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

FORM 10-K/A
(Amendment No. 1)

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

For the Fiscal Year Ended December 31, 2012

Commission File Number 000-54879

TONIX PHARMACEUTICALS HOLDING CORP.
(Exact name of registrant as specified in its charter)

Nevada		**26-1434750**
(State or other jurisdiction of incorporation or organization)		(IRS Employer Identification No.)
509 Madison Avenue, Suite 306 **New York, New York**	**10022**	**(212) 980-9155**
(Address of principal executive office)	(Zip Code)	(Registrant's telephone number, Including area code)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value $0.001 per share

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

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

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

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

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

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

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

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

There was no aggregate market value of the voting common stock held by non-affiliates as of June 30, 2011, as our common stock was not publicly traded at that time.

As of March 8, 2013, there were 43,182,599 shares of registrant's common stock outstanding.

EXPLANATORY NOTE

Tonix Pharmaceuticals Holding Corp. (the "Company") is filing this Amendment No. 1 on Form 10-K/A (the "Amended Filing") to the Company's Annual Report on Form 10-K for the year ended December 31, 2012 (the "Original Filing") filed with the Securities and Exchange Commission ("SEC") on March 11, 2013, in order to update the report from the Company's independent registered public accounting firm, the consolidated financial statements and the notes thereto (collectively, the "Financials") as was updated for the Company's registration statement on Form S-1 (SEC file 333-188547) (the "Registration Statement").

Subsequent to the Original Filing and prior to the Registration Statement, the Company effectuated a 1-for-20 reverse stock split of its outstanding common stock. As a result, all per share amounts and number of shares (other than authorized shares) in the Financials were retroactively restated in the Registration Statement to reflect the reverse stock split resulting in the transfer of $41,024 from common stock to additional paid in capital at December 31, 2012. As the Company intends to incorporate by reference the Financials in a registration statement on Form S-3, the Company is making this Amended Filing to facilitate the incorporation by reference of the Financials.

For the convenience of the reader, this Amended Filing sets forth the Original Filing in its entirety. However, this Amended Filing only amends the report from the Company's independent registered public accounting firm, the consolidated financial statements and the notes thereto, as disclosed above. No other information in the Original Filing is amended hereby. In addition, pursuant to the rules of the SEC, Item 15 of Part IV to the Original Filing has been amended to contain currently dated certifications from our Principal Executive Officer and Principal Financial Officer, as required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002. The certifications of our Principal Executive Officer and Principal Financial Officer are attached to this Amended Filing as Exhibits 31.01, 31.02 and 32.01.

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PART I

ITEM 1 - BUSINESS

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

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

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

This Annual Report on Form 10-K 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.

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, or 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 Pharmaceuticals, Inc., or 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 to 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 LLC, or 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 a Phase 2a trial of bedtime VLD CBP in fibromyalgia, or FM (the "Moldofsky Study"). 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 Inc., or 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, or 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 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 an Investigational New Drug application, or IND, filed in the US, 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 with the FDA 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.

As a result of these promising results, we are advancing TNX-102 SL for the management of FM. We held a Pre-Phase 3 meeting with the FDA in February 2013, at which we discussed 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 believe that positive results from two adequate, well-controlled safety and efficacy studies and the completion of long-term open-label safety exposure studies would support the approval of TNX-102 SL by the FDA for the management of FM. Under the IND, we plan to initiate a potential pivotal efficacy trial (Phase 2b) in FM in the third quarter of 2013.

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 third quarter of 2013. We then plan to conduct a clinical proof-of-concept trial of TNX-102 SL in PTSD in the fourth quarter of 2013.

CBP is the active pharmaceutical ingredient in our lead product candidate, TNX-102 SL. CBP has been approved by the FDA in the U.S. since 1977. We have utilized drug delivery technology to produce new formulations of CBP. In addition to CBP, TNX-102 SL contains excipients, which are well-characterized, are listed in the Inactive Ingredient Guide 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 promicellar gelatin capsule, or 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 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 current Good Manufacturing Practices, or cGMP, and the International Conference on Harmonisation, 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 may perform non-clinical development work on TNX-201 and possibly on TNX-301, but we do not expect to start clinical trials of either of these candidates until 2014 at the earliest.

The process to bring a new drug formulation from concept through testing to approval for a new indication by the FDA is a time-consuming, costly and 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 or more to complete, however, since we reformulate versions of approved drugs for new uses, we may need to devote less time to Phase 1 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 use either 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 this study 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 two to three months for data analysis. If the first pivotal study suggests the drug is safe and effective, then a second pivotal "confirmatory" Phase 3 study is conducted. The second pivotal study in FM typically takes 18 months to complete including data analysis. To meet the ICH long-term safety exposure requirement, we plan to conduct one or more long-term safety exposure studies of TNX-102 SL to support the chronic use of TNX-102 SL in FM. Assuming our clinical development of TNX-102 SL in FM meets with success, we would submit an NDA to the FDA seeking marketing approval of TNX-102 SL for the management of FM. We believe it would take approximately six months to prepare and file the NDA and another 14 months to obtain final 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 an approved drug to market for a different 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. Our use of this information 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, or CBP IR. 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 CBP IR, 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, or IR, 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 has discontinued the manufacture of Flexeril.

Despite the approved uses of CBP in treating muscle spasm, we believe current marketed formulations of CBP are limited for treating FM by slow and unpredictable absorption. Following the ingestion of CBP IR, it takes more than one hour for clinically-meaningful blood levels to be achieved. 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 provide rapid and consistent absorption of CBP, patients would be more likely to receive a drug exposure profile that is aligned with the intended period of exposure and 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 IR 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 third quarter of 2013, and into a Phase 2 trial in PTSD in the fourth quarter 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 in FM 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

