

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

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

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

26-1434750
(I.R.S. Employer
Identification Number)

509 Madison Avenue, Suite 1608
New York, New York 10022
(212) 980-9155

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

Seth Lederman
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Approximate date of commencement of proposed sale to public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging Growth Company

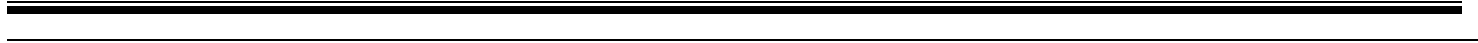
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)(2)	Amount of Registration Fee
Common Stock, par value \$0.001 per share (3)	\$ 5,000,001	
Series B Convertible Preferred Stock, par value \$0.001 per share (3)	\$ 5,000,000	
Common Stock issuable upon conversion of the Series B Convertible Preferred Stock	—	
Total	\$ 11,500,001 (4)	\$ 1,493

- (1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended. Includes shares to be sold upon exercise of the underwriter's option to purchase additional shares. See "Underwriting."
- (2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.
- (3) The proposed maximum aggregate offering price of the common stock proposed to be sold in the offering will be increased on a dollar-for-dollar basis on the proposed maximum offering price of any Series B Convertible Preferred Stock offered but not sold in the offering, and as such the proposed aggregate maximum offering price of the common stock and Series B Preferred Stock, if any, is \$10,000,001.
- (4) Includes the aggregate offering price of the additional shares that the underwriters have the option to purchase to cover over allotments, if any.

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



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

Preliminary Prospectus

Subject to Completion, dated January 21, 2020

3,225,807 shares of Common Stock

5,000 shares of Series B Convertible Preferred Stock

We are offering 3,225,807 shares of our common stock. The number of shares of common stock sold in this offering will increase to the extent that fewer, if any, shares of Series B Convertible Preferred Stock are purchased in this offering.

We are also offering to those purchasers, if any, whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing shares of common stock, to purchase shares of Series B Convertible Preferred Stock, or the Series B Preferred Shares, with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the shares of common stock. Assuming an offering price of \$1.55 (the closing price of our common stock as reported on The Nasdaq Global Market on January 17, 2020), the Series B Preferred Shares will be convertible into an aggregate of 3,225,807 shares of our common stock. The Series B Preferred Shares do not generally have any voting rights unless and until converted into shares of common stock.

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Series B Preferred Shares are sold in this offering and whether and to what extent holders of Series B Preferred Shares convert their shares to common stock. To the extent we sell any Series B Preferred Shares in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred Shares.

Our common stock is listed on The Nasdaq Global Market under the symbol "TNXP." On January 17, 2020, the last reported sale price of our common stock as reported on The Nasdaq Global Market was \$1.55 per share. The public offering price per share of common stock will be determined between us and the underwriter based on the closing price of our common stock prior to pricing and market conditions at the time of pricing, and may be at a discount to the current market price.

There is no established trading market for the Series B Preferred Shares, and we do not expect an active trading market to develop. We do not intend to list the Series B Preferred Shares on any securities exchange or other trading market. Without an active trading market, the liquidity of the Series B Preferred Shares will be limited.

This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading "Where You Can Find More Information."

Investing in our securities involves risks that are described in the "Risk Factors" section beginning on page 5 of this prospectus.

	Per Share of Common Stock	Per Share of Series B Preferred Stock	Total
Public offering price	\$	\$	\$
Underwriting discount(1)	\$		\$
Proceeds, before expenses, to us	\$		\$

(1) We refer you to the "Underwriting" section of this prospectus for additional information regarding total underwriter compensation.

We have granted a 45-day option to the underwriter to purchase additional shares of common stock in amounts up to 15% of the common stock offered and common stock issuable upon conversion of the Series B Preferred Shares solely to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the shares against payment therefor on or about _____, 2020.

Sole Book-Running Manager

A.G.P.

