not require human efficacy studies, which we believe will reduce our development costs and risks compared to the development of other NCEs or new biologic candidates.

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* 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.

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.

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

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

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

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

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

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

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

We are a development-stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to developing our technology and undertaking preclinical studies and clinical trials of our clinical-stage product candidates, TNX-102 SL and TNX-201. We have not yet obtained regulatory approvals for TNX-102 SL, TNX-201 or any of our other product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this prospectus and also include:

- our ability to obtain additional funding to develop our product candidates;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our clinical trials through all phases of clinical development, including our trials of TNX-102 SL and TNX-201;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for TNX-102 SL and TNX-201 or any of our other product candidates in the United States and foreign jurisdictions;
- potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
- our dependence on third party contract manufacturing organizations, or CMOs, to supply or manufacture our products;
- our dependence on third party contract research organizations, or CROs, to conduct our clinical trials and non-clinical research;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

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

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

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

We are largely dependent on the success of our clinical-stage product candidates, TNX-102 SL and TNX-201, and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have two product candidates in clinical stages of development for three indications: TNX-102 SL for the management of FM and PTSD, and TNX-201 for the treatment of ETTH, and the success of our business currently depends on their successful development, approval and commercialization. Any projected sales or future revenue predictions are predicated upon FDA approval and market acceptance of TNX-102 SL and TNX-201. If projected sales do not materialize for any reason, it would have a material adverse effect on our business and our ability to continue operations.

TNX-102 SL and TNX-201 have not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for these product candidates anywhere in the world. The clinical development programs for TNX-102 SL and TNX-201 may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or foreign regulatory authorities because our clinical trials fail to demonstrate to their satisfaction that these product candidates are safe and effective or a clinical program may be put on hold due to unexpected safety issues. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approvals for TNX-102 SL or TNX-201 in a timely manner would have a material adverse impact on our business and our stock price.

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

Because we have limited financial and human resources, we are currently focusing on the regulatory approvals of TNX-102 SL and TNX-201. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

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

- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated recruitment or retention rate of patients in clinical trials;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials;
- negative results of clinical trials; or
- adverse events.

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

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

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

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

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

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

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

If our planned Phase 3 trial of TNX-102 SL in FM is successful, we then expect to conduct a second Phase 3 confirmatory study in support of product registration. As these trials are intended to provide evidence to support marketing approval by the FDA, they are considered pivotal trials. The conduct of pivotal clinical trials and the submission of a successful NDA is a complicated process. Although members of our management team have extensive industry experience, including in the development, clinical testing and commercialization of drug candidates, our company has never conducted a pivotal clinical trial before, has limited experience in preparing, submitting and prosecuting regulatory filings, and has not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete these planned clinical trials in a way that leads to NDA submission and approval of TNX-102 SL and other product candidates we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent or delay commercialization of TNX-102 SL and other product candidates we are developing.

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

Serious adverse events or undesirable side effects from TNX-102 SL or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials, including TNX-102 SL, may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If TNX-102 SL or any of our other product candidates cause serious adverse events or undesirable side effects:

- regulatory authorities may impose a clinical hold or risk evaluation and mitigation strategies, or REMs, which could result in substantial delays, significantly increase the cost of development, and/or adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the patients who can receive the product;
- we may be subject to limitations on how we promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

If we are unable to file for approval of TNX-102 SL under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing NDAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for our product candidates and therefore possibly obtain a shortened review period for the applications. We held an End-of-Phase 2 meeting with the FDA in February 2013 to discuss our most advanced development program, in which we are developing TNX-102 SL for the management of FM. In late 2014, following the results of the BESTFIT trial, we corresponded with the FDA to further discuss our Phase 3 registration program plan. We held a pre-IND meeting with the FDA in October 2012 to discuss the development of TNX-102 SL in PTSD. Although our interactions with the FDA have encouraged our efforts to continue to develop TNX-102 SL for FM and PTSD, there is no assurance that we will satisfy the FDA's requirements for approval in these indications. The timeline for filing and review of our NDAs for TNX-102 SL is based on our plan to submit those NDAs under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any of our product candidates. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us. In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to obtain shortened review of our applications for TNX-102 SL, and the FDA may not agree that any of our products qualify for marketing approval. If CBP-containing products are withdrawn from the market by the FDA for any reason, we may not be able to reference such products to support a 505(b)(2) NDA for TNX-102 SL, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our product candidates.

