

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

POST-EFFECTIVE AMENDMENT NO. 1

to
FORM S-1
on
FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TONIX PHARMACEUTICALS HOLDING CORP.

(Name of registrant in its charter)

Nevada
(State or other Jurisdiction
of Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

26-1434750
(I.R.S. Employer
Identification No.)

509 Madison Avenue, Suite 306
New York, New York 10022
(212) 980-9155

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Seth Lederman
Chief Executive Officer
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small 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)

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

On May 10, 2013, Tonix Pharmaceuticals Holding Corp. (the “Company”) filed with the Securities and Exchange Commission (the “Commission”) a registration statement on Form S-1 (File No. 333-188547) (the “Registration Statement” or the “Form S-1”), which was amended by pre-effective amendments filed on June 20, 2013, June 21, 2013, July 2, 2013, July 31, 2013 and August 8, 2013 to register the offer and sale of 2,680,000 units (“Units”) of the Company, each Unit consisting of one share of common stock, par value \$0.001 per share (“Common Stock”) and one Series A Warrant (the “Warrants”) to purchase one share of Common Stock in connection with an underwritten public offering. The Registration Statement also registered (i) 402,000 additional Warrants to purchase up to 402,000 shares of Common Stock to cover over-allotments and (ii) warrants to purchase shares of Common Stock to the underwriters (the “Underwriter Warrants”). The Registration Statement was declared effective by the Commission on August 8, 2013. On August 14, 2013, the Company sold an aggregate of 2,680,000 shares of Common Stock and Warrants to purchase 3,082,000 shares of Common Stock, including the over-allotment option, pursuant to the Registration Statement. In addition, the Company issued Underwriter Warrants to purchase 107,200 shares of Common Stock. Since that date, 1,947,510 of the Warrants and 57,426 of the Underwriter Warrants have been exercised, leaving Warrants and Underwriter Warrants to purchase 1,134,490 and 49,774 shares of Common Stock, respectively, unexercised.

This Post-Effective Amendment No. 1 to Form S-1 on Form S-3 (this “Post-Effective Amendment”) is being filed to (i) convert the Form S-1 into a registration statement on Form S-3, and (ii) register only the exercise of the Warrants and Underwriter Warrants already issued and outstanding, consisting of an aggregate of 1,184,264 shares of Common Stock issuable upon exercise of the Warrants and Underwriter Warrants. No further offering will be made pursuant to this Post-Effective Amendment. All filing fees payable in connection with the registration of these securities were previously paid by the registrant in connection with the filing of the Form S-1.

Registration of Common Stock Upon Exercise of Warrants

This Post-Effective Amendment also contains an updated prospectus relating to an aggregate of 1,184,264 shares of common stock issuable upon the exercise of the Warrants and Underwriter Warrants previously issued that remain outstanding. This Post-Effective Amendment is being filed in compliance with Section 10(a)(3) of the Securities Act of 1933, as amended.

The information in this prospectus is not complete and may be changed. We may not sell these securities under this prospectus until the registration statement of which it is a part and filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

SUBJECT TO COMPLETION, DATED APRIL 9, 2014



**1,184,264 Shares of Common Stock Issuable
Upon Exercise of Outstanding Warrants**

We are offering up to 1,134,490 shares of our common stock that are issuable at a purchase price of \$4.25 per share from time to time upon exercise of currently outstanding warrants that we issued on August 14, 2013 as part of a public offering of our common stock and warrants. Additionally, we are offering up to 49,774 shares of common stock that are issuable at a purchase price of \$4.25 per share upon exercise of the outstanding warrants issued to the underwriter and its designees as part of our public offering. No securities are being offered pursuant to this prospectus other than the shares of our common stock that will be issued upon exercise of those currently outstanding warrants.

Our common stock is listed on The NASDAQ Capital Market under the symbol "TNXP." On April 8, 2014, the last reported sale price of our common stock on The NASDAQ Capital Market was \$11.43 per share.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this prospectus under "Risk Factors" beginning on page 6 of this prospectus.

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

This prospectus is dated __ , 2014

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC. As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC's website or its offices described below under the heading "Where You Can Find Additional Information".

You should rely only on the information that is contained in this prospectus or that is incorporated by reference into this prospectus. We have not authorized anyone to provide you with information that is in addition to or different from that contained in, or incorporated by reference into, this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it.

