As filed with the Securities and Exchange Commission on January 25, 2013
Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TONIX PHARMACEUTICALS HOLDING CORP.
(Name of registrant in its charter)

Nevada	**1000**	**26-1434750**
(State or other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

509 Madison Avenue, Suite 306
New York, New York
(212) 980-9155
(Address and telephone number of principal executive offices and principal place of business)

Seth Lederman, Chief Executive Officer
Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 306
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(212) 980-9155
(Name, address and telephone number of agent for service)

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APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC:
From time to time after this Registration Statement becomes effective.

If any 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, 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 post-effective amendment filed pursuant to Rule 462(d) 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. £

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 filed," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

CALCULATION OF REGISTRATION FEE

Title of Each Class Of Securities To Be Registered	Amount To Be Registered (1)	Proposed Maximum Offering Price Per Security (2)	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee
Common Stock, $.001 par value	8,904,167	$ 0.50	$ 4,452,083.50	$ 607.26
Common Stock, $.001 par value issuable upon exercise of warrants exercisable at $0.60 per share	8,904,167	$ 0.60	$ 5,342,500.20	$ 728.72
Total	17,808,334		$ 9,794,583.70	$ 1,335.98

(1) Includes shares of our common stock, par value $0.001 per share, which may be offered pursuant to this registration statement, which shares are issuable upon exercise of warrants held by the selling stockholders. In addition to the shares set forth in the table, the amount to be registered includes an indeterminate number of shares issuable upon exercise of the warrants, as such number may be adjusted as a result of stock splits, stock dividends and similar transactions in accordance with Rule 416. The number of shares of common stock registered hereunder represents a good faith estimate by us of the number of shares of common stock issuable upon exercise of the warrants. For purposes of estimating the number of shares of common stock to be included in this registration statement, we calculated a good faith estimate of the number of shares of our common stock that we believe will be issuable upon exercise of the warrants to account for market fluctuations, and antidilution and price protection adjustments, respectively. Should the conversion ratio result in our having insufficient shares, we will not rely upon Rule 416, but will file a new registration statement to cover the resale of such additional shares should that become necessary. In addition, should a decrease in the exercise price as a result of an issuance or sale of shares below the then current market price, result in our having insufficient shares, we will not rely upon Rule 416, but will file a new registration statement to cover the resale of such additional shares should that become necessary.

(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) and Rule 457(g) under the Securities Act of 1933, using the average of the high and low price as reported on the OTCQB on January 24, 2013, which was $0.50 per share.

Pursuant to Rule 429 promulgated under the Securities Act of 1933, the enclosed prospectus constitutes a combined prospectus also relating to an aggregate of up to 14,543,807 shares of our common stock that were previously registered for sale in a Registration Statement on Form S-1, Registration No. 333-180964. As such, this prospectus also constitutes post-effective amendment No. 1 to the Registration Statement on Form S-1, Registration No. 333-180964, which shall hereafter become effective concurrently with the effectiveness of this Registration Statement on Form S-1 in accordance with Section 8(c) of the Securities Act of 1933.

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.

The information in this prospectus is not complete and may be changed. The selling stockholders 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.

SUBJECT TO COMPLETION, DATED JANUARY 25, 2013

PROSPECTUS

Up to 17,808,334 Shares of Common Stock

This prospectus relates to the offering by the selling stockholders of Tonix Pharmaceuticals Holding Corp. of up to 17,808,334 shares of common stock, par value $0.001 per share. All of the shares of common stock offered by this prospectus are being sold by the selling stockholders. These shares consist of (i) 8,904,167 shares of common stock issued to investors in our December 2012 Financing and (ii) 8,904,167 shares of common stock issuable upon exercise of warrants to purchase 8,904,167 shares issued to investors in our December 2012 Financing.

The selling stockholders have advised us that they will sell the shares of common stock from time to time in the open market, on the OTCQB, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale or at prices related to the prevailing market prices or at negotiated prices.

The selling stockholders may sell the common shares to or through underwriters, brokers or dealers or directly to purchasers. Underwriters, brokers or dealers may receive discounts, commissions or concessions from the selling stockholders, purchasers in connection with sales of the common shares, or both. Additional information relating to the distribution of the common shares by the selling stockholders can be found in this prospectus under the heading “Plan of Distribution.” If underwriters or dealers are involved in the sale of any securities offered by this prospectus, their names, and any applicable purchase price, fee, commission or discount arrangement between or among them, will be set forth, or will be calculable from the information set forth, in a supplement to this prospectus. We will pay the expenses of registering these shares.

We will not receive any proceeds from the sale of common stock by the selling stockholders. We will receive proceeds from the selling stockholders from any exercise of their warrants on a cash basis.

We are a reporting company pursuant to Section 12(g) of the Securities Exchange Act of 1934, or the Exchange Act, and our common stock is traded on the OTCQB under the symbol “TNXP”. On January 22, 2013, the closing price of our common stock was $0.55 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 8 of this prospectus.

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

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

This prospectus is dated __ , 2013

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You should rely only on the information contained in this prospectus. We have not, and the underwriter has not, authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock. Our business, financial conditions, results of operations and prospects may have changed since that date.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, or Exchange Act. Forward-looking statements reflect the current view about future events. When used in this prospectus, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Such statements, include, but are not limited to, statements contained in this prospectus relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward–looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, a continued decline in general economic conditions nationally and internationally; decreased demand for our products and services; market acceptance of our products and services; our ability to protect our intellectual property rights; the impact of any infringement actions or other litigation brought against us; competition from other providers and products; our ability to develop and commercialize new and improved products and services; our ability to raise capital to fund continuing operations; changes in government regulation; our ability to complete customer transactions and capital raising transactions; and other factors (including the risks contained in the section of this prospectus entitled "Risk Factors") relating to our industry, our operations and results of operations and any businesses that may be acquired by us. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

ABOUT THIS PROSPECTUS

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

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

PROSPECTUS SUMMARY

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 8 of this prospectus and our financial statements and the accompanying notes beginning on page F-1 of 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") and Krele LLC, a Delaware limited liability company ("Krele"). Tonix Sub is a wholly-owned subsidiary of Tonix and Krele is a wholly-owned subsidiary of Tonix Sub.

Our Company

Corporate Structure

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. From inception through October 2011, we were involved in the acquisition, exploration and development of natural resource properties in the State of Nevada. On October 7, 2011 ("Closing Date" and the closing of the share exchange transaction, the "Closing"), we executed and consummated a share exchange agreement by and among Tonix Sub and the stockholders of 100% of the equity securities of Tonix Sub, including, the holders of 5,207,500 shares of common stock, 1,500,000 shares of Series A Preferred Stock and 2,275,527 shares of Series B Preferred Stock (the "Tonix Shareholders"), on the one hand, and us and David Moss ("Moss"), our then sole officer and director and majority shareholder, on the other hand (the "Share Exchange Agreement" and the transaction, the "Share Exchange").

In the Share Exchange, the Tonix Shareholders exchanged their shares of Tonix Sub for newly issued shares of our common stock ("Common Stock"). As a result, upon completion of the Share Exchange, Tonix Sub became our wholly-owned subsidiary.

Upon completion of the Share Exchange, the Tonix Shareholders received an aggregate of 22,666,667 shares of our Common Stock. Moss returned 1,500,000 shares of Common Stock to us, which were retired, and our existing stockholders retained 4,000,000 shares of Common Stock. The 22,666,667 shares issued to the Tonix Shareholders constituted approximately 85% of our 26,666,667 issued and outstanding shares of Common Stock post-Closing.

As a result of the Share Exchange, we acquired 100% of the capital stock of Tonix Sub and consequently, control of the business and operations of Tonix Sub and Krele. From and after the Closing Date of the Share Exchange, our primary operations consist of the business and operations of Tonix Sub and Krele.

On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp. to reflect our new business.

Corporate Background

In 1996, Seth Lederman, MD, and Donald Landry, MD, PhD, formed L&L Technologies, LLC, ("L&L"), to develop medications for central nervous system ("CNS") conditions. Dr. Lederman is our Chairman and Chief Executive Officer and Dr. Landry is a Director. L&L was a founder of Janus Pharmaceuticals, Inc., later renamed Vela Pharmaceuticals, Inc., ("Vela"), which developed various therapeutics, including a very low dose, or VLD, version of cyclobenzaprine, or CBP, under an agreement with L&L. Vela decided to focus its resources on other programs and transferred the rights in VLD CBP and certain other technologies to L&L in March 2006.

Tonix Sub formed in June 2007 as Krele Pharmaceuticals, Inc. by L&L and Krele Pharmaceuticals, LLC (now known as Plumbline LLC) ("Plumbline"). Dr. Lederman is managing partner of Plumbline. Plumbline possessed rights to certain technology for the treatment of alcohol dependence and abuse. In connection with founding Tonix Sub, L&L and Plumbline entered into an intellectual property transfer and assignment agreement with Tonix Sub for the purpose of assigning patents and transferring intellectual property and know-how in exchange for shares of common stock of Tonix Sub. As a result of economic conditions related to the financial crisis of 2007 and 2008, Tonix Sub was not successful in raising money to fund its programs until 2009. As a result, Tonix Sub was unable to advance the development programs and had little activity except for prosecuting and maintaining patents and maintaining contracts.

In 2009, Tonix Sub contracted with the Toronto Psychiatric Research Foundation to analyze the sleep data from the 2001 Phase 2a study of 36 patients with fibromyalgia syndrome, or FM (the "Moldofsky Study"), who were treated with bedtime VLD CBP or placebo. The Moldofsky Study was conducted in Canada by the Toronto Psychiatric Research Foundation, and Tonix Sub obtained the data from this study from L&L. In addition, in 2009, Tonix Sub contracted with Caliper Life Sciences (formerly, NovaScreen Bioscience Corp.) ("Caliper") to analyze the interactions of CBP with certain receptors. In June 2010, Tonix Sub entered into consulting agreements with L&L and Lederman & Co, LLC ("Lederman & Co") and also acquired certain rights to develop isometheptene mucate as a treatment for certain types of headaches from Lederman & Co., which we are developing as TNX-201. Dr. Lederman is managing partner of Lederman & Co. Between June 2010 and October 2011, Tonix Sub was active in recruiting new officers and directors and initiating preclinical and clinical development of novel CBP formulations.

Lederman & Co predominantly provides us with clinical development expertise. L&L predominantly provided us with scientific development expertise until the termination of the consulting agreement in June 2012. Relative to traditional pharmaceutical development companies, we can be considered a virtual company, since we contract with third-party vendors to provide many functions that are core to traditional pharmaceutical companies. For example, we have contracted with PharmaNet Canada, Inc., or PharmaNet Canada, to develop methods for analyzing CBP in the blood and to conduct human clinical studies to evaluate the performance of our formulation technology. Lederman & Co is responsible for overseeing the scientific and technical aspects of PharmaNet's contract work product.

In July 2010, Tonix Sub changed its name to Tonix Pharmaceuticals, Inc. In August 2010, Tonix Sub formed Krele.

Business Overview

We are a specialty pharmaceutical company focused on developing novel pharmaceutical products for challenging disorders of the CNS. We search for potential therapeutic solutions among known pharmaceutical agents that lack regulatory approval for the indications we seek, but may be approved for use in other indications. The ongoing evolution in the understanding of certain CNS disorders provides us with opportunities to develop such agents as proprietary products for new indications. We typically seek to create new dose and formulation options that are tailored to the therapeutic uses to which we apply these agents.

Many CNS drugs have been identified by physicians who observe unexpected improvements in their patients' CNS conditions despite being prescribed for a different purpose. One of our goals is to establish formal clinical study programs to determine if such anecdotal observations are, in fact, reflections of a compound's ability to treat a particular CNS condition. While some new applications can use the commercially-available form of a given drug, in other cases, reformulating the active ingredient may improve the active ingredient's safety or effectiveness in treating the condition. If we demonstrate success in our formal development programs, we will seek marketing approval from the U.S. Food and Drug Administration, or FDA.

We are currently devoting the majority of our efforts to the development of our lead product candidate, TNX-102 sublingual tablet, or TNX-102 SL. TNX-102 SL is a novel dose and formulation of CBP, the active pharmaceutical ingredient of two widely prescribed muscle relaxant products, Flexeril® and Amrix®. TNX-102 SL is distinct from these products as it is being developed at a dose level significantly below the lowest marketed doses of Flexeril and Amrix. TNX-102 SL is also distinct from these products with regard to its route of administration, as it is designed to be placed under the tongue and disintegrated to provide sublingual absorption, whereas Flexeril and Amrix are designed to be swallowed. TNX-102 SL is also intended for chronic use, whereas Flexeril and Amrix are marketed for two to three weeks of use. We are currently developing TNX-102 SL for the treatment of FM under a U.S. Investigational New Drug application, or IND, and under three Clinical Trial Applications, or CTAs, filed in Canada. We are also developing TNX-102 SL for the treatment of post-traumatic stress disorder, or PTSD, for which we held a pre-IND meeting in October 2012. We expect that any applications we submit for FDA 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 development as compared to that needed to fulfill the requirements of Section 505(b)(1), under which new chemical entities, or NCEs, are generally reviewed.

TNX-102 SL is a small, rapidly disintegrating tablet containing CBP for sublingual administration at bedtime. We designed TNX-102 SL to enable the efficient delivery of CBP to the systemic circulation via sublingual transmucosal absorption and to avoid first-pass liver metabolism. We also designed TNX-102 SL to provide CBP at doses lower than those currently available. We have conducted several clinical and pre-clinical pharmacokinetic studies of TNX-102 SL which we believe support its development as a novel therapeutic product for FM and PTSD, and which demonstrate a number of potentially advantageous characteristics as compared to current CBP-containing products, none of which are approved for these indications. Based on our Phase 1 comparative study, we have observed that, as compared to oral CBP tablets, TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following administration. TNX-102 SL was generally well-tolerated, with no serious adverse events reported in this study. 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.

Based on these promising results, we are advancing TNX-102 SL for the management of FM. We believe that TNX-102 SL could be approved by the FDA for the treatment of FM following two adequate, well-controlled safety and efficacy studies and, if required, a long-term safety exposure study that, together, would confirm the safety and efficacy of TNX-102 SL in a sufficient number of FM patients to satisfy the approval requirements under Section 505(b)(2). New drug products based on novel active ingredients, approved under Section 505(b)(1), need significantly more clinical studies, e.g. drug-drug interaction, special population pharmacokinetic, and long-term safety exposure studies, than will be required for TNX-102 SL. Under the IND, we plan to initiate a potential pivotal efficacy trial in the first half of 2013 that will evaluate this candidate in FM. A Type B Pre-Phase 3 meeting has been scheduled with the FDA in February 2013, at which we plan to discuss the design of the 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 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 for this indication in the first half of 2013. We then plan to conduct a clinical proof-of-concept trial of TNX-102 SL in PTSD in the second half of 2013.

CBP is the active pharmaceutical ingredient in our lead product candidate, TNX-102 SL. We are utilizing drug delivery technology to produce new formulations. In addition to CBP, TNX-102 SL contains inactive ingredients, called excipients, which are well-characterized, are listed in the FDA Inactive Ingredients Guide (IIG), and are approved for pharmaceutical use. As a result, we anticipate seeking FDA marketing approval of TNX-102 SL through the NDA process under Section 505(b)(2) of the FDCA, which we also refer to as a 505(b)(2) NDA. As one of three types of new drug applications, the 505(b)(2) NDA allows drug companies to obtain FDA approval of new drug products without having to conduct the full complement of safety and efficacy trials, which is often the most time-consuming and expensive part of the drug development process. As the 505(b)(2) NDA permits the drug manufacturer to rely on the agency's findings for a previously-approved drug, published literature, or both, it permits the FDA to make some safety and effectiveness determinations through the review of materials in the public domain or in already approved NDAs of products containing CBP. The 505(b)(2) regulatory pathway would spare us some of the burden of generating all of this data for ourselves and may allow TNX-102 SL to progress through a shorter development pathway than is typical for pharmaceutical products based on novel active ingredients. We have not filed an NDA for TNX-102 SL for any indications.

In addition to TNX-102 SL, we have developed other innovative formulations of CBP, including TNX-102 promicellar gelatin capsule, or TNX-102 gelcap. We have developed TNX-102 gelcap under an agreement with Lipocine, Inc. ("Lipocine"), a contract formulation developer and small-scale manufacturer. Although we had met with the FDA to discuss the TNX-102 gelcap development program in August 2011 and we have generated clinical data that support the further development of TNX-102 gelcap, we currently do not plan to advance this candidate.

We also have a pipeline of other product candidates, including TNX-201 and TNX-301. TNX-201 is based on isometheptene mucate and is under development as a treatment for certain types of headaches. For competitive reasons, we 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. Consistent with our mission, these product candidates are or likely will be reformulations of active ingredients that have been used in humans in other products and that are designed for new CNS therapeutic indications.

In other cases, the products will be formulated to match earlier, or predicate, products closely enough to be considered generic copies or similarly enough to other marketed products to rely (in part) on their regulatory review and approval, as well as available published data. The predicate product may be approved by the FDA under an NDA or may have been reviewed for safety and effectiveness by the National Academy of Sciences under the Drug Efficacy Study Implementation, or DESI, program, in which case they would be considered by FDA to be "unapproved products". For DESI products, it is our intent to develop NDA versions to meet the current Good Manufacturing Practice, or cGMP, and the International Conference on Harmonization, or ICH, requirements to seek approval under the 505(b)(2) regulatory pathway.

Because of our size and being in the development stage, we do not currently devote a significant amount of time or resources towards our other pipeline candidates. We anticipate that sometime in 2013 we will begin developing formulations for TNX-201 and possibly TNX-301, but do not expect to start clinical trials until 2014 at the earliest.

The process of taking a new drug formulation from concept through testing to approval for a new indication by the FDA is a time-consuming, costly and a high-risk process. Once a drug formulation has been tested in laboratories, we need to conduct clinical trials of the product candidate to test its uptake into the blood stream, elimination, effectiveness and safety. Neither laboratory nor animal studies predict the properties of drugs in humans, so designing new formulations can result in a large number of unexpected outcomes. The first set of clinical trials, which are sometimes referred to as Phase 1 studies, are performed by administering new drug formulations to a limited number of healthy human volunteers and are designed to test the initial concept of the drug formulation and to determine the correct dosage to be tested subsequently on patients affected with the target disorder. The initial Phase 1 studies can take up to a year to complete, however, since we reformulate versions of approved drugs for new uses, we may need to devote less time to Phase I studies since our testing is informed by significant prior human research that we believe allows us to reduce the possible safety-related outcomes. The next step in the process is to conduct a proof-of-concept efficacy study to identify the effective dose(s). A small Phase 2a efficacy study in the representative patient population will be done either using a pilot formulation or the formulation selected for further development. A larger study in which the selected formulation has been optimized for the target population can be referred to as a Phase 2b study. If the results of this study are positive and are accepted by the FDA as fulfilling the requirements of a registrational study, then it may be considered to be one of the two pivotal, or Phase 3, studies typically required for drug approval. The first pivotal study for a condition like FM typically takes a year to complete and then two to three months to interpret the data, but we believe we will be able to conduct our first potential pivotal study of TNX-102 SL in less time due to the nature of the trial design. If the first potential pivotal study suggests the drug is safe and effective, then a second pivotal study, sometimes referred to as a confirmatory study, is conducted. The second pivotal study in FM typically takes 18 months to complete if no additional long-term safety exposure data are necessary for an NDA filing. After the second pivotal study is completed, and if the results are deemed a success, we would submit an NDA to the FDA seeking approval of the new drug product. We believe it would take approximately six months to prepare and file the NDA and another 14 months for FDA approval. The drug could be marketed shortly after FDA approval. Therefore, it typically takes more than five years to bring a new formulation of a drug to market for a new indication, and any delays in the process, such as lack of capital necessary to run clinical trials, unexpected results, adverse effects, or difficulty in recruiting willing subjects for trials, would result in additional time before a drug could be approved for marketing.

In August 2010, we formed Krele to commercialize products that are generic versions of predicate NDA products. We anticipate that when our branded products lose patent protection, Krele may market authorized generic versions of them. Krele also may develop or acquire generic products approved under FDA abbreviated new drug applciations, or ANDAs, and we may market branded versions (branded generics) of such products. Krele has been issued a state license in New York.

The Offering

Common stock offered by the selling stockholders	Up to 17,808,334 shares of common stock, including the following: - 8,904,167 shares of common stock, and - up to 8,904,167 shares of common stock issuable upon the exercise of class A common stock purchase warrants at an exercise price of $0.60 per share (includes a good faith estimate of the shares underlying warrants to account for antidilution protection adjustments).
Common stock to be outstanding after the offering	Up to 52,086,766 shares.
Use of proceeds	We will not receive any proceeds from the sale of the common stock. However, we will receive the exercise price of any common stock we sell to the selling stockholder upon exercise of the Class A Warrants. The Class A Warrants entitle the holder to exercise their warrants on a cashless basis under certain conditions. In the event that any selling stockholder exercises their Class A Warrants on a cashless basis, then we will not receive any proceeds from the exercise of those warrants. We expect to use the proceeds received from the exercise of the Class A Warrants, if any, for general working capital purposes.
OTCQB symbol	TNXP

The above information regarding common stock to be outstanding after the offering is based on 43,182,599 shares of common stock outstanding as of January 22, 2013 and includes the 8,904,167 shares of common stock that are issuable upon the exercise of warrants that are registered pursuant to the registration statement that this prospectus is part of but does not include any shares of common stock issuable upon exercise of other outstanding warrants or options.

The following is a summary of the transactions relating to the securities being registered hereunder.

December 2012 Private Placement

In December 2012, we issued an aggregate of 8,904,167 units ("Units") to certain accredited investors (the "Purchasers") for aggregate cash proceeds of $2,615,000, at a price per Unit of $0.40, and the exchange of $710,000 in previously issued convertible debentures (the "Prior Debentures") of the Company that were converted into Units at a price of $0.30 per Unit (the "December 2012 Financing").

Each Unit consisted of one share of our common stock, $0.001 par value (the "Common Stock"), a Class A Warrant to purchase one share of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase one share of Common Stock (the "Class B Warrants" and together with the Class A Warrants, the "Warrants").The Class A Warrants have an exercise price of $0.60 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The Class A Warrants may be exercised on a cashless basis under certain circumstances. The Class B Warrants have an exercise price of $0.40 per share of Common Stock and will be exercisable for a period of one year from the date of issuance.

In connection with the December 2012 Financing, we granted each Purchaser registration rights. We are obligated to use our best efforts to cause a registration statement registering for resale the Common Stock included in the Units and the Common Stock underlying the Class A Warrants to be filed no later than 60 days from the date of the last closing of the December 2012 Financing and must be declared effective no later than 120 days from the date of the last closing of the December 2012 Financing. Moreover, we will maintain the effectiveness of the registration statement from its effective date unless all securities registered under the registration statement have been sold or are otherwise able to be sold pursuant to Rule 144 of the Securities Act of 1933, as amended (the "Securities Act"). If we fail to comply with the registration statement filing or effective date requirements, we are required to pay the investors a fee equal to 1.0% of the Purchaser's investment, for each 30-day period of delay, subject to a maximum payment of 10% to each Purchaser.

In connection with the December 2012 Financing, we paid Kema Partners LLC, a FINRA registered broker-dealer ("Kema Partners") a cash payment of $70,000, which represented a 7% commission of the gross proceeds delivered by Purchasers introduced by Kema Partners in the December 2012 Financing.

The shares included in the Units and shares underlying the Class A Warrants are registered pursuant to this prospectus.

Plan of Distribution

This offering is not being underwritten. The selling stockholders will sell their shares of our common stock at prevailing market prices or privately negotiated prices. The selling stockholders themselves directly, or through their agents, or through their brokers or dealers, may sell their shares from time to time, in (i) privately negotiated transactions, (ii) in one or more transactions, including block transactions in accordance with the applicable rules of the OTCQB or (iii) otherwise in accordance with the section of this prospectus entitled "Plan of Distribution." To the extent required, the specific shares to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agent, broker or dealer and any applicable commission or discounts with respect to a particular offer will be described in an accompanying prospectus supplement. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

For additional information on the methods of sale, you should refer to the section of this prospectus entitled "Plan of Distribution," beginning on page 76.

RISK FACTORS

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

RISKS RELATED TO OUR BUSINESS

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

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

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 received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2011 with respect to our ability to continue as a going concern. The existence of such a report may adversely affect our stock price and our ability to raise capital. There is no assurance that we will not receive a similar report for our year ended December 31, 2012.

In their report dated March 30, 2012, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern as we have incurred losses since inception of development stage, have a negative cash flow from operations and have working capital and stockholders' deficiencies and require additional financing to fund future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, obtaining loans and grants from various financial institutions where possible. Our continued net operating losses increase the difficulty in meeting such goals and there can be no assurances that such methods will prove successful.

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 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 six months, and we anticipate that we will require additional capital to complete the planned pivotal trial of TNX-102 SL in FM. 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 stockholders.

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. See “Business—Government Regulation.”

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 clinical research organizations 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
- side-effects of CBP.

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.

If we are unable to file for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act 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. While we met with the FDA at a pre-IND meeting in August 2011 to discuss initial plans for the future development of TNX-102 gelcap, we have not yet met with the FDA to discuss the future development of our lead product candidate, TNX-102 SL, although a meeting is scheduled in February 2013. We have also not yet come to full agreement with the FDA as to the nature or extent of any studies we may be required to conduct in order to achieve approval for any of our product candidates. The timeline for filing and review of our NDAs is based on our plan to submit those NDAs under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 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, and the FDA may not agree that 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.

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 life of Dr. Lederman. We are also highly dependent on the other principal members of our management and scientific team. We are not aware of any present intention of any of our key personnel to leave our company or to retire. However, we have no employment agreement with Dr. Lederman and while we have employment agreements with certain of our employees, all of our employees may terminate their employment at any time. 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, 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 third-party Contract Manufacturing Organizations, or 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 manufacturing 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 DEA and corresponding state and foreign agencies to ensure strict compliance with cGMP requirements and other requirements under Federal drug laws, other government regulations and corresponding foreign standards. If we or our third-party manufacturers fail to comply with applicable regulations, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure by the government to grant marketing approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions.

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

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

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

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical 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 successfully, our business, financial condition, and results of operations may be materially harmed.

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

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

The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate statistically significant 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 operation.

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 a New Drug Application, or NDA, under the Federal Food, Drug, and Cosmetic Act. 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 newly-approved health care products. 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.

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. We currently do not carry clinical trial insurance or product liability insurance. We intend to obtain such insurance in the future. 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.

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

There has been a limited trading market for our Common Stock and almost no market activity to date.

Currently, our Common Stock is available for quotation on the OTCQB under the symbol "TNXP." However, prior to February 2012, there was no trading activity in our Common Stock and limited trading has occurred to date. As of December 31, 2012, trading occurred on only 82 out of 229 possible trading days, with an average of less than 3,200 shares per possible trading day and less than 8,900 shares trades on each day when shares actually traded. It is anticipated that there will be a limited trading market for the Common Stock on the OTCQB. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies or technologies by using Common Stock as consideration.

You may have difficulty trading and obtaining quotations for our Common Stock.

Our Common Stock may not be actively traded, and the bid and asked prices for our Common Stock on the OTCQB may fluctuate widely. As a result, investors may find it difficult to dispose of, or to obtain accurate quotations of the price of, our securities. This severely limits the liquidity of the Common Stock, and would likely reduce the market price of our Common Stock and hamper our ability to raise additional capital.

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

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

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or disapproval of our 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.

Investor relations activities, nominal "float" and supply and demand factors may affect the price of our stock.

We expect to utilize various techniques such as non-deal road shows and investor relations campaigns in order to create investor awareness for our company. These campaigns may include personal, video and telephone conferences with investors and prospective investors in which our business practices are described. We may provide compensation to investor relations firms and pay for newsletters, websites, mailings and email campaigns that are produced by third-parties based upon publicly-available information concerning our company. We will not be responsible for the content of analyst reports and other writings and communications by investor relations firms not authored by us or from publicly available information. We do not intend to review or approve the content of such analysts' reports or other materials based upon analysts' own research or methods. Investor relations firms should generally disclose when they are compensated for their efforts, but whether such disclosure is made or complete is not under our control. In addition, investors in our company may be willing, from time to time, to encourage investor awareness through similar activities. Investor awareness activities may also be suspended or discontinued which may impact the trading market our common stock.

The SEC and FINRA enforce various statutes and regulations intended to prevent manipulative or deceptive devices in connection with the purchase or sale of any security and carefully scrutinize trading patterns and company news and other communications for false or misleading information, particularly in cases where the hallmarks of "pump and dump" activities may exist, such as rapid share price increases or decreases. We, and our shareholders may be subjected to enhanced regulatory scrutiny due to the small number of holders who initially will own the registered shares of our common stock publicly available for resale, and the limited trading markets in which such shares may be offered or sold which have often been associated with improper activities concerning penny-stocks, such as the OTC Bulletin Board or the OTCQB Marketplace (Pink OTC) or pink sheets. Until such time as our restricted shares are registered or available for resale under Rule 144, there will continue to be a small percentage of shares held by a small number of investors, many of whom acquired such shares in privately negotiated purchase and sale transactions that will constitute the entire available trading market. The Supreme Court has stated that manipulative action is a term of art connoting intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities. Often times, manipulation is associated by regulators with forces that upset the supply and demand factors that would normally determine trading prices. Since a small percentage of the outstanding common stock of our company will initially be available for trading, held by a small number of individuals or entities, the supply of our common stock for sale will be extremely limited for an indeterminate amount of time, which could result in higher bids, asks or sales prices than would otherwise exist. Securities regulators have often cited thinly-traded markets, small numbers of holders, and awareness campaigns as components of their claims of price manipulation and other violations of law when combined with manipulative trading, such as wash sales, matched orders or other manipulative trading timed to coincide with false or touting press releases. There can be no assurance that our or third-parties' activities, or the small number of potential sellers or small percentage of stock in the "float," or determinations by purchasers or holders as to when or under what circumstances or at what prices they may be willing to buy or sell stock will not artificially impact (or would be claimed by regulators to have affected) the normal supply and demand factors that determine the price of the stock.

We do not anticipate paying dividends on our Common Stock.

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.

If we or our existing shareholders sell a substantial number of shares of our common stock in the public market, our stock price may decline.

If we or our existing shareholders sell a large number of shares of our common stock, or the public market perceives that we or our existing shareholders might sell shares of common stock, particularly with respect to our affiliates, directors, executive officers or other insiders, the market price of our common stock could decline significantly.

In the future, we may issue additional shares to our employees, directors or consultants, in connection with corporate alliances or acquisitions, or to raise capital. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time.

Our officers, directors and principal shareholders own a controlling interest in our voting stock and Investors will not have any voice in our management.

Our officers, directors and principal shareholders, in the aggregate, beneficially own or control the votes of approximately 46.5% of our outstanding Common Stock. As a result, these stockholders, acting together, will have the ability to control substantially all matters submitted to our stockholders for approval, including:

- election of our board of directors;
- removal of any of our directors;
- amendment of our certificate of incorporation or bylaws; and
- adoption of measures that could delay or prevent a change in control or impede a merger, takeover or other business combination involving us.

As a result of their ownership and positions, our directors, executive officers and principal shareholders collectively are able to influence all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, sales of significant amounts of shares held by our directors, executive officers or principal shareholders, or the prospect of these sales, could adversely affect the market price of our Common Stock. Management's stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price.

Our common stock is not currently traded at high volume, and you may be unable to sell at or near ask prices or at all if you need to sell or liquidate a substantial number of shares at one time.

Our common stock is currently traded, but with very low, if any, volume, based on quotations on the OTCQB, meaning that the number of persons interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is still relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common stock will develop or be sustained, or that trading levels will be sustained.