The date of this prospectus is _____, 2020

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You should rely only on the information contained or incorporated by reference in this prospectus and any related free writing prospectus that we may provide to you in connection with this offering. We have not, and the underwriter has not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriter is not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing or incorporated by reference in this prospectus is accurate only as of the date on the front cover of this prospectus or the date of the applicable document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: neither we nor the underwriter has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus and any such free writing prospectus outside of the United States.

In this prospectus, we rely on and refer to information and statistics regarding our industry. We obtained this statistical, market and other industry data and forecasts from publicly available information.

SUMMARY

This summary highlights information contained in other parts of this prospectus and in the documents incorporated by reference. Because it is a summary, it does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this prospectus and the documents incorporated by reference in their entirety including “Risk Factors” included in this prospectus and incorporated by reference and “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and the financial statements and the notes to those financial statements included elsewhere in this prospectus.

When used herein, unless the context requires otherwise, references to the “Company,” “we,” “our” and “us” refer to Tonix Pharmaceuticals Holding Corp., a Nevada corporation.

All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Company Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Our most advanced drug development programs are focused on delivering safe and effective long-term treatments for posttraumatic stress disorder, or PTSD, and fibromyalgia, or FM. PTSD is a psychiatric condition characterized by the reliving of trauma through intrusive and vivid recollections, nightmares and flashbacks. FM is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. Both PTSD and FM are associated with chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden.

We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in their respective fields.

Our lead product candidate, TNX-102 SL, is a proprietary sublingual tablet formulation of cyclobenzaprine, or CBP, designed for bedtime administration. TNX-102 SL is an investigational new drug that has not been approved for any indication. TNX-102 SL is in development for PTSD, FM, agitation in Alzheimer’s disease (AAD) and alcohol use disorder (AUD). TNX-102 SL has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD, and Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of AAD.

TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD. The FDA has conditionally accepted the proposed trade name Tonmya[®] for TNX-102 SL for the treatment of PTSD. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling patients. RECOVERY is a double-blind, placebo-controlled study evaluating daily bedtime administration of TNX-102 SL in individuals with PTSD resulting from trauma that occurred within nine years of screening. Results from an interim analysis for a potential sample size adjustment are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. We are also developing TNX-102 SL as a bedtime treatment for the management of FM. We have started enrollment in the Phase 3 RELIEF trial (F304) in FM and expects to report results from an interim analysis in the second half of 2020. The AAD program is Phase 2 ready. The AUD program is in the pre-Investigational New Drug (IND) application stage, and we intend to submit an IND application in first quarter of 2020. Upon receiving clearance by the FDA of an IND application, the AUD program is expected to be Phase 2 proof-of-concept ready. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression, as well as for PTSD and neurocognitive dysfunction associated with corticosteroid use. The first efficacy study will be performed outside of the U.S. and is expected to be IND-ready in 2020. Our programs for treating addiction conditions also include TNX-1300 (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA.

Finally, our preclinical pipeline includes TNX-1600 (a triple reuptake inhibitor) which is a third product candidate being developed for PTSD, as a daytime treatment. TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (recombinant trefoil factor 2 or rTFF2), a biologic being developed to treat gastric and pancreatic cancers are also in the preclinical stages. Each of TNX-801 (live virus vaccine for percutaneous [scarification] administration), which is being developed to potentially prevent smallpox, and TNX-701 (undisclosed small molecule), which is being developed to prevent radiation effects, are being advanced as medical countermeasures to improve biodefense.

Disease and Market Overview

Our product candidates address disorders that are not well served by currently available therapies or have no approved treatment which represent large potential commercial market opportunities. Background information on the disorders and related commercial markets that may be addressed by our lead product candidates is set forth below.