The shares of common stock offered by this prospectus are not being offered in any jurisdiction where the offer or sale of such common stock is not permitted. You should not assume that the information contained in, or incorporated by reference into, this prospectus is accurate as of any date other than the date of this prospectus or, in the case of the documents incorporated by reference, the date of such documents, regardless of the date of delivery of this prospectus or any sale of the common stock offered by this prospectus. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

PROSPECTUS SUMMARY

This summary highlights information contained throughout this prospectus and is qualified in its entirety to the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information that should be considered before investing in our common stock. Investors should read the entire prospectus carefully, including the more detailed information regarding our business, the risks of purchasing our common stock discussed in this prospectus under "Risk Factors" beginning on page 6 of this prospectus and our financial statements and the accompanying notes incorporated by reference in this prospectus.

Unless otherwise indicated or unless the context requires otherwise, this prospectus includes the accounts of Tonix Pharmaceuticals Holding Corp. ("Tonix") and its wholly-owned subsidiaries, as follows, collectively referred to as "we", "us" or the "Company": Tonix Pharmaceuticals, Inc., a Delaware corporation ("Tonix Sub"), Krele LLC, a Delaware limited liability company ("Krele"), Tonix Pharmaceuticals (Canada), Inc., a corporation incorporated under the laws of the province of New Brunswick, Canada ("Tonix Canada") and Tonix Pharmaceuticals (Barbados) Ltd., a corporation incorporated under the laws of Barbados ("Tonix Barbados"). Tonix Sub is a wholly-owned subsidiary of Tonix, and Krele, Tonix Canada and Tonix Barbados are wholly-owned subsidiaries of Tonix Sub.

Business Overview

We are a pharmaceutical company dedicated to the development of novel pharmaceutical products for challenging problems. Our lead drug development programs are directed toward central nervous system (CNS) conditions that manifest with pain that originates in the brain, or central pain. Central pain results from abnormal sensory processing in the CNS, rather than from dysfunction in peripheral tissues where pain is perceived. Our most advanced development program is for the management of fibromyalgia, or FM, a central pain syndrome. We also have development programs for the management of post-traumatic stress disorder, or PTSD, in which central pain is a component, and for the relief of episodic tension-type headache, or ETTH. We also have a pipeline of additional product candidates that we plan to develop for other CNS indications.

TNX-102 SL

Our lead product candidate, TNX-102 sublingual tablet, or TNX-102 SL, is a small, rapidly disintegrating tablet containing CBP for sublingual administration. We are developing TNX-102 SL as a bedtime therapy for the management of FM and PTSD. CBP is the active pharmaceutical ingredient of two widely prescribed products, and we are pursuing the development of TNX-102 SL for indications distinct from those for which current CBP products are approved. We believe that TNX-102 SL is an optimized CBP product for the treatment of FM and PTSD, and is distinct from current CBP products in three ways: (1) it is being developed at a dose level significantly below the lowest marketed doses of current CBP products; (2) it is placed under the tongue, to disintegrate, dissolve and provide sublingual absorption, whereas current CBP products are swallowed and provide absorption in the small intestine; and (3) it is being developed for chronic use, whereas current CBP products are marketed for 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 marketed in the United States, are generally developed to meet the FDA's requirements for new drug approvals.

We have conducted several clinical and non-clinical pharmacokinetic studies of TNX-102 sublingual formulations, which we believe support the development of TNX-102 SL as a novel therapeutic product for FM and PTSD. Results from these studies demonstrate a number of potentially advantageous characteristics as compared to current CBP-containing products (Flexeril® and Amrix®), which are not approved for these indications. For example, our Phase 1 comparative studies showed that TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following administration relative to oral CBP tablets. TNX-102 SL was generally well-tolerated, with no serious adverse events reported in these studies. Some subjects experienced transient numbness on the tongue after TNX-102 SL administration, and other side-effects reported were similar to those associated with current CBP products.