Shareholders should be aware that, according to Commission Release No. 34-29093, the market for "penny stocks" has suffered in recent years from patterns of fraud and abuse. Such patterns include (1) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (2) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (3) boiler room practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (4) excessive and undisclosed bid-ask differential and markups by selling broker-dealers; and (5) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities. The occurrence of these patterns or practices could increase the future volatility of our share price.

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, 2013 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.

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in our securities is limited, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.

The Securities and Exchange Commission ("SEC") has adopted Rule 15g-9 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

FINRA sales practice requirements may also limit a shareholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

USE OF PROCEEDS

We will not receive any proceeds from the sale of common stock offered by the selling stockholders under this prospectus. However, we will receive up to $5,342,500 in the aggregate from the selling stockholders if they exercise in full, on a cash basis, the Class A Warrants to purchase 8,904,167 shares of common stock issued to the selling stockholders that are being offered by the selling stockholders under this prospectus. All of the Class A Warrants entitle the holder to exercise their warrants on a cashless basis under certain conditions. In the event that any selling stockholder exercises their Class A Warrants on a cashless basis, then we will not receive any proceeds from the exercise of those warrants. We would use such proceeds from the exercise of the Class A Warrants for working capital and other corporate purposes.

The warrant holders may exercise their Class A Warrants at any time until their expiration, as further described under "Description of Capital Stock." Because the warrant holders may exercise the Class A Warrants in their own discretion, if at all, we cannot plan on specific uses of proceeds beyond application of proceeds to general corporate purposes. We have agreed to bear the expenses (other than any underwriting discounts or commissions or agent's commissions) in connection with the registration of the common stock being offered hereby by the selling stockholders.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is currently traded on the OTCQB under the symbol "TNXP." Prior to July 23, 2012, our common stock was quoted on the Over-the-Counter Bulletin Board under the symbol "TNXP." Prior to October 19, 2011, our common stock was quoted on the Over-the-Counter Bulletin Board under the symbol "TAEI." Prior to February 2012, no public trades occurred in our common stock. For the periods indicated, the following table sets forth the high and low sale prices of our common stock as reported by NASDAQ.

	Fiscal Year 2012	
	High	**Low**
First Quarter	$ 2.06	$ 2.00
Second Quarter	$ 2.00	$ 0.83
Third Quarter	$ 1.00	$ 0.74
Fourth Quarter	$ 0.82	$ 0.25

	Fiscal Year 2013	
	High	**Low**
First Quarter (1)	$ 0.73	$ 0.44

(1) As of January 22, 2013.

HOLDERS

As of January 22, 2013, we had approximately 199 holders of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent of our common stock is vStock Transfer, LLC, 77 Spruce Street, Suite 201, Cedarhurst, NY 11516.

DIVIDENDS

We have not declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends to stockholders in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, and such other factors as the Board of Directors deem relevant.

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

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

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

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

Business Overview

We are a specialty pharmaceutical company focused on developing novel pharmaceutical products for challenging disorders of the CNS. We search for potential therapeutic solutions among known pharmaceutical agents that lack regulatory approval for the indications we seek, but may be approved for use in other indications. The ongoing evolution in the understanding of certain CNS disorders provides us with opportunities to develop such agents as proprietary products for new indications. We typically seek to create new dose and formulation options that are tailored to the therapeutic uses to which we apply these agents.

We are currently devoting the majority of our efforts to the development of our lead product candidate, TNX-102 sublingual tablet, or TNX-102 SL. TNX-102 SL is a novel dose and formulation of CBP, the active pharmaceutical ingredient of two widely prescribed muscle relaxant products, Flexeril and Amrix. TNX-102 SL is distinct from these products as it is being developed at a dose level significantly below the lowest marketed doses of Flexeril and Amrix. TNX-102 SL is also distinct from these products with regard to its route of administration, as it is designed to be placed under the tongue and disintegrated to provide sublingual absorption, whereas Flexeril and Amrix are designed to be swallowed. TNX-102 SL is also intended for chronic use, whereas Flexeril and Amrix are marketed for two to three weeks of use. We are currently developing TNX-102 SL for the treatment of FM under an IND and under three CTAs filed in Canada. We are also developing TNX-102 SL for the treatment of PTSD for which we held a pre-IND meeting in October 2012. We expect that any applications we submit for FDA approval of TNX-102 SL will be submitted under Section 505(b)(2) of the FDCA, which we believe will allow for a shorter timeline of clinical development as compared to that needed to fulfill the requirements of Section 505(b)(1), under which NCEs are generally reviewed.

TNX-102 SL is a small, rapidly disintegrating tablet containing CBP for sublingual administration at bedtime. We designed TNX-102 SL to enable the efficient delivery of CBP to the systemic circulation via sublingual transmucosal absorption and to avoid first-pass liver metabolism. We also designed TNX-102 SL to provide CBP at doses lower than those currently available. We have conducted several clinical and pre-clinical pharmacokinetic studies of TNX-102 SL which we believe support its development as a novel therapeutic product for FM and PTSD, and which demonstrate a number of potentially advantageous characteristics as compared to current CBP-containing products, none of which are approved for these indications. Based on our Phase 1 comparative study, we have observed that, as compared to oral CBP tablets, TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following administration. TNX-102 SL was generally well-tolerated, with no serious adverse events reported in this study. 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.

We also have a pipeline of other product candidates, including TNX-201 and TNX-301. TNX-201 is based on isometheptene mucate and is under development as a treatment for certain types of headaches. For competitive reasons, we 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. Consistent with our mission, these product candidates are or likely will be reformulations of active ingredients that have been used in humans in other products and that are designed for new CNS therapeutic indications.

In other cases, the products will be formulated to match predicate products closely enough to be considered generic copies or similarly enough to other marketed products to rely (in part) on their regulatory review and approval, as well as available published data. The predicate product may be approved by the FDA under an NDA or may have been reviewed for safety and effectiveness by the National Academy of Sciences under the DESI program, in which case they would be considered by FDA to be "unapproved products". For DESI products, it is our intent to develop NDA versions to meet cGMP and the ICH requirements to seek approval under the 505(b)(2) regulatory pathway.

Because of our size and being in the development stage, we do not currently devote a significant amount of time or resources towards our other pipeline candidates. We anticipate that sometime in 2013 we will begin developing formulations for TNX-201 and possibly TNX-301, but do not expect to start clinical trials until 2014 at the earliest.

On October 7, 2011, we executed and consummated the Share Exchange Agreement with Tonix Sub. Pursuant to the Share Exchange, each share of Tonix Sub's common stock was exchanged for 0.9 shares of our common stock, and each share of Tonix Sub's Series A and B preferred stock was exchanged for 4.8 shares of our common stock. Upon completion of the Share Exchange, the Tonix Sub shareholders, including holders of 1,396,982 restricted shares, which were subject to accelerated vesting, received in exchange for all of their shares, an aggregate of 22,666,667 shares of our common stock and our existing stockholders retained 4,000,000 shares of common stock. The 22,666,667 shares issued to the Tonix Sub shareholders constituted approximately 85% of our 26,666,667 shares of common stock issued and outstanding after the Share Exchange. Upon completion of the Share Exchange, Tonix Sub became our wholly-owned subsidiary. For accounting purposes, the acquisition has been treated as a recapitalization of Tonix Sub, accompanied by the issuance of our common stock for the outstanding common stock of Toxic Sub, which was recorded at a nominal value. The historical financial statements are those of Tonix Sub. The accompanying financial statements give retroactive effect to the recapitalization as if it had occurred on June 7, 2007 (inception date). Also, professional services expenses were allocated to research and development and general and administrative expenses in the 2010 and cumulative from inception through December 31, 2011 statement of operations to be consistent with the current period's presentation.

Current Operating Trends

Our current research and development efforts are focused on developing our lead product, TNX-102 SL, but we also expend some effort on our earlier pipeline programs. Our research and development expenses consist of manufacturing work and the cost of drug ingredients used in such work, fees paid to providers for conducting various clinical studies as well as for the analysis of the results of such studies, and for other medical research addressing the potential efficacy of our drugs. We believe that significant investment in product development is a competitive necessity, and we plan to continue these investments in order to be in a position to realize the potential of our product candidates and proprietary technologies.

We plan to start the next phase of clinical development for TNX-102 SL over the next six months, subject to raising necessary funds. Clinical trials can be very expensive. If these and additional necessary clinical trials are successful, we plan to prepare and submit applications to the FDA for marketing approval for our drug candidates. This process entails significant costs. As a result of these and other factors, we expect our research and development expenses to increase significantly over the next 12 to 24 months.

We expect that a larger percentage of our research and development expenses in the future will be incurred in support of our current and future preclinical and clinical development programs rather than technology development. These expenditures are subject to numerous uncertainties relating to timing and cost to completion. We test compounds in numerous preclinical studies for safety, toxicology and efficacy. At the appropriate time, subject to the approval of regulatory authorities, we expect to conduct early-stage clinical trials for each drug candidate. We anticipate funding these trials ourselves, and possibly with the assistance of federal grants. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. Completion of clinical trials may take several years, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate.

The commencement and completion of clinical trials for our products may be delayed by many factors, including lack of efficacy during clinical trials, unforeseen safety issues, slower than expected patient recruitment, or government delays. In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support the intended safety or efficacy of our product candidates, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. As a result of these risks and uncertainties, we are unable to accurately estimate the specific timing and costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates. Our business, financial condition and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval, insofar as cash in-flows from the relevant drug or program would be delayed or would not occur.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, such as the progress of our research and development efforts and the timing and outcome of regulatory submissions. Due to these uncertainties, accurate predictions of future operations are difficult or impossible to make.

Fiscal year Ended December 31, 2011 Compared to Fiscal year Ended December 31, 2010

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the fiscal years ended December 31, 2011 and 2010.

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2011 were $1,158,167, an increase of $573,869, or 98.2%, from $584,298 for the fiscal year ended December 31, 2010. In 2011, we incurred $342,398 and $318,616 in clinical cost and activities, respectively, as compared to $0 in 2010 for both.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2011 were $2,220,361, an increase of $875,971, or 65%, from $1,344,390 incurred in the fiscal year ended December 31, 2010. This increase is primarily due to payroll related expenses and professional services.

Payroll related expenses increased to $731,284 in the current year from $413,954 for the fiscal year ended December 31, 2010, an increase of $317,330, or 77%. Payroll related expenses include both cash and non-cash compensation associated with the vesting of restricted stock grants. The increase in payroll related costs was a result of a full year of payments to our members of the core management team who joined in June through August of 2010, along with the acceleration of vesting in conjunction with our reverse merger in 2011 of restricted stock previously issued to our employees.

Professional services for the fiscal year ended December 31, 2011 totaled $1,121,547, an increase of $440,642, or 65%, over the $680,905 recognized for the fiscal year ended December 31, 2010. Of professional services, legal fees totaled $373,075 for the fiscal year ended December 31, 2011, an increase of $15,657, or 4.4%, from $357,418 incurred for the fiscal year ended December 31, 2010. Consulting fees totaled $299,144 for the fiscal year ended December 31, 2011, an increase of $139,903 or 87.9%, from $159,241 for the fiscal year ended December 31, 2010. The increase was primarily a result of $189,691 in regulatory costs in the fiscal year ended December 31, 2011 compared to $0 in 2010, offset by a reduction in public relations expenses of $45,513. Accounting fees incurred in fiscal 2011 amounted to $243,003, an increase of $145,400, or 149%, from $97,603 incurred in fiscal 2010. The increase included costs associated with the audit of Tonix Sub's financial statements for the year ended December 31, 2010, review of our interim financial statements and filings with the SEC related to our recent reverse merger, completed in October 2011.

Travel, meals and entertainment costs for fiscal 2011 were $69,268, an increase of $34,548, or 100%, from $34,720 incurred in fiscal 2010. Travel, meals and entertainment costs include travel related to medical and life sciences conferences. Rent for fiscal 2011 totaled $128,228, an increase of $85,657, or 201%, from $42,571 incurred in fiscal 2010, due primarily to the opening of new office space in New York. Depreciation expense in fiscal 2011 totaled $9,300, an increase of $5,446, or 141%, over the expense of $3,854 incurred in fiscal 2010, as a result of the purchase of new office computers.

Interest Expense. Interest expense for the fiscal year ended December 31, 2011 totaled $91,585, an increase of $55,803, or 156%, from $35,782 incurred during the fiscal year ended December 31, 2010. In 2011, our interest costs were comprised primarily of amortization of deferred financing costs in conjunction with the issuance of our secured convertible debentures in October 2011. We incurred an aggregate of $249,543 in deferred financing costs, of which we amortized $53,377 as interest expense for the fiscal year ended December 31, 2011. In addition, we incurred interest expense related to $500,000 of notes payable and our secured convertible debentures.

Net Loss. As a result of the foregoing, net loss for the year ended December 31, 2011 was $3,470,113, compared to a net loss of $1,964,470 for the year ended December 31, 2010.

Three Months Ended September 30, 2012 Compared to Three Months September 30, 2011

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the three month periods ended September 30, 2012 and 2011.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2012 were $658,143, an increase of $166,119, or 34%, from $492,024 for the three months ended September 30, 2011. The increase in clinical and non-clinical cost and activities is primarily due to increased development work related to TNX-102 SL, including formulation development, manufacturing, human pharmacokinetic studies, and market research.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2012 were $1,076,199, an increase of $553,737, or 106%, from $522,462 incurred in the three months ended September 30, 2011. This increase is primarily due to an increase in payroll-related expenses, along with increases in investor and public relations expense, travel, meals and entertainment expense, and related-party consulting agreement expense, offset by decreases in accounting expense, rent, and other professional fees.

Payroll-related expenses increased to $554,753 in the current period from $149,936 for the three months ended September 30, 2011, an increase of $404,817, or 270%, primarily related to stock-based compensation and additional personnel. Payroll-related expenses include both cash and non-cash compensation associated with restricted stock grants in 2011 of $13,768 and options granted in 2012 of $342,798.

Professional services for the three months ended September 30, 2012 totaled $334,810, an increase of $59,377, or 22%, over the $275,433 incurred for the three month period ended September 30, 2011. The increase was primarily a result of $98,101 in investor and public relations in the three months ended September 30, 2012 compared to $24,675 in 2011. Accounting fees incurred in the three months ended September 30, 2012 amounted to $15,536, a decrease of $27,513, or 64%, from $43,049 incurred in the three months ended September 30, 2011. The decrease in accounting fees was a result of our public reporting obligations incurred prior to our merger in 2011, as we were still a private company at that time, although we were in the process of preparing to go public. Legal fees totaled $76,279 for the three months ended September 30, 2012, a decrease of $23,998, or 24%, from $100,277 incurred for the three months ended September 30, 2011. The decrease in legal fees is due to legal expenses incurred when we were a private company preparing for our merger in 2011, offset by expenses related to SEC filings. Other professional fees totaled $100,304 for the three months ended September 30, 2012, a decrease of $7,128 or 7%, from $107,432 for the three months ended September 30, 2011.

Travel, meals and entertainment costs for three months ended September 30, 2012 were $19,375, an increase of $4,592, or 31%, from $14,783 incurred in the three months ended September 30, 2011. Travel, meals and entertainment costs primarily include travel to contractors and consultants engaged in research and development activities related to TNX-102 as well as travel related to investor relations activities.

Rent for three months ended September 30, 2012 totaled $28,595, a decrease of $1,765, or 6%, from $30,360 incurred in the three months ended September 30, 2011. Depreciation expense in the three months ended September 30, 2012 totaled $4,076, an increase of $1,722, or 73%, over the expense of $2,354 incurred in the three months ended September 30, 2011, as a result of the purchase of new office computers.

Interest and Other Financing Costs. Interest income for the three months ended September 30, 2012 totaled $440, an increase of $432 from $8 income earned during the three months ended September 30, 2011. The increase was a result of having significantly more cash on hand during the quarter ended September 30, 2012.

Net Loss. As a result of the foregoing, net loss for the three months ended September 30, 2012 was $1,732,027, compared to a net loss of $1,014,478 for the three months ended September 30, 2011, an increase of $717,549, or 71%.

Nine Months Ended September 30, 2012 Compared to Nine Months September 30, 2011

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the nine month periods ended September 30, 2012 and 2011.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2012 were $1,883,559, an increase of $1,249,063, or 197%, from $634,496 for the nine months ended September 30, 2011. The increase in clinical and non-clinical cost and activities is primarily due to increased development work related to TNX-102, including formulation development, manufacturing, human and animal pharmacokinetic studies, and market research.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2012 were $2,862,085, an increase of $1,612,585, or 129%, from $1,249,500 incurred in the nine months ended September 30, 2011. This increase is primarily due to payroll-related expenses, professional services, travel, meals and entertainment expense, and marketing related expenses.

Payroll-related expenses increased to $1,350,267 in the current period from $442,924 for the nine months ended September 30, 2011, an increase of $907,343, or 205%. Payroll-related expenses include both cash and non-cash compensation associated with the restricted stock grants in 2011 of $139,063 and options granted in 2012 of $571,330. The increase in payroll-related costs was a result of headcount increases, salary increases and bonuses to our core management team along with the increase in stock based compensation. Upon closing of the private placement financing in January 2012, the salaries for our core management team were increased, and one-time bonuses were paid.

Professional services for the nine months ended September 30, 2012 totaled $942,665, an increase of $367,323, or 64%, over the $575,342 incurred for the nine month period ended September 30, 2011. The increase was primarily a result of $290,544 in investor and public relations activities in the nine months ended September 30, 2012 compared to $60,878 in 2011, an increase of $229,666, or 377%. Legal fees totaled $253,961 for the nine months ended September 30, 2012, an increase of $65,292, or 35%, from $188,669 incurred for the nine months ended September 30, 2011. The increase related to filings with the SEC, as we were a private company during the nine months ended September 30, 2011, as well as to the preparation and filing of patent applications. Accounting fees incurred in the nine months ended September 30, 2012 amounted to $149,417, an increase of $41,319, or 38%, from $108,098 incurred in the nine months ended September 30, 2011. The increase in accounting fees was a result of our public reporting obligations, which we did not have in 2011 as we were still a private company at that time although we were in the process of preparing to go public. Other professional fees totaled $204,155 for the nine months ended September 30, 2012, an increase of $40,232 or 25%, from $163,923 for the nine months ended September 30, 2011.

Travel, meals and entertainment costs for nine months ended September 30, 2012 were $84,507, an increase of $47,143, or 126%, from $37,364 incurred in the nine months ended September 30, 2011. Travel, meals and entertainment costs include travel to contractors and consultants engaged in research and development activities related to TNX-102 as well as travel related to investor relations activities.

Marketing related expenses for the nine months ended September 30, 2012 were $212,401, an increase of $179,816, or 452%, from $32,585 incurred in the nine months ended September 30, 2011. The increase in marketing is primarily due to $167,954 invested in market research in current period compared to $1,890 during the same period, last year.

Rent for nine months ended September 30, 2012 totaled $88,138, a decrease of $9,730, or 10%, from $97,868 incurred in the nine months ended September 30, 2011. Depreciation expense in the nine months ended September 30, 2012 totaled $10,192, an increase of $3,246, or 47%, over the expense of $6,946 incurred in the nine months ended September 30, 2011, as a result of the purchase of new office computers.

Other general expenses for the nine months ended September 30, 2012 were $136,147, an increase of $99,314, or 277%, from $35,833 incurred in the nine months ended September 30, 2011. Other general expenses are comprised of office operations, conventions and other administrative expenses. The increase primarily were financial reporting expenses associated with a public entity of $31,883 and conventions of $42,049 incurred in the current period as compared to $-0- and $9,404 during the same period, last year.

Interest and Other Financing Costs. Interest income (expense) for the nine months ended September 30, 2012 totaled $(899,909), a decrease of $(899,961) from $52 income earned during the nine months ended September 30, 2011. In 2012, our interest costs were comprised primarily of amortization and write-off of $196,166 of deferred financing costs related to the issuance of our secured convertible debentures in October 2011, allocated offering costs of $270,743 charged to interest as part of a financing and the fair value of $426,153, net with prior period accrual, of common stock and warrants issued to convertible debentures holders in connection with the conversion to a financing. In addition, we incurred interest expense related to our convertible debentures.

Change in fair value of warrant liability. In connection with our January and March 2012 financing, we issued warrants that contained certain reset provisions. As such, we were required to record the fair value as a liability and mark to market each reporting period. In June 2012, upon the effectiveness of our registration statement, these reset provisions expired. Therefore we adjusted the fair value of the warrants from their initial issuance in January and March 2012, charged operations for the increase in fair value of $1,177,026 and reclassified the fair value of warrants to equity.

Net Loss. As a result of the foregoing, net loss for the nine months ended September 30, 2012 was $6,820,705, compared to a net loss of $1,883,944 for the nine months ended September 30, 2011, an increase of $4,936,761, or 262%.

Liquidity and Capital Resources

As of September 30, 2012, we had a working capital deficit of $758,068, comprised primarily of cash of $35,653 and prepaid expenses of $43,076, which was offset by $697,383 of accounts payable and $136,303 of accrued expenses. For the nine months ended September 30, 2012, we used $4,207,624 of cash in operating activities. Cash provided by financing activities totaled $4,237,894 from the sale of shares of capital stock and warrants of $4,387,894, net with repayments of our convertible debentures of $150,000. In the comparable 2011 period, $612,000 was raised through the sale of shares of capital stock and $500,000 through issuance of convertible debentures. At September 30, 2012, we had cash of $35,653 compared to $41,123 at December 31, 2011. Our cash is held in bank deposit accounts. At September 30, 2012 and December 31, 2011, we had nil and $2,075,000 of secured convertible debentures outstanding, respectively.

Cash used in operations for the nine months ended September 30, 2012 and 2011 was $4,207,624 and $1,170,873, respectively, which represent cash outlays for research and development and general and administrative expenses in such periods. Increase in cash outlays principally resulted from manufacturing, pre-clinical, and clinical cost and activities, regulatory cost, payroll and rent.

Cash used in investing activities for the nine months ended September 30, 2012 was $35,740 compared to cash provided by investing activities of $347 in the nine months ended September 30, 2011. In the nine month periods ended September 30, 2012 and 2011, we purchased office furniture and computer equipment of $35,673 and $2,764, respectively.

In their report dated March 30, 2012, our independent registered public accounting firm stated at December 31, 2011, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is an issue raised due to our net losses and negative cash flows from operations since inception and our expectation that these conditions will continue for the foreseeable future. In addition, we will require additional financing to fund future operations. Further, we do not have any commercial products available for sale and have not generated revenues and there is no assurance that if approval of our products is received that we will be able to generate cash flow to fund operations. In addition, there can be no assurance that our research and development will be successfully completed or that any product will be approved or commercially viable. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, obtaining loans from various financial institutions or being awarded grants from government agencies, where possible. Our continued net operating losses increase the difficulty in meeting such goals and there can be no assurances that such methods will prove successful.

We expect to incur losses from operations for the near future. We expect to incur increasing research and development expenses, including expenses related to additional clinical trials. We expect that our general and administrative expenses will increase in the future as we expand our business development, add infrastructure and incur additional costs related to being a public company, including incremental audit fees, investor relations programs and increased professional services.

Our future capital requirements will depend on a number of factors, including the progress of our research and development of product candidates, the timing and outcome of regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing and our success in developing markets for our product candidates. We believe our existing cash will be sufficient to fund our operating expenses and capital equipment requirements for the next six months. We anticipate we will need approximately $2,000,000 in addition to our current cash to fund our operating expenses and capital equipment requirements for the next 12 months. We will have to raise additional funds to continue our operations and, while we have been successful in doing so in the past, there can be no assurance that we will be able to do so in the future. Our continuation as a going concern is dependent upon our ability to obtain necessary additional funds to continue operations and the attainment of profitable operations.

We presently do not have any available credit, bank financing or other external sources of liquidity. Due to our history and historical operating losses, our operations have not been a source of liquidity. We will need to obtain additional capital in order to expand operations and fund research and development activities. Future financing may include the issuance of equity or debt securities, obtaining credit facilities, or other financing mechanisms. Even if we are able to raise the funds required, it is possible that we could incur unexpected costs and expenses, fail to collect significant amounts owed to us, or experience unexpected cash requirements that would force us to seek alternative financing. Furthermore, if we issue additional equity or debt securities, stockholders may experience additional dilution or the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock.

If additional financing is not available or is not available on acceptable terms, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

March 2012 Private Placement

Between January and March, 2012, we consummated a private placement financing transaction (the “March 2012 Financing”) pursuant to which we issued an aggregate of 264.7106 units (the “March 2012 Units”) to certain investors for aggregate cash proceeds of $4,692,765 and the exchange of $1,925,000 in previously issued debentures that were converted into March 2012 Units.

Each March 2012 Unit had a purchase price of $25,000 per March 2012 Unit and consisted of twenty five thousand (25,000) shares of our Common Stock, a Class A warrant to purchase twenty five thousand (25,000) shares of common stock (the "March 2012 Class A Warrants"), and a Class B warrant to purchase up to twenty five thousand (25,000) shares of common stock (the "March 2012 Class B Warrants" and together with the March 2012 Class A Warrants, the "March 2012 Warrants").

The March 2012 Class A Warrants have an exercise price of $1.25 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The March 2012 Class B Warrants expired unexercised effective April 24, 2012.

In connection with the March 2012 Financing, we paid Dawson James Securities, Inc., a FINRA registered broker-dealer ("Dawson James") a cash payment of $466,777, which represented an 8% commission and a 2% non-accountable expense allowance of the gross proceeds delivered by investors in the March 2012 Financing. In addition, Dawson James earned warrants to purchase 466,777 shares of Common Stock (the "March 2012 Agent Warrants"), which have an exercise price of $1.25 per share of common stock, will be exercisable for a period of seven years, contain customary anti-dilution protection and are entitled to piggy-back registration rights.

2012 Promissory Notes

Between October and November 2012, we issued promissory notes in the amount of $320,000 (the "Notes") in exchange for $320,000 borrowed from six affiliated investors. The Notes bear no interest and were payable on demand.

2012 Bridge Financing

On November 14, 2012, we sold to accredited investors for aggregate cash proceeds of $390,000, convertible debentures (the "Debentures") in the principal face amount of $390,000 and the exchange of the Notes for Debentures in the principal face amount of $320,000.

The Debentures mature on the earlier of (i) November 14, 2013 or (ii) the date of closing of a private placement of equity, equity equivalent, convertible debt or debt financing in which we receive gross proceeds, in one or more transactions, of at least $100,000 (a "Subsequent Financing"). The Debentures bear interest at 8% per annum and are convertible at the holder's option into either (i) a Subsequent Financing at a price equal to a 25% discount to the price of securities sold in the Subsequent Financing or (ii) shares of our common stock at a conversion price per share equal to $1.00.

December 2012 Private Placement

In December 2012, we consummated the December 2012 Financing, pursuant to which we issued an aggregate of 8,904,167 Units to the Purchasers for aggregate cash proceeds of $2,615,000, at a price per Unit of $0.40, and the exchange of $710,000 in Debentures of the Company that were converted into Units at a price of $0.30 per Unit. The December 2012 Financing satisfied the requirements for the Subsequent Financing discussed above.

Each Unit consisted of one share of Common Stock, a Class A Warrant to purchase one share of Common Stock and a Class B Warrant to purchase one share of Common Stock. The Class A Warrants have an exercise price of $0.60 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The Class A Warrants may be exercised on a cashless basis under certain circumstances. The Class B Warrants have an exercise price of $0.40 per share of Common Stock and will be exercisable for a period of one year from the date of issuance.

In connection with the December 2012 Financing, we paid Kema Partners a cash payment of $70,000, which represented a 7% commission of the gross proceeds delivered by Purchasers introduced by Kema Partners in the December 2012 Financing.

Other

In July 2011, we entered into a contract with a contract research organization, or CRO, to investigate the feasibility of developing a new, proprietary formulation of CBP at a cost of $58,080. In August 2011, we authorized the initiation of formulation work and manufacturing of TNX-102 gelcap for clinical trials pursuant to a contract with Lipocine with respect to a research and development project for reformulation work on our leading products for a fee of $235,000. In September 2011, we entered into a contract with a CRO, Pharmanet Canada, for contract research work with respect to a pharmacokinetic study for TNX-102 gelcap. The full cost of the work to be performed is $637,231. Payment is due in four installments based on the achievement of certain performance milestones. In October 2011, we entered into an agreement with another CRO to develop, and perform an exploratory non-clinical pharmacokinetic study on, a new formulation of CBP for an approximate cost of $180,000.

In December 2011, we entered into an agreement with a public relations firm to provide news media placement and political intelligence from January 2012 through June 2012 for a total cost of $60,000, but subsequently amended the agreement to cover the period May 2012 through October 2012. In April 2012, we entered into an agreement with a CMO to formulate and manufacture TNX-102 SL drug material for clinical testing at a cost of $93,000. In May and June 2012, we entered into five contracts with a CMO to develop and manufacture sublingual formulations of CBP and related compounds for an approximate total cost of $335,000. Payment is due in four installments in four of these contracts, and is due in five installments in one contract. In May 2012, we entered into a contract with a CRO to perform an exploratory pharmacokinetic study, which evaluated TNX-102 SL, at a cost of $283,000, with payment due in three installments. In May 2012, we entered into an agreement with an investor relations firm to provide investor relations services, at a cost of $50,000 to be paid in four equal monthly installments. In September 2012, we entered into a contract with a CRO to perform technology transfer of manufacturing and formulation at a cost of $44,500, with payment due in two installments. In September 2012, we entered into a contract with a CMO to perform analytical work on TNX-102 SL at an approximate cost of $95,000, with payment due in three installments.

Transactions with Related Parties

Dr. Seth Lederman, our Chief Executive Officer and Chairman of the Board, and Dr. Donald Landry, one of our directors, are the primary founders of Tonix Sub. We have entered into various transactions with several companies under their control, including L&L Technologies, Plumbline, Targent Pharmaceuticals, LLC and Lederman & Co. In 2010, we entered into a two-year consulting agreement with Lederman & Co. for clinical development, strategic, management and operational consulting services. Lederman & Co. received $250,000 per annum for its services, until August 1, 2011, when it received $127,000 per annum until such time as we closed on the 2012 Financing. We first closed on the 2012 Financing in January 2012, and effective February 1, 2012, Lederman & Co. receives $250,000 per annum for its services. The consulting agreement renews automatically for subsequent terms of one year at $250,000 per annum. In January 2012, the related party companies received interest on the convertible notes in the aggregate amount of $6,183.

In connection with the March 2012 Financing, related party convertible debenture holders received an aggregate of 84,150 shares of common stock and 10,000 warrants to purchase the Company's common stock at an exercise price of $1.00 for three years (see Note 10 on page F-28). Upon exchange of debentures for units in the March 2012 Financing, related party debenture holders received an aggregate of 275,000 shares of the Company's common stock, 275,000 March 2012 Class A Warrants and 275,000 March 2012 Class B Warrants (see Note 10 pn page F-28).

Stock Compensation

In February 2012, we approved the 2012 Incentive Stock Options Plan ("2012 Plan"). The 2012 Plan provides for the issuance of options to purchase up to 4,000,000 shares of our common stock to officers, directors, employees and consultants. Under the terms of the 2012 Plan, we may issue Incentive Stock Options, as defined by the Internal Revenue Code, and nonstatutory options. The Board of Directors determines the exercise price, vesting and expiration period of the options granted under the 2012 Plan. However, the exercise price of an Incentive Stock Option must be at least 100% of fair value of the common stock at the date of the grant (or 110% for any stockholder that owns 10% or more of our common stock). The fair market value of the common stock determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in a good faith. Additionally, the vesting period of the grants under the 2012 Plan should not be more than five years and expiration period not more than ten years. We reserved 4,000,000 shares of our common stock for future issuance under the terms of the 2012 Plan. In May 2012, we issued options to purchase 3,500,000 shares of common stock pursuant to the 2012 Plan, with such options vesting 1/3rd on May 9, 2013 and 1/36th on the 9th of each month thereafter for 24 months, having an exercise price of $1.50 and expiring 10 years from date of issuance.