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

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

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

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

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

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

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

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

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

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

We have no manufacturing facilities, and we have no experience in the clinical or commercial-scale manufacture of drugs or in designing drug manufacturing processes. We intend to rely on CMOs to manufacture some or all of our product candidates in clinical trials and our products that reach commercialization. Completion of our clinical trials and commercialization of our product candidates requires the manufacture of a sufficient supply of our product candidates. We have contracted with outside sources to manufacture our development compounds, including TNX-102 SL. If, for any reason, we become unable to rely on our current sources for the manufacture of our product candidates, either for clinical trials or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for pre-clinical, clinical, and commercial purposes. Although we are in discussions with other manufacturers we have identified as potential alternative CMOs of TNX-102 SL, we may not be successful in negotiating acceptable terms with any of them.

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

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

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

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

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

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

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

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

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

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

Our product candidates are novel and still in development.

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

Successful development of our products is uncertain.

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

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

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

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

The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates.

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

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

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of biopharmaceutical products. The FDA regulates small molecule chemical entities as drugs, subject to an NDA under the FDCA. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If TNX-102 SL, TNX-201 or any of our other product candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, hurricanes, floods and fires; and
- difficulty in importing and exporting clinical trial materials and study samples.

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR STOCK

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

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

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

- the loss of any of our key scientific or management personnel.

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

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

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

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

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

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

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

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

Efforts to comply with recently enacted changes in securities laws and regulations will increase our costs and require additional management resources, and we still may fail to comply.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on their internal controls over financial reporting in their annual reports on Form 10-K. Effective January 1, 2015, we transitioned from a smaller reporting company to an accelerated filer. As a result, for the first time, the independent registered public accounting firm auditing our financial statements will be required to attest to the effectiveness of our internal controls over financial reporting for the year ended December 31, 2014. If we are unable to conclude that we have effective internal controls over financial reporting or if our independent registered public accounting firm is unable to provide us with a report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of January 30, 2015, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 21.9% 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.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and may impair our ability to raise capital in the future.

Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, including the ending of restriction on resale, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. 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 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 that could cause actual results and developments to differ materially from those expressed or implied in such statements.

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

You should read this prospectus and any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, 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 any accompanying prospectus supplement is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above, as well as the risk factors referred to on page 4 of this prospectus and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements

USE OF PROCEEDS

This prospectus relates to sale of shares of common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any proceeds from the sale of shares by the selling stockholders.

SELLING STOCKHOLDERS

This prospectus relates to the reoffer and resale of 13,978 shares of Common Stock acquired by the selling stockholders pursuant to the 2014 ESPP.

The following table sets forth (i) the number of shares of Common Stock beneficially owned by each selling stockholder as of January 30, 2015, (ii) the number of shares to be offered for resale by each selling stockholder (i.e., the total number of shares acquired by the selling stockholder under the 2014 ESPP), and (iii) the number and percentage of shares of Common Stock that each selling stockholder will beneficially own after completion of the offering, assuming that all shares of Common Stock that may be offered for resale are sold and no other shares of Common Stock beneficially owned by the selling stockholders also are sold.

Unless otherwise indicated, the address for each of the selling stockholders named below is c/o Tonix Pharmaceuticals Holding Corp., 509 Madison Avenue, Suite 306, New York, New York 10022.

Selling Security Holder	Number of Shares Beneficially Owned Prior to Offering (1)	Shares Being Registered	Number of Shares Beneficially Owned Upon Completion of Offering (1)	Percentage of Shares Beneficially Owned (1) Before Offering (2)	After Offering (2)
Bruce Daugherty	190,027(3)	1,749	188,278(3)	1.74%	1.72%
Jessica Edgar	1,494	1,494	0	*	*
Donald Kellerman	1,494	1,494	0	*	*
Gregory Sullivan	2,731	1,749	982	*	*
Bradley Saenger	1,749	1,749	0	*	*
Ronald Notvest	1,749	1,749	0	*	*
Amy Forst	1,749	1,749	0	*	*
Heather Juviden	1,155	1,155	0	*	*
Charlotte Stewart	493	493	0	*	*
Agata Magalinskaya	597	597	0	*	*
TOTAL	203,238	13,978	189,260	1.86%	1.73%

* Less than one percent (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 stockholder has sole or shared voting power or investment power and also any shares which the selling stockholder has the right to acquire within 60 days.