TNX-102 SL – Fibromyalgia Program

We are developing TNX-102 SL for the treatment of FM under a U.S. Investigational New Drug application, or IND, and we held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in February 2013. TNX-102 SL is currently in a Phase 2b/3 clinical trial for the improvement of pain in subjects with FM, from which we expect to report initial results in the fourth quarter of 2014. Our therapeutic strategy is supported by results from a randomized, double-blind, placebo-controlled Phase 2a study of low dose TNX-102 immediate release capsules, or TNX-102 capsules, which we have also referred to as VLD CBP, taken between dinner and bedtime in 36 subjects with FM, which demonstrated a significant decrease in pain and other symptoms after eight weeks of treatment. This study also demonstrated that TNX-102 capsules led to a significant improvement in objective measures of sleep quality, which we believe relates to the mechanism by which CBP leads to improvement of FM symptoms. We have completed four Phase 1 studies under Canadian Clinical Trial Applications. Our Phase 1 studies demonstrated TNX-102 SL to exhibit a pharmacokinetic profile that we believe supports chronic bedtime administration for the treatment of FM, and is distinct from those of currently-available CBP products.

FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. According to the National Institutes of Health, there are approximately five million people suffering from FM in the U.S. 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, Lyrica® (pregabalin), Cymbalta® (duloxetine), and Savella® (milnacipran), are approved by the FDA for the management of FM and are believed to act upon molecular pathways involved in central pain. Lyrica is believed to affect nerve signaling by blocking calcium channels on nerve cells, and is considered a nerve membrane stabilizer. Cymbalta and Savella 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.

As many products used for the treatment of FM are approved and marketed for other conditions, sales of these products related specifically to FM can only be estimated. Based on information obtained from publicly available sources, we believe U.S. sales of prescription drugs specifically for the treatment of FM totaled approximately \$1.5 billion in 2012, and we believe this segment had grown at a compounded annual growth rate of approximately 14% between 2007 and 2012. Based on information obtained from publicly available sources, we believe 2012 sales of Cymbalta, Lyrica, and Savella in FM were approximately \$600 million, \$475 million, and \$100 million, respectively.

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 taken ‘off-label’ 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 dependence on opiate analgesic as well as on benzodiazepine and non-benzodiazepine sedative-hypnotic medications by FM patients. Since 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.

At our End-of-Phase 2/Pre-Phase 3 meeting with the FDA, 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. We believe that positive results from two adequate, well-controlled safety and efficacy studies and the establishment of long-term safety for chronic use would support the approval of TNX-102 SL for the management of FM.

Phase 2b/3 “BESTFIT” Study

We are currently conducting the randomized, double-blind, placebo-controlled Phase 2b/3 BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy (BESTFIT) trial, which we initiated in September 2013 under the IND. In this multicenter clinical trial, subjects with FM are treated with either TNX-102 2.8 mg sublingual tablets (SL) or a placebo at bedtime daily for 12 weeks. We expect to enroll approximately 200 patients into this study. The primary efficacy endpoint is change in pain from baseline to week 12. If successful, this trial will serve as the first of two pivotal studies to support a New Drug Application (NDA) for TNX-102 SL in FM. We have engaged Premier Research International, LLC, a contract research organization, or CRO, to provide clinical and data management services for this Phase 2b/3 trial. We expect to report initial efficacy results from the BESTFIT trial in the fourth quarter of 2014.

The primary efficacy measure in this study will be the change in pain severity at week 12 with TNX-102 SL as compared to placebo, as assessed by the Numeric Rating Scale, or NRS. This endpoint is similar to that utilized in clinical trials of drug products currently approved for use in FM. We are also collecting information on other outcome measures, including NRS scores at other time points, the revised Fibromyalgia Impact Questionnaire, and the Patient Global Impression of Change.

Long-Term Safety Exposure Study

In December 2013, we announced the initiation of F203, a 12-month open-label extension study of TNX-102 SL to be taken daily at bedtime, into which patients who have completed the BESTFIT study may enroll. The goal is to obtain sufficient six and 12 month exposure data in FM patients to meet the NDA submission requirement.

TNX-102 SL – Post-Traumatic Stress Disorder Program

We are also advancing TNX-102 SL for the management of PTSD. We held a pre-IND meeting with the FDA in October 2012, and we plan to file an IND to pursue this indication in the second quarter of 2014. We plan to begin a Proof-of-Concept (POC) trial of TNX-102 SL in subjects with military-related PTSD in the third quarter of 2014. Based on the results of the POC trial, we will meet with the FDA to finalize the design of the registration studies to support the PTSD NDA. We believe the approval will be based upon positive results from two adequate, well-controlled efficacy and safety studies and long-term (6 and 12 month) safety exposure data. We expect the long-term safety exposure data generated by our clinical development of TNX-102 SL in FM can be used to support the PTSD indication.