Lease Commitments

In September 2010, we entered into a five-year lease for office space in New York City, with monthly payments escalating from approximately $10,000 in the first year to approximately $11,000 in the fifth year. The Company received a rent credit of $9,420 in each of the months of November 2010, December 2010 and January 2011. We issued a letter of credit in the amount of approximately $60,000 for the benefit of the landlord, which is collateralized by a money market account. Our future minimum lease payments under the operating lease are as follows:

Year Ending December 31,		
2013	$	127,889
2014		131,513
2015		100,719
	$	360,121

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development. Tonix outsources its research and development efforts and expenses related costs as incurred, including the cost of manufacturing product for testing, licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired was expensed as research and development costs, as it related to particular research and development projects and had no alternative future uses.

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

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

Recent Accounting Pronouncements

There were various updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to a have a material impact on the Company's consolidated financial position, results of operations or cash flows.

BUSINESS

Corporate Structure

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. From inception through October 2011, we were involved in the acquisition, exploration and development of natural resource properties in the State of Nevada. On October 7, 2011 ("Closing Date" and the closing of the share exchange transaction, the "Closing"), we executed and consummated a share exchange agreement by and among Tonix Sub and the stockholders of 100% of the equity securities of Tonix Sub, including, the holders of 5,207,500 shares of common stock, 1,500,000 shares of Series A Preferred Stock and 2,275,527 shares of Series B Preferred Stock (the "Tonix Shareholders"), on the one hand, and us and David Moss ("Moss"), our then sole officer and director and majority shareholder, on the other hand (the "Share Exchange Agreement" and the transaction, the "Share Exchange").

In the Share Exchange, the Tonix Shareholders exchanged their shares of Tonix Sub for newly issued shares of our common stock ("Common Stock"). As a result, upon completion of the Share Exchange, Tonix Sub became our wholly-owned subsidiary.

Upon completion of the Share Exchange, the Tonix Shareholders received an aggregate of 22,666,667 shares of our Common Stock. Moss returned 1,500,000 shares of Common Stock to us, which were retired, and our existing stockholders retained 4,000,000 shares of Common Stock. The 22,666,667 shares issued to the Tonix Shareholders constituted approximately 85% of our 26,666,667 issued and outstanding shares of Common Stock post-Closing.

As a result of the Share Exchange, we acquired 100% of the capital stock of Tonix Sub and consequently, control of the business and operations of Tonix Sub and Krele. From and after the Closing Date of the Share Exchange, our primary operations consist of the business and operations of Tonix Sub and Krele.

On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp. to reflect our new business.

Corporate Background

In 1996, Seth Lederman, MD, and Donald Landry, MD, PhD, formed L&L to develop medications for CNS conditions. Dr. Lederman is our Chairman and Chief Executive Officer and Dr. Landry is a Director. L&L was a founder of Janus Pharmaceuticals, Inc., which later became Vela Vela, which developed various therapeutics, including a VLD version of CBP under an agreement with L&L. Vela decided to focus its resources on other programs and transferred the rights in VLD CBP and certain other technologies to L&L in March 2006.

Tonix Sub formed in June 2007 as Krele Pharmaceuticals, Inc. by L&L and Plumbline. Dr. Lederman is managing partner of Plumbline. Plumbline possessed rights to certain technology for the treatment of alcohol dependence and abuse. In connection with founding Tonix Sub, L&L and Plumbline entered into an intellectual property transfer and assignment agreement with Tonix Sub for the purpose of assigning patents and transferring intellectual property and know-how in exchange for shares of common stock of Tonix Sub. As a result of economic conditions related to the financial crisis of 2007 and 2008, Tonix Sub was not successful in raising money to fund its programs until 2009. As a result, Tonix Sub was unable to advance the development programs and had little activity except for prosecuting and maintaining patents and maintaining contracts.

In 2009, Tonix Sub contracted with the Toronto Psychiatric Research Foundation to analyze the sleep data from the Moldofsky Study, who were treated with bedtime VLD CBP or placebo. The Moldofsky Study was conducted in Canada by the Toronto Psychiatric Research Foundation, and Tonix Sub obtained the data from this study from L&L. In addition, in 2009, Tonix Sub contracted with Caliper to analyze the interactions of CBP with certain receptors. In June 2010, Tonix Sub entered into consulting agreements with L&L and Lederman & Co and also acquired certain rights to develop isometheptene mucate as a treatment for certain types of headaches from Lederman & Co., which we are developing as TNX-201. Dr. Lederman is managing partner of Lederman & Co. Between June 2010 and October 2011, Tonix Sub was active in recruiting new officers and directors and initiating preclinical and clinical development of novel CBP formulations.

Lederman & Co predominantly provides us with clinical development expertise. L&L predominantly provided us with scientific development expertise until the termination of the consulting agreement in June 2012. Relative to traditional pharmaceutical development companies, we can be considered a virtual company, since we contract with third-party vendors to provide many functions that are core to traditional pharmaceutical companies. For example, we have contracted with PharmaNet Canada to develop methods for analyzing CBP in the blood and to conduct human clinical studies to evaluate the performance of our formulation technology. Lederman & Co is responsible for overseeing the scientific and technical aspects of PharmaNet's contract work product.

In July 2010, Tonix Sub changed its name to Tonix Pharmaceuticals, Inc. In August 2010, Tonix Sub formed Krele.

Business Overview

We are a specialty pharmaceutical company focused on developing novel pharmaceutical products for challenging disorders of the CNS. We search for potential therapeutic solutions among known pharmaceutical agents that lack regulatory approval for the indications we seek, but may be approved for use in other indications. The ongoing evolution in the understanding of certain CNS disorders provides us with opportunities to develop such agents as proprietary products for new indications. We typically seek to create new dose and formulation options that are tailored to the therapeutic uses to which we apply these agents.

Many CNS drugs have been identified by physicians who observe unexpected improvements in their patients' CNS conditions despite being prescribed for a different purpose. One of our goals is to establish formal clinical study programs to determine if such anecdotal observations are, in fact, reflections of a compound's ability to treat a particular CNS condition. While some new applications can use the commercially-available form of a given drug, in other cases, reformulating the active ingredient may improve the active ingredient's safety or effectiveness in treating the condition. If we demonstrate success in our formal development programs, we will seek marketing approval from the FDA.

We are currently devoting the majority of our efforts to the development of our lead product candidate, TNX-102 SL. TNX-102 SL is a novel dose and formulation of CBP, the active pharmaceutical ingredient of two widely prescribed muscle relaxant products, Flexeril and Amrix. TNX-102 SL is distinct from these products as it is being developed at a dose level significantly below the lowest marketed doses of Flexeril and Amrix. TNX-102 SL is also distinct from these products with regard to its route of administration, as it is designed to be placed under the tongue and disintegrated to provide sublingual absorption, whereas Flexeril and Amrix are designed to be swallowed. TNX-102 SL is also intended for chronic use, whereas Flexeril and Amrix are marketed for two to three weeks of use. We are currently developing TNX-102 SL for the treatment of FM under an IND and under three CTAs filed in Canada. We are also developing TNX-102 SL for the treatment of PTSD for which we held a pre-IND meeting in October 2012. We expect that any applications we submit for FDA approval of TNX-102 SL will be submitted under Section 505(b)(2) of FDCA, which we believe will allow for a shorter timeline of clinical development as compared to that needed to fulfill the requirements of Section 505(b)(1), under which NCEs are generally reviewed.

TNX-102 SL is a small, rapidly disintegrating tablet containing CBP for sublingual administration at bedtime. We designed TNX-102 SL to enable the efficient delivery of CBP to the systemic circulation via sublingual transmucosal absorption and to avoid first-pass liver metabolism. We also designed TNX-102 SL to provide CBP at doses lower than those currently available. We have conducted several clinical and pre-clinical pharmacokinetic studies of TNX-102 SL which we believe support its development as a novel therapeutic product for FM and PTSD, and which demonstrate a number of potentially advantageous characteristics as compared to current CBP-containing products, none of which are approved for these indications. Based on our Phase 1 comparative study, we have observed that, as compared to oral CBP tablets, TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following administration. TNX-102 SL was generally well-tolerated, with no serious adverse events reported in this study. 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.

Based on these promising results, we are advancing TNX-102 SL for the management of FM. We believe that TNX-102 SL could be approved by the FDA for the treatment of FM following two adequate, well-controlled safety and efficacy studies and, if required, a long-term safety exposure study that, together, would confirm the safety and efficacy of TNX-102 SL in a sufficient number of FM patients to satisfy the approval requirements under Section 505(b)(2). New drug products based on novel active ingredients, approved under Section 505(b)(1), need significantly more clinical studies, e.g. drug-drug interaction, special population pharmacokinetic, and long-term safety exposure studies, than will be required for TNX-102 SL. Under the IND, we plan to initiate a potential pivotal efficacy trial in the first half of 2013 that will evaluate this candidate in FM. A Type B Pre-Phase 3 meeting has been scheduled with the FDA in February 2013, at which we plan to discuss the design of the 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 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 for this indication in the first half of 2013. We then plan to conduct a clinical proof-of-concept trial of TNX-102 SL in PTSD in the second half of 2013.

CBP is the active pharmaceutical ingredient in our lead product candidate, TNX-102 SL. We are utilizing drug delivery technology to produce new formulations. In addition to CBP, TNX-102 SL contains excipients, which are well-characterized, are listed in the IIG, and are approved for pharmaceutical use. As a result, we anticipate seeking FDA marketing approval of TNX-102 SL through a 505(b)(2) NDA. As one of three types of new drug applications, the 505(b)(2) NDA allows drug companies to obtain FDA approval of new drug products without having to conduct the full complement of safety and efficacy trials, which is often the most time-consuming and expensive part of the drug development process. As the 505(b)(2) NDA permits the drug manufacturer to rely on the agency's findings for a previously-approved drug, published literature, or both, it permits the FDA to make some safety and effectiveness determinations through the review of materials in the public domain or in already approved NDAs of products containing CBP. The 505(b)(2) regulatory pathway would spare us some of the burden of generating all of this data for ourselves and may allow TNX-102 SL to progress through a shorter development pathway than is typical for pharmaceutical products based on novel active ingredients. We have not filed an NDA for TNX-102 SL for any indications.

In addition to TNX-102 SL, we have developed other innovative formulations of CBP, including TNX-102 gelcap. We have developed TNX-102 gelcap under an agreement with Lipocine, a contract formulation developer and small-scale manufacturer. Although we had met with the FDA to discuss the TNX-102 gelcap development program in August 2011 and we have generated clinical data that support the further development of TNX-102 gelcap, we currently do not plan to advance this candidate.

We also have a pipeline of other product candidates, including TNX-201 and TNX-301. TNX-201 is based on isometheptene mucate and is under development as a treatment for certain types of headaches. For competitive reasons, we 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. Consistent with our mission, these product candidates are or likely will be reformulations of active ingredients that have been used in humans in other products and that are designed for new CNS therapeutic indications.

In other cases, the products will be formulated to match predicate products closely enough to be considered generic copies or similarly enough to other marketed products to rely (in part) on their regulatory review and approval, as well as available published data. The predicate product may be approved by the FDA under an NDA or may have been reviewed for safety and effectiveness by the National Academy of Sciences under the DESI program, in which case they would be considered by FDA to be "unapproved products". For DESI products, it is our intent to develop NDA versions to meet cGMP and the ICH requirements to seek approval under the 505(b)(2) regulatory pathway.

Because of our size and being in the development stage, we do not currently devote a significant amount of time or resources towards our other pipeline candidates. We anticipate that sometime in 2013 we will begin developing formulations for TNX-201 and possibly TNX-301, but do not expect to start clinical trials until 2014 at the earliest.

The process of taking a new drug formulation from concept through testing to approval for a new indication by the FDA is a time-consuming, costly and a high-risk process. Once a drug formulation has been tested in laboratories, we need to conduct clinical trials of the product candidate to test its uptake into the blood stream, elimination, effectiveness and safety. Neither laboratory nor animal studies predict the properties of drugs in humans, so designing new formulations can result in a large number of unexpected outcomes. The Phase 1 studies are performed by administering new drug formulations to a limited number of healthy human volunteers and are designed to test the initial concept of the drug formulation and to determine the correct dosage to be tested subsequently on patients affected with the target disorder. The initial Phase 1 studies can take up to a year to complete, however, since we reformulate versions of approved drugs for new uses, we may need to devote less time to Phase I studies since our testing is informed by significant prior human research that we believe allows us to reduce the possible safety-related outcomes. The next step in the process is to conduct a proof-of-concept efficacy study to identify the effective dose(s). A small Phase 2a efficacy study in the representative patient population will be done either using a pilot formulation or the formulation selected for further development. A larger study in which the selected formulation has been optimized for the target indication can be referred to as a first pivotal study, a Phase 2b study or a Phase 3 study. If the results of this study are positive and are accepted by the FDA as fulfilling the requirements of a registrational study, then it may be considered to be one of the two pivotal studies typically required for drug approval. The first pivotal study for a condition like FM typically takes a year to complete and then two to three months to interpret the data, but we believe we will be able to conduct our first pivotal study of TNX-102 SL in less time due to the nature of the trial design. If the first pivotal study suggests the drug is safe and effective, then a second pivotal Phase 3 study is conducted. The second pivotal study in FM typically takes 18 months to complete if no additional long-term safety exposure data are necessary for an NDA filing. After the second pivotal study is completed, and if the results are deemed a success, we would submit an NDA to the FDA seeking approval of the new drug product. We believe it would take approximately six months to prepare and file the NDA and another 14 months for FDA approval. The drug could be marketed shortly after FDA approval. Therefore, it typically takes more than five years to bring a new formulation of a drug to market for a new indication, and any delays in the process, such as lack of capital necessary to run clinical trials, unexpected results, adverse effects, or difficulty in recruiting willing subjects for trials, would result in additional time before a drug could be approved for marketing.

In August 2010, we formed Krele to commercialize products that are generic versions of predicate NDA products. We anticipate that when our branded products lose patent protection, Krele may market authorized generic versions of them. Krele also may develop or acquire generic products approved under ANDAs and we may market branded versions (branded generics) of such products. Krele has been issued a state license in New York.

Our Strategy

Our objective is to develop and commercialize our product candidates to treat CNS conditions, including FM and PTSD. The principal components of our strategy to achieve this objective are to:

- pursue development and regulatory approval pathways by reformulating versions of approved drugs for new uses and by using the Section 505(b)(2) regulatory pathway for NDA approval;
- adopt a multi-pronged patent strategy to protect our products, including patents which protect methods of use for the active ingredients in our products, the formulation technology employed in our products, and the performance characteristics of our products in the human body;
- provide clear value propositions to third-party payers, such as managed care companies or government programs like Medicare, to merit reimbursement for our product candidates; and
- enter into collaborations with other pharmaceutical companies with respect to, among others, our FM and PTSD product candidates and other products that will benefit from development or marketing resources beyond those in our Company.

Pursue development and regulatory approval pathways. We believe our lead product candidates may be approvable under pathways that are potentially shorter than those typically available for drug products based on novel active ingredients (Section 505(b)(1)). By focusing on developing new formulations of approved drugs for new uses, we believe that we will be able to use the Section 505(b)(2) regulatory pathway for NDA approval. This pathway can reduce the time and expense required for our development programs by allowing our use of previously-generated safety and efficacy information regarding the active pharmaceutical ingredients in our lead product candidates to support the filing and approval of our NDA application. Doing so may help reduce the size and scope of our preclinical and clinical trials. The FDA has strict requirements on the marketing of drugs, and FDA approves each drug for specific uses which are called the label indications. The use of a drug product for the treatment of a condition other than one of its approved label indications is called off-label use. The development of an existing FDA-approved drug for the treatment of a condition other than one of its approved label indications is considered a "new use". For companies involved in the ethical development and marketing of prescription drugs in the US, FDA approval of a new use or new label indication is the only legal basis of marketing claims for that use or indication. Off-label use is not recognized by the FDA or FDA-regulated companies as a new use.

Adopt a multi-pronged patent strategy. We are pursuing a multi-pronged patent strategy by seeking intellectual property protection on several aspects of our products. Aspects we seek to protect include, among others, methods of use for certain known active pharmaceutical ingredients, formulation technologies incorporated into our products, and performance characteristics of our products in the human body. With respect to methods of use patents, we believe the therapeutic uses we target are new uses for these active ingredients and we have been issued patents directed to certain aspects of our new uses. For example, the invention of bedtime VLD CBP as a treatment for FM was novel and unexpected when our patents were filed in 2000. We are seeking additional patents to cover other new uses. For example, we filed a patent application seeking to protect the use of CBP in PTSD. With respect to formulation patents, we believe our products will be protected by patents that describe inventions of technology for making new formulations, which may include novel routes of delivery for the active ingredients. With respect to patents related to the performance characteristics of our products in the human body, we believe our products will be protected by patents that describe novel pharmacokinetic properties of the active ingredient, as well as of its active metabolites, at certain times after administration. For example, we filed a patent application seeking to protect novel pharmacokinetic properties of CBP as enabled by TNX-102 SL.

Provide clear value propositions to third-party payors to merit reimbursement for our product candidates. We are designing our clinical development programs to demonstrate compelling competitive advantages to patients and prescribers and also to demonstrate value propositions to third-party payors. We believe TNX-102 SL might help in the management of FM by reducing pain and other symptoms, such as fatigue. In addition, we believe that bedtime treatment with TNX-102 SL will have fewer day time side-effects than off-label bedtime treatment with immediate release CBP. For FM, we believe an FDA-approved product would capture some of the off-label use of generic CBP. Because FDA approvals are based on objective data, we believe that third-party payors will provide reimbursement for an FDA approved product, even at a premium price relative to other drugs that are used off-label, such as immediate-release CBP, tizanidine, baclofen, carisoprodol or metaxalone. For example, third-party payors reimburse the use of Lyrica® and Cymbalta® for FM despite the availability of off-label generic versions of drugs with similar mechanisms of action, for example, Neurontin® (gabapentin) and generic anti-depressants, respectively.

Enter into collaborations to maximize the value of our technology. We believe certain of our drug development candidates, including TNX-102 SL, can be developed and marketed more effectively by companies that already have significant drug development and marketing capabilities. We will seek to enter into collaborations with pharmaceutical or biotechnology companies for the commercialization of these product candidates at the times we believe most effective.

Our Lead Product Candidates

Our lead product candidate is TNX-102 SL, for the treatment of FM and PTSD. TNX-102 SL consists of CBP in a mixture of inactive ingredients that are called "excipients", which we believe will improve the absorption rate of CBP in ways that will optimize the product for bedtime treatment. The excipients used in TNX-102 SL are approved by the FDA for pharmaceutical uses.

Cyclobenzaprine

CBP was first synthesized in 1961 by Merck, and the 10 mg Flexeril immediate-release dose form was FDA approved in 1977 for the relief of muscle spasm associated with acute, painful musculoskeletal conditions as an adjunct to rest and physical therapy.

Although a number of clinical studies have addressed the potential use and benefit of CBP in treating symptoms of FM, to our knowledge these studies have not motivated a sponsor to pursue FDA approval.

Based on CBP's safety and efficacy for treating muscle spasm, in the 1990s, Merck conducted studies to support an application to market a 5 mg Flexeril tablet (low dose) for the over-the-counter, or OTC, market, whereby patients can purchase medicine without a physician's prescription. Although Merck's studies re-affirmed the safety and demonstrated efficacy of 5 mg Flexeril in several large trials, the OTC division of the FDA rejected the application for use without a prescription, apparently, we believe, because muscle spasm was deemed a condition that required a physician to diagnose and supervise treatment.

Merck divested the Flexeril franchise to Alza Pharmaceuticals, or Alza. Alza subsequently was acquired by Johnson and Johnson and Flexeril is part of their McNeil Specialty Pharmaceuticals division. Based largely on the Merck studies, McNeil won approval of Flexeril 5 mg tablets as a prescription medicine to treat muscle spasm. McNeil promoted Flexeril 5 mg tablets for the three year period of market exclusivity based on The Drug Price Competition and Patent Term Restoration Act of 1984, generally referred to as the Hatch-Waxman Act. Following this exclusivity period, several generics entered the market and took market share from Flexeril. McNeil continues to manufacture Flexeril, but we believe McNeil no longer actively promotes it.

Despite the approved uses of CBP in treating muscle spasm, we believe current marketed formulations of CBP are limited for treating FM by unpredictable absorption. As described in the Flexeril package insert, the amount of CBP absorbed into the bloodstream varies between 33-55% of the dose ingested. The variability in absorption may be due to several factors, including effects of the stomach pH (acidity or base) on the dissolution of the tablets, as well as the context of either an empty stomach or a recent meal. Food in the stomach and small intestine from a recent meal contributes to variability in absorbing other drugs. The uncertainties in absorption rates make it challenging for a physician contemplating a bedtime treatment for FM to ensure the intended therapeutic effect is achieved without risking side effects like next-day drowsiness, which could result if the patient has too much CBP remaining in the bloodstream the next day.

If a product could deliver a predictable absorption rate of CBP, it would mean patients would be less likely to receive too little drug to receive a therapeutic effect. Conversely, patients would be less likely to be over-dosed, which might lead to potential side effects, including next-day drowsiness. An optimal VLD CBP product could have faster absorption, faster clearance and more predictable effects than the immediate release tablet format. We have tested a number of technologies to optimize the properties of VLD CBP as a bedtime therapy for FM and PTSD. Our lead product, TNX-102 SL is a novel sublingual tablet form of VLD CBP that we have tested in pre-clinical and clinical studies. We intend to enter TNX-102 SL into a potential pivotal clinical trial program in FM in the first half of 2013, and into a Phase 2 trial in PTSD in the second half of 2013. We believe the unique properties of TNX-102 SL, as demonstrated by the results of our studies, support its development in both FM and PTSD. We have developed other innovative formulations of CBP, including TNX-102 gelcap. Although we had met with the FDA to discuss the TNX-102 gelcap development program in August 2011 and we have generated clinical data that support the further development of TNX-102 gelcap, we currently do not plan to advance this candidate.

TNX-102 SL in Fibromyalgia Syndrome

TNX-102 SL, our most advanced product candidate, is a rapidly disintegrating tablet containing VLD CBP that is designed to be placed under the tongue at bedtime. The development of TNX-102 SL is supported by the results of the Moldofsky study, which evaluated oral administration of CBP at doses below the lowest marketed dose in the evening, as well as by preclinical and comparative clinical pharmacokinetic studies.

In the Moldofsky study, which was a randomized, double-blind, placebo-controlled, Phase 2a trial, it was demonstrated that VLD CBP in a capsule swallowed between dinner and bedtime resulted in significant decreases in next-day pain and other core FM symptoms, as well as in a significant improvement in sleep quality. We believe that CBP exerts its benefit in FM via its ability to improve the restorative quality of sleep, which has been shown to be frequently impaired in patients with FM or PTSD. Current CBP products are believed to be widely used off-label by FM patients.

FM is diagnosed by groups of symptoms that have been defined by committees of the American College of Rheumatology, or ACR, and a committee of experts from the organization Outcome Measures in Rheumatology. In 2007, Pfizer's Lyrica (pregabalin) became the first medicine approved by the FDA for the management of FM. In 2008, Eli Lilly's Cymbalta (duloxetine) became the second medicine approved by the FDA for the management of FM. In 2009, Savella® (milnacipran) was the third medicine approved by the FDA for the management of FM. Savella is marketed by Forest Laboratories.

Product Development Plan

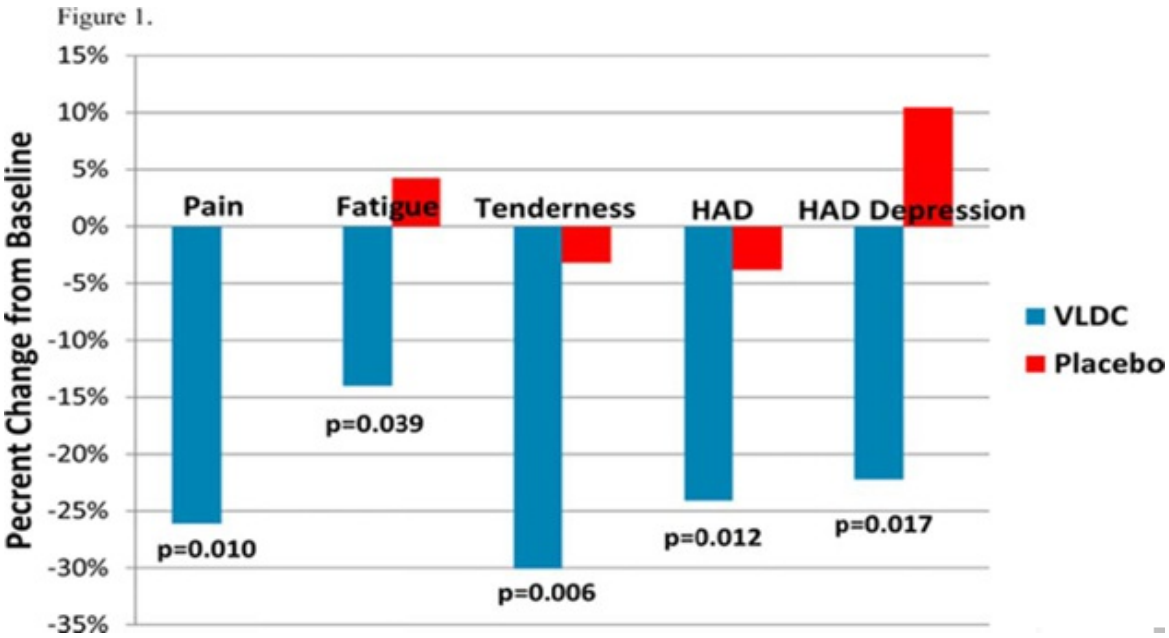
Phase 2a Data of VLD Cyclobenzaprine in FM Patients

Our motivation to focus our efforts on developing TNX-102 SL for FM stems from the results of the Moldofsky study, the related rights to which we acquired from L&L. Specifically, this study was a randomized, double-blind, placebo-controlled, dose-escalating eight week trial conducted at two study centers. The study subjects met ACR criteria for FM.

Patients received VLD CBP immediate-release 1 mg capsules or corresponding placebo capsules to ingest after dinner and before bedtime. Initially, patients took one capsule each evening, but over the course of the study, they were allowed to increase the number of tablets taken in increments of one capsule per week. The maximum number of capsules allowed was four per evening, which would be a total dose of 4 mg immediate-release CBP.

Patients treated with VLD CBP demonstrated significant improvements in pain, fatigue and tenderness at week 8 relative to baseline, whereas placebo-treated patients did not improve (Figure 1). Although this study excluded patients who met formal criteria for major depressive disorder or any anxiety disorder, there is a high degree of co-existing symptoms of depression and anxiety associated with FM. VLD CBP treatment resulted in significant reductions in total Hospital Anxiety and Depression Scale, or HAD, which measures symptoms of anxiety and depression, and the HAD depression subscale which measures depressive symptoms (Figure 1).

Figure 1.



This study showed treatment with VLD CBP:

- provided benefit in core symptoms of FM, including pain and fatigue;

- improved mood, by demonstrating a significant decrease in HAD scores; and
- was well tolerated, with no serious adverse events, or SAEs, or discontinuations due to adverse events, or AEs.

This study also showed that VLD CBP taken between dinner and bedtime resulted in a significant improvement in sleep quality. We believe that CBP exerts its benefit in FM via its ability to improve the restorative quality of sleep, which has been shown to be frequently impaired in patients with FM.

This research was published in the *Journal of Rheumatology*, in an article entitled "Effects of Bedtime Very Low Dose (VLD) Cyclobenzaprine (CBP) on Symptoms and Sleep Physiology in Patients with Fibromyalgia Syndrome (FM): A Double-blind, Randomized, Placebo-controlled Study." The citation is: Moldofsky H, Harris H, Kwong T, Archambault WT and Lederman S. *J Rheum* 2011 Dec;38(12):2653-63.

Pharmacokinetic and Bioequivalence Studies

We have conducted two preclinical and two clinical studies of our sublingual formulations of CBP, which have evaluated the pharmacokinetics of these formulations as well as their bioequivalence to oral CBP.

Our preclinical animal studies demonstrated that our sublingual formulations provide faster delivery and more efficient systemic absorption of CBP as compared to current oral forms of the drug.

Our first clinical study of sublingual CBP evaluated a solution formulation in which certain key ingredients of TNX-102 SL were delivered under the tongue in a small volume of water. This single-dose study was conducted in Canada. The trial enrolled 23 healthy volunteers, and subjects received one of: a sublingual solution containing 2.4 mg of CBP and sublingual absorption-enabling ingredients of TNX-102 SL (Arm 1), a sublingual solution that was designed to simulate crushed immediate-release CBP tablets, i.e., without the sublingual absorption-enabling ingredients (2.4 mg) (Arm 2), an immediate-release oral CBP tablet (5 mg) (Arm 3), or intravenous CBP (2.4 mg) (Arm 4). The study measured circulating blood levels of CBP at pre-defined time-points over six days after receiving study medication. Patients receiving sublingual formulations were instructed to spit and rinse 90 seconds following administration. The results demonstrated that the solution formulation of TNX-102 SL (Arm 1) delivered CBP to the systemic circulation more efficiently than the sublingual solution of a simulated crushed tablet (Arm 2) and faster than the ingested tablet (Arm 3). In the study, all of the CBP formulations were well-tolerated, and there were no unexpected adverse events.

Our second clinical study of sublingual CBP evaluated TNX-102 SL, the tablet formulation we expect to advance into further development. This study was conducted in Canada under the U.S. IND. This study enrolled 24 healthy volunteers and evaluated a single dose of one 2.4 mg tablet or two tablets (4.8 mg) of TNX-102 SL or the currently-marketed 5 mg CBP tablet. In comparison to oral administration of the 5 mg CBP tablet, both sublingual doses of TNX-102 SL demonstrated faster systemic absorption. After administration of TNX-102 SL, blood levels of CBP were significantly higher at 20, 30, 45 and 60 minutes relative to administration of the 5 mg CBP tablet. In the study, TNX-102 SL was generally well tolerated. There were no unexpected adverse events, with the exception of a mild, temporary numbness at the tongue experienced by less than one-third of the subjects that received TNX-102 SL tablets.

Prospective Phase 2b Study

We expect to advance the clinical development of TNX-102 SL for the management of FM by conducting a Phase 2b study. In this multicenter, randomized, double-blind, placebo-controlled clinical trial, FM patients will be administered either TNX-102 SL or placebo at bedtime nightly for 12 weeks. We expect to enroll 100-200 patients into this study. We expect that our proposed Phase 2b study, if successful and accepted by the FDA, will be one of the two pivotal studies required to support the NDA approval.

We expect 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 by drug products currently approved for use in FM. We will also collect information on other outcome measures, including NRS scores at other timepoints, the Fibromyalgia Impact Questionnaire, and the Patient Global Impression of Change. We will seek FDA concurrence on the study design at the February 2013 Pre-Phase 3 meeting, and expect to engage a CRO to conduct and manage this study under our direction. We expect the study will begin enrollment in the first half of 2013 and will be completed in the first quarter of 2014.