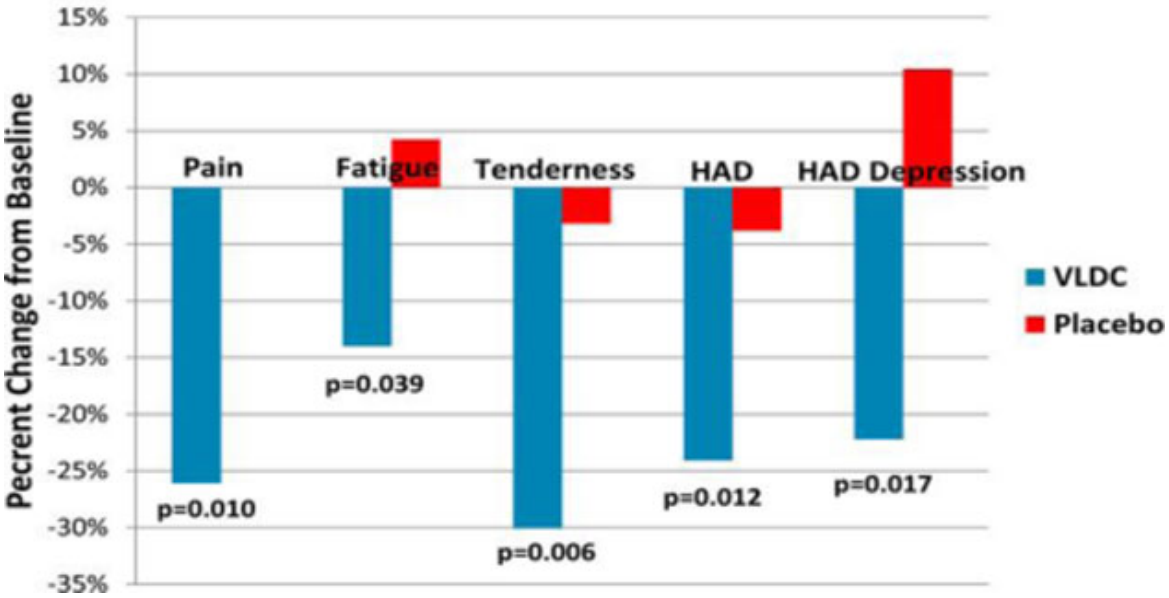
Phase 2a Data of VLD CBP in FM Patients

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 IR 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 capsules 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 CBP IR.

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 CBP IR tablets, i.e., without the sublingual absorption-enabling ingredients (2.4 mg) (Arm 2), an oral CBP IR 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 sublingual tablet formulation we expect to advance into further development. This study was conducted in Canada. 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, containing 2.8 mg CBP, 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 expect to engage a clinical research organization, or CRO, to conduct and manage this study under our direction. Subsequent to receiving FDA concurrence with our proposed protocol, including the methodology for primary endpoint analysis, the study will begin enrollment in the third quarter of 2013 and will be completed in the second half of 2014. We have contracted with a contract manufacturing organization, or CMO, to manufacture and perform stability testing on TNX-102 SL tablets for this Phase 2b study.

Prospective Multi-dose Pharmacokinetic Study

Since CBP will be used chronically in TNX-102 SL, we will study TNX-102 SL in comparison to CBP IR in a multiple-day dosing (once daily) study. Subjects will receive TNX-102 SL or CBP IR 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 IR tablet and our sublingual TNX-102 SL 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 CBP IR tablet as the reference product in our submission of a Section 505(b)(2) NDA for TNX-102 SL.

Prospective Study Comparing Safety and Tolerability of TNX-102 SL with CBP IR

We plan to conduct a small study designed to evaluate next morning drowsiness and other cognitive measures following the bedtime use of TNX-102 SL and the bedtime use of CBP IR. The goal of this study is to determine the potential benefit of TNX-102 SL compared with CBP IR on next morning drowsiness and on other cognitive functions.

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 evaluate the safety of TNX-102 SL for chronic use, we expect to conduct one or more long-term open-label safety exposure studies. The FDA agreed that the safety database needed to support a 505(b)(2) NDA submission for TNX-102 SL would contain a total exposure of at least 300 FM patients, with at least 100 patients receiving TNX-102 SL for six months and at least 50 patients for one year. We plan to conduct open-label extension studies in which patients may be eligible to enroll following their completion of our Phase 2b and Phase 3 safety and efficacy trials in FM.

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. We held a Pre-Phase 3 meeting with the FDA in February 2013, at which we discussed the nature and extent of the Phase 2b and Phase 3 clinical trials we need to conduct to 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 in 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. We held a pre-IND meeting 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 et al, Posttraumatic stress disorder, tenderness, and fibromyalgia syndrome: are they different entities? J. Psychosom. Res. 2006, 61(5):663-9), 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 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 VLD CBP improves FM symptoms, a disorder having significant overlap with PTSD;
- our clinical studies that VLD 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.

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 our 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 third quarter of 2013, and to conduct a Phase 2 trial in the fourth quarter 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 will be a randomized, double-blind, placebo-controlled, crossover study in 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, the PTSD Checklist, the Clinical Global Impression of Improvement, the Pittsburgh Sleep Quality Index and the Beck Depression Inventory. In addition, polysomnograms may 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 12 weeks' duration and of crossover design. We expect the results of the Phase 2 trial to determine dose levels 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 featured in the Phase 2 study, and as with the Phase 2 study, in addition to standardized measures of PTSD symptomatology and severity, polysomnograms may 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 suitable for chronic use 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 505(b)(2) NDA for TNX-102 SL for the management of PTSD.

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 for the treatment of depression in Europe.

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 in FM was driven by switching from off-label analgesics, and Cymbalta's and Savella's growth in FM was driven by switching from 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 CBP IR 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 or twice-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 February 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
61/754,281	"Isometheptene Isomer"	U.S.A.
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 FM study and/or PTSD Phase 2 POC study

All of our compounds are small molecules, synthesized using industry standard processes, and our drug products are formulated using commercially available 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 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 for a U.S. study is submitted to the FDA as part of the IND.

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

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are generally conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks. Phase 2 clinical trials, in particular Phase 2b trials, can be undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites.
- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, 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 recommendations 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 CBP IR 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. In February 2013, we held a Pre-Phase 3 meeting with the FDA to discuss the clinical and nonclinical requirements to register TNX-102 SL for the management of FM based on the 505(b)(2) regulatory pathway.

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 March 8, 2013, 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.

ITEM 1A - RISK FACTORS

RISKS RELATED TO OUR BUSINESS

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

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

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, 2012 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, 2013.

In their report dated March 8, 2013, 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 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 CROs and outside consultants, to conduct, supervise or monitor some or all aspects of preclinical testing or clinical trials involving our product candidates. We have less control over the timing and other aspects of these preclinical testing or clinical trials than if we performed the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our preclinical testing or clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in preclinical and clinical testing could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

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

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

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

- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated recruitment or retention rate of patients in clinical trials;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials;
- negative results of clinical trials; or
- 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. We met with the FDA in February 2013 to discuss the development of our lead product candidate, TNX-102 SL, in FM. We had held a pre-IND meeting in August 2011 to discuss initial plans for the development of TNX-102 gelcap in FM. Although these interactions with the FDA have encouraged our efforts to continue to develop TNX-102 SL for FM, there is no assurance that we will satisfy the FDA's requirements for approval in this indication. We have not come to any agreement with the FDA as to the nature and extent of studies we may be required to conduct in order to achieve approval of TNX-102 SL in PTSD. The timeline for filing and review of our NDAs 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 and we recently applied for key-man insurance for Leland Gershell, our Chief Financial Officer, and for Bruce Daugherty, our Senior Director of Drug Development. We are also highly dependent on our directors and scientific team. We are not aware of any present intention of any of our key personnel to leave our company or to retire. 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 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 Drug Enforcement Agency and corresponding state and foreign agencies to ensure strict compliance with cGMP requirements and other requirements under Federal drug laws, other government regulations and corresponding foreign standards. If we or our third-party manufacturers fail to comply with applicable regulations, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure by the government to grant marketing approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions.