(2) Percentage is based upon 10,805,220 shares of common stock outstanding as of January 30, 2015.

(3) Includes 55,392 shares of common stock issuable upon exercise of warrants and 75,118 shares of common stock issuable upon exercise of stock options.

PLAN OF DISTRIBUTION

Timing of Sales

The selling stockholders may offer and sell the shares covered by this prospectus at various times. The selling stockholders will act independently of our company in making decisions with respect to the timing, manner and size of each sale.

No Known Agreements to Resell the Shares

To our knowledge, no selling stockholder has any agreement or understanding, directly or indirectly, with any person to resell the common shares covered by this prospectus.

Offering Price

The sales price offered by the selling stockholders to the public may be:

1. the market price prevailing at the time of sale;
2. a price related to such prevailing market price; or
3. such other price as the selling stockholders determine from time to time.

Manner of Sale

The common shares may be sold by means of one or more of the following methods:

1. a block trade in which the broker-dealer so engaged will attempt to sell the common shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
2. Purchases by a broker-dealer as principal and resale by that broker-dealer for its account pursuant to this prospectus;
3. ordinary brokerage transactions in which the broker solicits purchasers;
4. through options, swaps or derivatives;
5. in transactions to cover short sales;
6. privately negotiated transactions; or
7. in a combination of any of the above methods.

The selling stockholders may sell their common shares directly to purchasers or may use brokers, dealers, underwriters or agents to sell their common shares. Brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers may receive commissions, discounts or concessions from the selling stockholders, or, if any such broker-dealer acts as agent for the purchaser of common shares, from the purchaser in amounts to be negotiated immediately prior to the sale. The compensation received by brokers or dealers may, but is not expected to, exceed that which is customary for the types of transactions involved.

Broker-dealers may agree with a selling stockholder to sell a specified number of common shares at a stipulated price per common share, and, to the extent the broker-dealer is unable to do so acting as agent for a selling stockholder, to purchase as principal any unsold common shares at the price required to fulfill the broker-dealer commitment to the selling stockholder.

Broker-dealers who acquire common shares as principal may thereafter resell the common shares from time to time in transactions, which may involve block transactions and sales to and through other broker-dealers, including transactions of the nature described above, on The NASDAQ Global Market or otherwise at prices and on terms then prevailing at the time of sale, at prices then related to the then-current market price or in negotiated transactions. In connection with resales of the common shares, broker-dealers may pay to or receive from the purchasers of shares commissions as described above.

If our selling stockholders enter into arrangements with brokers or dealers, as described above, we are obligated to file a post-effective amendment to this registration statement disclosing such arrangements, including the names of any broker-dealers acting as underwriters.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the sale of the common shares may be deemed to be “underwriters” within the meaning of the Securities Act. In that event, any commissions received by broker-dealers or agents and any profit on the resale of the common shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act.

Sales Pursuant to Rule 144

Any common shares covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus.

Regulation M

The selling stockholders must comply with the requirements of the Securities Act and the Exchange Act in the offer and sale of the common stock. In particular we will advise the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of common shares in the market and to the activities of the selling stockholders and their affiliates. Regulation M under the Exchange Act prohibits, with certain exceptions, participants in a distribution from bidding for, or purchasing for an account in which the participant has a beneficial interest, any of the securities that are the subject of the distribution.

Accordingly, during such times as a selling stockholder may be deemed to be engaged in a distribution of the common stock, and therefore be considered to be an underwriter, the selling stockholder must comply with applicable law and, among other things:

1. may not engage in any stabilization activities in connection with our common stock;

2. may not cover short sales by purchasing shares while the distribution is taking place; and

3. may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities other than as permitted under the Exchange Act.

State Securities Laws

Under the securities laws of some states, the common shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the common shares may not be sold unless the shares have been registered or qualified for sale in the state or an exemption from registration or qualification is available and is complied with.