TNX-201 – Episodic Tension-Type Headache Program

TNX-201 is a single isomer of isometheptene mucate (IMH) and is under development as a treatment for ETTH, an indication believed to affect approximately 20% of the global adult population. Although currently not approved for any indication, IMH has an extensive history of use as a prescription pharmaceutical in the U.S. as a mixture of two mirror-image isomers, also known as a racemic mixture. Racemic IMH has been marketed in combination products for the relief of tension and vascular headaches (examples include Midrin® and MigraTen®). The selection of a single isomer of IMH for development may confer an improved clinical profile as compared to the racemic mixture, consistent with the FDA Stereoisomeric Drugs Development Policy, and is supported by our pharmacology data. We held a pre-IND meeting with the FDA in January 2014 to discuss the regulatory pathway for the development of TNX-201 for the treatment of ETTH. The initial IND for TNX-201 will not require any additional nonclinical data to support a first-in-man study, and we plan to conduct a Phase I comparative pharmacokinetic and safety study in the fourth quarter of 2014. Although the development of TNX-201 will be based on the available information on racemic IMH, the NDA approval will be required to conform with the 505(b)(1) NDA requirement.

Additional Product Candidates

We also have a pipeline of other product candidates, including TNX-301. TNX-301 is a fixed dose combination of two FDA-approved drugs, disulfiram and selegiline. We intend to develop TNX-301 under the 505(b)(2) provision as a treatment for alcohol abuse and dependence, and plan to begin formulation work on TNX-301 in 2014. In addition, we recently acquired rights to intellectual property on the development of protective agents against radiation exposure and on the development of novel smallpox vaccines. The radio- and chemo-protective technology relates to proprietary forms of a small molecular pharmaceutical agent, which is believed to protect against ionizing radiation after oral administration. The smallpox vaccine technology relates to proprietary forms of live vaccinia vaccines which may be safer than ACAM2000, which is the only currently available replication competent, live vaccinia vaccine to protect against smallpox disease. As we interact with the United States Department of Defense and related biodefense agencies regarding our development of TNX-102 SL for PTSD, we believe these technologies will expand our interaction and cooperation with such agencies. We plan to perform non-clinical research and development on these programs in 2014.

For competitive reasons, we typically do not disclose the identities of the active ingredients or targeted indications in our pipeline until a U.S. patent has been allowed or issued.

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.

The Offering

Securities being offered by us	1,134,490 shares of common stock issuable upon the exercise of the warrants issued as a part of the securities sold in our August 2013 public offering and 49,774 shares of common stock that are issuable upon exercise of the warrants issued to the underwriter and its designees as part of our public offering, which warrants are exercisable until August 14, 2018 at an exercise price of \$4.25 per share.
Common stock to be outstanding after this offering if all of the warrants are exercised	11,083,761 shares.
Use of proceeds	We intend to use the net proceeds of this offering to fund our research and development activities and for working capital and general corporate purposes. See “ <i>Use of Proceeds</i> ” for further information.
Risk Factors	See “ <i>Risk Factors</i> ,” as well as other information included in this prospectus, for a discussion of factors you should read and consider carefully before investing in our securities.
Trading Market	Our common stock is traded on The NASDAQ Capital Market under the symbol “TNXP.”

The number of shares of our common stock to be outstanding after this offering as shown above is based on 9,899,497 shares outstanding as of April 2, 2014, includes the 1,184,264 shares offered hereby but excludes:

- 550,000 shares of our common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$17.39 per share as of April 2, 2014; and
- 824,775 shares of our common stock issuable upon exercise of outstanding warrants, not including the 1,184,264 shares of common stock underlying warrants in this offering, at a weighted average exercise price of \$17.72 per share as of April 2, 2014.

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 supplement and the accompanying 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 lead product candidate, TNX-102 SL. We have not yet obtained regulatory approvals for TNX-102 SL or any of our other product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this 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;
- 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 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 CMOs to supply or manufacture our products;
- our dependence on 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 lead product candidate, TNX-102 SL, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical 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 one lead product candidate, TNX-102 SL for the treatment of FM, and the success of our business currently depends on its successful development, approval and commercialization. Any projected sales or future revenue predictions are predicated upon FDA approval and market acceptance of TNX-102 SL. If projected sales do not materialize for any reason, it would have a material adverse effect on our business and our ability to continue operations.