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

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

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

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

Our product candidates are novel and still in development.

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

Successful development of our products is uncertain.

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

Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially 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 health care products to be approved in the future. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for any of our products.

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

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

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

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

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

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

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

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

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 continue to 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 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 provide compensation to investor relations firms and may 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:

- 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.

ITEM 1B – UNRESOLVED STAFF COMMENTS

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

ITEM 2 – 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 annual report.

ITEM 3 - LEGAL PROCEEDINGS

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

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Price Range of Common Stock

Our common stock is 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	$ 0.24

(1) As of March 8, 2013.

On March 8, 2013, the closing sale price of our common stock, as reported by Nasdaq, was $0.33 per share. On March 8, 2013, there were 186 holders of record of our common stock.

Dividend Policy

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

Recent Sales of Unregistered Securities

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 6 – SELECTED FINANCIAL DATA

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

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a number of forward-looking statements that reflect Management's current views with respect to future events and financial performance. You can identify these statements by forward-looking words such as "may" "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. Those statements include statements regarding the intent, belief or current expectations of us and members of its management team as well as the assumptions on which such statements are based. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risk and uncertainties, and that actual results may differ materially from those contemplated by such forward-looking statements.

Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission. Important factors known to us could cause actual results to differ materially from those in forward-looking statements. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes in the future operating results over time. We believe that its assumptions are based upon reasonable data derived from and known about our business and operations and the business and operations of the Company. No assurances are made that actual results of operations or the results of our future activities will not differ materially from its assumptions. Factors that could cause differences include, but are not limited to, expected market demand for the Company's services, fluctuations in pricing for materials, and competition.

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, 2012 Compared to Fiscal year Ended December 31, 2011

Revenues and Cost of Goods Sold. We had no revenues or cost of goods sold during the fiscal years ended December 31, 2012 and 2011.

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2012 were $2,583,308, an increase of $1,425,141, or 123%, from $1,158,167 for the fiscal year ended December 31, 2011. This increase is primarily due to increased development work related to TNX-102 SL, including formulation development, manufacturing, human and animal pharmacokinetic studies, and market research. In 2012, we incurred $552,953, $836,278 and $468,509 in manufacturing cost, clinical activities and cost, non-clinical activities cost, respectively, as compared to $0, $318,616 and $342,398 in 2011, respectively.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2012 were $4,078,102, an increase of $1,857,741, or 84%, from $2,220,361 incurred in the fiscal year ended December 31, 2011. This increase is primarily due to payroll related expenses and professional services.

Payroll related expenses increased to $1,820,877 in the current year from $731,285 for the fiscal year ended December 31, 2011, an increase of $1,089,592, or 149%. We incurred $865,157 in stock based compensation in connection with the vesting of stock options issued to board members, officers and employees in 2012 as compared to $159,596 in stock based compensation in 2011 relating to the acceleration of vesting in conjunction with our reverse merger in 2011 of restricted stock previously issued to our employees. The increase in cash payroll related costs of $384,032 was a result of the hiring of new employees, cash bonuses to employees, and severance payments to a former employee.

Professional services for the fiscal year ended December 31, 2012 totaled $1,444,455, an increase of $322,908, or 29%, over the $1,121,547 recognized for the fiscal year ended December 31, 2011. Of professional services, legal fees totaled $465,523 for the fiscal year ended December 31, 2012, an increase of $92,448, or 25%, from $373,075 incurred for the fiscal year ended December 31, 2011. Consulting fees totaled $734,520 for the fiscal year ended December 31, 2012, an increase of $435,376 or 146%, from $299,144 for the fiscal year ended December 31, 2011. The increase was primarily a result of $451,619 in public and investor relations costs in the fiscal year ended December 31, 2012 compared to $100,378 in 2011. Accounting fees incurred in the fiscal year ended December 31, 2012 amounted to $244,164, an increase of $1,161, or 0%, from $243,003 incurred in fiscal 2011.

Travel, meals and entertainment costs for the fiscal year ended December 31, 2012 were $108,248, an increase of $38,980, or 56%, from $69,268 incurred in the fiscal year ended December 31, 2011. Travel, meals and entertainment costs include travel related to medical and life sciences conferences, which accounted for the primary increase from 2011. Rent for the fiscal year ended December 31, 2012 totaled $116,732, a decrease of $11,496, or 9%, from $128,228 incurred in fiscal 2011, due primarily to the opening of new office space in New York in late 2011. Market research and analysis for the fiscal year ended December 31, 2012 was $229,546, an increase of $169,757 or 284% from $59,789 incurred in the fiscal year ended December 31, 2011. We continue to research and analyze the potential market for our products. Depreciation expense in fiscal 2012 totaled $14,329, an increase of $5,029, or 54%, over the expense of $9,300 incurred in fiscal 2011, as a result of the purchase of new office computers.

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.

Interest Expense. Interest expense for the fiscal year ended December 31, 2012 totaled $1,613,039, an increase of $1,521,454, or 1,661%, from $91,585 incurred during the fiscal year ended December 31, 2011. In the fiscal year ended December 31, 2012, our interest costs were comprised primarily of a beneficial conversion feature related to our issuance of convertible debentures in December 2012 charged to interest of $710,000, $196,166 of deferred financing costs related to the issuance of our secured convertible debentures in October 2011 and December 2012, allocated offering costs of $270,743 charged to interest as part of a financing, and the fair value of $426,152, 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. 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, 2012 was $9,449,600, compared to a net loss of $3,470,113 for the year ended December 31, 2011.

Liquidity and Capital Resources

As of December 31, 2012, we had working capital of $871,257, comprised primarily of cash of $1,785,390 and prepaid expenses and other assets of $224,659, which was offset by $825,837 of accounts payable and $309,800 of accrued expenses. For the year ended December 31, 2012, we used $5,712,864 of cash in operating activities. Cash provided by financing activities totaled $7,492,894 from the sale of shares of capital stock and warrants of $6,932,894, issuance of notes payable of $710,000 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, $1,501,000 through issuance of convertible debentures and $500,000 through the issuance of other notes payable. At December 31, 2012, we had cash of $1,785,390 compared to $41,123 at December 31, 2011. Our cash is held in bank deposit accounts. At December 31, 2012 and 2011, we had nil and $2,075,000 of secured convertible debentures outstanding, respectively.