Expenses of Registration

We are bearing all costs relating to the registration of the common stock. These expenses are estimated to be $5,000, including, but not limited to, legal, accounting, printing and mailing fees. The selling stockholders, however, will pay any commissions or other fees payable to brokers or dealers in connection with any sale of the common stock.

LEGAL MATTERS

The validity of the common stock has been passed upon, for us by Sichenzia Ross Friedman Ference LLP, New York, New York.

EXPERTS

The consolidated financial statements of Tonix Pharmaceuticals Holding Corp. appearing in Tonix Pharmaceuticals Holding Corp.'s Annual Report (Form 10-K) for the year ended December 31, 2013, have been audited by EisnerAmper LLP, independent registered public accounting firm, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of said firm as experts in accounting and auditing.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The Registrant hereby incorporates by reference into this Registration Statement the following documents previously filed with the Commission:

(a) The Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (the "Annual Report"), filed with the Commission on March 28, 2014 (Commission File No. 001-36019), pursuant to Section 13 of the Securities Exchange Act of 1934, as amended (the "Exchange Act");

(b) All other reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act since the end of the fiscal year covered by the Annual Report (other than portions of these documents not deemed to be filed); and

(c) The description of the Registrant's common stock contained in the Registrant's Registration Statement on Form 8-A, as filed with the Commission on July 23, 2013, pursuant to Section 12(b) of the Exchange Act, including any amendment or report filed for the purpose of updating such description.

In addition, all documents filed by the Registrant pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act on or after the date of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold shall be deemed to be incorporated by reference in this Registration Statement and to be part hereof from the date of filing of such documents; *provided*, *however*, that documents or information deemed to have been furnished and not filed in accordance with the rules of the Commission shall not be deemed incorporated by reference into this Registration Statement. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any subsequently filed document which also is deemed to be incorporated by reference herein 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 Registration Statement.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a Registration Statement on Form S-8 that we filed with the SEC. We are subject to the informational reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to file reports, proxy statements and other information with the SEC. All such filings are available at the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our filings are also available free of charge at the website of the SEC at www.sec.gov. A copy of any document incorporated by reference in the registration statement of which this reoffer prospectus forms a part but which is not delivered with this reoffer prospectus will be provided by us without charge to any person to whom this reoffer prospectus has been delivered upon oral or written request to that person. Requests for documents should be directed to Tonix Pharmaceuticals Holding Corp., Attention: Secretary, 509 Madison Avenue, Suite 306, New York, New York 10022, (212) 980-9155.

TONIX PHARMACEUTICALS HOLDING CORP.

13,978 SHARES

COMMON STOCK, PAR VALUE $0.001

Prospectus

February 10, 2015

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

Item 3. Incorporation of Documents by Reference.

The Registrant hereby incorporates by reference into this Registration Statement the following documents previously filed with the Securities and Exchange Commission (the "Commission"):

(a) The Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (the "Annual Report"), filed with the Commission on March 28, 2014 (Commission File No. 001-36019), pursuant to Section 13 of the Securities Exchange Act of 1934, as amended (the "Exchange Act");

(b) All other reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act since the end of the fiscal year covered by the Annual Report (other than portions of these documents not deemed to be filed); and

(c) The description of the Registrant's common stock contained in the Registrant's Registration Statement on Form 8-A, as filed with the Commission on July 23, 2013, pursuant to Section 12(b) of the Exchange Act, including any amendment or report filed for the purpose of updating such description.

In addition, all documents filed by the Registrant pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act on or after the date of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold shall be deemed to be incorporated by reference in this Registration Statement and to be part hereof from the date of filing of such documents; *provided*, *however*, that documents or information deemed to have been furnished and not filed in accordance with the rules of the Commission shall not be deemed incorporated by reference into this Registration Statement. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any subsequently filed document which also is deemed to be incorporated by reference herein 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 Registration Statement.

Item 4. Description of Securities.

Not applicable.

Item 5. Interests of Named Experts and Counsel.

Not applicable.

Item 6. Indemnification of Directors and Officers.