TNX-102 SL has not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for this product candidate anywhere in the world. The clinical development program for TNX-102 SL 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 this product candidate is safe and effective or the clinical program may be put on hold due to unexpected safety issues with marketed CBP products. 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 approval for TNX-102 SL in a timely manner would have a material adverse impact on our business and our stock price.

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

Because we have limited financial and human resources, we are currently focusing on the regulatory approval of TNX-102 SL. 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 initiate 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 lead 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 Phase 2b/3 trial of TNX-102 SL in FM, will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. 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 pivotal clinical trial or submitted an NDA before, and may be unable to do so for TNX-102 SL and other product candidates we are developing.

If our Phase 2b/3 study of TNX-102 SL is successful, we then expect to conduct a 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 which could result in substantial delays and 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 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/Pre-Phase 3 meeting with the FDA in February 2013 to discuss the development of our lead product candidate, TNX-102 SL, in FM. Although our interactions with the FDA have encouraged our efforts to continue to develop TNX-102 SL for FM, there is no assurance that we will satisfy the FDA's requirements for approval in this indication. We have not come to any agreement with the FDA as to the nature and extent of studies we may be required to conduct in order to achieve approval of TNX-102 SL in PTSD. 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, wherein we will 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 lead 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 Sub 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. We have key-man insurance on the lives of Dr. Lederman, Dr. Leland Gershell, our Chief Financial Officer, and Dr. Bruce Daugherty, our Chief Scientific Officer. We are also highly dependent on our directors and scientific team. We are not aware of any present intention of any of our key personnel to leave our company or to retire. While we have employment agreements with all our executives, they may terminate their employment at any time upon 30 days notice. 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, our work force is located in the "Pharmaceutical Corridor" that spans New York, New Jersey and Pennsylvania, as well as in the San Francisco Bay Area, where 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 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 pharmaceutical company focused on the development of drug product candidates, all of which are still in development. Our drug development methods may not lead to commercially viable drugs for any of several reasons. For example, we may fail to identify appropriate targets or compounds, our drug candidates may fail to be safe and effective in clinical 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 successful, 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 products 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 products 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;
- flat or declining use of off-label muscle-relaxant products for fibromyalgia prior to the launch of TNX-102 SL;
- 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 lead 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 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

Sales of additional shares of our common stock, including by us or our directors and officers following expiration or early release of the lock-up periods, could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale, by us or others, including the issuance of common stock upon exercise of outstanding options and warrants, could adversely affect the price of our common stock. In connection with a public offering in January 2014, our directors and officers have entered into lock-up agreements for 90 days following such offering (which period may be extended under certain circumstances). Our directors and officers may be released from lock-up prior to the expiration of the lock-up periods at the sole discretion of Roth Capital Partners, LLC. We may sell additional shares and our directors and officers, upon expiration or earlier release of the lock-up, may sell shares into the market, which could adversely affect the market price of shares of our common stock.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

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 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 products 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 products 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. In addition, in the event we are no longer a smaller reporting company, the independent registered public accounting firm auditing our financial statements would be required to attest to the effectiveness of our internal controls over financial reporting. Such attestation requirement by our independent registered public accounting firm would not be applicable to us until the report for the year ended December 31, 2014 at the earliest, if at all. If we are unable to conclude that we have effective internal controls over financial reporting or if our independent registered public accounting firm is required to, but 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 April 2, 2014, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 21.2% 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.

DISCLOSURE 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 3 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

We estimate that the proceeds of this offering will be approximately \$5.0 million. We expect to use the net proceeds received from this offering to fund our research and development activities and for working capital and general corporate purposes.

We cannot currently determine with absolute certainty how we will use the proceeds from this offering. As a result, our management will retain broad discretion in the allocation and use of the net proceeds from this offering. We will pay all of the costs associated with registering the securities covered by this prospectus.