Posttraumatic Stress Disorder

PTSD is a chronic condition that may develop after a person is exposed to one or more traumatic events, such as warfare, sexual assault, serious injury, or threat of imminent death. The core symptom clusters of PTSD are avoidance, emotional numbing, hyperarousal, and intrusion, where the triggering traumatic event is commonly re-experienced by the individual through intrusive, recurrent recollections, flashbacks, and nightmares. People with PTSD suffer significant impairment in their daily functioning, including occupational activities and social relations, and are at elevated risk for impulsive violent behaviors toward others and themselves, including suicide. Of those who experience significant trauma, approximately 20% of women and 8% of men develop PTSD. An estimated 12 million adults annually in the U.S. suffer from PTSD. According to the U.S. Department of Veterans Affairs, the prevalence rate of PTSD in the military population is higher than that among civilians. As of 2012, there were approximately 638,000 veterans receiving treatment for PTSD in the Veterans Health Administration, or VHA. Based on March 2015 VHA data, more than 19% of military veterans involved in recent conflicts in Iraq and Afghanistan were seen at VHA facilities for potential or provisional PTSD.

Many patients fail to adequately respond to the medications approved for PTSD and approved medications show little evidence of a treatment effect in men, lack evidence of efficacy in those for whom the traumatic event was combat-related, and carry suicidality warnings. Sleep disturbances are central features of PTSD and are predictive of disease severity, depression, substance abuse, and suicidal ideation, yet are resistant to the approved medications and present a difficult therapeutic challenge. Current PTSD treatments include off-label use of anxiolytics, sedative-hypnotics, and antipsychotics, many of which lack reliable evidence of efficacy, and many have significant safety liabilities and dependence risk.

Fibromyalgia

FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. The peak incidence of FM occurs between 20-50 years of age, and 80-90% of diagnosed patients are female. FM may have a substantial negative impact on social and occupational function, including disrupted relationships with family and friends, social isolation, reduced activities of daily living and leisure activities, avoidance of physical activity, and loss of career or inability to advance in career or education. According to the American Chronic Pain Association, an estimated six to twelve million adults in the U.S. have FM.

According to a report by Frost and Sullivan that we commissioned, despite the availability of approved medications, the majority of patients fail therapy due to either insufficient efficacy or poor tolerability, or both. Prescription pain and sleep medications are frequently prescribed off-label for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic benefit, and many of these medications carry significant safety risks and risk of dependence. For example, approximately 30% of patients diagnosed with FM take chronic opioids, despite the lack of evidence for their effectiveness and the risk of addiction and toxicity, including overdose.

Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider all of the information in this prospectus and in the documents incorporated by reference prior to investing in our securities. These risks are discussed more fully in the section titled "Risk Factors" herein. These risks and uncertainties include, but are not limited to, the following:

- We have incurred significant losses and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- Our profitability depends on our ability to develop and commercialize our current and future product candidates.
- Our ability to continue as a going concern will require us to obtain additional financing to fund our current operations, which may be unavailable on acceptable terms, or at all.
- Because our product candidates are in the clinical stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.
- We may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities.
- It may be difficult for us to predict the time and cost of product development. Unforeseen problems may prevent further development or approval of our product candidates.
- We will require substantial additional financing to achieve our goals, and a failure to obtain necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.
- We face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and other intellectual property rights do not adequately protect our product candidates, others could compete against us (including directly), which could materially harm our business, results of operations and financial condition.

Corporate Information

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp. Our principal executive offices are located at 509 Madison Avenue, Suite 1608, New York, New York 10022, and our telephone number is (212) 980-9155. Our website addresses are www.tonixpharma.com, www.tonix.com, and www.krele.com. The information on our websites is not part of this prospectus. We have included our website addresses as a factual reference and do not intend them to be active links to our websites.