As permitted by Section 78.7502 of the Nevada Revised Statutes ("NRS"), the articles of incorporation of the Registrant provide that the Registrant shall indemnify each and every officer and director to the fullest extent permitted by applicable state law. Consequently, the directors and officers of the Registrant generally will not be personally liable to the Registrant or the stockholders for monetary damages unless:

- The director's or officer's act or failure to act constitutes a breach of his or her fiduciary duties as a director or officer, and his breach of those duties involves intentional misconduct, fraud or a knowing violation of law; or
- The director or officer does not act in good faith and in a manner which he or she reasonably believes to be in or not opposed to the best interests of the Registrant and, with respect to any criminal action or proceeding, the director or officer has reasonable cause to believe his or her conduct was unlawful.

The Registrant's bylaws provide that the Registrant shall indemnify and hold harmless each person who shall serve at any time as a director or officer from and against any and all claims, judgments and liabilities to which such person shall become subject by reason of having been a director or officer of the Registrant, or by reason of any action alleged to have been taken or omitted to have been taken by him or her as such director or officer. The bylaws further provide that the Registrant shall reimburse each such person for all legal and other expenses reasonably incurred in connection with any such claim or liability; provided, however that no such person shall be indemnified against, or be reimbursed for, any expense incurred in connection with any claim or liability arising out of his or her own negligence or willful misconduct. The right of any person to be indemnified under the bylaws is subject to the right of the Board of Directors, in lieu of such indemnity, to settle any such claim, action, suit or proceeding at the expense of the Registrant by the payment of the amount of such settlement and the costs and expenses incurred in connection therewith.

The rights accruing to any person under the provisions of the Registrant's bylaws do not exclude any other right to which an officer or director may be entitled, including rights pursuant to the NRS, articles of incorporation, indemnification agreements, a vote of stockholders or disinterested directors, or otherwise.

In accordance with permissive provisions in the Registrant's bylaws, we may maintain insurance on behalf of any person who is a director or officer against any loss arising from any claim asserted against him and incurred by him in any such capacity, subject to certain exclusions.

At present, the Registrant is not aware of any pending litigation or proceeding involving any person who is or was a director, officer, employee or other agent of the Registrant or is or was serving at the Registrant's request as a director, officer, employee or agent of another entity regarding which indemnification is sought, and the Registrant not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to the Registrant's directors, officers and controlling persons 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
5.1	Opinion of Sichenzia Ross Friedman Ference LLP
23.1	Consent of EisnerAmper LLP
23.2	Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1)
24.1	Power of Attorney (contained on signature page hereto)
99.1	Tonix Pharmaceuticals Holding Corp. 2014 Employee Stock Purchase Plan (1)

(1) Incorporated by reference to Annex B of the Registrant's Proxy Statement, dated May 2, 2014 (File No. 001-36019), filed with the Commission on May 2, 2014.

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 February 10, 2015.

TONIX PHARMACEUTICALS HOLDING CORP.

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

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Seth Lederman and Leland Gershell, 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	February 10, 2015
/s/ LELAND GERSHELL Leland Gershell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 10, 2015
/s/ STUART DAVIDSON Stuart Davidson	Director	February 10, 2015
/s/ PATRICK GRACE Patrick Grace	Director	February 10, 2015
/s/ DONALD W. LANDRY Donald W. Landry	Director	February 10, 2015
/s/ ERNEST MARIO Ernest Mario	Director	February 10, 2015

Charles Mather IV	Director	February 10, 2015
/s/ JOHN RHODES John Rhodes	Director	February 10, 2015
/s/ SAMUEL SAKS Samuel Saks	Director	February 10, 2015

Exhibit 5.1

SICHENZIA ROSS FRIEDMAN FERENCE LLP
Attorneys At Law
61 Broadway, 32nd Floor
New York, New York 10006

Telephone: (212) 930-9700
Facsimile: (212) 930-9725

February 10, 2015

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 5.01 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 Friedman Ference LLP
Sichenzia Ross Friedman Ference LLP

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-8) of Tonix Pharmaceuticals Holding Corp. for the registration of 300,000 shares of its common stock reserved for issuance under the Tonix Pharmaceuticals Holding Corp. 2014 Employee Stock Purchase Plan and to the incorporation by reference therein of our report dated March 28, 2014, with respect to the consolidated financial statements of Tonix Pharmaceuticals Holding Corp. included in its Annual Report (Form 10-K) for the year ended December 31, 2013, filed with the Securities and Exchange Commission.

/ s / E I S N E R A M P E R L L P

New York, New York
February 10, 2015