Cash used in operations for the year ended December 31, 2012 and 2011 was $5,712,864 and $2,637,578, 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 year ended December 31, 2012 was $35,763 compared to cash provided by investing activities of $302 in the year ended December 31, 2011. In the year ended December 31, 2012 and 2011, we purchased office furniture and computer equipment of $35,673 and $2,764, respectively.

In their report dated March 8, 2013, our independent registered public accounting firm stated at December 31, 2012, 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 we exchanged 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.

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, Plumbline, Targent Pharmaceuticals, LLC, or Targent, 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-15). 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 on page F-15).

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.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The 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, 2012 and 2011, and 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, 2012 and the consolidated statements of stockholders' (deficiency) equity for each of the five years in the period ended December 31, 2012 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2012 and 2011, the consolidated results of its operations and its cash flows for the years then ended and for the period from June 7, 2007 (inception) through December 31, 2012 and consolidated changes in stockholders' (deficiency) equity for each of the five years in the period ended December 31, 2012 and for the period from June 7, 2007 (inception) 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 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 8, 2013, except for the third paragraph of Note 15, as to which the date is May 1, 2013 and the fourth through seventh paragraphs of Note 15, as to which the date is August 14, 2013

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2012 AND 2011

	2012	2011
ASSETS		
Current assets:		
Cash	$ 1,785,390	$ 41,123
Prepaid expenses and other	224,659	102,430
Total current assets	2,010,049	143,553
Furniture and equipment, net	46,894	25,550
Deferred financing costs, net	—	196,166
Restricted cash	60,267	60,177
Total assets	$ 2,117,210	$ 425,446
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable, including $6,809 and $27,483 to related parties as of December 31, 2012 and 2011, respectively	$ 825,837	$ 695,198
Accrued expenses	309,800	10,229
Accrued interest, including $3,155 and $5,006 to related parties as of December 31, 2012 and 2011, respectively	3,155	38,306
Liability to placement agent	—	31,543
Convertible debentures	—	150,000
Total current liabilities	1,138,792	925,276
Convertible debentures, including $265,000 to related parties	—	1,925,000
Deferred rent payable	19,710	29,083
Total liabilities	1,158,502	2,879,359
Commitments	—	—
Stockholders' equity (deficiency):		
Preferred stock, $0.001 par value; 5,000,000 and -0- shares authorized as of December 31, 2012 and 2011, respectively; none issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 and 75,000,000 shares authorized as of December 31, 2012 and 2011, respectively; 2,159,156 and 1,353,350 shares issued and outstanding as of December 31, 2012 and 2011, respectively	2,159	1,353
Additional paid in capital	16,800,829	3,939,414
Deficit accumulated during development stage	(15,844,280)	(6,394,680)
Total stockholders' equity (deficiency)	958,708	(2,453,913)
Total liabilities and stockholders' equity (deficiency)	$ 2,117,210	$ 425,446

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,		From June 7, 2007 (date of inception) Through December 31, 2012
	2012	2011	
COSTS AND EXPENSES:			
Research and development	$ 2,583,308	$ 1,158,167	$ 4,535,262
General and administrative	4,078,102	2,220,361	8,333,349
	6,661,410	3,378,528	12,868,611
Operating Loss	(6,661,410)	(3,378,528)	(12,868,611)
Gain on extinguishment of debt	—	—	7,908
Other income	1,875	—	1,875
Change in fair value of warrants liability	(1,177,026)		(1,177,026)
Interest and other financing costs, net	(1,613,039)	(91,585)	(1,808,426)
NET LOSS	$(9,449,600)	$(3,470,113)	$ (15,844,280)
Net loss per common share, basic and diluted	$ (5.58)	$ (3.24)	
Weighted average common shares outstanding, basic and diluted	1,693,436	1,071,295	

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIENCY)

	Preferred stock		Common stock		Additional	Deficit	Total
	Shares	Amount	Shares	Amount	Paid in Capital	Accumulated During Development Stage	
Shares issued to founders for intellectual property in June 2007 ($3.00 per share)	—	$ —	29,451	$ 29	$ 87,721	$ —	$ 87,750
Shares issued to bankers for services in June 2007 ($3.00 per share)	—	—	3,272	3	9,747	—	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	—	—	32,723	32	121,655	(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	—	—	32,723	32	194,218	(739,263)	(545,013)
Conversion of senior convertible notes into Preferred stock in June 2009 ($2.60 per share)	—	—	360,004	360	199,640	—	200,000
Shares issued to directors in July 2009 ($3.00 per share)	—	—	1,571	2	4,678	—	4,680
Capital contribution in June 2009	—	—	—	—	23,725	—	23,725
Net loss	—	—	—	—	—	(220,834)	(220,834)
Balance at December 31, 2009	—	$ —	394,298	$ 394	$ 422,261	$ (960,097)	$ (537,442)
Conversion of demand notes into capital stock in July 2010 ($4.60 per share)	—	$ —	104,729	$ 105	$ 479,895	$ —	$ 480,000
Conversion of accrued interest on demand notes into capital stock in July 2010 ($4.60 per share)	—	—	15,072	15	69,063	—	69,078
Issuance of capital stock in August to December 2010 ($4.60 per share)	—	—	292,804	293	1,341,708	—	1,342,001
Shares issued to founders for intellectual property in June 2010 ($4.52 per share)	—	—	65,447	66	295,434	—	295,500
Issuance of restricted shares to directors, employees and consultants in June to November 2010 ($4.76 per share)	—	—	29,386	29	139,853	—	139,882
Net loss	—	—	—	—	—	(1,964,470)	(1,964,470)
Balance at December 31, 2010	—	—	901,735	902	2,748,214	(2,924,567)	(175,451)
Vesting and issuance of capital stock in January to September 2011 ($4.60 per share)	—	—	133,530	133	611,867	—	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 agreement in October 2011 ($4.60 per share)	—	—	98,084	98	435,553	—	435,651

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIENCY) – (continued)