PLAN OF DISTRIBUTION

We will deliver shares of our common stock upon exercise of the outstanding warrants we issued in August 2014. As of the date of this prospectus, these warrants were exercisable for a total of 1,184,264 shares of our common stock, and no more of these warrants will be issued. We will not issue fractional shares upon exercise of these warrants. Each of these warrants contains instructions for exercise. In order to exercise any of these warrants, the holder must deliver to us the information required in the warrants, along with payment for the exercise price of the shares to be purchased. We will then deliver shares of our common stock in the manner described below in the section titled “Description of Capital Stock – August 2013 Warrants” and “Description of Capital Stock – Underwriter Warrants”.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of all material characteristics of our capital stock as set forth in our articles of incorporation and bylaws. The summary does not purport to be complete and is qualified in its entirety by reference to our articles of incorporation and bylaws, and to the provisions of the Nevada Business Corporation Act of the State of Nevada, as amended.

Common Stock

We are authorized to issue up to 150,000,000 shares of our common stock, par value \$0.001 per share. As of April 2, 2014, there were 9,899,497 shares of our common stock issued and outstanding. The outstanding shares of our common stock are validly issued, fully paid and nonassessable.

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

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

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, par value \$0.001 per share, none of which are currently outstanding. The shares of preferred stock may be issued in series, and shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the resolution or resolutions providing for the issuance of such stock adopted from time to time by the board of directors. The board of directors is expressly vested with the authority to determine and fix in the resolution or resolutions providing for the issuances of preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Nevada.

Options

As of April 2, 2014, there are an aggregate of 550,000 options to purchase shares of our common stock issued and outstanding. 150,000 of the options are exercisable at \$30.00 per share, expire on May 9, 2022 and vest 1/3rd on May 9, 2013 and 1/36th on the 9th of each month thereafter for 24 months. 226,500 of the options are exercisable at \$10.20 per share, expire on February 12, 2023 and vest 1/3rd on February 12, 2014 and 1/36th on the 12th of each month thereafter for 24 months. 173,500 of the options are exercisable at \$15.88 per share, expire on February 11, 2024 and vest 1/3rd on February 11, 2015 and 1/36th on the 12th of each month thereafter for 24 months.

Warrants

In connection with a financing in 2011, we issued conversion warrants to purchase 13,750 shares of common stock. In addition, we issued warrants to a placement agent to purchase 788 shares of common stock. These warrants have a three year term and \$20.00 exercise price. The conversion warrants may be exercised on a cashless basis.

In connection with a financing in March 2012, we issued March 2012 Class A Warrants to purchase 330,889 shares of common stock. In addition, we issued 2012 Agent Warrants to the placement agent to purchase 23,339 shares of common stock. The March 2012 Class A Warrants have a five year term and \$25.00 exercise price. The 2012 Agent Warrants have a seven year term and \$25.00 exercise price. The March 2012 Class A Warrants and 2012 Agent Warrants may be exercised on a cashless basis and contain customary anti-dilution protection.

In connection with a financing in December 2012, we issued Class A Warrants to purchase 445,209 shares of common stock. The Class A Warrants have a five year term and \$12.00 exercise price. The Class A Warrants may be exercised on a cashless basis under certain conditions.

On January 1, 2013, we issued warrants to non-employees to purchase 10,800 shares of our common stock at an exercise price of \$12.00 per share expiring five years from the date of issuance vesting ratably over twelve months beginning January 1, 2013 in connection with services.

August 2013 Warrants

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of the warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part of. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.

Exercisability. The warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

Exercise Price. The initial exercise price per share of common stock purchasable upon exercise of the warrants is \$4.25 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Certain Adjustments. The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

Transferability. Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

Fundamental Transaction. If, at any time while the warrants are outstanding, (1) we distribute to all holders of Common Stock (and not to the holders of the warrants) evidences of our indebtedness or assets (including cash and cash dividends), (2) we consolidate or merge with or into another corporation and we are not the surviving corporation, (3) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (4) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (5) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, (6) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, or (7) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock, each, a 'Fundamental Transaction,' then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Underwriter Warrants

In connection with our August 2013 public offering, we issued to the underwriters, Roth Capital Partners, LLC, National Securities Corporation, and Dawson James Securities, Inc., the representative warrants to purchase up to a total of 107,200 shares of common stock. The warrants are exercisable at a per share price equal to \$4.25, exercisable immediately and expire on August 14, 2018. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. In addition, the underwriter warrants may be exercised on a cashless basis.

Convertible Securities

None.