Prospective Multi-dose Pharmacokinetic Study

Since CBP will be used chronically in TNX-102 SL, we will study TNX-102 SL in comparison to immediate-release CBP in multiple-day dosing (once daily). Subjects will receive TNX-102 SL or immediate-release CBP for four or more consecutive days. Peak and trough blood levels of CBP will be measured. The results of this study will provide information regarding blood levels of CBP resulting from use of the marketed immediate-release tablet and our sublingual tablet when taken in a multiple day regimen. We expect the data from this study to serve as a 'bridge', in that they will allow us to use the immediate-release CBP tablet as the reference product in our submission of a Section 505(b)(2) NDA for TNX-102 SL.

Prospective Study Comparing Side-effects of TNX-102 SL with Immediate-Release Cyclobenzaprine

We plan to conduct a small study designed to compare the bedtime use of TNX-102 SL and immediate-release CBP on next morning drowsiness. The goal of this study is to determine the potential benefit of TNX-102 SL compared with immediate-release CBP on next morning drowsiness.

Prospective Phase 3 Study

If our Phase 2b study of TNX-102 SL is successful, then we expect to conduct a Phase 3 confirmatory study in support of product registration. At that time, we plan to conduct a randomized, double-blind, placebo-controlled Phase 3 study in which patients with FM will receive TNX-102 SL or placebo at bedtime nightly for 12 weeks. It is likely that the primary efficacy measure in this study will be the change in pain severity with TNX-102 SL as compared to placebo at week 12, assessed by the NRS, similar to the primary efficacy measure of the Phase 2b study. Secondary outcome measures will be carefully considered to best support desired label claims and to optimize the marketing message for product differentiation. We expect approximately 300 FM patients will be enrolled in this trial.

Safety Exposure Study

To study the safety of our product in chronic use, we expect to conduct an open label study in which approximately 300 FM subjects would receive TNX-102 SL for up to one year. Together with our other studies, we believe this safety exposure study will be sufficient to meet ICH long-term safety exposure requirements, which require us to provide data for at least 300 subjects treated with TNX-102 SL for six months and at least 100 subjects treated for one year.

Regulatory Strategy

The FDA approvals of Lyrica, Cymbalta and Savella establish a regulatory approval standard for the management of FM. However, given the heterogeneity of patients with this disease, it may not prove to be the only pathway or approval requirement. We hope to register TNX-102 SL with the FDA through the provisions of Section 505(b)(2). This regulatory pathway may help to accelerate product development and reduce overall business risk. The 505(b)(2)-based product development plan for TNX-102 SL is designed to leverage the safety data that have been generated by other manufacturers for CBP-containing products and accepted by the FDA in support of their product registrations, in addition to the safety data we generate. TNX-102 SL contains significantly less active CBP than other marketed products. We believe that the safety data package from these products and the CBP prescriptions utilization database analyzed by IMS Health Incorporated will provide adequate safety margin to support TNX-102 SL development. A Type B Pre-Phase 3 meeting with the FDA is scheduled for February 2013, at which we plan to discuss the design of our anticipated Phase 2b and Phase 3 trials for TNX-102 SL so as to receive regulatory acceptance of our proposed NDA plan for a differentiated product for the management of FM.

If NDA approval of TNX-102 SL is granted, in addition to the three-year marketing exclusivity granted by law, we expect this product to be protected by patents that extend through at least 2021, during which time it should not be subject to generic substitution. We plan to continue to support the TNX-102 SL program with new patent applications as we obtain data from the clinical evaluation of our new formulation in healthy human subjects and FM patients. For example, we have recently filed patent applications on TNX-102 SL which, if issued, would be expected to provide protection from generic substitution until 2033.

TNX-102 SL in Post-Traumatic Stress Disorder

We are also developing TNX-102 SL for the management of PTSD, a psychiatric disorder that begins in the aftermath of traumatic experiences. A Type B pre-IND meeting was held with the FDA in October 2012, at which our clinical program for PTSD was discussed. We have not yet conducted any clinical trials on PTSD patients.

Parallels Between FM and PTSD

A number of parallels have been noted between FM and PTSD. In addition, symptom overlaps may exist between patients diagnosed with FM or PTSD. In a survey of males with PTSD or major depression (Amital, Fostick et al, Posttraumatic stress disorder, tenderness, and fibromyalgia syndrome: are they different entities? J. Psychosom Res 2006. 61(5):663-9.2006), 49% of PTSD patients met the ACR criteria for FM compared to 5% of major depression patients. Conversely, in a different survey of FM patients (Cohen, Neumann et al., Prevalence of post-traumatic stress disorder in fibromyalgia patients: overlapping syndromes or post-traumatic fibromyalgia syndrome? Semin Arthritis Rheum 2002. 32(1):38-50), 57% of the sample had symptoms associated with PTSD.

A core feature of PTSD is sleep disturbance, including insomnia and nightmares. Sleep disturbances are believed to exacerbate daytime symptoms of PTSD, including irritability, poor concentration, and diminished interest in significant activities. We believe the sleep disturbances of PTSD bear similarity to those associated with FM.

Emerging Market Opportunity

The selective serotonin reuptake inhibitors Paxil® (paroxetine) and Zoloft® (sertraline) are FDA approved for PTSD, but are not satisfactory treatments for many patients. Other drugs that show promise for the treatment of PTSD, but are not FDA approved, include antidepressants such as nefazodone, mirtazapine and trazodone; the antihistamine cyproheptadine; certain atypical antipsychotics such as olanzapine and risperidone; and an adrenergic alpha-1 receptor blocker, prazosin. Prazosin may decrease nightmares and insomnia and has been associated with improvements in daytime PTSD symptoms, depression, and quality of life.

Our rationale for studying the effects of CBP in PTSD derives from the following:

- our clinical studies that very low dose CBP improves FM symptoms, a disorder having significant overlap with PTSD;
- our clinical studies that very low dose CBP can improve sleep quality, which is impaired in PTSD; and
- in studies conducted by Caliper, CBP interacts with a receptor on brain cells called the serotonin type 2a receptor. Based on numerous peer-reviewed scientific publications, we have identified a number of compounds that bind this receptor that have been shown to have effects in treating PTSD. Therefore, it is our belief that CBP, because it binds to the serotonin type 2a receptor, will have a therapeutic effect in treating PTSD like other compounds that bind to it.

As very little information was available on the biochemical effects of CBP and its primary metabolite, norcyclobenzaprine, or nCBP, in the central nervous system, we have engaged several CROs to better understand the interactions of these agents with certain receptors in the brain. CROs we have engaged in this effort include Caliper, Cerep, Millipore, and DiscoveRx. Results from a series of binding and functional studies show that both of these molecules are potent antagonists of the serotonin type 2a and the histamine H1 receptors, which known to have effects on sleep and sleep maintenance. The results also show that CBP and nCBP antagonize the adrenergic alpha 1A and 1B receptors, which may have effects on autonomic dysfunction. The results of some of these studies were presented at a poster session during the 2012 American College of Rheumatology Annual Meeting (Daugherty et al, “Cyclobenzaprine (CBP) and its Major Metabolite Norcyclobenzaprine (nCBP) are Potent Antagonists of Human Serotonin Receptor 2a (5-HT2a), Histamine Receptor H1 and Alpha-Adrenergic Receptors: Mechanistic and Safety Implications for Treating Fibromyalgia Syndrome by Improving Sleep Quality”, Abstract #960).

Product Development Path

We anticipate that the dose of TNX-102 SL sufficient to treat PTSD symptoms may be higher than that sufficient to treat FM. We plan to utilize the data obtained from our pharmacokinetic studies of TNX-102 SL to inform the design of efficacy trials in PTSD.

Based on the recommendations and guidance received at the October 2012 pre-IND meeting with the FDA, we plan to file an IND application for TNX-102 SL in the PTSD indication in the first half of 2013, and to conduct a Phase 2 trial in the second half of 2013. We expect to be able to use TNX-102 SL tablets manufactured for the FM studies in the initial PTSD clinical trials.

Prospective Proof-of-Concept Phase 2 Study

We plan to use the IND to support a small clinical study to ascertain the potential efficacy of TNX-102 SL in this disorder. This randomized, double-blind, placebo-controlled, crossover study will enroll approximately 15 subjects with PTSD. TNX-102 SL and placebo will be administered once daily at bedtime. The primary efficacy measure will be the change in the Clinician-Administered PTSD Scale from baseline to week six. Secondary outcome variables may include the PTSD Dream Rating Scale, PTSD Checklist, CGI-I, Pittsburgh Sleep Quality Index and the Beck Depression Inventory. In addition, polysomnograms will be obtained at baseline and at specified times during the trial.

Prospective Phase 3 Studies

If our Phase 2 trial of TNX-102 SL in PTSD is successful, we intend to conduct two multicenter, double-blind, placebo-controlled, Phase 3 studies designed to evaluate the efficacy, safety, and tolerability of TNX-102 SL in patients with PTSD. We expect both of these Phase 3 studies to be of crossover design. We plan to conduct one 24-week study (TNX-102 SL and placebo treatment for 12 weeks) and one six-month study (TNX-102 SL and placebo treatment for 3 months). We expect the results of the Phase 2 trial to determine dosing in these Phase 3 trials, but like the Phase 2 trial, TNX-102 SL may be dosed flexibly. The primary endpoints for both Phase 3 studies are anticipated to be similar to those proposed to be feature in the Phase 2 study, and as with the Phase 2 study, in addition to standardized measures of PTSD symptomatology and severity, polysomnograms will be obtained.

Regulatory Strategy

The approvals by the FDA of Paxil (paroxetine) and Zoloft (sertraline) for treating PTSD establish a regulatory approval pathway for symptom reduction in PTSD. We believe our clinical development program of TNX-102 SL and the chronic safety data generated from the TNX-102 SL FM NDA program will result in a differentiated product for the treatment of PTSD. We believe that our planned clinical trials in PTSD, if successful, will provide sufficient evidence of clinical efficacy and safety to support a Section 505(b)(2) NDA.

Drug Delivery Technology

TNX-102 SL

TNX-102 SL is a small tablet that rapidly disintegrates in saliva and transmucosally delivers CBP into the systemic circulation. TNX-102 SL contains sublingual absorption-enabling ingredients that promote a local oral environment that facilitates oromucosal absorption of CBP. We own all rights to TNX-102 SL in all geographies, and we bear no obligations to third-parties for any future development or commercialization.

TNX-102 Gelcap

In June 2007, we entered into a Feasibility and Option Agreement with Lipocine, which was amended in October 2010 (the "Feasibility Agreement"). Pursuant to the Feasibility Agreement, we identified and obtained an exclusive worldwide option on technology from Lipocine that employs mixtures of different types of lipids to envelop CBP molecules in the small intestine and facilitate absorption into the bloodstream. We believe this approach has potential for more consistent absorption and decreased variability in blood levels.

The Feasibility Agreement provided for two stages of work, stated as Stage I and Stage II. The Stage I work involved developing methods and testing compatibility between Lipocine's technology and our drug formulation. The Stage II work involved supporting us in our efforts to conduct a clinical trial study, based on the Stage I work, and is expected to conclude upon the completion of a final report on the results of the clinical study (the "Final Report"). Upon completion of the Final Report, we have the right, within 30 days after the Final Report, to exercise an exclusive worldwide license to the Lipocine technology.

Under the Feasibility Agreement, Lipocine completed the Stage I work, which involved studying a number of combinations of lipids for their ability to form micelles that solubilize the free base of CBP and which might serve as inactive ingredients in a gelatin capsule formulation. We selected a candidate formulation, TNX-102 gelcap, based on properties that included the dispersion of the active ingredient in simulated gastric or small-intestinal fluids and the stability of the formulation over time prior to testing. Lipocine was also engaged to manufacture gelatin capsules of TNX-102 gelcap for use in a pharmacokinetic trial.

In August 2011, we provided notice to Lipocine that we intended to move forward with the Stage II work. The clinical phase of the Stage II trial was completed during the fourth quarter of 2011. Some of the data has been collected and some data is still awaiting the development and validation of assays. We are working to analyze the data and write the Final Report, which is anticipated to be completed in 2013. After completion of the Final Report, we will have 30 days to decide whether to exercise the option to license Lipocine's US patent 6,294,192 "Triglyceride-free compositions and methods for improved delivery of hydrophobic therapeutic agents" and US Patent 6,451,339 "Compositions and methods for improved delivery of hydrophobic agents". These patents expire on September 24, 2021 and September 16, 2022, respectively.

If we elect to exercise the option, we will execute a license agreement with Lipocine. If we exercise the option to license these patents, we will be obligated to pay Lipocine low single-digit percentage royalties based on net sales or mid-teen sublicense fees based on the consideration that we receive from a licensee. The maximum amount of milestone payments we could be required to pay to Lipocine pursuant to the Feasibility Agreement is $3,000,000. We currently do not plan to exercise the option with Lipocine.

Market Dynamics

We believe the U.S. market for products that treat CNS conditions has several characteristics that make it an attractive market for pharmaceuticals, including that the customer base is driven by physicians who are involved in long-term care of patients with chronic disorders. Patients with CNS disorders sometimes carry disease burdens that require long-term treatment.

We believe the market for FDA-approved FM treatments is underserved and that there is a constant need for new treatment options, since many prescription drugs provide relief only to some of the affected patients, only to some of some patients' symptoms, or provide relief only for limited periods of time.

In 2007, Lyrica (pregabalin) became the first medicine approved by the FDA for the management of FM. Lyrica previously had been approved and marketed to treat pain in other conditions as well as epilepsy. In 2008, Cymbalta (duloxetine) became the second medicine approved by the FDA for the management of FM. Cymbalta previously had been approved and marketed to treat depression. FM shares a number of symptoms with depression, and a number of FM patients are believed to experience depression as a co-existing condition. Savella (milnacipran) was the third medicine approved by the FDA for the management of FM. Savella's active ingredient, milnacipran, is approved in Europe to treat depression.

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. According to Decision Resources, U.S. sales of prescription drugs specifically for the treatment of FM totaled $1.4 billion in 2011. This figure includes sales of Cymbalta, Lyrica, and Savella of $595 million, $504 million, and $110 million, respectively. Despite the availability of FDA approved products, we believe the current treatment options for FM continue to leave many patients dissatisfied.

Prior to 2007, the landscape of prescription drugs used to treat FM was characterized by off-label use of generically-available therapies. Drugs that had been prescribed as the primary treatments for FM were approved for other indications, with analgesics, antidepressants, and muscle relaxants among the categories receiving the greatest use by the FM population. Despite the significant FM-related sales growth of the three products approved for FM following their approvals for this indication, according to Adivo Associates, the unit volume of medications prescribed to specifically treat FM has been nearly flat since 2007, implying that the sales growth of the approved products was mainly driven by patients switching from off-label, generic medications to on-label, branded medications. In particular, these market dynamics are consistent with the interpretation that Lyrica's growth came at the expense of off-label analgesics and Cymbalta's and Savella's growth came at the expense of off-label anti-depressants.

Despite the wide use of muscle relaxants by FM patients, this category lacks a product approved for FM. Demand continues to be satisfied by off-label medicines such as CBP, tizanidine, baclofen, carisoprodol and metaxalone. These muscle relaxants have generic and branded versions. According to Adivo Associates, 20 million daily doses of the Flexeril brand and its associated immediate-release CBP generic products were prescribed off-label for FM in 2011 and accounted for approximately 48% of the daily doses of muscle relaxants prescribed for FM that year. These figures indicate that muscle relaxants in general, and CBP in particular, have been widely adopted in FM despite the lack of an approval for this disorder.

Challenges in the Market for CNS Therapies

Developers of pharmaceutical treatments for syndromes and disorders that affect the CNS face special challenges. In many cases, the causes and exacerbating factors of CNS conditions remain unknown. Frequently, key symptoms are known only by patient reports and cannot be objectively validated or measured. Symptoms like pain, fatigue, disturbed sleep or altered mood are characteristics of more than one condition. Often, physicians may not agree that a particular patient is affected by one or another condition or by more than one co-existing conditions.

CNS conditions are typically defined by committees of expert professionals who set criteria based on the presence of several symptoms or groups of symptoms. Sometimes groups of subjective symptoms are insufficient to describe CNS disorders and further refinement of diagnostic categories can be achieved by patient demographics, such as gender, age or concurrent medical processes, such as menopause or adolescence. Many CNS conditions, including syndromes and disorders, have not yet been characterized by laboratory tests, such as blood tests or x-ray imaging. However, laboratory tests are often important to exclude other conditions, such as inflammatory or infectious processes. Consequently, a CNS condition is sometimes called a diagnosis of exclusion because inflammation and infection should typically be ruled out by laboratory tests before applying the criteria of groups of symptoms to diagnose it.

Once a CNS condition is diagnosed, physicians may select from among treatment options based on a patient's symptoms and history. Some medications improve or relieve only one or another symptom in a condition. Consequently, physicians may prescribe several different medications concurrently to treat individual symptoms or groups of symptoms. A desirable quality for CNS medications is the ability to relieve more than one symptom of a CNS condition. Another desirable quality for CNS medications is safety, particularly if a medicine is safe enough to be used with other medicines concurrently or at different times of the day.

Opportunity for New Treatments of FM

We believe the market for the treatment of FM is underserved, which we believe fuels a need for new therapeutic options. Due to the market acceptance of FM treatments (such as Lyrica, Cymbalta and Savella), we believe there will be a growing interest in alternative drug treatment options.

We believe that if TNX-102 SL won FDA approval, it would be an appealing option because it has an entirely different mechanism of action from the currently approved products and we expect TNX-102 SL will be recommended for use at bedtime. Lyrica is recommended for twice or three-times daily dosing. Cymbalta was found effective at once-daily dosing and is generally restricted to daytime use and not recommended for bedtime use. Cymbalta and Savella act on the CNS in ways that are believed to interfere with sleep, while data support the view that CBP, the active ingredient in TNX-102 SL, improves sleep quality.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe that key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, price and reimbursement level. Many of our potential competitors, including many of the organizations named below, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Further, the development of new treatment methods for the conditions we are targeting could render our drugs non-competitive or obsolete.

The markets for medicines to treat FM, PTSD and other CNS conditions are well developed and populated with established drugs marketed by large and small pharmaceutical, biotechnology and generic drug companies. Pfizer (Lyrica), Eli Lilly (Cymbalta) and Forest Laboratories/Cyprus Biosciences (Savella) market FDA approved drugs for FM. Pfizer (Zoloft) and GlaxoSmithKline (Paxil) market FDA approved drugs for PTSD.

As of January 2013, we are aware of several companies pursuing treatments for FM, including Chelsea Therapeutics, Johnson and Johnson, Meda, Pfizer, Synthetic Biologics, Teva, and Theravance. Clinical trials in the U.S. are registered with the FDA and reported on the website www.clinicaltrials.gov.

A number of companies are specifically engaged in developing drugs for PTSD, including AstraZeneca, UCB, GlaxoSmithKline, Ortho-McNeil Janssen Scientific Affairs, and Pfizer. Medications that may be used for the treatment of PTSD include anti-depressants such as: nefazodone and trazodone; the antihistamine cyproheptadine and certain atypical antipsychotics such as olanzapine and risperidone. Several of these products are supported by companies such as AstraZeneca, GlaxoSmithKline and Pfizer.

Intellectual Property

Proprietary protection for our product candidates, technology and processes are important to our business and we seek patent protection in the U.S. and internationally when we deem appropriate. We also rely on trade secrets, know-how and continuing technological advances to protect various aspects of our core technology. We require our employees, consultants and scientific collaborators to execute confidentiality and invention assignment agreements with us.

We own numerous patents and have patent applications pending in the United States and abroad. In addition, we have one trademark application pending.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot assure you that our pending patent applications will result in issued patents.

Approved Patents

Our current patents owned are as follows:

Number	Name	Jurisdiction	Expiration Date
6,541,523	"Methods For Treating Or Preventing Fibromyalgia Using Very Low Doses Of Cyclobenzaprine"	U.S.A.	August 11, 2020
6,395,788	"Methods And Compositions For Treating Or Preventing Sleep Disturbances And Associated Illnesses Using Very Low Doses Of Cyclobenzaprine"	U.S.A.	August 11, 2020
6,358,944	"Methods And Compositions For Treating Generalized Anxiety Disorder"	U.S.A.	August 11, 2020
EP 1202722	"Uses of Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine"	European Patent Office, Belgium, France, Ireland, Luxembourg, Monaco, Portugal, Switzerland and United Kingdom	August 11, 2020
AT 299369	"Uses of Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine"	Austria	August 11, 2020
DE 60021266	"Uses of Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine"	Germany	August 11, 2020
NZ 516749	"Uses of Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine"	New Zealand	August 11, 2020
ES 2245944	"Uses of Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine"	Spain	August 11, 2020
HK 1047691	"Uses of Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine"	Hong Kong	August 11, 2020
8,093,300	"Compositions and Methods for Increasing Compliance with Therapies using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism"	U.S.A.	May 25, 2023
AU 2002354017	"Compositions and Methods for Increasing Compliance with Therapies using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism"	Australia	November 4, 2022
CA 2463987	"Compositions and Methods for Increasing Compliance with Therapies using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism"	Canada	November 4, 2022
EP 1441708	"Compositions and Methods for Increasing Compliance with Therapies using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism"	European Patent Office, Austria, Belgium, Switzerland, Denmark, Luxembourg, Monaco, Germany, France, Portugal and United Kingdom	November 4, 2022
NZ 532583	"Compositions and Methods for Increasing Compliance with Therapies using Aldehyde Dehydrogenase Inhibitors and Treating Alcoholism"	New Zealand	November 4, 2022

Patent Applications

Our current patent applications that are pending are as follows:

Number	Name	Jurisdiction
61/660,593	"Compositions and Methods for Transmucosal Absorption"	U.S.A.
61/667,774	"Compositions and Methods for Transmucosal Absorption"	U.S.A.
61/725,402	"Compositions and Methods for Transmucosal Absorption"	U.S.A.
61/281,661	"Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine"	U.S.A.
12/948,828	"Methods And Compositions For Treating Symptoms Associated With Post-Traumatic Stress Disorder Using Cyclobenzaprine"	U.S.A.
10831895.7	"Methods And Compositions For Treating Symptoms Associated With Post-Traumatic Stress Disorder Using Cyclobenzaprine"	European Patent Office
61/449,838	"Methods and Compositions for Treating Depression Using Cyclobenzaprine"	U.S.A.
13/157,270	"Method for Improving Fatigue Using Low Dose Cyclobenzaprine"	U.S.A.
PCT/US 10/02979	"Methods And Compositions For Treating Symptoms Associated With Post-Traumatic Stress Disorder Using Cyclobenzaprine"	PCT
PCT/US 11/01529	"Method for Treating Cocaine Addiction"	PCT
12/151,200	"Method For Treating Neurodegenerative Dysfunction"	U.S.A.
CA 2723688	"Method For Treating Neurodegenerative Dysfunction"	Canada
EP 2299822	"Method For Treating Neurodegenerative Dysfunction"	European Patent Office

Trademark Application

We have one trademark application that is pending as follows:

Number	Name	Jurisdiction
85088881	Tonix Pharmaceuticals	U.S.A.

Research and Development

We have one employee dedicated to research and development. We anticipate that our research and development expenditures will increase several fold as we advance TNX-102 SL into late-stage clinical development and advance other candidates in our pipeline. We need to raise additional capital to fund our development plans and there is no certainty that we will be successful in continuing to attract new investments. Our research and development operations are located in New York, NY. We have used, and expect to continue to use, third parties to conduct our preclinical and clinical studies.

Manufacturing

We have contracted with third parties for the manufacture of TNX-102 SL for investigational purposes, including preclinical and clinical testing, as follows:

CMO	Purpose
Lipocine Inc.	TNX-102 gelcap used in our completed pharmacokinetic study on this candidate
KABS Laboratories, Inc. (Quebec, Canada)	TNX-102 intravenous and sublingual solutions
Laboratorio Farmacologico Milanese S.r.l. (Milan, Italy)	TNX-102 SL tablets used in our completed pharmacokinetic studies
Pharmatek Laboratories	TNX-102 SL tablets to be used in our planned Phase 2b study

All of our compounds are small molecules, generally constructed using industry standard processes and use readily accessible raw materials.

Government Regulation

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the FDCA and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

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

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

Clinical Trials

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

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

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are generally conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks. Phase 2 clinical trials, in particular Phase 2b trials, can be undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites.
- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

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

New Drug Applications

Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality product within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market.

Section 505(b)(2) NDAs

There are two types of NDAs: the Section 505(b)(1) NDA, or full NDA, and the Section 505(b)(2) NDA. When possible, we intend to file Section 505(b)(2) NDAs that might, if accepted by the FDA, save time and expense in the development and testing of our product candidates. A full NDA is submitted under Section 505(b)(1) of the FDCA, and must contain full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug. A Section 505(b)(2) NDA may be submitted for a drug for which one or more of the investigations relied upon by the applicant was not conducted by or for the applicant and for which the applicant has no right of reference from the person by or for whom the investigations were conducted. A Section 505(b)(2) NDA may be submitted based in whole or in part on published literature or on the FDA's finding of safety and efficacy of one or more previously approved drugs, which are known as reference drugs. Thus, the filing of a Section 505(b)(2) NDA may result in approval of a drug based on fewer clinical or nonclinical studies than would be required under a full NDA. The number and size of studies that need to be conducted by the sponsor depends on the amount and quality of data pertaining to the reference drug that are publicly available, and on the similarity of and differences between the applicant's drug and the reference drug. In some cases, extensive, time-consuming, and costly clinical and nonclinical studies may still be required for approval of a Section 505(b)(2) NDA.

Because we are developing new formulations of previously approved chemical entities, such as CBP, our drug approval strategy is to submit Section 505(b)(2) NDAs to the FDA. The FDA may not agree that our product candidates are approvable as Section 505(b)(2) NDAs. If the FDA determines that Section 505(b)(2) NDAs are not appropriate and that full NDAs are required for our product candidates, the time and financial resources required to obtain FDA approval for our product candidates could substantially and materially increase, and our products might be less likely to be approved. If the FDA requires full NDAs for our product candidates, or requires more extensive testing and development for some other reason, our ability to compete with alternative products that arrive on the market more quickly than our product candidates would be adversely impacted. If CBP-containing products are withdrawn from the market by the FDA for any reason, we may not be able to reference such products to support our anticipated TNX-102 SL 505(b)(2) NDA, and we may be required to follow the requirements of Section 505(b)(1).

Based on our intent to file under Section 505(b)(2) with respect to our lead product candidate, we believe it is unlikely the development process for this product candidate will follow the ordinary course of Phase 1, Phase 2 and Phase 3 studies. Our human pharmacokinetic studies of reformulated CBP dosage forms represented the first use of TNX-102 SL and TNX-102 gelcap, or collectively, TNX-102, in humans and could therefore be described as "Phase 1." However, because these studies compared TNX-102 to existing approved formulations of CBP and specified the comparable ability to deliver effective levels of CBP to the bloodstream of FM patients, these studies provide a reference to the therapeutic effects previously observed in our dose-ranging clinical study of immediate-release CBP capsules in FM patients. For these reasons, rather than always identifying clinical trials by Phase, we find it more illustrative to describe in a narrative form the purpose of the studies and the nature and potential significance of the results. Because our double-blind, randomized, placebo-controlled, dose-ranging study on bedtime CBP was performed in Canada, we did not meet with the FDA's Center for Drug Evaluation and Research to discuss our approach and plans until August 2011.

Patent Protections

An applicant submitting a Section 505(b)(2) NDA must certify to the FDA with respect to the patent status of the reference drug upon which the applicant relies in support of approval of its drug. With respect to every patent listed in the FDA's Orange Book, which is the FDA's list of approved drug products, as claiming the reference drug or an approved method of use of the reference drug, the Section 505(b)(2) applicant must certify that: (1) there is no patent information listed by the FDA for the reference drug; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date; (4) the listed patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the product in the Section 505(b)(2) NDA; or (5) if the patent is a use patent, that the applicant does not seek approval for a use claimed by the patent. If the applicant files a certification to the effect of clause (1), (2) or (5), FDA approval of the Section 505(b)(2) NDA may be made effective immediately upon successful FDA review of the application, in the absence of marketing exclusivity delays, which are discussed below. If the applicant files a certification to the effect of clause (3), the Section 505(b)(2) NDA approval may not be made effective until the expiration of the relevant patent and the expiration of any marketing exclusivity delays.

If the Section 505(b)(2) NDA applicant provides a certification to the effect of clause (4), referred to as a paragraph IV certification, the applicant also must send notice of the certification to the patent owner and the holder of the NDA for the reference drug. The filing of a patent infringement lawsuit within 45 days of the receipt of the notification may prevent the FDA from approving the Section 505(b)(2) NDA for 30 months from the date of the receipt of the notification unless the court determines that a longer or shorter period is appropriate because either party to the action failed to reasonably cooperate in expediting the action. However, the FDA may approve the Section 505(b)(2) NDA before the 30 months have expired if a court decides that the patent is invalid, unenforceable, or not infringed, or if a court enters a settlement order or consent decree stating the patent is invalid or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged in court, the FDA may be required to change its interpretation of Section 505(b)(2) which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit. The pharmaceutical industry is highly competitive, and it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Moreover, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of Section 505(b)(2) NDAs, thereby delaying a Section 505(b)(2) product from entering the market. The FDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity prohibits the submission of a Section 505(b)(2) NDA for any drug product containing the active ingredient during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years, but if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the Section 505(b)(2) NDA may automatically be stayed until 7 1/2 years after the NCE approval date. The FDCA also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application. Five-year and three-year exclusivity will not delay the submission or approval of another full NDA; however, as discussed above, an applicant submitting a full NDA under Section 505(b)(1) would be required to conduct or obtain a right of reference to all of the preclinical and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other types of exclusivity in the United States include orphan drug exclusivity and pediatric exclusivity. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or a Section 505(b)(2) NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Section 505(b)(2) NDAs are similar to full NDAs filed under Section 505(b)(1) in that they are entitled to any of these forms of exclusivity if they meet the qualifying criteria. They also are entitled to the patent protections described above, based on patents that are listed in the FDA's Orange Book in the same manner as patents claiming drugs and uses approved for NDAs submitted as full NDAs.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution and disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Food and Drug Administration Amendments Act of 2007

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, became law. This legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, the new law significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

The FDA has not yet implemented many of the provisions of the FDAAA, so we cannot predict the impact of the new legislation on the pharmaceutical industry or our business. However, the requirements and changes imposed by the FDAAA may make it more difficult, and more costly, to obtain and maintain approval for new pharmaceutical products, or to produce, market and distribute existing products. In addition, the FDA's regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our products. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

Employees

As of December 31, 2012, we had two full-time employees, Leland Gershell, our Chief Financial Officer, and Bruce Daugherty, our Senior Director of Drug Development and Controller, as well as one part-time senior director of research.

In addition, we rely on consultants instead of employees for critical activities, including Seth Lederman who serves as our Chief Executive Officer and as President of Tonix Sub pursuant to a consulting agreement with Lederman & Co. None of our employees are represented by a labor union, and we believe that our relations with our employees are good.

DESCRIPTION OF PROPERTIES

We maintain our principal office at 509 Madison Avenue, Suite 306, New York, New York 10022. Our telephone number at that office is (212) 980-9155 and our fax number is (212) 923-5700. Our current office space consists of approximately 2,355 square feet. The lease expires in September 2015. The base rent is as follows:

Lease Period	Amount Per Annum	
October 1, 2010 – September 30, 2011	$	120,105.00
October 1, 2011 – September 30, 2012	$	123.496.20
October 1, 2012 – September 30, 2013	$	126,989.14
October 1, 2013 – September 30, 2014	$	130,586.86
October 1, 2014 – September 30, 2015	$	134,292.52

We believe that our existing facilities are suitable and adequate to meet our current business requirements. We maintain websites at www.tonixpharma.com and www.krele.com and the information contained on those websites is not deemed to be a part of this prospectus.