	Preferred stock		Common stock		Additional Paid in Capital	Deficit Accumulated During Development Stage	Total
	Shares	Amount	Shares	Amount			
Common stock issued in connection with the share exchange transaction in October 2011	—	—	200,000	200	(200)	—	—
Common stock issued in October 2011 in exchange for services rendered ($7.20 per share)	—	—	20,000	20	143,980	—	144,000
Net loss	—	—	—	—	—	(3,470,113)	(3,470,113)
Balance at December 31, 2011	—	$ —	1,353,350	$ 1,353	$ 3,939,414	$ (6,394,680)	$(2,453,913)
Issuance of common stock in January 2012 to holders of convertible debentures ($12.40 per share)	—	$ —	29,700	$ 30	$ 368,250	$ —	$ 368,280
Issuance of common stock in January and March 2012 ($12.40 per share) net of transaction expenses of $435,713	—	—	330,892	331	3,631,980	—	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
Issuance of common stock and warrants in December 2012 to holders of convertible debentures ($6.00) per share	—	—	118,335	118	709,882		710,000
Issuance of common stock and warrants in December 2012 ($8.00 per share) net of transaction expenses of $70,000	—	—	326,879	327	2,544,673	—	2,545,000
Beneficial conversion feature in connection with convertible debentures	—	—	—	—	710,000	—	710,000
Capital contribution of accrued interest	—	—	—	—	3,111	—	3,111
Stock based compensation	—	—	—	—	865,158	—	865,158
Net loss	—	—	—	—	—	(9,449,600)	(9,449,600)
Balance at December 31, 2012	—	$ —	2,159,156	$ 2,159	$16,800,829	$(15,844,280)	$ 958,708

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		From June 7, 2007 (date of inception) Through December 31,
	2012	2011	2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(9,449,600)	$(3,470,113)	$(15,844,280)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	14,329	9,300	31,641
Amortization and write off of deferred financing costs	196,166	53,377	249,543
Non cash interest, consisting of beneficial conversion feature in connection with convertible debentures	710,000	—	710,000
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	865,158	435,651	1,551,871
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	(122,229)	(79,117)	(224,659)
Accounts payable	130,639	377,453	825,837
Accrued interest	(32,040)	38,306	6,266
Accrued expenses	293,125	(12,304)	404,065
Deferred rent payable	(2,927)	9,909	26,156
Net cash used in operating activities	(5,712,864)	(2,637,538)	(10,203,703)
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	(90)	(90)	(60,267)
Net cash (used in) provided by investing activities	(35,763)	302	(138,802)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from demand notes	—	—	480,000
Proceeds from other notes payable	320,000	500,000	1,020,000
Proceeds, net of expenses of $24,000 as of December 31, 2011, from Convertible Debentures	390,000	1,501,000	1,891,000
Repayment of Convertible Debentures	(150,000)	—	(150,000)
Proceeds, net of expenses of $374,870 from sale of units consisting of common stock and warrants	6,932,894	—	6,932,894
Proceeds from the sale of capital stock	—	612,000	1,954,001
Net cash provided by financing activities	7,492,894	2,613,000	12,127,895
Net increase (decrease) in cash	1,744,267	(24,236)	1,785,390
Cash, beginning of the period	41,123	65,359	—
Cash, end of period	$ 1,785,390	$ 41,123	$ 1,785,390
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	$ 3,111	$ —	$ 26,836
Demand notes together with accrued interest converted into capital stock	$ —	$ —	$ 549,078
Common stock issued for deferred financing costs	$ —	$ 144,000	$ 144,000
Exchange of Notes Payable for Convertible Debenture	$ 320,000	$ —	$ 820,000
Warrants Liability reclassified to Stockholders' Equity	$ 3,938,946	$ —	$ 3,938,946
Exchange of Convertible Debenture for Units consisting of common stock and warrants	$ 2,635,000	$ —	$ 2,635,000

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2012 AND 2011

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 0.045 shares of Tamandare's common stock and each share of Tonix Pharmaceuticals, Inc.'s Series A and B preferred stock was exchanged for 0.24 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 1,133,334 shares of Tamandare's common stock and Tamandare's existing stockholders retained 200,000 shares of common stock. The 1,133,334 shares issued to the Tonix Pharmaceuticals, Inc. shareholders constituted approximately 85% of Tamandare's 1,333,334 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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

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, although the Company has approximately $900,000 of working capital at December 31, 2012, the Company will require additional financing to fund future operations as it is expected that cash to be used in operations will increase significantly over the next several years. 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.

As described in Note 15, on August 14, 2013, the Company received net proceeds of approximately $10,000,000 from the sale of units, consisting of common stock and warrants, in an underwritten public offering. 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.

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 assumptions used in the fair value of stock-based compensation and the fair value of other equity instruments.

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.

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES – (continued)

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, 2012 and 2011, 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 service period. Stock-based payments to nonemployees are recognized as an expense over the period of performance. Such payments are measured at fair value at the earlier of the date a performance commitment is reached or the date performance is completed. In addition, for awards that vest immediately and are non forfeitable the measurement date is the date the award is issued.

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, which was accounted for as a recapitalization of the Company (see Note 1), and to the 1-for-20 reverse stock split, which was effected on May 1, 2013 (see Note 15).

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 199,250 common shares. In January 2012, the debentures were exchanged for units or repaid (see Note 5). In computing diluted net loss per share for 2011, no effect has been given to such shares as their effect would be anti-dilutive.

During the year ended December 31, 2012, upon completion of the various financings, the Company issued warrants to purchase an aggregate of 1,259,934 shares of the Company's common stock (see Note 11). In addition, in May 2012, the Company issued to employees options to acquire an aggregate of 175,000 shares of the Company's common stock of which 150,000 were outstanding at December 31, 2012 (see Note 10). In computing diluted net loss per share for 2012, 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 December 31, 2012 and 2011 is summarized as follows:

	2012	2011
Office furniture and equipment	$ 78,535	$ 42,862
Less: accumulated depreciation	(31,641)	(17,312)
	$ 46,894	$ 25,550

Depreciation expense for the years ended December 31, 2012 and 2011 was $14,329 and $9,300, respectively.

NOTE 4 — RESTRICTED CASH

Restricted cash at December 31, 2012 and 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 (see Note 12).

NOTE 5 — 2011 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, 20,000 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 matured 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 bore 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 199,250 shares based on the outstanding shares of the Company common stock as of December 31, 2011.

Upon the January 2012 Financing (See Note 6), $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 13,750 Debenture Warrants exercisable at $20.00 per share with a fair value of $83,289 and 29,700 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

NOTE 5 — 2011 CONVERTIBLE DEBENTURES – (continued)

common stock such purchasers were entitled to receive upon conversion of their Convertible Debentures or an aggregate of approximately 4,400 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 1,538 warrants exercisable at $20.00 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 $12.40 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 Debentures were recorded as deferred financing costs: fair value of 20,000 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 was charged to interest expense in the statement of operations and the remaining balance of $196,166 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 one thousand two hundred and fifty (1,250) shares of the Company's common stock, a Class A Warrant to purchase one thousand two hundred and fifty (1,250) shares of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase up to one thousand two hundred and fifty (1,250) 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 $25.00 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

NOTE 6 — JANUARY AND MARCH 2012 FINANCING – (continued)

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 year ended December 31, 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	$12.40	$17.00
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	$25.00	$25.00

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 $15.00 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 $15.00 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 $34.60 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 23,339 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 $25.00 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.