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is vStock Transfer, LLC, 77 Spruce Street, Suite 201, Cedarhurst, NY 11516.

LEGAL MATTERS

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

EXPERTS

The financial statements at December 31, 2013 and 2012 and for the years then ended incorporated by reference in this prospectus have been so incorporated in reliance on the report of EisnerAmper LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act. As permitted by the SEC's rules, this prospectus and any prospectus supplement, which form a part of the registration statement, do not contain all the information that is included in the registration statement. You will find additional information about us in the registration statement. Any statements made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read, without charge, and copy the documents we file at the SEC's public reference rooms in Washington, D.C. at 100 F Street, NE, Room 1580, Washington, DC 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public at no cost from the SEC's website at <http://www.sec.gov>.

INCORPORATION OF DOCUMENTS BY REFERENCE

This prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. The Securities and Exchange Commission permits us to "incorporate by reference" the information contained in documents we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Information that we file later with the Securities and Exchange Commission will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the Securities and Exchange Commission, and incorporate by reference in this prospectus:

- Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 28, 2014;
- Current Reports on Form 8-K (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed on January 14, 2014, January 24, 2014, January 30, 2014, February 14, 2014, March 19, 2014, March 21, 2014, March 31, 2014 and April 1, 2014; and
- The description of our common stock contained in our Form 8-A filed on July 23, 2013.

We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of the registration statement of which this prospectus is a part until the offering of the particular securities covered by a prospectus supplement or term sheet has been completed. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

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

Leland Gershell
Chief Financial Officer
Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 306
New York, New York 10022
Telephone (212) 980-9155

**DISCLOSURE OF COMMISSION POSITION ON
INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

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

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the Company pursuant to the foregoing provisions, the Company has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

We estimate that expenses payable by us in connection with the offering described in this registration statement will be as follows:

SEC registration fee	\$ 3,339
FINRA filing fee	\$ 4,723
NASDAQ listing fee	\$ 50,000
Legal fees and expenses	\$ 275,000
Accounting fees and expenses	\$ 75,000
Transfer agent fees and expenses	\$ 3,000
Printing and engraving expenses	\$ 50,000
Miscellaneous expenses	\$ 38,938
Total	\$ 500,000

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

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

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

ITEM 16. EXHIBITS

a) Exhibits.

- 3.01 Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on April 9, 2008 and incorporated herein by reference.
- 3.02 Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.
- 3.03 Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on February 23, 2012 and incorporated herein by reference.
- 4.01 * Form of Series A Warrant.
- 4.02 * Form of Underwriters Warrant.
- 5.01 * Opinion of Sichenzia Ross Friedman Ference LLP.
- 23.01 ** Consent of EisnerAmper LLP.
- 23.02 * Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.01).
- 24.01 * Power of Attorney

* Previously filed.

** Filed herewith.

ITEM 17. 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 this 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 this registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of the 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; and

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

provided, however, that the undertakings set forth in paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) above 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 Securities Exchange Act of 1934, as amended (the "Exchange Act") that are incorporated by reference in this registration statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of this 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 therein, 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.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, 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 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-3 and has duly caused this Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on April 9, 2014.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: April 9, 2014

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

Date: April 9, 2014

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ SETH LEDERMAN</u> Seth Lederman	Chief Executive Officer (Principal Executive Officer) and Director	April 9, 2014
<u>/s/ LELAND GERSHELL</u> Leland Gershell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 9, 2014
<u>*</u> Stuart Davidson	Director	April 9, 2014
<u>*</u> Patrick Grace	Director	April 9, 2014
<u>*</u> Donald W. Landry	Director	April 9, 2014
<u>*</u> Ernest Mario	Director	April 9, 2014
<u>*</u> Charles Mather IV	Director	April 9, 2014
<u>*</u> John Rhodes	Director	April 9, 2014
<u>*</u> Samuel Saks	Director	April 9, 2014

*By: /s/ SETH LEDERMAN
Seth Lederman
Attorney-in-fact

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" in Post Effective Amendment No. 1 to the Registration Statement [Form S-1 on Form S-3 (No. 333-188547)] and related prospectus of Tonix Pharmaceuticals Holding Corp. for the registration of 1,184,264 shares of its common stock issuable upon exercise of outstanding warrants 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/ EISNERAMPER LLP

New York, New York
April 9, 2014