LEGAL PROCEEDINGS

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

MANAGEMENT

The names of our executive officers and directors and their age, title, and biography as of December 31, 2012 are set forth below:

Name	Age	Title
Seth Lederman	55	President, CEO and Chairman of the Board of Directors
Leland Gershell	40	Chief Financial Officer and Treasurer
Bruce Daugherty	55	Senior Director of Drug Development, Controller and Secretary
Stuart Davidson	55	Director
Patrick Grace	56	Director
Donald W. Landry	58	Director
Ernest Mario	74	Director
Charles E. Mather IV	52	Director
John Rhodes	56	Director
Samuel Saks	58	Director

Directors are elected annually and hold office until the next annual meeting of the stockholders of the Company and until their successors are elected. Officers are elected annually and serve at the discretion of the Board of Directors.

Seth Lederman, MD became our President, Chief Executive Officer, Chairman of the Board and a Director in October 2011. Dr. Lederman founded Tonix Sub in June of 2007 and has acted as its Chairman of the Board of Directors since inception and as President since June 2010. Dr. Lederman has been the Chairman of Krele since its inception in August 2010. Since 1996, Dr. Lederman has been an Associate Professor at Columbia University. As an Assistant Professor at Columbia, Dr. Lederman discovered and characterized the CD40-ligand and invented therapeutic candidates to treat autoimmune diseases and transplant rejection. Dr. Lederman has been a Manager of L&L Technologies LLC since 1996. In addition, Dr. Lederman has been the Managing Member of Seth Lederman Co, LLC since January 2007 and the Managing Member of Lederman & Co, LLC since 2002, both of which are biopharmaceutical consulting and investing companies. Dr. Lederman has also been the Managing Member of Targent Pharmaceuticals since 2000, and Managing Member of Plumbline LLC since 2002. Targent Pharmaceuticals, LLC was a founder of Targent Pharmaceuticals Inc. on which Board of Directors Dr. Lederman served from inception in 2001 until the sale of its assets to Spectrum Pharmaceuticals Inc. in 2006. Between January 2007 and November 2008, Dr. Lederman was a Managing Partner of Konanda Pharma Partners, LLC, a Director of Konanda Pharma Fund I, LP, and a Managing Partner of Konanda General Partner, LLC, which were related private growth equity fund entities. As well, between January 2007 and November 2008, Dr. Lederman was Chairman of Validus Pharmaceuticals, Inc. and Fontus Pharmaceuticals, Inc., which were portfolio companies of the Konanda private growth equity fund. Since December 2011, Dr. Lederman has served as CEO and Chairman of Leder Laboratories Inc. and Starling Pharmaceuticals Inc, which are biopharmaceutical development companies. Between 2006 and 2011, Dr. Lederman was a director of Research Corporation, a New York-based non-profit Dr. Lederman received his BA degree in Chemistry from Princeton University in 1979 and his MD from Columbia University in 1983. Dr. Lederman has been a New York State licensed physician since 1985. Dr. Lederman's significant experience with our patent portfolio and his experience as an entrepreneur, seed capital investor, fund manager, and director of start-up biopharmaceutical companies were instrumental in his selection as a member of the board of directors.

Leland Gershell, MD PhD became our Chief Financial Officer on April 1, 2012 and our Treasurer in November 2012. From May 2011 to December 2011, Dr. Gershell was Managing Director and Senior Analyst at Madison Williams and Company, where he was responsible for equity research coverage of specialty pharmaceutical and biotechnology companies. From April 2010 to October 2010, Dr. Gershell was Senior Analyst at Favus Institutional Research, where he was responsible for issuing research reports on a variety of healthcare companies to institutional investors. From October 2008 to October 2009, Dr. Gershell was Senior Analyst at Apothecary Capital, a healthcare investment firm. From November 2004 to September 2008, Dr. Gershell was an equity research analyst at Cowen and Company, most recently as Vice President, where he was responsible for the equity research coverage of small and middle capitalization biotechnology companies. Dr. Gershell earned his M.D. and Ph.D. in Organic Chemistry from Columbia University and his B.A. magna cum laude in Chemistry and Asian Studies from Dartmouth College. Dr. Gershell is an inventor on Columbia's patents for SAHA/vorinostat, which is marketed by Merck as Zolinza® and is the first histone deacetylase (HDAC) inhibitor to receive FDA approval.

Bruce Daugherty, PhD became our Senior Director of Drug Development and Controller on April 1, 2012 and our Secretary in November 2012. Since January 2009, Dr. Daugherty has worked as a consultant to academia and biotechnology companies in drug discovery/development and licensing through his consulting company, LeClair Pharma Consulting, LLC. Dr. Daugherty was a consultant to our company between November 2011 and March 2012. In 2009, Dr. Daugherty was employed at Assumption College in Mendham, New Jersey, where he was a lecturer in Biology for freshman students. From 1987 to 2008, Dr. Daugherty was employed at Merck & Co., where he was a scientist in drug discovery and development. Dr. Daugherty earned his MBA from Emory University's Goizueta Business School, his PhD in Molecular Genetics and Microbiology from UMDNJ-Robert Wood Johnson Medical School, his MS in Zoology from Rutgers University and his BA in Biology from Washington University in St. Louis.

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

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

Donald W. Landry, MD, PhD became a Director in October 2011. Between June 2007 and October 2011, Dr. Landry served as a director of Tonix Sub. Dr. Landry has been a member of the faculty of Columbia University since 1986, and has served as the Samuel Bard Professor of Medicine, Chair of the Department of Medicine and Physician-in-Chief at New York Presbyterian Hospital/Columbia University since 2008. Dr. Landry was a co-founder and has been a member of L&L Technologies, LLC since 1996. Dr. Landry received his BS degree in Chemistry from Lafayette College in 1975, his PhD in Organic Chemistry from Harvard University in 1979 and his M.D. from Columbia University in 1983. Dr. Landry has been a New York State licensed physician since 1985. In 2008, Dr. Landry was awarded the Presidential Citizens Medal, the second-highest award that the President can confer upon a civilian. Dr. Landry's significant medical and scientific background was instrumental in his selection as a member of the board of directors.

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

Charles E. Mather IV became a Director in October 2011. Between April and October 2011, Mr. Mather served as a director of Tonix Sub. Mr. Mather has been the Head of Private and Alternative Capital and Co-Head of ECM at Janney Montgomery Scott since December 2009. Between October 2008 and December 2009, Mr. Mather served as an independent consultant to various securities firms. Between May 2007 and September 2008, Mr. Mather was the head of the Structured Equity Group at Jefferies Group Inc. Prior to that, Mr. Mather held various senior investment banking positions at Cowen and Company, including as Co-Head of the Private Equity Group. Mr. Mather received a BA in History from Brown University and an MBA in Finance from The Wharton School, University of Pennsylvania. Mr. Mather's extensive experience as an investment banker was instrumental in his selection as a member of our board of directors.

John Rhodes became a Director in October 2011. Mr. Rhodes has served as director of the Center for Market Innovation at Natural Resources Defence Council since January 2012. Between October 2010 and October 2011, Mr. Rhodes served as a director of Tonix Sub. Mr. Rhodes has been a director of Dewey Electronics Company, a manufacturer of electronic and electromechanical systems for the military and commercial markets, since 2005. Between April 2007 and June 2010, Mr. Rhodes was a Senior Advisor to Good Energies, Inc., a renewable energy company. Mr. Rhodes is a former Vice President of Booz Allen Hamilton, Inc. Mr. Rhodes is a graduate of Princeton University and the Yale School of Management. Mr. Rhodes' extensive business and consulting experience, along with his membership on the board of directors of a public company was instrumental in his selection as a member of our board of directors.

Samuel Saks, MD became a Director in May 2012. Between 2003 and April 2009, Dr. Saks was the chief executive officer and a director of Jazz Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, which he co-founded in 2003. From April 2011 until February 2012, Dr. Saks served as interim Chief Medical Officer of Threshold Pharmaceuticals, a publicly-held biopharmaceutical company. From 2001 until 2003, Dr. Saks was company group chairman of ALZA Corporation and a member of the Johnson & Johnson Pharmaceuticals Operating Committee. From 1992 until 2001, Dr. Saks held various positions at ALZA, including Chief Medical Officer and Group Vice President, where he was responsible for clinical, regulatory and commercial activities. Previously, Dr. Saks held clinical research and development management positions with Schering-Plough, Xoma and Genentech. Dr. Saks formerly served as a scientific advisor to ArQule Pharmaceuticals, CMEA Ventures and ProQuest Investments. Dr. Saks is currently a Director of Auspex Pharmaceuticals, Inc. (since 2009), Depomed (since 2012), Bullet Biotechnology, Inc. (since 2012) and Velocity Pharmaceutical Development LLC (since 2011). From September 2005 until October 2010, Dr. Saks served on the board of directors of Trubion Pharmaceuticals, a publicly-held biopharmaceutical company. Between September 2007 and July 2009, Dr. Saks served on the board of directors of Cougar Biotechnology, a publicly-held biopharmaceutical company. Dr. Saks has also served on the board of directors of Corixa, Coulter and Ribozyme. Dr. Saks is board certified in oncology and received a B.S. and an M.D. from the University of Illinois. Mr. Saks' extensive scientific and medical expertise and experience in formulating partnering and business development strategies, including those involving larger pharmaceutical companies, was instrumental in his selection as a member of our board of directors.

Family Relationships

None.

Board Independence

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

Meetings and Committees of the Board of Directors

During the fiscal year ended December 31, 2012, our board of directors held five meetings and approved certain actions by unanimous written consent. We expect our directors to attend all board and committee meetings and to spend the time needed and meet as frequently as necessary to properly discharge their responsibilities.

Audit Committee

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

Our Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent auditors, (ii) appointing, replacing and discharging the independent auditor, (iii) pre-approving the professional services provided by the independent auditor, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditor, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditor. The Audit Committee has reviewed and discussed with management the Company's audited financial statements for the year ended December 31, 2011.

Compensation Committee

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

Our Compensation Committee has responsibility for assisting the Board of Directors in, among other things, evaluating and making recommendations regarding the compensation of our executive officers and directors, assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy, producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC, periodically evaluating the terms and administration of our incentive plans and benefit programs and monitoring of compliance with the legal prohibition on loans to our directors and executive officers.

Governance and Nominating Committee

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

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

Involvement in Certain Legal Proceedings

Our Directors and Executive Officers have not been involved in any of the following events during the past ten years:

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

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

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

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

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

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

EXECUTIVE COMPENSATION

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Chief Executive Officer, the two highest paid executive officers and up to two other highest paid individuals whose total annual salary and bonus exceeded $100,000 for fiscal years 2012 and 2011.

Name & Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Seth Lederman (1)	2012	-	-	-	822,715	-	-	277,167(2)	1,099,882
Chief Executive Officer	2011	-	-	-	-	-	-	300,750(2)	300,750
Leland Gershell (3)	2012	138,542	-	-	587,654	-	-	-	726,196
Chief Financial Officer									
Bruce Daugherty (4)	2012	110,833	-	-	470,123	-	-	-	580,956
Senior Director of Drug Development									
Benjamin Selzer (5)	2012	192,708	-	-	-	-	-	-	192,708
Chief Operating Officer									
David J. Moss (6)	2011	-	-	-	-	-	-	-	-
Chief Executive Officer									
Rhonda Rosen (7)		160,104							160,104
Chief Financial Officer	2011	140,463	-	-	-	-	-	-	140,463
Susan Oliver (8)	2011	113,249	-	-	-	-	-	-	113,249
Secretary									

(1) Dr. Lederman became our President and Chief Executive Officer on October 7, 2011. His compensation reflects payments made to him either through Tonix or Tonix Sub.

(2) Represents $48,000 and $96,000 of consulting fees paid to L&L Technologies, $229,167 and $198,750 of consulting fees paid to Lederman & Co. and $0 and $6,000 of director fees paid for the years ended December 31, 2012 and 2011, respectively.

(3) Dr. Gershell became our Chief Financial Officer on April 1, 2012 and our Treasurer in November 2012.

(4) Dr. Daugherty became our Senior Director of Drug Development and Controller on April 1, 2012 and our Secretary in November 2012

(5) Mr. Selzer became our Chief Operating Officer in October 2011 and our interim Chief Financial Officer, Secretary and Treasurer in February 2012. Mr. Selzer resigned as our interim Chief Financial Officer on April 1, 2012. Mr. Selzer was terminated effective October 26, 2012.

(6) Mr. Moss become our Chief Executive Officer on November 22, 2010 and resigned effective October 7, 2011.

(7) Ms. Rosen become our Chief Financial Officer on October 7, 2011. Her compensation reflects payments made to her either through Tonix or Tonix Sub. Ms. Rosen was terminated effective February 16, 2012.

(8) Ms. Oliver was terminated effective October 20, 2011.

Option/SAR Grants in Fiscal Year Ended December 31, 2012

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Share)	Grant Date Fair Value of Stock and Option Awards ($)
Seth Lederman	5/9/2012	700,000	$ 1.50	$ 822,715
Leland Gershell	5/9/2012	500,000	$ 1.50	$ 587,654
Bruce Daugherty	5/9/2012	400,000	$ 1.50	$ 470,123

Outstanding Equity Awards at Fiscal Year-End Table

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2012.

Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($/Sh)	Option Expiration Date
Seth Lederman	-	700,000	$ 1.50	5/9/2022
Leland Gershell	-	500,000	$ 1.50	5/9/2022
Bruce Daugherty	-	400,000	$ 1.50	5/9/2022

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,000,000	$ 1.50	1,000,000
Equity compensation plans not approved by security holders	-	-	-
Total	3,000,000	$ 1.50	1,000,000

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

Employment Agreement with Leland Gershell

Effective April 1, 2012, we entered into an employment agreement (the "Gershell Agreement") with Dr. Gershell to serve as Chief Financial Officer. The base salary under the Gershell Agreement is $175,000 per annum, which shall increase to $325,000 per annum upon our consummation of an equity sale of securities in excess of $20 million (the "Gershell Threshold"). The Gershell Agreement provides for at-will employment and can be terminated at any time by either party, provided, however, that if we terminate Dr. Gershell for any reason other than cause (as defined in the Gershell Agreement), then Dr. Gershell shall be entitled to six weeks of severance, which severance payment shall increase to six months if such termination occurs after the Gershell Threshold. In addition, Dr. Gershell is entitled to participate in any and all benefit plans, from time to time, in effect for our employees, along with vacation, sick and holiday pay in accordance with its policies established and in effect from time to time.

Employment Agreement with Bruce Daugherty

Effective April 1, 2012, we entered into an employment agreement (the "Daugherty Agreement") with Dr. Daugherty to serve as Senior Director of Drug Development. The base salary under the Daugherty Agreement is $140,000 per annum, which shall increase to $220,000 per annum upon our consummation of an equity sale of securities in excess of $20 million (the "Daugherty Threshold"). The Daugherty Agreement provides for at-will employment and can be terminated at any time by either party, provided, however, that if we terminate Dr. Daugherty for any reason other than cause (as defined in the Daugherty Agreement), then Dr. Daugherty shall be entitled to six weeks of severance, which severance payment shall increase to six months if such termination occurs after the Daugherty Threshold. In addition, Dr. Daugherty is entitled to participate in any and all benefit plans, from time to time, in effect for our employees, along with vacation, sick and holiday pay in accordance with its policies established and in effect from time to time.

Director Compensation

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2012 for services to our company.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)	Total ($)
Stuart Davidson	-	235,062	235,062
Patrick Grace	-	235,062	235,062
Donald Landry	-	235,062	235,062
Ernest Mario	-	235,062	235,062
Charles Mather IV	-	235,062	235,062
John Rhodes	-	235,062	235,062
Samuel Saks	-	235,062	235,062
Total:	-	1,645,434	1,645,434

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Other than as disclosed below, since January 1, 2011, there have been no transactions, or proposed transactions, which have materially affected or will materially affect us in which any director, executive officer or beneficial holder of more than 5% of the outstanding common, or any of their respective relatives, spouses, associates or affiliates, has had or will have any direct or material indirect interest. We have no policy regarding entering into transactions with affiliated parties.

On June 4, 2010, Tonix Sub entered into a consulting agreement with Lederman & Co., LLC, of which our Chairman, CEO and President Seth Lederman is the Managing Member. Pursuant to this agreement, Lederman & Co. shall provide clinical development, strategic, management and operational consulting services. In exchange for its services, Tonix Sub shall pay Lederman & Co. compensation of $250,000 per annum and issued to Lederman & Co. 261,784 shares of its common stock, 20% of which vested on the date of the agreement and the remainder vesting in equal amounts on each of the first, second, third and fourth anniversaries of the date of the agreement. On August 1, 2011, the cash compensation was reduced to $127,000 per annum. On February 1, 2012, the cash compensation was increased to $250,000 per annum. Immediately prior to the Share Exchange, the unvested shares of common stock vested.

On June 4, 2010, Tonix Sub entered into a technology transfer and assignment agreement with Lederman & Co., LLC. Pursuant to this agreement, Lederman & Co. transferred intellectual property rights related to isometheptene mucate to Tonix Sub. In exchange for the assignment of the intellectual property rights, Tonix Sub issued to Lederman & Co. 1,308,921 shares of its common stock.

On June 4, 2010 Tonix Sub entered into a consulting agreement with L&L Technologies, LLC, of which our Chairman, CEO and President Seth Lederman is the Manager. Pursuant to this agreement, L&L Technologies shall provide scientific and medical consulting services. In exchange for its services, Tonix Sub shall pay L&L Technologies compensation of $96,000 per annum, or such greater amount as the Board may designate from time to time, and issued to L&L Technologies 1,026,194 shares of its common stock, 25% of which vested on the date of the agreement and the remainder vesting in equal amounts on each of the first, second and third anniversaries of the date of the agreement. Immediately prior to the Share Exchange, the unvested shares of common stock vested.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of our common stock as of January 22, 2013:

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

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

NAME OF OWNER	TITLE OF CLASS	NUMBER OF SHARES OWNED (1)	PERCENTAGE OF COMMON STOCK (2)
Seth Lederman	Common Stock	9,508,949(3)	35.06%
Leland Gershell	Common Stock	162,500(4)	*
Bruce Daugherty	Common Stock	500,001(5)	*
Stuart Davidson	Common Stock	1,838,289(6)	3.90%
Patrick Grace	Common Stock	130,906	*
Donald Landry	Common Stock	1,933,532(7)	6.83%
Ernest Mario	Common Stock	1,663,746(8)	3.39%
Charles Mather IV	Common Stock	260,569(9)	*
John Rhodes	Common Stock	1,651,936(10)	2.63%
Samuel Saks	Common Stock	500,001(11)	*
Officers and Directors as a Group (10 persons)	Common Stock	16,115,488(12)	42.74%
Lederman & Co., LLC (13)	Common Stock	5,963,565(14)	17.35%
Eli Lederman (15)	Common Stock	2,352,810(16)	6.85%
Technology Partners Fund VIII, LP (17)	Common Stock	1,924,857(18)	5.61%

* Denotes less than 1%

(1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of January 22, 2013 are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person.

(2) Percentage based upon 43,182,599 shares of common stock issued and outstanding as of January 22, 2013.

(3) Includes 3,692,558 shares of common stock and 2,090,000 shares of common stock underlying warrants owned by Lederman & Co., LLC, 649,138 shares of common stock and 486,666 shares of common stock underlying warrants owned by L&L Technologies, LLC, 1,179,424 shares of common stock and 165,000 shares of common stock underlying warrants owned by Targent Pharmaceuticals, LLC, 83,333 shares of common stock and 166,666 shares of common stock underlying warrants owned by Leder Laboratories, Inc. and 83,333 shares of common stock and 166,666 shares of common stock underlying warrants owned by Starling Pharmaceuticals, Inc. Seth Lederman, as the Managing Member of Lederman & Co., LLC and Targent Pharmaceuticals, LLC, the Manager of L&L Technologies, Inc. and the Chairman of Leder Laboratories, Inc. and Starling Pharmaceuticals, Inc., has investment and voting control over the shares held by these entities.

(4) Includes 100,000 shares of common stock underlying warrants.

(5) Includes 333,334 shares of common stock underlying warrants.

(6) Includes 1,324,049 shares of common stock and 383,334 shares of common stock underlying warrants owned by Lysander, LLC and 130,906 shares owned by Oystercatcher Trust. Stuart Davidson, as the Member of Lysander, LLC and Trustee of Oystercatcher Trust, has investment and voting control over the shares held by these entities.

(7) Includes 649,138 shares of common stock and 486,666 shares of common stock underlying warrants owned by L&L Technologies, LLC. Donald Landry, as a Member of L&L Technologies, LLC, has investment and voting control over the shares held by this entity.

(8) Includes 383,334 shares of common stock underlying warrants.

(9) Includes 110,000 shares of common stock underlying warrants.

(10) Includes 550,000 shares of common stock underlying warrants.

(11) Includes 333,334 shares of common stock underlying warrants.

(12) Includes 3,692,558 shares of common stock and 2,090,000 shares of common stock underlying warrants owned by Lederman & Co., LLC, 649,138 shares of common stock and 486,666 shares of common stock underlying warrants owned by L&L Technologies, LLC, 1,179,424 shares of common stock and 165,000 shares of common stock underlying warrants owned by Targent Pharmaceuticals, LLC, 83,333 shares of common stock and 166,666 shares of common stock underlying warrants owned by Leder Laboratories, Inc., 83,333 shares of common stock and 166,666 shares of common stock underlying warrants owned by Starling Pharmaceuticals, Inc., 1,324,049 shares of common stock and 383,334 shares of common stock underlying warrants owned by Lysander, LLC, 130,906 shares owned by Oystercatcher Trust and 1,835,002 shares of common stock underlying warrants owned directly by the executive officers and directors.

(13) Seth Lederman, our President and Chief Executive Officer, has investment and voting control over the shares held by this entity. The mailing address for this entity is 245 E. 93 rd St. 14E, New York, New York 10128.

(14) Includes 2,090,000 shares of common stock underlying warrants.

(15) The mailing address for this beneficial owner is Malt House Cottage, Hurley, Berkshire, SL6 5LT, United Kingdom.

(16) Includes 300,000 shares of common stock underlying warrants.

(17) The mailing address for this beneficial owner is 100 Shoreline Highway, Suite 282-B, Mill Valley, California 94941. Sheila Mutter and Roger Quy are the managing members of TP Management VIII, LLC, the general partner of Technology Partners Fund VIII, LP and have voting and investment power over the securities owned by it.

(16) Includes 2,015,266 shares of common stock underlying warrants and represents the maximum beneficial ownership percentage pursuant to exercise limitations contained within warrants owned by this beneficial owner.

DESCRIPTION OF SECURITIES

Common Stock

We are authorized to issue up to 150,000,000 shares of our common stock, par value $0.001 per share. As of January 22, 2013, there were 43,182,599 shares of our common stock issued and outstanding. The outstanding shares of our common stock are validly issued, fully paid and nonassessable.

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

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

Preferred Stock

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

Options

As of January 22, 2013, there are an aggregate of 3,000,000 options to purchase shares of our common stock issued and outstanding. All of the options are exercisable at $1.50 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

Warrants

In connection with the 2011 Financing, we issued Conversion Warrants to purchase 275,000 shares of Common Stock. In addition, we issued 2011 Agent Warrants to the placement agents to purchase an aggregate of 30,750 shares of Common Stock. The Conversion Warrants have a three year term and $1.00 exercise price. The 2011 Agent Warrants have a $1.00 exercise price and 15,000 have a two year term and the remaining 15,750 have a three year term. The Conversion Warrants may be exercised on a cashless basis.

In connection with the March 2012 Financing, we issued March 2012 Class A Warrants to purchase 6,617,765 shares of Common Stock. In addition, we issued 2012 Agent Warrants to the placement agent to purchase 466,777 shares of Common Stock. The March 2012 Class A Warrants have a five year term and $1.25 exercise price. The 2012 Agent Warrants have a seven year term and $1.25 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 the December 2012 Financing, we issued Class A Warrants to purchase 8,904,167 shares of Common Stock and Class B Warrants to purchase 8,904,167 shares of Common Stock. The Class A Warrants have a five year term and $0.60 exercise price and the Class B Warrants have a one year term and $0.40 exercise price. The Class A Warrants may be exercised on a cashless basis under certain conditions.

Convertible Securities

None.

INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Chapter 78 of the Nevada Revised Statutes ("NRS") provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he is not liable pursuant to NRS Section 78.138 or acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. NRS Chapter 78 further provides that a corporation similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred in connection with the defense or settlement of such action or suit if he is not liable pursuant to NRS Section 78.138 or acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the court or other court of competent jurisdiction in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the court or other court of competent jurisdiction shall deem proper.

Our bylaws provide that we may indemnify our officers, directors, employees, agents and any other persons to the maximum extent permitted by the NRS.

PLAN OF DISTRIBUTION

We are registering the shares of common stock previously issued and the shares of common stock issuable upon exercise of the warrants to permit the resale of these shares of common stock by the holders of the common stock and warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock held by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, pursuant to one or more of the following methods:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing or settlement of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

In addition, the selling stockholders may transfer the shares of common stock by other means not described in this prospectus. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

To the extent required by the Securities Act and the rules and regulations thereunder, the selling stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed, which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or re-allowed or paid to broker-dealers.

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

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be approximately $106,336 in total, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act in accordance with the registration rights agreements or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreements or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

SELLING STOCKHOLDERS

This prospectus relates to the offering by the selling stockholders identified in the table below of up to 17,808,334 shares of common stock, par value $0.001 per share. All of the shares of common stock offered by this prospectus are being sold by the selling stockholders. These shares consist of (i) 8,904,167 shares of common stock issued to investors in our December 2012 Financing and (ii) 8,904,167 shares of common stock issuable upon exercise of warrants to purchase 8,904,167 shares issued to investors in our December 2012 Financing.

The table below has been prepared based upon the information furnished to us by the selling stockholders. The selling stockholders identified below may have sold, transferred or otherwise disposed of some or all of their shares since the date on which the information in the following table is presented in transactions exempt from, or not subject to, the registration requirements of the Securities Act. Information concerning the selling stockholders may change from time to time and, if necessary, we will amend or supplement this prospectus accordingly. We cannot provide an estimate as to the number of shares of common stock that will be held by the selling stockholders upon termination of the offering covered by this prospectus because the selling stockholders may offer some or all of their shares of common stock under this prospectus. The selling stockholders may also sell, transfer or otherwise dispose of all or a portion of their shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares.

The following table sets forth, based on information provided to us by the selling stockholders or known to us, the name of each selling stockholder, the nature of any position, office or other material relationship, if any, which the selling stockholder has had, within the past three years, with us or with any of our predecessors or affiliates, and the number of shares of our common stock beneficially owned by the stockholder before this offering. The number of shares owned are those beneficially owned, as determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement.

We have assumed all shares of common stock reflected on the table will be sold from time to time in the offering covered by this prospectus. Because the selling stockholders may offer all or any portions of the shares of common stock listed in the table below, no estimate can be given as to the amount of those shares of common stock covered by this prospectus that will be held by the selling stockholders upon the termination of the offering.

Selling Stockholder	Shares of Common Stock Owned Before this Offering	Shares of Common Stock Underlying Warrants Owned Before this Offering (1)	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering (3)	Shares of Common Stock Beneficially Owned After this Offering (4)	Percentage of Common Stock Beneficially Owned After this Offering (2)
Bruce Daugherty (5)	166,667	333,334	1.15%	333,334	166,667*	
Lysander, LLC (6)	1,324,049	383,334	3.92%	333,334	1,374,049	2.63%
L&L Technologies, LLC (7)	649,138	486,666	2.60%	466,666	669,138	1.28%
Lederman & Co., LLC (8)	3,692,558	2,090,000	12.77%	2,000,000	3,782,558	7.11%
Leder Laboratories, Inc. (9)	83,333	166,666*		166,666	83,333*	
Starling Pharmaceuticals, Inc. (10)	83,333	166,666*		166,666	83,333*	
Charles E. Mather IV (11)	150,569	110,000*		100,000	160,569*	
John Rhodes (12)	1,101,936	550,000	3.78%	500,000	1,151,936	2.20%
Ernest Mario (13)	1,280,412	383,334	3.82%	333,334	1,330,412	2.54%
Marcia Fox	62,500	125,000*		125,000	62,500*	
Eli Lederman (14)	2,427,810	300,000	6.27%	250,000	2,477,810	4.74%
Samuel Saks (15)	166,667	333,334	1.15%	333,334	166,667*	

Selling Stockholder	Shares of Common Stock Owned Before this Offering	Shares of Common Stock Underlying Warrants Owned Before this Offering (1)	Percentage of Common Stock Beneficially Owned Before this Offering (2)	Shares of Common Stock Being Offered in this Offering (3)	Shares of Common Stock Beneficially Owned After this Offering (4)	Percentage of Common Stock Beneficially Owned After this Offering (2)
Theodore A. McGraw, Jr.	125,000	250,000	1.37%	250,000	125,000*	
Charles Lowery	250,000	500,000	1.72%	500,000	250,000*	
David Lummis	250,000	500,000	1.72%	500,000	250,000*	
Matthew Harad	62,500	125,000*		125,000	62,500*	
Ju Innovation Partners I, L.P. (16)	125,000	250,000*		250,000	125,000*	
Peabody Capital Partners, LP (17)	500,000	1,000,000	3.40%	1,000,000	500,000*	
Gates P. Torrey	125,000	250,000*		250,000	125,000*	
Leland & Lauren Gershell, JTWROS (18)	62,500	100,000*		75,000	87,500*	
Jupiter Financial Services, LLC (19)	1,540,000	3,080,000	4.99% (25)	3,080,000	1,540,000	2.87%
The Fontinalis Trust (20)	125,000	250,000*		250,000	125,000*	
The 1901 Trust (21)	125,000	250,000*		250,000	125,000*	
Bluestein Capital Opportunities Fund, L.P. (22)	125,000	250,000*		250,000	125,000*	
Richard M. Furlaud, Jr.	125,000	250,000*		250,000	125,000*	
Technology Partners Fund VIII, LP (23)	2,500,000	5,000,000	9.99% (25)	5,000,000	2,500,000	4.58%
The 2012 Quinine Fund (24)	335,000	670,000	2.29%	670,000	335,000*	
TOTALS:	**17,782,150**	**18,153,334**		**17,808,334**	**18,127,150**	

* Represents less than 1%.

(1) Represents shares of our common stock remaining issuable under warrants issued in connection with the 2011 Financing, the 2012 Financing and/or the December 2012 Financing. All warrants are immediately exercisable, subject to exercise limitations contains therein relating to beneficial ownership percentages.

(2) Applicable percentage ownership before the offering is based on 43,182,599 shares of common stock outstanding as of December 31, 2012. Applicable percentage ownership after the offering is based on 52,086,766 shares of common stock, which includes the 8,904,167 shares of common stock issuable upon exercise of the Class A Warrants to purchase common stock registered pursuant to this prospectus.

(3) Assumes that (i) all of the shares of common stock to be registered on the registration statement of which this prospectus is a part, including all shares of common stock underlying warrants held by the selling stockholders, are sold in the offering and (ii) that no other shares of common stock are acquired or sold by the selling stockholder prior to the completion of the offering. However, subject to the restrictions of transfer agreed to by the selling stockholders (see "Plan of Distribution" in this prospectus), the selling stockholders may sell all, some or none of the shares offered pursuant to this prospectus and may sell other shares of our common stock that they may own pursuant to another registration statement under the Securities Act or sell some or all of their shares pursuant to an exemption from the registration provisions of the Securities Act, including under Rule 144.

(4) 50% of such total shares represent shares of common stock issuable upon exercise of the Class A Warrants.

(5) Bruce Daugherty is an executive officer of the Company.