NOTE 6 — JANUARY AND MARCH 2012 FINANCING – (continued)

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 — 2012 CONVERTIBLE DEBENTURES

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

The previously issued promissory notes were issued between October and November 2012 in the amount of $320,000 in exchange for $320,000 borrowed from six affiliated investors. The Notes bore no interest and were payable on demand.

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 $20.00.

On December 4, 2012, upon completion of a Subsequent Financing, the $710,000 of Debentures were converted into Units at a price of $6.00 per Unit representing a 25% discount to the price ($8.00) of securities sold (the "Financing"). Accordingly, the Company recorded a beneficial conversion feature in connection with the Debentures at the date of conversion of $710,000 as a charge to interest expense and a credit to additional paid in capital.

The beneficial conversion feature, which was contingent on a Subsequent Financing, was computed based on the excess of the number of shares received upon conversion based on the adjusted conversion price ($6.00) over the number of shares that would have been received based on the original conversion price ($20.00) multiplied by the stock price ($10.20) on November 14, 2012, the date the Debentures were issued, limited to the amount of proceeds allocated to the Debentures, or $710,000.

NOTE 8 — DECEMBER 2012 FINANCING

On December 4, 2012, the Company issued an aggregate of 6,404,167 units ("Units") to certain accredited investors for aggregate cash proceeds of $1,615,000, at a price per Unit of $0.40, and the exchange of $710,000 in previously issued convertible debentures of the Company that were converted into Units at a price of $0.30 per Unit. On December 21, 2012, the Company issued 2,500,000 Units to a single accredited investor for cash proceeds of $1,000,000, at a price per Unit of $0.40. In connection with the Financing, the Company paid an agent a cash payment of $70,000, which represented a 7% commission of the gross proceeds delivered by the investor in the financing.

Each Unit consisted of.05 share of the Company's common stock, $0.001 par value, a Class A Warrant to purchase.05 share of Common Stock (the "Class A Warrants"), and a Class B Warrant to purchase.05 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 $12.00 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 $8.00 per share of Common Stock and will be exercisable for a period of one year from the date of issuance.

NOTE 8 — DECEMBER 2012 FINANCING – (continued)

In connection with the Financing, the Company granted each Purchaser registration rights. The Company is obligated to use its 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 (as amended) from the date of termination of the Financing and must be declared effective no later than 120 days from the date of termination of the Financing. Moreover, the Company 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 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. On January 25, 2013, the Company filed the required registration statement.

NOTE 9 — 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 10 — SHARE BASED COMPENSATION

2010 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 (the "2010 Plan") whereby the Company reserved 228,232 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.

No options were granted under the 2010 Plan. Following is a summary of activity for the year ended December 31, 2011, with respect to restricted stock granted under the 2010 Plan:

Nonvested Restricted Stock	Number of Restricted Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2010	84,893	$ 4.60
Granted	18,436	$ 4.60
Vested prior to Share Exchange	(28,243)	$ 4.60
Vested pursuant to Share Exchange	(69,849)	$ 4.60
Forfeited	(5,237)	$ 4.60
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 the Share Exchange and remaining expense of $296,588 was recognized on October 7, 2011, the date of the Share Exchange, upon which all non vested restricted shares vested and the 2010 Plan ceased to exist.

NOTE 10 — SHARE BASED COMPENSATION – (continued)

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 200,000 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 200,000 shares of its common stock for future issuance under the terms of the 2012 Plan. On May 9, 2012, 175,000 options had been granted under the 2012 Plan (of which 25,000 were subsequently canceled and 150,000 are outstanding at December 31, 2012) with an exercise price of $30.00, a 10 year life and fair value of $23.50. 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 $865,158 was recognized for the year ended December 31, 2012.

The assumptions used in the valuation of stock options granted during the year ended December 31, 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 term of the options as of the grant date. The expected term of options is 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 December 31, 2012, the Company had approximately $2,742,000 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 10 — SHARE BASED COMPENSATION – (continued)

A summary of the stock options activity and related information for the 2012 Incentive Stock Option Plan for the year ended December 31, 2012 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	—			
Grants	175,000	$ 30.00	10.00	$ —
Exercised	—			
Forfeitures or expirations	(25,000)	30.00		
Outstanding at December 31, 2012	150,000	$ 30.00	9.35	$ —
Vested and expected to vest at December 31, 2012	150,000	$ 30.00	9.35	$ —
Exercisable at December 31, 2012	—	$ —	—	$ —

The aggregate intrinsic value in the preceding tables represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price of $11.00 as of December 31, 2012, which would have been received by the option holders had those option holders exercised their options as of that date.

NOTE 11 — 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 December 31, 2012:

Exercise Price	Number Outstanding	Expiration Date
$ 8.00	445,209	December 2013
12.00	445,209	December 2017
$ 20.00	15,288	January 2014 to January 2015
25.00	354,228	January 2017 to March 2019
	1,259,934	

On January 20, 2012, the Company issued an aggregate of 13,750 and 1,538 warrants to purchase the Company's common stock at an exercise price of $20.00 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 and March 2012 Financing, the Company issued to investors an aggregate of 215,148 and 115,741 warrants, respectively, to purchase the Company's common stock at an exercise price of $25.00 per share expiring five years from the date of issuance. In addition, the Company issued an aggregate of 11,765 and 11,574 warrants to purchase the Company's common stock at an exercise price of $25.00 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).

In connection with the December 2012 Financing, the Company issued to investors of 445,209 and 445,209 Class A warrants and Class B warrants, respectively to purchase the Company's common stock. The Class A warrant is exercisable at $12.00 per share expiring five years from the date of issuance and may be exercised on a cashless basis under certain circumstances. The Class B warrant is exercisable at $8.00 per share expiring one year from the date of issuance. These warrants are covered under a registration rights agreement (see Note 8).

NOTE 12 — 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,	
2013	$ 127,889
2014	131,513
2015	100,719
	$ 360,121

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, 2012 and 2011, rent expense was $116,732 and $128,228, respectively and as of December 31, 2012 and 2011 deferred rent payable was $26,156 and $29,083, respectively.

Consulting agreements

In June 2010, the Company entered into a two-year consulting agreement with L & L Technologies, LLC ("L&L"), 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 received $96,000 per annum and 51,310 shares of restricted common stock which were granted at the inception of the agreement. 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 25,655 restricted shares accelerated on October 7, 2011, the date of the Share Exchange. The consulting agreement expired in June 2012.

In June 2010, the Company entered into a two-year consulting agreement with Lederman & Co., LLC ("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 13,090 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 7,855 restricted shares accelerated on October 7, 2011, the date of the Share Exchange. 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.

During 2011 and 2012, the Company entered into contracts with various contract research organizations for which there are outstanding commitments aggregating approximately $650,000 at December 31, 2012 for future work to be performed.

NOTE 12 — COMMITMENTS – (continued)

Employment agreements

In October 2011, the position of Vice President of Strategy was eliminated and 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.

Effective April 1, 2012, the Company 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.

Effective April 1, 2012, the Company 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.

On October 26, 2012, the Company elected to voluntarily terminate Benjamin Selzer as Chief Operating Officer, Secretary and Treasurer, effective immediately and under the terms of his employment agreement, no severance was paid. In conjunction with the termination, 25,000 unvested options previously issued to Mr. Selzer were cancelled.

NOTE 13 — INCOME TAXES

There is no provision for federal or state income taxes for the years ended December 31, 2012 and 2011 since the Company has established a valuation allowance equal to the total deferred tax asset related to losses incurred during such periods.

NOTE 13 — INCOME TAXES – (continued)

Deferred tax assets and liabilities and related valuation allowance as of December 31, 2012 and 2011 are as follows:

	December 31,	
	2012	2011
Deferred tax assets:		
Organization costs	$ —	$ 733
Research and development credit carryforward[1]	6,188	6,188
Net operating loss carryforwards	5,207,759	2,329,829
Other	147,003	132,482
Total deferred tax assets	5,360,950	2,469,232
Valuation allowance	(5,360,950)	(2,469,232)
Net deferred tax assets	$ 0	$ 0

(1) The Company has incurred research and development ("R&D") expenses, a portion of which may qualify for tax credits. The Company has not conducted an R&D credit study to quantify the amount of credits and has not claimed an R&D credit on its federal tax returns filed except for $6,188 in 2007. The Company may conduct the study in future years and may establish the R&D credit carryforward for prior years. In such event, the net operating loss carryforward will be correspondingly reduced by the amount of the credit.

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, 2012 and 2011 was $2,891,718 and $1,380,642, respectively.

At December 31, 2012, the Company has available unused net operating loss carryforwards of approximately $12.3 million that expire from 2027 to 2032 for federal tax purposes and the same amount for New Jersey state tax purposes, which expire from 2014 to 2019. The Company also has approximately $11.6 million of net operating loss carryforwards for New York state and New York City purposes expiring from 2030 to 2032. At December 31, 2012, the Company has a research and development carryforward of $6,188 for federal tax purposes that expires in 2027. These net operating loss and research and development credit carryforwards may be subject to annual limitations in their use in accordance with IRC Section 382. Accordingly, the extent to which such carryforwards can be used to offset future taxable income may be limited.

The Company's federal and state tax returns remain open and subject to examination by the tax authorities for the tax years 2009 and after.

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,	
	2012	2011
Statutory federal income tax	(34.0)%	(34.0)%
State income tax, net of federal tax effect	(10.5)%	(5.9)%
Permanent difference	13.9%	5.0%
Increase in valuation allowance	30.6%	34.9%
Income tax provision	0%	0%

NOTE 14 — 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 the Company. We have entered into various transactions with several companies under their control, including L&L, Plumbline, Targent Pharmaceuticals, LLC and Lederman & Co (see Note 12 — Consulting Agreements). Total expenses paid under these agreements were $300,583 and $294,750 during the years ended December 31, 2012 and 2011, respectively.

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). In January 2012, the related party companies received interest on the convertible notes in the aggregate amount of $6,183.

Between October and November 2012, the Company issued promissory notes in the amount of $320,000 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 officers, members of the board of directors and their related parties for aggregate cash proceeds of $390,000, debentures (the "Debentures") in the principal face amount of $390,000 and the exchange of the promissory notes described above for Debentures in the principal face amount of $320,000. In December 2012, the Debentures were exchanged for the December 2012 Units at a conversion price of $6.00 per share. Interest expense on the Debentures for the year ended December 31, 2012 was $3,155 (See Note 8).

NOTE 15 — SUBSEQUENT EVENTS

On February 12, 2013, the Company's Board of Directors approved the Amended and Restated 2012 Incentive Stock Option Plan (the "Amended and Restated 2012 Plan"), subject to stockholder approval. The Amended and Restated 2012 Plan includes amendments which: 1) authorize 550,000 shares of the Company's common stock for issuance; and 2) prohibit the issuance of any options with terms or features that would cause the options to be nonqualified deferred compensation that fails to comply with, or be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended.

On February 12, 2013, 226,500 options were granted under the Amended and Restated 2012 Plan, with an exercise price of $10.20 and a 10 year life. The exercise price is equal to the volume weighted average price of the Company's common stock during the immediate prior 30 calendar day period. The options vest 1/3rd on February 12, 2014 and 1/36th on the 12th of each month thereafter for 24 months.

On May 1, 2013, the Company filed an amendment to its Articles of Incorporation and effected a 1-for-20 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value, whereby 43,182,599 outstanding shares of the Company's common stock were exchanged for 2,159,156 newly issued shares of the Company's common stock. Under the terms of the reverse stock split, fractional shares issuable to stockholders were rounded up to the nearest whole share, resulting in a reverse split slightly less than 1-for-20 in the aggregate. All per share amounts and number of shares (other than authorized shares) in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split resulting in the transfer of $41,024 from common stock to additional paid in capital at December 31, 2012.

On August 9, 2013, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Roth Capital Partners, LLC, as representative of the underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to offer to the public through the Underwriters an aggregate of 2,680,000 units (each a "Unit", and collectively, the "Units") at a public offering price of $4.25 per Unit in an underwritten public offering (the "August 2013 Financing"). Each Unit consisted of (i) one share of common stock and (ii) one Series A Warrant (the "Warrants") to purchase one share of common stock. The Warrants are exercisable at an exercise price of $4.25 per share, subject to anti-dilutive adjustment, and expire on the fifth anniversary of the date of issuance. The Warrants will be exercisable on a "cashless" basis in certain circumstances. Pursuant to the Underwriting Agreement, the Company also granted the Underwriters an option for a period of 45 days to purchase up to (i) 402,000 additional Units or (ii) 402,000 additional shares of common stock and/or additional Warrants to purchase up to 402,000 shares of common stock, on the same terms, to cover over-allotments, if any.