(6) Stuart Davidson, a member of our board of directors, is a member of Lysander LLC and has voting and investment power over the securities owned by it.

(7) Seth Lederman, our chairman and chief executive officer, is the manager of L&L Technologies, LLC and has voting and investment power over the securities owned by it.

(8) Seth Lederman, our chairman and chief executive officer, is the managing member of Lederman & Co, LLC and has voting and investment power over the securities owned by it.

(9) Seth Lederman, our chairman and chief executive officer, is the chairman of Leder Laboratories, Inc. and has voting and investment power over the securities owned by it.

(10) Seth Lederman, our chairman and chief executive officer, is the chairman of Starling Pharmaceuticals, Inc. and has voting and investment power over the securities owned by it.
(11) Charles Mather IV is a member of our board of directors.
(12) John Rhodes is a member of our board of directors.
(13) Ernest Mario is a member of our board of directors.
(14) Eli Lederman is the brother of Seth Lederman, our chairman and chief executive officer. Seth Lederman disclaims beneficial ownership of the securities held by Eli Lederman.
(15) Samuel Saks is a member of our board of directors.
(16) William Ju is the member of William David Ju, L.L.C., the general partner of Ju Innovation Partners I, L.P. and has voting and investment power over the securities owned by it.
(17) James A. Torrey is the general partner of Peabody Capital Partners, LP and has voting and investment power over the securities owned by it.
(18) Leland Gershell is an executive officer of the Company.
(19) David T. Altshuler is the member of Jupiter Financial Services, LLC and has voting and investment power over the securities owned by it.
(20) William C. Ford, Jr. is the trustee of The Fontinalis Trust and has voting and investment power over the securities owned by it.
(21) Elena A. Ford is the trustee of The 1901 Trust and has voting and investment power over the securities owned by it.
(22) Robert H. Bluestein and Jeffrey N. Bluestein are the president and senior managing director, respectively, of R. J. Bluestein & Company, the general partner of Bluestein Capital Opportunities Fund, L.P. and have voting and investment power over the securities owned by it.
(23) Sheila Mutter and Roger Quy are the managing members of TP Management VIII, LLC, the general partner of Technology Partners Fund VIII, LP and have voting and investment power over the securities owned by it.
(24) Hill C. Snellings is the trustee of The 2012 Quinine Fund and has voting and investment power over the securities owned by it.
(25) Represents maximum beneficial ownership percentage pursuant to exercise limitations contained within the warrants.

December 2012 Private Placement

In December 2012, we consummated the December 2012 Financing, pursuant to which we issued an aggregate of 8,904,167 Units to the Purchasers for aggregate cash proceeds of $2,615,000, at a price per Unit of $0.40, and the exchange of $710,000 in Debentures of the Company that were converted into Units at a price of $0.30 per Unit.

Each Unit consisted of one share of Common Stock, a Class A Warrant to purchase one share of Common Stock and a Class B Warrant to purchase one share of Common Stock. The Class A Warrants have an exercise price of $0.60 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The Class A Warrants may be exercised on a cashless basis under certain circumstances. The Class B Warrants have an exercise price of $0.40 per share of Common Stock and will be exercisable for a period of one year from the date of issuance.

In connection with the December 2012 Financing, we granted each Purchaser registration rights. We are obligated to use our best efforts to cause a registration statement registering for resale the Common Stock included in the Units and the Common Stock underlying the Class A Warrants to be filed no later than 60 days from the date of the last closing of the December 2012 Financing and must be declared effective no later than 120 days from the date of the last closing of the December 2012 Financing. Moreover, we will maintain the effectiveness of the registration statement from its effective date unless all securities registered under the registration statement have been sold or are otherwise able to be sold pursuant to Rule 144 of the Securities Act of 1933, as amended (the "Securities Act"). If we fail to comply with the registration statement filing or effective date requirements, we are required to pay the investors a fee equal to 1.0% of the Purchaser's investment, for each 30-day period of delay, subject to a maximum payment of 10% to each Purchaser.

The shares included in the Units and shares underlying the Class A Warrants are registered pursuant to this prospectus.

LEGAL MATTERS

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

EXPERTS

EisnerAmper LLP, an independent registered public accounting firm, has audited, as set forth in its report thereon appearing elsewhere herein, our financial statements at December 31, 2011 and 2010 and for the years then ended that appear in the prospectus. The financial statements referred to above are included in this prospectus in reliance upon the independent registered public accounting firm's report given on their authority as experts in accounting and auditing.

AVAILABLE INFORMATION

We have filed a registration statement on Form S-1 under the Securities Act of 1933, as amended, relating to the shares of common stock being offered by this prospectus, and reference is made to such registration statement. This prospectus constitutes the prospectus of Tonix Pharmaceuticals Holding Corp., filed as part of the registration statement, and it does not contain all information in the registration statement, as certain portions have been omitted in accordance with the rules and regulations of the Securities and Exchange Commission.

We are subject to the informational requirements of the Securities Exchange Act of 1934 which requires us to file reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements and other information may be inspected at public reference facilities of the SEC at 100 F Street, N.E., Washington D.C. 20549. Copies of such material can be obtained from the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549 at prescribed rates. Because we file documents electronically with the SEC, you may also obtain this information by visiting the SEC's Internet website at http://www.sec.gov.

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TONIX PHARMACEUTICALS HOLDING CORP.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Tonix Pharmaceuticals Holding Corp.

We have audited the accompanying consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. (a development stage company) (the "Company") as of December 31, 2011 and 2010, the related consolidated statements of operations and cash flows for the years then ended and for the period from June 7, 2007 (inception) through December 31, 2011 and the consolidated statements of stockholders' deficiency for each of the four years in the period ended December 31, 2011 and for the period from June 7, 2007 (inception) through December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits include consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Tonix Pharmaceuticals Holding Corp. as of December 31, 2011 and 2010, the consolidated results of its operations and its cash flows for the years ended December 31, 2011 and 2010 and for the period from June 7, 2007 (inception) through December 31, 2011 and consolidated changes in stockholders' deficiency for each of the four years in the period ended December 31, 2011 and for the period June 7, 2007 through December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring net losses and negative cash flows from operations, has both working capital and stockholders' deficiencies at December 31, 2011 and requires additional financing to fund future operations. These events and conditions, among others referred to in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/EisnerAmper LLP
EisnerAmper LLP
New York, New York
March 30, 2012

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2011 AND 2010

	2011	2010
ASSETS		
Current assets:		
Cash	$ 41,123	$ 65,359
Prepaid expenses	102,430	23,313
Total current assets	143,553	88,672
Furniture and equipment, net	25,550	32,086
Deferred financing costs, net	196,166	-
Restricted cash	60,177	60,087
Security deposit	-	3,156
	$ 425,446	$ 184,001
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities:		
Accounts payable	$ 695,198	$ 317,745
Accrued expenses	10,229	22,533
Accrued interest, including $5,006 to related parties	38,306	-
Liability to placement agent	31,543	-
Convertible Debentures	150,000	-
Total current liabilities	925,276	340,278
Convertible Debentures, including $265,000 to related parties	1,925,000	-
Deferred rent payable	29,083	19,174
Total liabilities	2,879,359	359,452
Commitments (Note 6)	-	-
Stockholders' deficiency:		
Common stock, $0.001 par value; 75,000,000 shares authorized, 27,066,667 and 18,034,483 shares issued and outstanding as of December 31, 2011 and 2010, respectively	27,067	18,035
Additional paid in capital	3,913,700	2,731,081
Deficit accumulated during development stage	(6,394,680)	(2,924,567)
Total stockholders' deficiency	(2,453,913)	(175,451)
	$ 425,446	$ 184,001

See notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31, 2011	2010	From June 7, 2007 (date of inception) Through December 31, 2011
Costs and expenses:			
Research and development	$ 1,158,167	$ 584,298	$ 1,951,954
General and administrative	2,220,361	1,344,390	4,255,247
	3,378,528	1,928,688	6,207,201
Operating loss	(3,378,528)	(1,928,688)	(6,207,201)
Gain on extinguishment of debt	-	-	7,908
Interest expense, net	(91,585)	(35,782)	(195,387)
Net loss	$ (3,470,113)	$ (1,964,470)	$ (6,394,680)
Net loss per common share, basic and diluted	$ (0.16)	$ (0.18)	
Weighted average common shares outstanding, basic and diluted	21,425,632	11,175,096	

See notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIENCY

	Common stock Shares	Common stock Amount	Additional Paid in Capital	Deficit Accumulated During Development Stage	Total
Shares issued to founders for intellectual property in June 2007 ($0.15 per share)	589,014	$ 589	$ 87,161	$ -	$ 87,750
Shares issued to bankers for services in June 2007 ($0.15 per share)	65,446	66	9,684	-	9,750
Compensation related to restricted share awards issued to directors in November 2007	-	-	24,187	-	24,187
Net loss	-	-	-	(537,001)	(537,001)
Balance at December 31, 2007	654,460	655	121,032	(537,001)	(415,314)
Compensation related to cancelled restricted share awards in December 2008	-	-	72,563	-	72,563
Net loss	-	-	-	(202,262)	(202,262)
Balance at December 31, 2008	654,460	655	193,595	(739,263)	(545,013)
Conversion of senior convertible notes into capital stock in June 2009 ($0.03 per share)	7,200,000	7,200	192,800	-	200,000
Shares issued to directors in July 2009 ($0.15 per share)	31,414	31	4,649	-	4,680
Capital contribution in June 2009	-	-	23,725	-	23,725
Net loss	-	-	-	(220,834)	(220,834)
Balance at December 31, 2009	7,885,875	7,886	414,769	(960,097)	(537,442)
Conversion of demand notes into capital stock in July 2010 ($0.23 per share)	2,094,547	2,095	477,905	-	480,000
Conversion of accrued interest on demand notes into capital stock in July 2010 ($0.23 per share)	301,430	301	68,777	-	69,078
Issuance of capital stock in August to December 2010 ($0.23 per share)	5,856,005	5,856	1,336,145	-	1,342,001
Shares issued to founders for intellectual property in June 2010 ($0.23 per share)	1,308,921	1,309	294,191	-	295,500
Issuance of restricted shares to directors, employees and consultants in June to November 2010 ($0.24 per share)	587,705	588	139,294	-	139,882
Net loss	-	-	-	(1,964,470)	(1,964,470)
Balance at December 31, 2010	18,034,483	18,035	2,731,081	(2,924,567)	(175,451)
Vesting and issuance of capital stock in January to September 2011 ($0.23 per share)	2,670,548	2,670	609,330	-	612,000
Vesting and issuance of restricted shares to directors, employees and consultants in February to April 2011 and vesting of restricted shares pursuant to Share Exchange in October 2011	1,961,636	1,962	433,689	-	435,651
Common stock issued in connection with the share exchange transaction in October 2011	4,000,000	4,000	(4,000)	-	-
Common stock issued in October 2011 in exchange for services rendered ($0.36 per share)	400,000	400	143,600	-	144,000
Net loss	-	-	-	(3,470,113)	(3,470,113)
Balance at December 31, 2011	27,066,667	$ 27,067	$ 3,913,700	$ (6,394,680)	$ (2,453,913)

See notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2011	2010	From June 7, 2007 (date of inception) Through December 31, 2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (3,470,113)	$ (1,964,470)	$ (6,394,680)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	9,300	3,854	17,312
Amortization of deferred financing costs	53,377	-	53,377
Common stock issued in exchange for intellectual property	-	295,500	383,250
Stock based compensation	435,651	139,882	686,713
Gain on extinguishment of debt	-	-	(7,908)
Changes in operating assets and liabilities:			
Prepaid expenses	(79,117)	(19,315)	(102,430)
Accounts payable	377,453	294,132	695,198
Accrued interest	38,306	32,691	38,306
Accrued expenses	(12,304)	(34,789)	110,940
Deferred rent payable	9,909	19,174	29,083
Net cash used in operating activities	(2,637,538)	(1,233,341)	(4,490,839)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of furniture and equipment	(2,764)	(34,279)	(42,862)
Repayment of security deposit	3,156	-	-
Payment of restricted cash	(90)	(60,087)	(60,177)
Net cash provided by (used in) investing activities	302	(94,366)	(103,039)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from demand notes	-	50,000	480,000
Proceeds from notes payable	500,000	-	700,000
Proceeds from Convertible Debentures	1,501,000	-	1,501,000
Proceeds from the sale of capital stock	612,000	1,342,001	1,954,001
Net cash provided by financing activities	2,613,000	1,392,001	4,635,001
Net (decrease) increase in cash	(24,236)	64,294	41,123
Cash, beginning of the period	65,359	1,065	-
Cash, end of period	$ 41,123	$ 65,359	$ 41,123
Non cash investing and financing activities:			
Senior convertible notes exchanged for preferred shares	$ -	$ 200,000	$ 200,000
Capital contribution of accrued interest on convertible notes	$ -	$ -	$ 23,725
Demand notes together with accrued interest converted into capital stock	$ -	$ 549,078	$ 549,078
Common stock issued for deferred financing costs	$ 144,000	$ -	$ 144,000

See notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2011 AND 2010

NOTE 1 –BUSINESS AND RECAPITALIZATION

Tonix Pharmaceuticals Holding Corp. through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. is attempting to develop safer and more effective versions of widely prescribed central nervous system ("CNS") drugs. While some new applications can use the commercially available form of the drug, in other cases reformulating the active ingredient improves its safety or effectiveness in treating the CNS condition. When formal development programs have proven successful in clinical tests, Tonix Pharmaceuticals, Inc. intends to seek marketing approval from the Food and Drug Administration ("FDA").

On August 16, 2010, Tonix Pharmaceuticals, Inc. formed Krele LLC ("Krele") in the state of Delaware. Krele is a limited liability corporation whose sole member is Tonix Pharmaceuticals Inc. Krele was established to commercialize products that are generic versions of predicate new drug application products or versions of drug efficacy study implementation products. The Company expects that its relationship to Krele will be similar to that of several other pharmaceutical companies and their subsidiaries that market generic versions of the parent's branded products at different periods in their product life-cycle.

On October 7, 2011, Tonix Pharmaceuticals, Inc. (formerly Krele Pharmaceuticals, Inc. incorporated on June 7, 2007 in the State of Delaware) and a publicly traded non-operating shell company Tamandare Explorations Inc. (“Tamandare”), incorporated under the laws of the State of Nevada, along with certain other parties executed and consummated a share exchange agreement (the “Share Exchange”). Pursuant to the Share Exchange, each share of Tonix Pharmaceuticals Inc.’s common stock was exchanged for 0.9 shares of Tamandare’s common stock and each share of Tonix Pharmaceuticals, Inc.’s Series A and B preferred stock was exchanged for 4.8 shares of Tamandare’s common stock. Upon completion of the Share Exchange, the Tonix Pharmaceuticals, Inc. shareholders, including holders of restricted shares, which were subject to accelerated vesting, received in exchange for all of their shares, an aggregate of 22,666,667 shares of Tamandare’s common stock and Tamandare’s existing stockholders retained 4,000,000 shares of common stock. The 22,666,667 shares issued to the Tonix Pharmaceuticals, Inc. shareholders constituted approximately 85% of Tamandare’s 26,666,667 issued and outstanding shares of common stock after the Share Exchange. Upon completion of the Share Exchange, Tonix Pharmaceuticals, Inc. became Tamandare’s wholly-owned subsidiary and in October 2011 Tamandare was renamed Tonix Pharmaceuticals Holding Corp. As the owners and management of Tonix Pharmaceuticals, Inc. obtained voting and operating control of Tamandare after the Share Exchange and Tamandare was non-operating, had no assets or liabilities and did not meet the definition of a business, the transaction has been accounted for as a recapitalization of Tonix Pharmaceuticals, Inc., accompanied by the issuance of its common stock for outstanding common stock of Tamandare, which was recorded at a nominal value. The accompanying financial statements and related notes give retroactive effect to the recapitalization as if it had occurred on June 7, 2007 (inception date) and accordingly all share and per share amounts have been adjusted.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation:

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its wholly owned subsidiaries, Tonix Pharmaceuticals, Inc. and Krele LLC (hereafter referred to as the “Company” or “Tonix”). All significant intercompany balances and transactions have been eliminated in consolidation.

As the Company is devoting substantially all of its efforts to establishing a new business, and while planned principal operations have commenced, there has been no revenue generated from sales, license fees or royalties, the Company is considered a development stage enterprise. Accordingly, the Company's consolidated financial statements are presented in accordance with authoritative accounting guidance related to a development stage enterprise. Financial position, results of operations and cash flows of a development stage enterprise are presented in conformity with generally accepted accounting principles that apply to established operating enterprises.

As a development stage enterprise, the Company's primary efforts are devoted to conducting research and development for the treatment of CNS diseases. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. In addition, the Company has both working capital and stockholders' deficiencies at December 31, 2011 and requires additional financing to fund future operations. Although, in the first quarter of 2012, the Company raised approximately $4,700,000 (see Note 11), it’s expected that cash used in operations will increase significantly over the next several years. The Company intends to raise additional capital to complete the development and commercialization of its current product candidates through equity or debt financing; however the Company does not have any commitments or definitive or binding arrangements for such funds. There can be no assurance that such funds, if available at all, can be obtained on terms reasonable to the Company. If the Company is unsuccessful in raising additional capital it will need to reduce costs and operations substantially. Further, the Company does not have any commercial products available for sale and has not generated revenues and there is no assurance that if approval of their products is received that the Company will be able to generate cash flow to fund operations. In addition, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable.

The above factors raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

Use of estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets and assumptions used in the fair value of stock-based compensation.

Research and Development costs

The Company outsources its research and development efforts and expenses related costs as incurred, including the cost of manufacturing product for testing, licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired was expensed in 2007 and 2010 as research and development costs, as it related to particular research and development projects and had no alternative future uses.

Reclassifications

The accompanying 2010 financial statements together with cumulative amounts from inception have been reclassified to allocate professional services expenses to research and development and general and administrative expenses to be consistent with current year presentation.

Furniture and equipment

Furniture and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life, which is three years for computer assets and five years for furniture and all other equipment. Expenditures for maintenance and repairs are expensed as incurred.

Income taxes

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

The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2011 and 2010, the Company has not recorded any unrecognized tax benefits.

Stock-based compensation

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

Per share data:

Basic and diluted net loss per common share is calculated by dividing net loss, by the weighted average number of outstanding shares of common stock, adjusted to give effect to the exchange ratio in the Share Exchange in October 2011 (see Note 1), which was accounted for as recapitalization of the Company.

In October 2011, upon completion of the share exchange referred to above, the Company issued Convertible Debentures in the amount of $2,075,000 which as of December 31, 2011 were convertible into approximately 3,985,000 common shares. In computing diluted net loss per share, no effect has been given to such shares as their effect would be antidilutive. See Notes 5 and 10 for subsequent issuance of securities.

NOTE 3 – FURNITURE AND EQUIPMENT

Furniture and equipment as of December 31, 2011 and 2010 is summarized as follows:

	2011	2010
Office furniture and equipment	$ 42,862	$ 40,098
Less: accumulated depreciation	(17,312)	(8,012)
	$ 25,550	$ 32,086

Depreciation expense for the years ended December 31, 2011 and 2010 was $9,300 and $3,854, respectively.

NOTE 4 - RESTRICTED CASH

Restricted cash at December 31, 2011 and 2010 collateralizes a letter of credit in the amount of approximately $60,000 issued in connection with the lease of office space in New York City (see Note 6).

NOTE 5 - CONVERTIBLE DEBENTURES

On October 7, 2011, concurrently with the Share Exchange, the Company issued secured Convertible Debentures ("Convertible Debentures") in the amount of $1,625,000 of which $1,125,000 were sold to certain investors for aggregate cash proceeds of $1,065,000, net of selling commissions to a placement agent of $40,000 and $20,000 of legal fees, and $500,000 were exchanged for 8% Notes Payable ("Notes Payable") issued on September 9, 2011. In addition, 400,000 shares of common stock with the fair market value of $144,000 were issued to a second placement agent. On November 16, the Company issued Convertible Debentures in the amount of $450,000 for aggregate cash proceeds of $436,000, net of selling commissions to a third placement agent of $14,000.

The Convertible Debentures mature on the earlier of (i) one year from the date of issuance or (ii) the date of closing of a private placement of equity, equity equivalent, convertible debt or debt financing in which the Company receives gross proceeds, in one or more transactions, of at least $3,425,000 (a "Subsequent Financing"). The Convertible Debentures bear interest at 8% per annum and are convertible at the holder's option into a Subsequent Financing. In the event that a Subsequent Financing has not occurred within 12 months from the date of issuance of the Convertible Debentures, the holder has the option to convert into a number of shares of the Company's common stock equal to 1% of the Company's shares of common stock on a fully diluted basis for every $125,000 of Convertible Debentures (the "Conversion Shares") or an aggregate of approximately 3,985,000 shares based on the outstanding shares of the Company common stock as of December 31, 2011. A Subsequent Financing comprised of Units consisting of common stock and warrants took place on January 20, 2012 and $1,925,000 of debentures were exchanged for Units (see Note 10). The remaining $150,000 of debentures were repaid. As a result of the exchange, $1,925,000 principal amount of debentures are classified as a non-current liability in the accompanying balance sheet at December 31, 2011.

Upon conversion or repayment of the Convertible Debenture, the holder is entitled to receive, at the holder's option, either (i) a warrant (the "Warrant"), which has a three year term and is exercisable at the offering price in a Subsequent Financing, to purchase such number of shares of the Company's common stock equal to the principal amount of the Convertible Debenture divided by the offering price in a Subsequent Financing, (the "Warrant Shares") or (ii) shares of the Company's common stock equal to 33% of the principal amount of the Debenture divided by the offering price in a Subsequent Financing (the "Incentive Shares"). The value of the Warrant Shares or Incentive Shares will be measured and number of such shares determined upon occurrence of any Subsequent Financing. The Conversion Shares, Warrant Shares and Incentive Shares are entitled to piggyback registration rights. Upon the Subsequent Financing on January 20, 2012, the holders $1,925,000 principal amount of Convertible Debentures elected to receive 250,000 Warrants exercisable at $1 per share and 536,250 Incentive Shares, and holders of the remaining $150,000 principal amount of Convertible Debentures, which were redeemed, received 25,000 Warrants exercisable at $1 per share and 57,750 Incentive Shares. The value of the Warrants and Incentive Shares will be charged to operations in the first quarter of 2012.

In addition to selling commissions paid to the placement agents on the sale of certain Convertible Debentures, the placement agents received warrants which expire in October 2013 and November 2013, respectively, and are exercisable at the offering price in a Subsequent Financing to purchase shares of the Company's common stock equal to 3% and 9%, respectively, of the gross proceeds delivered by purchasers introduced by such placement agents divided by the purchase price per share in the Subsequent Financing. In the event that the Subsequent Financing has not occurred within 12 months from the date of issuance of the Convertible Debentures, the placement agents will receive, in lieu of the warrants, shares of common stock equal to 3% and 9%, respectively, of the number of shares of the Company's common stock such purchasers are entitled to receive upon conversion of their Convertible Debentures or an aggregate of approximately 88,000 shares based on the outstanding shares of the Company's common stock as of December 31, 2011. The Company recognized a liability to placement agents to issue shares of its common stock based on their fair value of approximately $32,000 as of December 31, 2011. Upon the Subsequent Financing on January 20, 2012, the placement agents become entitled to receive 30,750 warrants exercisable at $1.00 per share.

The following expenses in connection with the issuance of Convertible Debenture are recorded as deferred financing costs: fair value of 400,000 shares of the Company's common stock issued to the placement agent valued at $144,000, cash payments to the placement agents of $54,000, legal expenses of $20,000 and fair value of the liability to placement agent to issue the Company's shares of common stock in the amount of $32,000. The deferred financing costs are being amortized using the effective interest method over the twelve month term of the Convertible Debentures. During the year ended December 31, 2011, amortization of deferred financing costs amounted to approximately $53,000 and charged to interest expenses in the statement of operations. The unamortized balance will be charged to operations in connection with the extinguishment of the debentures resulting from their exchange for the Units and repayment in 2012.

Pursuant to a Pledge and Security Agreement and Subsidiary Guaranty, the Company granted the Debenture holders a first priority lien on all its assets.

NOTE 6 - COMMITMENTS

Operating leases

On September 28, 2010, the Company entered into a five-year lease for office space in New York City, with monthly payments escalating from approximately $10,000 in first year to approximately $11,000 in fifth year. The Company received a rent credit of $9,420 in each of the months of November 2010, December 2010 and January 2011. The Company has posted a letter of credit in the amount of approximately $60,000 for the benefit of the landlord which is collateralized by a money market account (see Note 4 - Restricted Cash).

Future minimum lease payments under the operating lease are as follows:

Year Ending December 31,		
2012	$	124,370
2013		127,889
2014		131,513
2015		100,719
	$	484,491

Rent expense charged to operations, which differs from rent paid due to the rent credits and to increasing amounts of base rent, is calculated by allocating total rental payments on a straight-line basis over the term of the lease. During the years ended December 31, 2011 and 2010, rent expense was $128,228 and $42,570, respectively and as of December 31, 2011 and 2010 deferred rent payable was $29,083 and $19,174, respectively. The Company utilized office space in New York City provided by founders without remuneration until October 2010.

Consulting agreements

In June 2010, the Company entered into a two-year consulting agreement with L&L Technologies, an entity controlled by a member of the Company's Board of Directors, for scientific and medical consulting services. In consideration for such services, L&L Technologies will receive $96,000 per annum and 1,026,194 shares of restricted common stock which were granted at the inception of the agreement. The consulting agreement renews automatically for subsequent terms of one year at $96,000 per annum. The restricted shares vest as follows: 25% on the grant date (June 4, 2010) and 25% on each of the first and second annual anniversaries of the grant date and, if the consulting agreement is renewed, 25% on the third anniversary of the grant date. Vesting of the unvested 513,097 restricted shares accelerated on October 7, 2011, the date of the Share Exchange.

In June 2010, the Company entered into a two-year consulting agreement with Lederman & Co., an entity controlled by a member of the Company's Board of Directors, for clinical development, strategic, management and operational consulting services. In consideration for such services, Lederman & Co. will receive $250,000 per annum and 261,784 shares of restricted common stock which were granted at the inception of the agreement. The consulting agreement renews automatically for subsequent terms of one year at $250,000 per annum. The restricted shares vest as follows: 20% on the grant date (June 4, 2010) and 20% on each of the first and second anniversaries of the grant date and, if the consulting agreement is renewed, 20% on each of the third and fourth anniversaries of the grant date. Vesting of the unvested 157,087 restricted shares accelerated on October 7, 2011, the date of the Share Exchange.

In June 2010, the Company entered into an agreement with Burns McClellan, Inc. to provide media and investor relations services, including preparation of investor presentations and press releases, media outreach and training and investor targeting and introductions, for a fee of $20,000 per month, plus expenses. The agreement was terminated in January 2011.

In October 2010, the Company entered into an agreement with Frost & Sullivan to prepare an assessment of the U.S. fibromyalgia market, including current market size and historical and projected growth rates, as well as a formal presentation supporting their findings for a fee of $109,400, all of which was recognized in 2010.

In July 2011, the Company entered into an agreement with Catalent Pharma Solutions, LLC to investigate, for $58,080, the feasibility of developing the active pharmaceutical ingredient ("API") used in TNX-102, one of the Company's product candidates, for use in a new, proprietary formulation

In August 2011, the Company entered into an agreement with Porter, LeVay & Rose, Inc. to provide media and investor relations services, including preparation of investor presentations and press releases, media outreach and training and investor targeting and introductions, for a fee of $12,000 per month, plus expenses. Also in August 2011, the Company entered into an agreement with JFC Technologies, LLC ("JFC") for product development work for an initial fee of $75,000, of which $35,000 was paid upon signing. In September 2011, JFC was acquired by Cyalume Specialty Products, Inc. ("Cyalume") and the Company's agreement was transferred to Cyalume. Additionally, in August 2011 the Company authorized the initiation of stage 2 work pursuant to a contract with Lipocine Inc. with respect to a research and development project for reformulation work on TNX-102 for a fee of $235,000, which work started in the third quarter of 2011.

In September 2011, the Company entered into two contracts with Pharmanet Canada for contract research work with respect to the development of methods to measure the active ingredient of TNX-102 in blood and urine. The full cost of the work to be performed is approximately $90,000. Payment is due in three installments based on the achievement of certain performance milestones. Also, in September 2011, the Company entered into a contract with Pharmanet Canada for contract research work with respect to the pharmacokinetic study for TNX-102. The full cost of the work to be performed is $637,231. Payment is due in four installments based on the achievement of certain performance milestones.

In October 2011, the Company entered into an agreement with Applied Pharma Research to develop, and perform an exploratory pharmacokinetic study on a new formulation of the API used in TNX-102 for an approximate cost of $180,000.

Employment agreements

In 2010, the Company entered into employment agreements with the Chief Operating Officer and the Vice President of Marketing which expire in August 2012 and June 2012, respectively. Under the terms of the employment agreements, the Chief Operating Officer and the Vice President of Marketing shall receive annual base compensation of $250,000 and $150,000, respectively, which shall be adjusted to $320,000 and $200,000, respectively, or such other rate as the Board may designate from time to time, upon completion of an initial public offering with net proceeds of at least $15,000,000. The agreements will be automatically renewed for additional one-year periods (the "Renewal Terms") unless either party notifies the other in writing of its intention not to renew within 90 days prior to the expiration of the Initial Term or any Renewal Terms. Upon termination without cause, as defined in the agreements, the executives will continue to receive compensation for up to nine months if termination is in connection with or following an initial public offering.

In February 2011, the Company entered into an employment agreement with the Chief Business Officer which expires in February 2013. Under the terms of the employment agreement, the Chief Business Officer shall receive annual base compensation of $150,000 which shall increase, with a retroactive adjustment, upon the completion of an underwritten public offering, as defined, or certain other events. The employment agreement will be automatically renewed for additional renewal terms unless either party notifies the other in writing of its intention not to renew within 90 days prior to the expiration of the initial term or any renewal terms. Upon termination without cause, as defined in the employment agreement, the Chief Business Officer will continue to receive compensation for six months, or nine months if termination is in connection with or following certain events.

In April 2011, the Company terminated existing employment agreements with the three executive employees referred to in the first two paragraphs above and entered into new employment agreements which stipulate such employees will receive minimum wage salary ($7.25 per hour) for a 40 hour week until the Company receives new capital of at least $500,000 through the sale of equity securities. The expiration dates of the new agreements remain the same as the terminated agreements. In addition, the Chief Business Officer assumed the title of Chief Operating Officer and the Chief Operating Officer assumed the title of Chief Financial Officer and Chief Administrative Officer and the Vice President of Marketing assumed the title of Vice President of Strategy. Upon receipt of $500,000 or more in new capital, the employees will receive a lump sum payment in the amount of $50,000 each for the Chief Operating Officer and Chief Financial Officer and $30,000 for the Vice President of Strategy. Further, base salaries for all three employees will be increased with a retroactive adjustment upon the completion of an underwritten offering, as defined, or certain other events. All other terms remain the same. In October 2011, the position of Vice President of Strategy was eliminated and the employment agreement was terminated. In conjunction with this event, the Company paid $37,500 in December 2011 in exchange for the release from future obligations. In February 2012, the Company terminated its employment agreement with its Chief Financial Officer and in accordance with the agreement paid such officer approximately $88,000.

In July 2011, the Company entered into agreements with the executive employees to defer payment of the lump sum amounts referred to above until the closing of a private placement of securities, as defined. In addition, salaries of the Chief Financial Officer and Chief Operating Officer were adjusted to $175,000 per annum effective August 2011. The salary of the Chief Operating Officer shall increase to $250,000 per annum on the first anniversary of the Share Exchange provided that the Company has raised at least $500,000 in additional equity securities.