The August 2013 Financing closed on August 14, 2013. The Underwriters purchased the Units at an eight-percent discount to the public offering price, for an aggregate discount of approximately $911,200 (or $0.34 per unit). The Company received net cash proceeds of $10,038,013 after deducting underwriting discounts and commissions and offering expenses of $440,787. On August 14, 2013, the Underwriters exercised their over-allotment option by purchasing for $4,020 additional Warrants to purchase 402,000 shares of common stock.

The Underwriters received warrants to purchase up to an aggregate of 107,200 shares of common stock, or four percent of the total number of shares included in the Units, which warrants have an exercise price of $4.25.

The Units were sold pursuant to the Registration Statement declared effective by the Securities and Exchange Commission on August 8, 2013.

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

None.

ITEM 9A – CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

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

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

(b) Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(c) Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

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

ITEM 9B – OTHER INFORMATION

None.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The names of our executive officers and directors and their age, title, and biography as of March 8, 2013 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 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 since 2002, both of which are biopharmaceutical consulting and investing companies. Dr. Lederman has also been the Managing Member of Targent since 2000, and Managing Member of Plumbline since 2002. Targent was a founder of Targent Pharmaceuticals Inc. on which Board of Directors Dr. Lederman served from inception in 2001 until the sale of its assets to Spectrum Pharmaceuticals Inc. in 2006. Between January 2007 and November 2008, Dr. Lederman was a Managing Partner of Konanda Pharma Partners, LLC, a Director of Konanda Pharma Fund I, LP, and a Managing Partner of Konanda General Partner, LLC, which were related private growth equity fund entities. As well, between 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 organization. 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), 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 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 Defense 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, 2012. Based on the reviews and discussions referred to above, the Audit Committee has recommended to the Board of Directors that the financial statements referred to above be included in this Form 10-K.

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.

Section 16(a) Beneficial Owner Reporting Compliance

During the year ended December 31, 2012, we were governed under Section 15(d) of the Exchange Act. As a result, we were not required to file reports of executive officers and directors and persons who own more than 10% of a registered class of our equity securities pursuant to Section 16(a) of the Exchange Act.

Code of Ethics

We have adopted a Code of Ethics and Business Conduct that applies to all of our directors, officers and employees. A copy of the Code of Ethics is incorporated by reference as an exhibit.

ITEM 11 - EXECUTIVE COMPENSATION

Summary Compensation Table

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	-	-	279,750(2)	1,102,465
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 $40,000 and $96,000 of consulting fees paid to L&L, $239,750 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

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 8, 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	4,515,266 (18)	9.99%

* Denotes less than 1%

(1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of March 8, 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 March 8, 2013.

(3) Includes 3,692,558 shares of common stock and 2,090,000 shares of common stock underlying warrants owned by Lederman & Co, 649,138 shares of common stock and 486,666 shares of common stock underlying warrants owned by L&L, 1,179,424 shares of common stock and 165,000 shares of common stock underlying warrants owned by Targent, 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 and Targent, the Manager of L&L 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. Donald Landry, as a Member of L&L, 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, 649,138 shares of common stock and 486,666 shares of common stock underlying warrants owned by L&L, 1,179,424 shares of common stock and 165,000 shares of common stock underlying warrants owned by Targent, 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.

(18) Based upon a Schedule 13G filed with the SEC on February 19, 2013. 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.

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

Other than as disclosed below, during the last two fiscal years, 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, 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. 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, of which our Chairman, CEO and President Seth Lederman is the Manager. Pursuant to this agreement, L&L shall provide scientific and medical consulting services. In exchange for its services, Tonix Sub shall pay L&L compensation of $96,000 per annum, or such greater amount as the Board may designate from time to time, and issued to L&L 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.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees . The aggregate fees billed by our independent registered public accounting firm, for professional services rendered for the audit of our annual financial statements for the years ended December 31, 2012 and 2011, including review of our interim financial statements were $115,000 and $140,000, respectively.

Audit Related Fees .. We incurred fees to our independent registered public accounting firm of $32,730 and $80,333 for audit related fees during the fiscal years ended December 31, 2012 and 2011, respectively, which related to filings with the SEC related to our recent reverse merger.

Tax and Other Fees .. We incurred fees to our independent registered public accounting firm of $-0- for tax and fees during the fiscal years ended December 31, 2012 and 2011.

The Audit Committee pre-approves all auditing services and all permitted non-auditing services (including the fees and terms thereof) to be performed by our independent registered public accounting firm.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibits:

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.
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.
14.01	Code of Ethics and Business Conduct for Officers, Directors and Employees, 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.
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.
31.01	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.
101 INS	XBRL Instance Document*
101 SCH	XBRL Taxonomy Extension Schema Document*
101 CAL	XBRL Taxonomy Calculation Linkbase Document*
101 LAB	XBRL Taxonomy Labels Linkbase Document*
101 PRE	XBRL Taxonomy Presentation Linkbase Document*
101 DEF	XBRL Taxonomy Extension Definition Linkbase Document*

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† Confidential treatment is requested 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.

* Users of this data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these

sections.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: November 22, 2013

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

Date: November 22, 2013

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ SETH LEDERMAN Seth Lederman	Director	November 22, 2013
/s/ STUART DAVIDSON Stuart Davidson	Director	November 22, 2013
/s/ PATRICK GRACE Patrick Grace	Director	November 22, 2013
/s/ DONALD W. LANDRY Donald W. Landry	Director	November 22, 2013
/s/ ERNEST MARIO Ernest Mario	Director	November 22, 2013
/s/ CHARLES MATHER IV Charles Mather IV	Director	November 22, 2013
/s/ JOHN RHODES John Rhodes	Director	November 22, 2013
/s/ SAMUEL SAKS Samuel Saks	Director	November 22, 2013

EXHIBIT 31.01

CERTIFICATION

I, Seth Lederman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 22, 2013

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

EXHIBIT 31.02

CERTIFICATION

I, Leland Gershell, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 22, 2013

/s/ LELAND GERSHELL
Leland Gershell
Chief Financial Officer

Exhibit 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the amended Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K/A for the fiscal year ended December 31, 2012 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this amended Annual Report on Form 10-K/A fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: November 22, 2013

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

I, Leland Gershell, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the amended Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K/A for the fiscal year ended December 31, 2012 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this amended Annual Report on Form 10-K/A fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date:November 22, 2013

By: /s/ LELAND GERSHELL
Name: Leland Gershell
Title: *Chief Financial Officer*