NOTE 7 - INCOME TAXES

There is no provision for federal or state income taxes for the years ended December 31, 2011 and 2010 since the Company has established a valuation allowance equal to the total deferred tax asset related to losses incurred during such periods.

Deferred tax assets and liabilities and related valuation allowance as of December 31, 2011 and 2010 are as follows:

	December 31, 2011	December 31, 2010
Deferred tax assets:		
Organization costs	$ 733	$ 2,494
Research and development credit carryforward	6,188	6,188
Net operating loss carryforwards	2,329,829	1,107,688
Other	132,482	121,091
Total deferred tax assets	2,469,232	1,237,461
Deferred tax liabilities:		
Restricted stock compensation(1)	-	(148,871)
Net deferred tax assets	2,469,232	1,088,590
Valuation allowance	(2,469,232)	(1,088,590)
Net deferred tax assets	$ 0	$ 0

(1) Relates to restricted stock grants for which Internal Revenue Code ("IRC") Section 83(b) elections were filed in 2010, resulting in tax deductions in excess of related compensation expense for financial reporting purposes in 2010.

Based on the Company's historical losses and its expectation of continuation of losses for the foreseeable future, the Company has determined that it is not more likely than not that the deferred tax assets will be realized and, accordingly, has provided a valuation allowance. The increase in the valuation allowance for the years ended December 31, 2011 and 2010 was $1,380,642 and $783,696, respectively.

At December 31, 2011, the Company has available unused net operating loss carryforwards of approximately $5.8 million that expire from 2027 to 2031 for federal tax purposes and the same amount for New Jersey state tax purposes, which expire from 2014 to 2018. The Company also has approximately $3 million of net operating loss carryforwards for New York state purposes expiring in 2031. These net operating loss carryforwards may be subject to annual limitations in their use in accordance with IRC Section 382. Accordingly, the extent to which the net operating loss carryforwards can be used to offset future taxable income may be limited. At December 31, 2011, the Company has a research and development credit carryforward of $6,188 for federal tax purposes that expires in 2027.

The Company's federal and state tax returns remain open and subject to examination by the tax authorities for the tax years 2008 and 2007, respectively through 2011.

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

	Year Ended December 31,	
	2011	2010
Statutory federal income tax	(34.0)%	(34.0)%
State income tax, net of federal tax effect	(5.9)%	(5.9)%
Permanent difference	0.0%	5.0%
Increase in valuation allowance	39.9%	34.9%
Income tax provision	0%	0%

NOTE 8 – STOCK PLAN

In June and August 2010, respectively, the board of directors and stockholders of Tonix Pharmaceuticals, Inc. approved, and in December 2010 and February 2011, the board of directors amended, the terms and provisions of the 2010 Stock Plan ("Plan") whereby the Company reserved 4,564,641 shares of its Common Stock for issuance pursuant to the Plan. The Plan allowed for grants of options to purchase shares of Common Stock and awards of restricted Common Stock to employees, officers, directors, consultants and advisors of the Company.

In 2010, the Company granted shares of restricted Common Stock under the Plan to employees ("Employee Granted Shares") as follows: 196,359 shares to the Chief Operating Officer, 109,088 shares to the Vice President of Clinical Development, 130,906 shares to the Vice President of Marketing and 196,359 shares to the Chief Medical Officer. Employee Granted Shares vest: 20% on the grant date and 20% on each of the first, second, third and fourth anniversaries of the grant date. Upon termination of the Chief Medical Officer's employment with Tonix, 157,087 unvested shares held by him were forfeited and he retained 39,272 shares of fully vested Common Stock. Upon termination of the Vice President of Clinical Development's employment with Tonix, 87,270 unvested shares held by him were forfeited and he retained 21,818 shares of fully vested Common Stock.

In 2010, the Company granted 1,288,112 shares of restricted Common Stock under the Plan to consultants.

In 2010, the Company granted 556,786 shares of restricted Common Stock under the Plan to directors and also granted 52,362 shares of restricted Common Stock under the Plan to members of the Scientific Advisory Board which vest: 25% on the grant date and 25% on each of the first, second and third anniversaries of the grant date.

In February 2011, the Company granted shares of restricted Common Stock to employees as follows: 196,359 shares to the Chief Business Officer and 130,906 shares to the incoming President of Krele. The shares vest: 20% on the grant date and 20% on each of the first, second, third and fourth anniversaries of the grant date. In August 2011, upon resignation of the President of Krele, 104,725 unvested shares were forfeited.

In March and April 2011, the Company granted 19,636 and 21,818 shares of restricted Common Stock, respectively, to newly appointed members of the Scientific Advisory Board and the Board of Directors which vest: 25% on the grant date and 25% on each of the first, second and third anniversaries of the grant date.

Following is a summary of the status of the Company's nonvested restricted stock as of December 31, 2011 and the changes during the years 2010 and 2011:

Nonvested Restricted Stock	Number of Restricted Shares	Weighted Average Grant-Date Fair Value
Nonvested at January 1, 2010		
Granted	2,529,971	$ 0.23
Vested	(587,767)	$ 0.23
Forfeited	(244,357)	$ 0.23
Nonvested at December 31, 2010	1,697,847	$ 0.23
Granted	368,718	$ 0.23
Vested prior to Share Exchange	(564,858)	$ 0.23
Vested pursuant to Share Exchange	(1,396,982)	$ 0.23
Forfeited	(104,725)	$ 0.23
Nonvested at December 31, 2011	0	$ 0

Restricted stock is not considered to be issued until the stock vests.

The Company recognized share-based compensation expense of $139,063 prior to Share Exchange and remaining expense of $296,588 was recognized on October 7, 2011, the date of Share Exchange, upon which all nonvested restricted shares vested and the Plan ceased to exist. Stock based compensation expense for the year ended December 31, 2010 was $139,882.

NOTE 9 - RELATED PARTY TRANSACTIONS

Dr. Seth Lederman and Dr. Donald Landry are primary founders of the Company and serve on the board of directors. They have entered into various transactions with the Company through several companies under their control, including L&L Technologies and Lederman & Co as described in Note 6.

During 2007, the Company issued senior convertible promissory notes (the "Senior Convertible Notes") pursuant to the Note Purchase Agreements among the Company and National Holdings Corporation, Lederman & Co., LLC, Eli Lederman PhD and Dr. Seth Lederman, all but one of whom are direct or indirect stockholders of the Company (collectively referred to herein as the "Noteholders"), in the amount of $50,000 per Senior Convertible Note, or $200,000 in the aggregate. The Senior Convertible Notes bore interest at the rate of 8% per annum and were payable together with the interest accrued thereon on the two year anniversary of the Senior Convertible Notes. The outstanding principal and interest accrued thereon were to be automatically converted into fully paid shares of capital stock upon the closing of a Qualified Financing of capital stock or securities convertible into preferred stock which resulted in gross proceeds of at least $2,000,000.

In June 2009, although a Qualified Financing had not occurred, the Noteholders agreed to exchange the Senior Convertible Notes for shares of capital stock of the Company at the rate of one share of capital per $0.13 of the outstanding principal balance of such notes. The accrued interest on the notes in the amount of $31,633 was forgiven. The excess of the carrying value of the notes including accrued interest over the fair value of the capital stock for which they were exchanged amounted to $31,633 of which $23,725, representing the excess related to the Noteholders who are direct or indirect stockholders, has been accounted for as a capital contribution and credited to additional paid-in capital and the remaining $7,908 was recorded as a gain on extinguishment of debt. Interest expense relating to the Senior Convertible Notes for the year ended December 31, 2009 was $8,044.

In 2007, Lederman & Co. loaned the Company $10,000. On December 19, 2008, the Company issued to Lederman & Co. a demand note in the amount of $280,000, which included new cash proceeds of $270,000 as well as the amount loaned in 2007, with interest accruing on the total demand note balance commencing December 19, 2008. On December 7, 2009, the Company borrowed an additional $150,000 from Lederman & Co. and issued a demand note. The principal balance of the demand notes outstanding as of December 31, 2009 was $430,000 with accrued interest owed at December 31, 2009 of $36,387. On March 5, 2010, the Company issued to Dr. Donald Landry a demand note in the amount of $50,000. The demand notes accrue interest at the rate of 12% per annum.

On July 30, 2010, the demand notes and all interest accrued thereon were converted into shares of capital stock. Demand notes held by Lederman & Co. totaling $430,000 and accrued interest thereon of $66,629 were converted into 2,166,444 shares of capital stock, at a conversion price of $0.23 per share of capital stock. The demand note held by Donald Landry totaling $50,000 and accrued interest thereon of $2,449 was converted into 228,835 shares of capital stock, at a conversion price of $0.23 per share of capital stock.

On September 9, 2011, the Company sold $500,000 principal amount of 8% convertible notes (the "Notes") to members of the board of directors and their related parties. The Notes were due one year from the date of issuance, and were exchangeable for a future financing (the "New Financing") at the option of the holders. Interest is payable on either the maturity date or on the date the Notes are exchanged into the New Financing, or such accrued interest can be converted into the New Financing. On October 7, 2011, the Notes were exchanged into debentures issued by the Company concurrently with the Share Exchange (see Note 5).

Interest expense on the demand notes for the years ended December 31, 2010 and 2009 was $32,691 and $35,267, respectively.

NOTE 10 - SUBSEQUENT EVENTS

The Company amended and restated its Bylaws and Articles of Incorporation on February 16, 2012 and among other changes, increased the number of authorized shares of common stock, $0.001 par value to 150,000,000. Additionally, the Company is now authorized to issue 5,000,000 shares of preferred stock, $0.001 par value with such designations, references and participating, optional or other special rights and qualifications, limitations or restrictions thereof as shall be determined by the Company's Board of Directors.

On February 12, 2012 the Company's Board of Directors approved the 2012 Incentive Stock Options Plan (the "Plan"). The Plan provides for the issuance of options to purchase up to 4,000,000 shares of the Company's common stock to officers, directors, employees and consultants of the Company. Under the terms of the Plan the Company may issue Incentive Stock Options as defined by the Internal Revenue Code to employees of the Company only and nonstatutory options. The Board of Directors of the Company determines the exercise price, vesting and expiration period of the grants under the Plan. However, the exercise price of an Incentive Stock Option should not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more stockholder and 100% of fair value for a grantee who is not 10% stockholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the Plan should not be more than five years and expiration period not more than ten years. The Company reserved 4,000,000 shares of its common stock for future issuance under the terms of the Plan.

Subsequent financing

On January 20, 2012, the Company issued an aggregate of 172.118 units ("Units") to certain investors (the "Purchasers") for aggregate cash proceeds of $2,377,950 and $1,925,000 in previously issued Convertible Debentures of the Company that were exchanged for Units (the "Financing"). On March 1, 2012, the Company issued an aggregate of 92.5926 units to certain investors for aggregate cash proceeds of $2,314,815.

Each Unit had a purchase price of $25,000 per Unit and consisted of twenty five thousand (25,000) shares of the Company's common stock, a Class A Warrant to purchase twenty five thousand (25,000) shares of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase up to twenty five thousand (25,000) shares of Common Stock (the "Class B Warrants" and together with the Class A Warrants, the "Warrants").

The Class A Warrants have an exercise price of $1.25 per share of common stock and will be exercisable for a period of five years from the date of issuance. The Class B Warrants are exercisable automatically on their expiration date by cashless exercise or expire without exercise. In the event that the average of the Company's daily volume weighted average price is below $0.75 during the 10 trading days after the Announcement Date (as hereinafter defined) (the "Measuring Period"), then the holder will be entitled to receive additional shares of the Company's Common Stock upon the exercise of the Class B Warrants on the expiration date, which is the 12th trading day after the Announcement Date. In the event that the Company's average daily volume weighted average price is at or above $0.75 during the Measuring Period, the Class B Warrants will expire unexercised. The Announcement Date is the earlier of (1) the date on which the Company announces via press release the results of the pharmacokinetic study of its TNX-102 drug formulation; or (2) June 1, 2012.

In connection with the Financing, the Company paid a placement agent (the "Agent") an aggregate cash payment of $466,777, which represented an 8% commission and a 2% non-accountable expense allowance of the gross proceeds delivered by Purchasers in the Financing. In addition, the Agent earned warrants to purchase shares of Common Stock equal to 10% of the gross proceeds delivered by Purchasers in the Financing (the "Agent Warrants"), which have an exercise price of $1.25 per share of common stock, exercisable for a period of seven years, contain customary anti-dilution protection and are entitled to piggy-back registration rights.

Pursuant to the Warrants, no Purchaser may exercise such Purchaser's Warrant if such exercise would result in the Purchaser beneficially owning in excess of 4.99% of the Company's then issued and outstanding common stock. A Purchaser may, however, increase or decrease this limitation (but in no event exceed 9.99% of the number of shares of Common Stock issued and outstanding) by providing the Company with 61 days' notice that such holder wishes to increase or decrease this limitation.

In connection with the Financing, the Company entered into a Registration Rights Agreements with Purchasers. The Company is required to file a registration statement registering for resale the common stock included in the Units and the common stock underlying the Warrants and the Agent Warrants to be filed no later than 60 days from the date of termination of the Financing on March 1, 2012 and must be declared effective no later than 120 days from the date of termination of the Financing (June 29, 2012). The Company is required to maintain the effectiveness of the registration statement from its effective date unless all securities registered under the registration statement have been sold or are otherwise able to be sold. If the Company fails to comply with the registration statement filing or effective date requirements, the Company is required to pay the investors a fee equal to 1.0% of the Purchaser's investment, for each 30-day period of delay, subject to a maximum payment of 10% to each Purchaser.

The Company determined the offering price for the purpose of calculation of number of Warrants or Incentive Share to be issued to Convertible Debenture holders and warrants to be issued the placement agents of Convertible Debentures to be $1.00 (see Note 5).

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash	$ 35,653	$ 41,123
Prepaid expenses and other	43,076	102,430
Total current assets	78,729	143,553
Furniture and equipment, net	51,031	25,550
Deferred financing costs, net	-	196,166
Restricted cash	60,244	60,177
Total assets	$ 190,004	$ 425,446
LIABILITIES AND STOCKHOLDERS' (DEFICIENCY)		
Current liabilities:		
Accounts payable, including $20,778 and $27,483 to related parties as of September 30, 2012 and December 31, 2011, respectively	$ 697,383	$ 695,198
Accrued expenses	136,303	10,229
Accrued interest, including $3,111 and $5,006 to related parties as of September 30, 2012 and December 31, 2011, respectively	3,111	38,306
Liability to placement agent	-	31,543
Convertible debentures	-	150,000
Total current liabilities	836,797	925,276
Convertible debentures, including $265,000 to related parties	-	1,925,000
Deferred rent payable	27,543	29,083
Total liabilities	864,340	2,879,359
Commitments	-	-
Stockholders' (deficiency):		
Preferred stock, $0.001 par value; 5,000,000 and -0- authorized as of September 30, 2012 and December 31, 2011, respectively; none issued or outstanding	-	-
Common stock, $0.001 par value; 150,000,000 and 75,000,000 authorized as of September 30, 2012 and December 31, 2011, respectively; 34,278,432 and 27,066,667 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	34,278	27,067
Additional paid in capital	12,506,771	3,913,700
Deficit accumulated during development stage	(13,215,385)	(6,394,680)
Total stockholders' (deficiency)	(674,336)	(2,453,913)
Total liabilities and stockholders' (deficiency)	$ 190,004	$ 425,446

See the accompanying notes to condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended September 30,		Nine months ended September 30,		From June 7, 2007 (date of inception) through
	2012	2011	2012	2011	September 30, 2012
COSTS AND EXPENSES:					
Research and development	$ 658,143	$ 492,024	$ 1,883,559	$ 634,496	$ 3,835,513
General and administrative	1,076,199	522,462	2,862,086	1,249,500	7,117,333
	1,734,342	1,014,486	4,745,645	1,883,996	10,952,846
Operating Loss	(1,734,342)	(1,014,486)	(4,745,645)	(1,883,996)	(10,952,846)
Gain on extinguishment of debt	-	-	-	-	7,908
Other income	1,875	-	1,875	-	1,875
Change in fair value of warrants liability	-	-	(1,177,026)	-	(1,177,026)
Interest and other financing costs, net	440	8	(899,909)	52	(1,095,296)
NET LOSS	$ (1,732,027)	$ (1,014,478)	$ (6,820,705)	$ (1,883,944)	$ (13,215,385)
Net loss per common share, basic and diluted	$ (0.05)	$ (0.05)	$ (0.20)	$ (0.10)	
Weighted average common shares outstanding, basic and diluted	34,278,432	20,667,466	33,405,648	19,687,742	

See the accompanying notes to condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' (DEFICIENCY)
For the Nine Months Ended September 30, 2012
(unaudited)

	Preferred stock		Common stock		Additional Paid in	Deficit Accumulated During Development	
	Shares	Amount	Shares	Amount	Capital	Stage	Total
Balance at December 31, 2011	-	$ -	27,066,667	$ 27,067	$ 3,913,700	$ (6,394,680)	$ (2,453,913)
Common stock issued in January 2012 to holders of convertible debentures ($0.62 per share)	-	-	594,000	594	367,686	-	368,280
Issuance of common stock in January and March 2012 ($0.62 per share) net of transaction expenses	-	-	6,617,765	6,617	3,625,694	-	3,632,311
Warrants issued in January 2012 to holders of convertible debentures	-	-	-	-	83,289	-	83,289
Warrants issued to placement agent in January 2012	-	-	-	-	6,126	-	6,126
Warrants reclassified to equity upon expiry of reset provisions	-	-	-	-	3,938,946	-	3,938,946
Stock based compensation	-	-	-	-	571,330	-	571,330
Net loss	-	-	-	-	-	(6,820,705)	(6,820,705)
Balance at September 30, 2012	-	$ -	34,278,432	$ 34,278	$ 12,506,771	$(13,215,385)	$ (674,336)

See the accompanying notes to condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Nine months ended September 30, 2012	2011	From June 7, 2007 (date of inception) through September 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (6,820,705)	$ (1,883,944)	$ (13,215,385)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	10,192	6,946	27,504
Amortization and write down of deferred financing costs	196,166	-	249,543
Non cash interest, consisting of common stock and warrants issued in connection with convertible debentures	426,152	-	426,152
Non-cash financing costs related to January and March 2012 financing	81,337	-	81,337
Stock based compensation	571,330	139,064	1,258,043
Loss in change in fair value of warrant liability	1,177,026	-	1,177,026
Common stock issued in exchange for intellectual property	-	-	383,250
Gain on extinguishment of debt	-	-	(7,908)
Changes in operating assets and liabilities:			
Prepaid expenses	59,354	20,539	(43,076)
Accounts payable	2,185	539,571	697,383
Accrued interest	(35,195)	-	3,111
Accrued expenses	126,074	(3,472)	237,014
Deferred rent payable	(1,540)	10,423	27,543
Net cash used in operating activities	(4,207,624)	(1,170,873)	(8,698,463)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of furniture and fixtures	(35,673)	(2,764)	(78,535)
Proceeds from security deposit	-	3,156	-
Payment of restricted cash and interest earned on restricted cash	(67)	(45)	(60,244)
Net cash (used in) provided by investing activities	(35,740)	347	(138,779)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from demand notes	-	-	480,000
Proceeds from other notes payable	-	-	700,000
Proceeds, net of expenses of $24,000 from Convertible Debentures	-	500,000	1,501,000
Repayment of Convertible Debentures	(150,000)	-	(150,000)
Proceeds, net of expenses of $304,870, from sale of units consisting of common stock and warrants	4,387,894	-	4,387,894
Proceeds from the sale of capital stock	-	612,000	1,954,001
Net cash provided by financing activities	4,237,894	1,112,000	8,872,895
Net (decrease) increase in cash	(5,470)	(58,526)	35,653
Cash, beginning of the period	41,123	65,359	-
Cash, end of period	$ 35,653	$ 6,833	$ 35,653
Supplemental disclosures of cash flow information:			
Interest paid	$ 35,195	$ -	$ -
Non cash investing and financing activities:			
Senior convertible notes exchanged for preferred shares	$ -	$ -	$ 200,000
Capital contribution of accrued interest	$ -	$ -	$ 23,725
Demand notes together with accrued interest converted into capital stock	$ -	$ -	$ 549,078
Common stock issued for deferred financing costs	$ -	$ -	$ 144,000
Exchange of Notes Payable for Convertible Debenture	$ -	$ -	$ 500,000
Warrants Liability reclassified to Stockholders' Equity	$ 3,938,946	$ -	$ 3,938,946
Exchange of Convertible Debenture for Units consisting of common stock and warrants	$ 1,925,000	$ -	$ 1,925,000

See the accompanying notes to condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(Formerly known as Tamandare Explorations Inc.)
(a development stage company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2012 AND 2011 (UNAUDITED)

NOTE 1 – BUSINESS AND RECAPITALIZATION

Tonix Pharmaceuticals Holding Corp. (the "Company"), through its wholly owned subsidiary Tonix Pharmaceuticals, Inc., or Tonix Sub, is attempting to develop safer and more effective versions of widely prescribed central nervous system ("CNS") drugs. While some new applications can use the commercially available form of the drug, in other cases, reformulating the active ingredient improves its safety or effectiveness in treating the CNS condition. When formal development programs have proven successful in clinical tests, Tonix Sub intends to seek marketing approval from the Food and Drug Administration ("FDA").

On August 16, 2010, Tonix Sub formed Krele LLC ("Krele") in the state of Delaware. Krele is a limited liability corporation whose sole member is Tonix Sub. Krele was established to commercialize products that are generic versions of predicate new drug application products or versions of drug efficacy study implementation products. The Company expects that its relationship to Krele will be similar to that of several other pharmaceutical companies and their subsidiaries that market generic versions of the parent's branded products at different periods in their product life-cycle.

On October 7, 2011, Tonix Sub (formerly Krele Pharmaceuticals, Inc. incorporated on June 7, 2007 in the State of Delaware) and a publicly traded non-operating shell company Tamandare Explorations Inc. (“Tamandare”), incorporated under the laws of the State of Nevada, along with certain other parties executed and consummated a share exchange agreement (the “Share Exchange”). Pursuant to the Share Exchange, each share of Tonix Sub’s common stock was exchanged for 0.9 shares of Tamandare’s common stock and each share of Tonix Sub’s Series A and B preferred stock was exchanged for 4.8 shares of Tamandare’s common stock. Upon completion of the Share Exchange, the Tonix Sub shareholders, including holders of restricted shares, which were subject to accelerated vesting, received in exchange for all of their shares, an aggregate of 22,666,667 shares of Tamandare’s common stock and Tamandare’s existing stockholders retained 4,000,000 shares of common stock. The 22,666,667 shares issued to the Tonix Sub shareholders constituted approximately 85% of Tamandare’s 26,666,667 issued and outstanding shares of common stock after the Share Exchange. Upon completion of the Share Exchange, Tonix Sub became Tamandare’s wholly-owned subsidiary and in October 2011 Tamandare was renamed Tonix Pharmaceuticals Holding Corp. As the owners and management of Tonix Sub obtained voting and operating control of Tamandare after the Share Exchange and Tamandare was non-operating, had no assets or liabilities and did not meet the definition of a business, the transaction has been accounted for as a recapitalization of Tonix Sub, accompanied by the issuance of its common stock for outstanding common stock of Tamandare, which was recorded at a nominal value. The accompanying financial statements and related notes give retroactive effect to the recapitalization as if it had occurred on June 7, 2007 (inception date) and accordingly all share and per share amounts have been adjusted.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Interim Financial Statements

The unaudited condensed consolidated interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included.

The condensed consolidated balance sheet as of December 31, 2011 contained herein have been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of results that may be expected for the year ending December 31, 2012. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2011 included in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2012.

Basis of presentation

As a development stage enterprise, the Company's primary efforts are devoted to conducting research and development for the treatment of CNS diseases. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. In addition, the Company has working capital and stockholders' deficiencies as of September 30, 2012, The Company requires additional financing, for which there are no existing commitments to fund its working capital deficiency and future operations and no assurances can be given that the Company will be able to obtain sufficient financing on terms acceptable to it, if at all. Further, the Company does not have any commercial products available for sale and there is no assurance that if approval of their products is received that the Company will be able to generate cash flow to fund operations. In addition, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable.

The above factors raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

During the nine months ended September 30, 2012, the Company issued common stock and warrants and obtained net cash proceeds in the aggregate of $4,387,894. In addition, $1,925,000 in previously issued notes were exchanged for common stock and warrants (see Note 6). The Company expects that cash used in operations will increase significantly over the next several years and it is the Company's intent to raise additional capital to complete the development and commercialization of its current product candidates through equity or debt financing. There can be no assurance that such funds, if available at all, can be obtained on terms reasonable to the Company. If the Company is unsuccessful in raising additional capital it will need to reduce costs and may be required to reduce or cease operations.

Use of estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and disclosures of contingent assets and liabilities at the date of the financial statements. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets and assumptions used in the fair value of stock-based compensation.

Research and development costs

The Company outsources its research and development efforts and expenses related costs as incurred, including the cost of manufacturing products for testing, licensing fees and costs associated with planning and conducting clinical trials. The value ascribed to patents and other intellectual property acquired was expensed in 2007 and 2010 as research and development costs, as it related to particular research and development projects and had no alternative future uses.

Income taxes

Income tax provisions or benefits for interim periods are computed based on the Company’s estimated annual effective tax rate. Based on the Company's historical losses and its expectation of continuation of losses for the foreseeable future, the Company has determined that it is more likely than not that deferred tax assets will not be realized and, accordingly, has provided a full valuation allowance. As the Company anticipates or anticipated that its net deferred tax assets at December 31, 2012 and 2011 would be fully offset by a valuation allowance, there is no federal or state income tax benefit for the periods ended September 30, 2012 and 2011 related to losses incurred during such periods.

Per share data

Basic and diluted net loss per common share is calculated by dividing net loss, by the weighted average number of outstanding shares of common stock, adjusted to give effect to the exchange ratio in the Share Exchange in October 2011 (see Note 1), which was accounted for as a recapitalization of the Company.

During the nine months ended September 30, 2012, upon the completion of the January and March financing (see Note 6), the Company issued warrants to purchase an aggregate 7,390,292 shares of the Company's common stock. In addition, in May 2012, the Company issued to employees options to acquire an aggregate of 3,500,000 shares of the Company's common stock (see Note 8). In computing diluted net loss per share, no effect has been given to such options and warrants as their effect would be anti-dilutive.

NOTE 3 – FURNITURE AND EQUIPMENT

Furniture and equipment as of September 30, 2012 and December 31, 2011 is summarized as follows:

	September 30, 2012	December 31, 2011
Office furniture and equipment	$ 78,535	$ 42,862
Less: accumulated depreciation	(27,504)	(17,312)
	$ 51,031	$ 25,550

Depreciation expense for the three and nine months ended September 30, 2012 was $4,076 and $10,192, respectively; and $2,354 and $6,946 for the three and nine months ended September 30, 2011, respectively.

NOTE 4 – RESTRICTED CASH

Restricted cash at September 30, 2012 and December 31, 2011 collateralizes a letter of credit in the amount of approximately $60,000 issued in connection with the lease of office space in New York City.

NOTE 5 – CONVERTIBLE DEBENTURES

On October 7, 2011, concurrently with the Share Exchange, the Company issued secured Convertible Debentures ("Convertible Debentures") in the amount of $1,625,000 of which $1,125,000 were sold to certain investors for aggregate cash proceeds of $1,065,000, net of selling commissions to a placement agent of $40,000 and $20,000 of legal fees, and $500,000 were exchanged for 8% Notes Payable ("Notes Payable") issued on September 9, 2011. In addition, 400,000 shares of common stock with the fair market value of $144,000 were issued to a second placement agent. On November 16, the Company issued Convertible Debentures in the amount of $450,000 for aggregate cash proceeds of $436,000, net of selling commissions to a third placement agent of $14,000.

The Convertible Debentures mature on the earlier of (i) one year from the date of issuance or (ii) the date of closing of a private placement of equity, equity equivalent, convertible debt or debt financing in which the Company receives gross proceeds, in one or more transactions, of at least $3,425,000 (a "Subsequent Financing"), which took place on January 20, 2012 ("January 2012 Financing") (see Note 6). The Convertible Debentures bear interest at 8% per annum and were convertible at the holder's option into a Subsequent Financing. In the event that a Subsequent Financing has not occurred within 12 months from the date of issuance of the Convertible Debentures, the holder had the option to convert into a number of shares of the Company's common stock equal to 1% of the Company's shares of common stock on a fully diluted basis for every $125,000 of Convertible Debentures (the "Conversion Shares") or an aggregate of approximately 3,985,000 shares based on the outstanding shares of the Company common stock as of December 31, 2011.

Upon the January 2012 Financing, $1,925,000 of debentures were exchanged for Units and the remaining $150,000 of debentures were repaid. As a result of the exchange, $1,925,000 principal amount of debentures are classified as a non-current liability in the accompanying balance sheet at December 31, 2011.

Upon conversion or repayment of the Convertible Debenture, the holder was entitled to receive, at the holder's option, either (i) a warrant (the "Debenture Warrant"), which has a three year term and is exercisable at the offering price in a Subsequent Financing, to purchase such number of shares of the Company's common stock equal to the principal amount of the Convertible Debenture divided by the offering price in a Subsequent Financing, (the "Warrant Shares") or (ii) shares of the Company's common stock equal to 33% of the principal amount of the Convertible Debenture divided by the offering price in a Subsequent Financing (the "Incentive Shares"). The Conversion Shares, Warrant Shares and Incentive Shares are entitled to piggyback registration rights. Upon the January 2012 Financing, the holders of the Convertible Debenture elected to receive 275,000 Debenture Warrants exercisable at $1 per share with fair value of $83,289 and 594,000 Incentive Shares valued at $368,280. The value of the Debenture Warrants and Incentive Shares was charged to operations as interest expense in the first quarter of 2012.

In addition to selling commissions paid to the placement agents on the sale of certain Convertible Debentures, the placement agents received warrants that expire in January 2014 and 2015 ("Agents Warrants"), respectively, and are exercisable at the offering price in a Subsequent Financing to purchase shares of the Company's common stock equal to 3% and 9%, respectively, of the gross proceeds delivered by purchasers introduced by such placement agents divided by the purchase price per share in the Subsequent Financing. In the event that the Subsequent Financing has not occurred within 12 months from the date of issuance of the Convertible Debentures, the placement agents were entitled to receive, in lieu of the warrants, shares of common stock equal to 3% and 9%, respectively, of the number of shares of the Company's common stock such purchasers were entitled to receive upon conversion of their Convertible Debentures or an aggregate of approximately 88,000 shares based on the outstanding shares of the Company's common stock as of December 31, 2011. The Company recognized a liability to placement agents to issue shares of its common stock based on their fair value of approximately $32,000 as of December 31, 2011. Upon the January 2012 Financing, the placement agents become entitled to receive 30,750 warrants exercisable at $1.00 per share with a fair value $6,126, which was charged to operations as interest expense in the first quarter of 2012. Additionally the liability to placement agent of $32,000 was credited to interest expense in the first quarter of 2012.

The fair value of the Debenture and Agents Warrants was determined using the Black Scholes option pricing model with the following assumptions: fair value of the Company's common stock $0.62 per share determined based on January and March 2012 proceeds; dividends yield 0%; expected terms 2 to 3 years; risk free interest rate: 0.91%; and expected volatility: 73 to 94%.

The following expenses in connection with the issuance of Convertible Debenture were recorded as deferred financing costs: fair value of 400,000 shares of the Company's common stock issued to the placement agent valued at $144,000, cash payments to the placement agents of $54,000, legal expenses of $20,000 and fair value of the liability to placement agent to issue the Company's shares of common stock in the amount of $32,000. The deferred financing costs were amortized using the effective interest method over the twelve month term of the Convertible Debentures. During the year ended December 31, 2011, amortization of deferred financing costs amounted to approximately $53,000 and charged to interest expense in the statement of operations and remaining balance was charged to operations in connection with the extinguishment of the debentures resulting from their exchange and repayment in 2012.

Pursuant to a Pledge and Security Agreement and Subsidiary Guaranty, the Company granted the Debenture holders a first priority lien on all its assets.

NOTE 6 – JANUARY AND MARCH 2012 FINANCING

On January 20, 2012, the Company issued an aggregate of 172.118 units ("Units") to certain investors (the "Purchasers") for aggregate cash proceeds of $2,377,950 and $1,925,000 in previously issued Convertible Debentures of the Company that were exchanged for Units ("January 2012 Financing"). On March 1, 2012, the Company issued an aggregate of 92.5926 units to certain investors for aggregate cash proceeds of $2,314,815 ("March 2012 Financing").

Each Unit had a purchase price of $25,000 per Unit and consisted of twenty five thousand (25,000) shares of the Company's common stock, a Class A Warrant to purchase twenty five thousand (25,000) shares of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase up to twenty five thousand (25,000) shares of Common Stock (the "Class B Warrants" and together with the Class A Warrants, the "Warrants").

The Class A Warrants have an exercise price of $1.25 per share of common stock and will be exercisable for a period of five years from the date of issuance. The warrants had certain anti-dilutive provisions that were set to expire the earlier of i) one year or ii) upon effectiveness of a registration of all shares covered by Class A Warrants, which took place on June 6, 2012. The Company determined the fair value of the Class A Warrants and the Agent Warrants, described below, to be $2,549,684 and $212,235 on the issuance dates and initially classified them as a liability due to transactions which cause an adjustment to the conversion rate (reset provisions) contained in the warrant agreements. On June 6, 2012, upon the Company's registration statement being declared effective by the Securities and Exchange Commission, the reset provisions expired and the Company reclassified $3,938,946, the fair value of the Class A Warrants and Agent Warrants as of that date to equity. The increase of $1,177,026 in fair value of warrants liability was included in results of operations for the nine months ended September 30, 2012.

The following assumptions were used in the Binomial Lattice model to determine fair value of the Class A Warrants and the Agent Warrants:

	Issuance date January 20 and March 1, 2012	Expiration date June 6, 2012
Price of the Company's common stock	$ 0.62	$ 0.85
Dividend yield	0%	0%
Expected terms	5 – 7 years	4.6 - 6.7 years
Risk free interest rate	0.89 - 1.47%	0.73 - 1.11%
Expected volatility	96.68 - 96.69%	95.73%
Expected price at which holders are likely to exercise their warrants	$ 1.25	$ 1.25

The Class B Warrants were exercisable automatically on their expiration date by cashless exercise or expire without exercise. In the event that the average of the Company's daily volume weighted average price was below $0.75 during the 10 trading days after the Announcement Date (as hereinafter defined) (the "Measuring Period"), then the holder was entitled to receive additional shares of the Company's Common Stock upon the exercise of the Class B Warrants on the expiration date, which is the 12th trading day after the Announcement Date. In the event that the Company's average daily volume weighted average price was at or above $0.75 during the Measuring Period, the Class B Warrants were to expire unexercised. The Announcement Date was the earlier of (1) the date on which the Company announces via press release the results of the pharmacokinetic study of its TNX-102 drug formulation; or (2) June 1, 2012. On April 5, 2012 the Company issued a press release announcing the results of the pharmacokinetic study of its TNX-102 drug formulation, which is defined as an Announcement Date for the purpose of the Class B Warrants. Based on the Company's average daily volume weighted average price, which was $1.73 per share, during the Measuring Period, the Class B Warrants expired unexercised.

In connection with the January and March 2012 Financing, the Company paid a placement agent (the "Agent") an aggregate cash payment of $466,777, which represented an 8% commission and a 2% non-accountable expense allowance of the gross proceeds delivered by Purchasers in the January and March 2012 Financing. In addition, the Agent earned an aggregate of 466,777 warrants to purchase shares of common stock equal to 10% of the gross proceeds delivered by Purchasers in the January and March 2012 Financing (the "Agent Warrants"), which have an exercise price of $1.25 per share of common stock, exercisable for a period of seven years, contained anti-dilution protection and are entitled to piggy-back registration rights. Total expenses related to the financing, including cash and the fair value of warrants given to the Agent, amounted to $706,511, of which $435,713 was charged to additional paid-in capital and $270,798, deemed initially allocable to the warrant liability, was charged to current and other financing costs.

In connection with the financings, the Company entered into a Registration Rights Agreement with Purchasers. The Company is required to file a registration statement registering for resale the common stock included in the Units and the common stock underlying the Class A Warrants and the Agent Warrants to be filed no later than 60 days from the date of termination of the financings on March 1, 2012 and must be declared effective no later than 120 days from the date of termination of the Financing (June 29, 2012). On April 26, 2012, the Company filed the registration statement, which was declared effective on June 6, 2012. The Company is required to maintain the effectiveness of the registration statement from its effective date unless all securities registered under the registration statement have been sold or are otherwise able to be sold. If the Company failed to comply with the registration statement filing or effective date requirements, the Company was required to pay the investors a fee equal to 1.0% of the Purchaser's investment, for each 30-day period of delay, subject to a maximum payment of 10% to each Purchaser.

NOTE 7 – STOCKHOLDERS' EQUITY

On May 2, 2012, the Company filed amended and restated Articles of Incorporation. Among other changes, the Company increased the number of authorized shares of common stock, $0.001 par value to 150,000,000. Additionally, the Company is now authorized to issue 5,000,000 shares of preferred stock, $0.001 par value with such designations, preferences and participating, optional or other special rights and qualifications, limitations or restrictions thereof as shall be determined by the Company's Board of Directors.

NOTE 8 – SHARE BASED COMPENSATION

2010 Stock Plan

In June and August 2010, respectively, the Board of Directors and stockholders of Tonix Sub. approved, and in December 2010 and February 2011, the Board of Directors amended, the terms and provisions of the 2010 Stock Plan (the "2010 Plan") whereby the Company reserved 4,564,641 shares of its Common Stock for issuance pursuant to the 2010 Plan. The 2010 Plan allowed for grants of options to purchase shares of Common Stock and awards of restricted Common Stock to employees, officers, directors, consultants and advisors of the Company.

In February 2011, the Company granted shares of restricted Common Stock to employees as follows: 196,359 shares to the Chief Business Officer and 130,906 shares to the incoming President of Krele. The shares vest: 20% on the grant date and 20% on each of the first, second, third and fourth anniversaries of the grant date. In August 2011, upon resignation of the President of Krele, 104,725 unvested shares were forfeited.

In March and April 2011, the Company granted 19,636 and 21,818 shares of restricted Common Stock, respectively, to newly appointed members of the Scientific Advisory Board and the Board of Directors which vest: 25% on the grant date and 25% on each of the first, second and third anniversaries of the grant date.

The Company recognized share-based compensation expense of $139,063 prior to Share Exchange and remaining expense of $296,588 was recognized on October 7, 2011, the date of Share Exchange, upon which all non vested restricted shares vested and the 2010 Plan ceased to exist.

2012 Incentive Stock Option Plan

On February 12, 2012, the Company's Board of Directors approved the 2012 Incentive Stock Option Plan (the "2012 Plan"). The 2012 Plan provides for the issuance of options to purchase up to 4,000,000 shares of the Company's common stock to officers, directors, employees and consultants of the Company. Under the terms of the 2012 Plan, the Company may issue Incentive Stock Options as defined by the Internal Revenue Code to employees of the Company only and nonstatutory options. The Board of Directors of the Company determines the exercise price, vesting and expiration period of the grants under the 2012 Plan. However, the exercise price of an Incentive Stock Option should not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more stockholder and 100% of fair value for a grantee who is not 10% stockholder. The fair value of the common stock is determined based on quoted market price or in absence of such quoted market price, by the Board of Directors in good faith. Additionally, the vesting period of the grants under the 2012 Plan should not be more than five years and expiration period not more than ten years. The Company reserved 4,000,000 shares of its common stock for future issuance under the terms of the 2012 Plan. On May 9, 2012, 3,500,000 options had been granted under the 2012 Plan (all of which are outstanding at September 30, 2012) with an exercise price of $1.50, a 10 year life and fair value of $1.175. The options vest 1/3rd on May 9, 2013 and 1/36th on the 9th of each month thereafter for 24 months.

The Company measures the fair value of stock options on the date of grant, based on a Binomial option pricing model using certain assumptions discussed in the following paragraph, and the closing market price of the Company's common stock on the date of the grant. Stock options granted vest over a three year period and expire ten years from the date of grant. Share-based compensation expense related to awards is amortized over the applicable vesting periods using the straight-line method. Share-based compensation expense of $571,330 was recognized for the nine month period ended September 30, 2012.

The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2012 were as follows:

Risk-free interest rate		1.87%
Expected term of option		6.5 years
Expected stock price volatility		95.89%
Expected dividend yield	$	0.0

The risk-free rate of return is based on the yield of Daily U.S. Treasury Yield Curve Rates with terms equal to the expected life of the options as of the grant date. The expected term of options determined using the simplified method and the expected stock price volatility is based on comparable companies' historical stock price volatility since the Company does not have sufficient historical exercise data because its equity shares have been publicly traded for only a limited period of time.

As of September 30, 2012, the Company had approximately $3,542,246 of total unrecognized compensation cost related to non-vested awards granted under the Company's 2012 Plan, which the Company expects to recognize over approximately a three-year period.

NOTE 9 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company, all of which were exercisable, at September 30, 2012:

Exercise Price	Number Outstanding	Expiration Date
$ 1.00	305,750	January 2014 to January 2015
1.25	7,084,542	January 2017 to March 2019
	7,390,292	

On January 20, 2012, the Company issued an aggregate of 275,000 and 30,750 warrants to purchase the Company's common stock at an exercise price of $1.00 per share expiring five and seven years from the date of issuance to convertible debenture holders and debenture placement agents, respectively (see Note 5).

In connection with the January 2012 and March 2012 Financing, the Company issued to investors an aggregate of 4,302,950 and 2,314,815 warrants, respectively, to purchase the Company's common stock at an exercise price of $1.25 per share expiring five years from the date of issuance. In addition, the Company issued an aggregate of 235,295 and 231,482 warrants to purchase the Company's common stock at an exercise price of $1.25 per share expiring seven years from the date of issuance to placement agents. These warrants contained certain anti-dilutive provisions and are covered under a registration rights agreement (see Note 6).

NOTE 10 – RELATED PARTY TRANSACTIONS

Dr. Seth Lederman, our Chief Executive Officer and Chairman of the Board, and Dr. Donald Landry, one of our directors, are the primary founders of Tonix Sub. We have entered into various transactions with several companies under their control, including L&L Technologies, Plumbline, Targent Pharmaceuticals, LLC and Lederman & Co. Lederman & Co. received $250,000 per annum for its services, until August 1, 2011, when it received $127,000 per annum until such time as we closed on the 2012 Financing. We first closed on the 2012 Financing in January 2012, and effective February 1, 2012, Lederman & Co. receives $250,000 per annum for its services. The consulting agreement renews automatically for subsequent terms of one year at $250,000 per annum. Total expenses paid under these agreements were $107,333 and $246,083 during the three and nine months ended September 30, 2012, respectively; and $44,281 and $239,000 during the three and nine months ended September 30, 2011, respectively. In January 2012, the related party companies received interest on the convertible notes in the aggregate amount of $6,183.

In connection with the January 2012 Financing, related party convertible debenture holders received an aggregate of 84,150 shares of common stock and 10,000 warrants to purchase the Company's common stock at an exercise price of $1.00 for three years (see Note 5). Upon exchange of debentures for units in the January 2012 Financing, related party debenture holders received an aggregate of 275,000 shares of the Company's common stock, 275,000 Class A Warrants and 275,000 Class B Warrants (see Note 6).

NOTE 11 – COMMITMENTS

Employment agreements

Effective April 1, 2012, the Company entered into an employment agreement with Leland Gershell (the "Gershell Agreement") to serve as Chief Financial Officer. The base salary under the Gershell Agreement is $175,000 per annum, which shall increase to $325,000 per annum upon the Company consummating an equity sale of securities in excess of $20 million (the "Gershell Threshold"). The Gershell Agreement provides for at-will employment and can be terminated at any time by either party, provided, however, that if the Company terminates Dr. Gershell for any reason other than cause (as defined in the Gershell Agreement), then Dr. Gershell shall be entitled to six weeks of severance, which severance payment shall increase to six months if such termination occurs after the Gershell Threshold. In addition, Dr. Gershell is entitled to participate in any and all benefit plans, from time to time, in effect for the Company's employees, along with vacation, sick and holiday pay in accordance with its policies established and in effect from time to time.

Effective April 2, 2012, the Company entered into an employment agreement (the "Selzer Agreement") with Benjamin Selzer to serve as Chief Operating Officer. The Selzer Agreement replaces and terminates the employment agreement Mr. Selzer had previously entered into with Tonix Sub. The base salary under the Selzer Agreement is $175,000 per annum, which shall increase to $250,000 per annum effective October 7, 2012, and shall increase to $320,000 per annum upon the Company consummating an underwritten public offering of equity securities in excess of $10 million net to the Company (the "Selzer Threshold"). In the event that the Selzer Threshold occurs subsequent to October 7, 2012, Mr. Selzer shall be entitled to retroactive adjustment of the base salary to the $320,000 per annum rate, not to exceed an aggregate adjustment of $170,000. The Selzer Agreement has an initial term of two years, and renews thereafter for additional one year terms unless either party provides 90 days written notice prior to the termination of a term not to extend the Selzer Agreement.

NOTE 12 – SUBSEQUENT EVENTS

Effective October 5, 2012, the Company entered into an amendment to its employment agreement (the "Selzer Amendment") with Benjamin Selzer, which amended the employment agreement entered into with Mr. Selzer on April 2, 2012 (the "Selzer Agreement") to serve as Chief Operating Officer. Pursuant to the Selzer Amendment, the base salary under the Selzer Agreement remains $175,000 per annum through March 31, 2013, at which time it shall increase to $250,000 per annum, and shall increase to $320,000 per annum upon the Company consummating an underwritten public offering of equity securities in excess of $10 million net to the Company (the "Selzer Threshold").

Pursuant to the Selzer Agreement, the base salary was to increase to $250,000 effective October 7, 2012. In addition, pursuant to the Selzer Amendment, a retroactive adjustment of the base salary to the $320,000 per annum rate, not to exceed an aggregate adjustment of $170,000, that Mr. Selzer would have been entitled to upon the Selzer Threshold occurring after October 7, 2012 was eliminated.

On October 26, 2012, the Company elected to voluntarily terminate Benjamin Selzer as Chief Operating Officer, Secretary and Treasurer, effective immediately. In conjunction with the termination, 500,000 unvested options previously issued to Mr. Selzer were cancelled.

Between October and November 2012, the Company issued promissory notes in the amount of $320,000 (the "Notes") in exchange for $320,000 borrowed from six affiliated investors. The Notes bear no interest and were payable on demand.

On November 14, 2012, the Company sold to accredited investors for aggregate cash proceeds of $390,000, convertible debentures (the "Debentures") in the principal face amount of $390,000 and the exchange of the Notes for Debentures in the principal face amount of $320,000.

The Debentures mature on the earlier of (i) November 14, 2013 or (ii) the date of closing of a private placement of equity, equity equivalent, convertible debt or debt financing in which we receive gross proceeds, in one or more transactions, of at least $100,000 (a "Subsequent Financing"). The Debentures bear interest at 8% per annum and are convertible at the holder's option into either (i) a Subsequent Financing at a price equal to a 25% discount to the price of securities sold in the Subsequent Financing or (ii) shares of the Company's common stock at a conversion price per share equal to $1.00.

In December 2012, the Company issued an aggregate of 8,904,167 units ("Units") to certain accredited investors (the "Purchasers") for aggregate cash proceeds of $2,615,000, at a price per Unit of $0.40, and the exchange of $710,000 in previously issued convertible debentures (the "Prior Debentures") of the Company that were converted into Units at a price of $0.30 per Unit.

Each Unit consisted of one share of the Company's common stock, $0.001 par value (the "Common Stock"), a Class A Warrant to purchase one share of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase one share of Common Stock (the "Class B Warrants" and together with the Class A Warrants, the "Warrants").The Class A Warrants have an exercise price of $0.60 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The Class A Warrants may be exercised on a cashless basis under certain circumstances. The Class B Warrants have an exercise price of $0.40 per share of Common Stock and will be exercisable for a period of one year from the date of issuance.

Tonix Pharmaceuticals Holding Corp.

PROSPECTUS

Up to 17,808,334 shares of
Common Stock, par value $0.001 per share

_____ , 2013

Dealer Prospectus Delivery Obligation

Until [*], 2013, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that which is set forth in this prospectus. We are offering to sell shares of our common stock and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of these securities. Our business, financial condition, results of operation and prospects may have changed after the date of this prospectus.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth the estimated costs and expenses to be incurred in connection with the issuance and distribution of the securities registered under this Registration Statement. All amounts are estimates except the Securities and Exchange Commission registration fee. The total expenses for this offering, borne solely by the registrant, are estimated to be approximately $106,336, including:

SEC registration fee	$	1,336
Legal fees and expenses	$	60,000
Accounting fees and expenses	$	40,000
Miscellaneous expenses	$	5,000
Total	$	106,336

ITEM 14. 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 15. RECENT SALES OF UNREGISTERED SECURITIES.

During the past three years, the registrant has sold the following securities which were not registered under the Securities Act of 1933, as amended.

On October 7, 2011, we issued 22,666,667 shares of our common stock to the shareholders of Tonix Sub in exchange for 100% of the issued and outstanding shares of common stock of Tonix Sub. The shares were issued to accredited investors pursuant to Rule 506 of Regulation D or non-U.S. Persons pursuant to Rule 903 of Regulation S of the Securities Act of 1933, as amended.

On October 7, 2011, we issued 400,000 shares of our common stock to a placement agent in connection with an amendment to a placement agent agreement. The shares were issued to an accredited investor pursuant to Rule 506 of Regulation D or Section 4(2) of the Securities Act of 1933, as amended.

Between October and November 2011, we sold to certain investors (the "Purchasers") for aggregate cash proceeds of $1,575,000, secured convertible debentures (the "Debentures") in the principal face amount of $1,575,000 and the exchange of $500,000 in previously issued notes of Tonix Sub that were converted into Debentures in the principal face amount of $500,000 (the "2011 Financing"). The Debentures were sold to accredited investors pursuant to Rule 506 of Regulation D or non-U.S. Persons pursuant to Rule 903 of Regulation S of the Securities Act of 1933, as amended.

The Debentures mature on the earlier of (i) one year from the date of issuance or (ii) the date of closing of a private placement of equity, equity equivalent, convertible debt or debt financing in which we receive gross proceeds, in one or more transactions, of at least $3,425,000 (a "Subsequent Financing"). The Debentures bear interest at 8% per annum and are convertible at the holder's option into a Subsequent Financing. In the event that a Subsequent Financing has not occurred within 12 months from the date of issuance of the Debenture, the holder has the option to convert the Debenture into a number of shares of our common stock equal to 1% of our shares of common stock on a fully diluted basis for every $125,000 of Debentures (the "Conversion Shares").

In addition, upon conversion or repayment of the Debenture, the holder is entitled to receive, at the holder's option, either (i) a warrant (the "Warrant") to purchase such number of shares of common stock equal to the principal amount of the Debenture divided by the offering price in a Subsequent Financing (the "Warrant Shares") or (ii) shares of our common stock equal to 33% of the principal amount of the Debenture divided by the offering price in a Subsequent Financing (the "Incentive Shares").

In connection with the 2011 Financing, placement agents earned warrants to purchase shares of our common stock equal to 3% or 9% of the gross proceeds delivered by Purchasers introduced by such placement agents in the 2011 Financing divided by the purchase price per share in the Subsequent Financing (collectively, the "2011 Agent Warrants"). In the event that the Subsequent Financing has not occurred within 12 months from the date of issuance of the Debentures, the placement agents will receive, in lieu of the 2011 Agent Warrants, shares of common stock equal to 3% or 9% of the number of shares of our common stock such Purchasers introduced by such placement agent in the 2011 Financing are entitled to receive upon conversion of their Debentures.

Between January and March, 2012, we consummated the 2012 Financing pursuant to which we issued an aggregate of 264.7106 Units to certain investors for aggregate cash proceeds of $4,692,765 and the exchange of $1,925,000 in previously issued debentures that were converted into Units.

Each Unit had a purchase price of $25,000 per Unit and consisted of twenty five thousand (25,000) shares of our Common Stock, 25,000 Class A Warrants and 25,000 Class B Warrants.

The Class A Warrants have an exercise price of $1.25 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The Class B Warrants were not exercisable by the Purchasers and would be exercised automatically on their expiration date by cashless exercise or expire without exercise. Effective April 24, 2012, the Class B Warrants expired unexercised.

In connection with the Financing, we issued Dawson James 466,777 2012 Agent Warrants.

Between October and November 2012, we issued promissory notes in the amount of $320,000 (the "Notes") in exchange for $320,000 borrowed from six affiliated investors. The Notes bear no interest and were payable on demand.

On November 14, 2012, we sold to accredited investors for aggregate cash proceeds of $390,000, convertible debentures (the "Debentures") in the principal face amount of $390,000 and the exchange of the Notes for Debentures in the principal face amount of $320,000.

The Debentures mature on the earlier of (i) November 14, 2013 or (ii) the date of closing of a private placement of equity, equity equivalent, convertible debt or debt financing in which we receive gross proceeds, in one or more transactions, of at least $100,000 (a "Subsequent Financing"). The Debentures bear interest at 8% per annum and are convertible at the holder's option into either (i) a Subsequent Financing at a price equal to a 25% discount to the price of securities sold in the Subsequent Financing or (ii) shares of our common stock at a conversion price per share equal to $1.00.

In December 2012, the Company issued an aggregate of 8,904,167 units ("Units") to certain accredited investors (the "Purchasers") for aggregate cash proceeds of $2,615,000, at a price per Unit of $0.40, and the exchange of $710,000 in previously issued convertible debentures (the "Prior Debentures") of the Company that were converted into Units at a price of $0.30 per Unit.

Each Unit consisted of one share of the Company's common stock, $0.001 par value (the "Common Stock"), a Class A Warrant to purchase one share of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase one share of Common Stock (the "Class B Warrants" and together with the Class A Warrants, the "Warrants").The Class A Warrants have an exercise price of $0.60 per share of Common Stock and will be exercisable for a period of five years from the date of issuance. The Class A Warrants may be exercised on a cashless basis under certain circumstances. The Class B Warrants have an exercise price of $0.40 per share of Common Stock and will be exercisable for a period of one year from the date of issuance.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

The following exhibits are included as part of this Form S-1. References to "the Company" in this Exhibit List mean Tonix Pharmaceuticals Holding Corp., a Nevada corporation.

2.01	Share Exchange Agreement, dated as of October 7, 2011 by and among Tamandare Explorations Inc., David J. Moss, Tonix Pharmaceuticals, Inc. and the shareholders of Tonix Pharmaceuticals, Inc. filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
3.01	Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "Commission") on April 9, 2008 and incorporated herein by reference.
3.02	Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.
3.03	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.
5.01	Opinion of Sichenzia Ross Friedman Ference LLP.
10.01	Feasibility and Option Agreement, dated as of June 20, 2007, by and between Krele Pharmaceuticals, Inc. (now, Tonix Pharmaceuticals, Inc.) and Lipocine, Inc., filed as an exhibit to the amended Current Report on Form 8-K/A, filed with the Commission on April 3, 2012 and incorporated herein by reference. †
10.02	Consulting Agreement, dated as of June 4, 2010, by and between Krele Pharmaceuticals, Inc. (now, Tonix Pharmaceuticals, Inc.) and Lederman & Co., LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
10.03	Technology Transfer and Assignment Agreement, dated as of June 4, 2010, by and between Krele Pharmaceuticals, Inc. (now, Tonix Pharmaceuticals, Inc.) and Lederman & Co., LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
10.04	Lease Agreement, dated as of September 28, 2010, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the amended Current Report on Form 8-K/A, filed with the Commission on February 3, 2012 and incorporated herein by reference.

10.05 Amendment to Feasibility and Option Agreement, dated as of October 4, 2010, by and between Tonix Pharmaceuticals, Inc. and Lipocine, Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference. †

10.06 Engagement Agreement, dated as of October 6, 2010, by and between Tonix Pharmaceuticals, Inc. and Frost and Sullivan, filed as an exhibit to the amended Current Report on Form 8-K/A, filed with the Commission on April 3, 2012 and incorporated herein by reference.

10.07 Amendment to Consulting Agreement, dated as of December 9, 2010, by and between Tonix Pharmaceuticals, Inc. and Lederman & Co., LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.08 Employment Agreement, dated as of April 1, 2011, by and between Tonix Pharmaceuticals, Inc. and Rhonda Rosen, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.09 Employment Agreement, dated as of April 1, 2011, by and between Tonix Pharmaceuticals, Inc. and Benjamin A. Selzer, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.10 Employment Agreement, dated as of April 1, 2011, by and between Tonix Pharmaceuticals, Inc. and Susan Oliver (now, Susan Kerridge), filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.11 API Supply and Development Agreement, dated as of April 7, 2011, by and between Tonix Pharmaceuticals, Inc. and JFC Technologies, Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.12 Consulting Agreement, dated as of June 2, 2011, by and between Tonix Pharmaceuticals, Inc. and Pharmanet Canada, Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.13 Amendment to Employment Agreement, dated as of July 27, 2011, by and between Tonix Pharmaceuticals, Inc. and Rhonda Rosen, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.14 Amendment to Employment Agreement, dated as of July 27, 2011, by and between Tonix Pharmaceuticals, Inc. and Benjamin A. Selzer, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.15 Amendment to Employment Agreement, dated as of July 27, 2011, by and between Tonix Pharmaceuticals, Inc. and Susan Oliver (now, Susan Kerridge), filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.16 Financial Public Relations Agreement, dated as of August 1, 2011, by and between Tonix Pharmaceuticals, Inc. and Porter, LeVay & Rose, Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.17 Form of 8% Secured Convertible Debenture, issued October 7, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.18 Form of Subscription Agreement, dated October 7, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

10.19	Form of Pledge and Security Agreement, dated as of October 7, 2011, by and among Tamandare Explorations Inc., Tonix Pharmaceuticals, Inc., Krele LLC and the investors, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
10.20	Form of Subsidiary Guaranty, dated as of October 7, 2011, by and among Tonix Pharmaceuticals, Inc., Krele LLC and Sandor Capital Master Fund L.P., on behalf of the investors, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
10.21	Form of Subscription Agreement, dated January 20, 2012, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 23, 2012 and incorporated herein by reference.
10.22	Form of Class A Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 23, 2012 and incorporated herein by reference.
10.23	Form of Class B Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 23, 2012 and incorporated herein by reference.
10.24	Form of Registration Rights Agreement, dated January 20, 2012, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 23, 2012 and incorporated herein by reference.
10.25	Amendment to Consulting Agreement, dated as of March 30, 2012 but effective as of July 27, 2011, by and between Tonix Pharmaceuticals, Inc. and Lederman & Co., LLC, filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on March 30, 2012 and incorporated herein by reference.
10.26	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Leland Gershell, dated April 1, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on April 5, 2012 and incorporated herein by reference.
10.27	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Benjamin Selzer, dated April 2, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on April 5, 2012 and incorporated herein by reference.
10.28	Amendment to Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Benjamin Selzer, dated October 5, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 10, 2012 and incorporated herein by reference.
10.29	Form of Subscription Agreement, dated November 13, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on November 14, 2012 and incorporated herein by reference.
10.30	Form of Convertible Debenture, dated November 13, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on November 14, 2012 and incorporated herein by reference.
10.31	Form of Subscription Agreement, dated December 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 5, 2012 and incorporated herein by reference.
10.32	Form of Class A Warrant, dated December 4, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 5, 2012 and incorporated herein by reference.
10.33	Form of Class B Warrant, dated December 4, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 5, 2012 and incorporated herein by reference.
10.34	Form of Registration Rights Agreement, dated December 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 5, 2012 and incorporated herein by reference.

10.35	Form of Class A Warrant, dated December 21, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 27, 2012 and incorporated herein by reference.
10.36	Form of Class B Warrant, dated December 21, 2012, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 27, 2012 and incorporated herein by reference.
10.37	Form of Amendment No. 1 to the Purchase Agreement, Registration Rights Agreement and Escrow Agreement, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on December 27, 2012 and incorporated herein by reference.
21.01	List of Subsidiaries, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
23.01	Consent of EisnerAmper LLP
24.01	Power of Attorney (included on signature page to the registration statement).
99.01	Frost & Sullivan Fibromyalgia Market Study, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.
99.02	Lipocine Cyclobenzaprine Study Results, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 14, 2011 and incorporated herein by reference.

† Confidential treatment granted for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act. In accordance with Rule 24b-2, these confidential portions have been omitted from this exhibit and filed separately with the Commission.

ITEM 17. UNDERTAKINGS.

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 of 1933, as amended (the “Securities Act”);

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

(2) That, for the purpose of determining any liability under the Securities Act of 1933, 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) For determining liability of the undersigned registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned 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.

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

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

Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. 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 first use, 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 date of first use.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on this 25th day of January, 2013.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: January 25, 2013

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

Date: January 25, 2013

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

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ SETH LEDERMAN Seth Lederman	Chief Executive Officer (Principal Executive Officer) and Director	January 25, 2013
/s/ LELAND GERSHELL Leland Gershell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	January 25, 2013
/s/ STUART DAVIDSON Stuart Davidson	Director	January 25, 2013
/s/ PATRICK GRACE Patrick Grace	Director	January 25, 2013
/s/ DONALD W. LANDRY Donald W. Landry	Director	January 25, 2013
/s/ ERNEST MARIO Ernest Mario	Director	January 25, 2013
/s/ CHARLES MATHER IV Charles Mather IV	Director	January 25, 2013
/s/ JOHN RHODES John Rhodes	Director	January 25, 2013
/s/ SAMUEL SAKS Samuel Saks	Director	January 25, 2013

Exhibit 5.01

SICHENZIA ROSS FRIEDMAN FERENCE LLP
61 Broadway, 32nd Flr.
New York, NY 10006

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

January 25, 2013

VIA ELECTRONIC TRANSMISSION

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

RE:Tonix Pharmaceuticals Holding Corp.
Form S-1 Registration Statement (File No. 333-)

Ladies and Gentlemen:

We refer to the above-captioned registration statement on Form S-1 (the "Registration Statement") under the Securities Act of 1933, as amended (the "Act"), filed by Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Company"), with the Securities and Exchange Commission.

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

Based on our examination mentioned above, we are of the opinion that the 8,904,167 shares of common stock being sold pursuant to the Registration Statement are duly authorized, legally and validly issued, fully paid and non-assessable and the 8,904,167 shares of common stock, issuable upon exercise of warrants and being sold pursuant to the Registration Statement, will be, when issued in the manner described in the Registration Statement, duly authorized, legally and validly issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion as Exhibit 5.01 to the Registration Statement and to the reference to our firm under "Legal Matters" in the related Prospectus. In giving the foregoing consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Act, or the rules and regulations of the Securities and Exchange Commission.

/s/ Sichenzia Ross Friedman Ference LLP

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 30, 2012, in the Registration Statement (Form S-1) and related Prospectus of Tonix Pharmaceuticals Holding Corp. for the registration of up to 17,808,334 shares of its common stock.

/s/ EISNERAMPER LLP

New York, New York
January 25, 2013