THE OFFERING

Common stock offered by us	3,225,807 shares.
Series B Convertible Preferred Stock offered by us	5,000 shares of Series B Preferred Shares are also being offered to those purchasers, if any, whose purchase of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering. Each Series B Preferred Share will convert into 645.1613 shares of our common stock (subject to adjustment as provided in the related certificate of designation) at any time at the option of the holder. The Series B Preferred Shares generally do not have any voting rights and will not be certificated. See “Description of Securities — Preferred Stock — Series B Convertible Preferred Stock” for a discussion of the terms of the Series B Preferred Shares.
Common stock outstanding immediately prior to this offering (as of January 17, 2020)	8,533,082 shares.
Common stock to be outstanding immediately following this offering	14,984,695 shares, assuming 6,451,613 shares of common stock are sold and no Series B Preferred Shares are sold in this offering. Excludes shares of common stock that may be issued upon exercise of the underwriter’s over-allotment option. If the underwriter’s option to purchase additional securities is exercised in full, the total number of shares of our common stock outstanding immediately following the option exercise will be 15,952,437 shares.
Underwriter’s option to purchase additional securities	We have granted a 45-day option to the underwriter to purchase additional shares of common stock, in amounts up to 15% of the common stock offered and common stock issuable upon conversion of the Series B Preferred Shares to cover over-allotments, if any.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately \$9.0 million, or approximately \$10.4 million if the underwriters exercise their option to purchase additional securities in full, based upon an assumed public offering price of \$1.55 per share of common stock (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020), and \$1,000 per Series B Preferred Share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, to fund Phase 3 development for our lead product candidate, TNX-102 SL, to advance the development of our other product candidates, including in-licensed product candidates, to repurchase shares of our common stock pursuant to a stock buyback program, and for working capital and other general corporate purposes. See “Use of Proceeds.”
Dividend Policy	We have never declared or paid any cash dividends on our common stock, and currently do not plan to declare cash dividends on shares of our common stock in the foreseeable future. We expect that we will retain all of our available funds and future earnings, if any, for use in the operation and expansion of our business. See the section titled “Dividend Policy” for a more complete description of our dividend policy.
Risk Factors	An investment in our securities involves a high degree of risk. You should read the “Risk Factors” section of this prospectus beginning on page 5 for a discussion of factors to consider carefully before deciding to invest in this offering.
The Nasdaq Global Market symbol	TNXP There is no established public trading market for the Series B Preferred Shares, and we do not expect an active trading market to develop. We do not intend to list the Series B Preferred Shares on any securities exchange or other trading market. Without an active trading market, the liquidity of the Series B Preferred Shares will be limited.

The number of shares of common stock to be outstanding after this offering is based on 8,533,082 shares of common stock outstanding at January 17, 2020 and excludes the following:

- shares of common stock that may be issued upon conversion of the Series B Preferred Shares to be issued in this offering;
- 109,036 shares of common stock issuable upon exercise of stock options outstanding at a weighted-average exercise price of \$199.57 per share;
- 5,138,158 shares of common stock issuable upon exercise of warrants outstanding at a weighted-average exercise price of \$5.82 per share;
- 55,825 shares of common stock reserved and available for issuance under our equity compensation plan; and
- 11,041 shares of common stock reserved and available for issuance under our employee stock purchase plan.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- no issuance or exercise of stock options or warrants on or after January 17, 2020; and
- no exercise by the underwriter of its option to purchase up to an additional shares of common stock in this offering.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included or incorporated by reference in this prospectus. The risks described below are material risks currently known, expected or reasonably foreseeable by us. However, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. If any of these risks actually materialize, our business, prospects, financial condition, and results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

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

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

- our ability to obtain additional funding to develop our product candidates;
- delays in the commencement, enrollment and timing of clinical studies;
- the success of our clinical studies through all phases of clinical development, including studies of our most advanced product candidate, TNX-102 SL for PTSD and FM;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidate TNX-102 SL for PTSD and FM or any of our other product candidates in the United States and foreign jurisdictions;
- potential nonclinical toxicity and/or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of REMS, or cause an approved drug to be taken off the market;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; and
- potential product liability claims;

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

RISKS RELATED TO PRODUCT DEVELOPMENT, REGULATORY APPROVAL, MANUFACTURING AND COMMERCIALIZATION

Our product candidates are novel and still in development.

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

Further, we and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical studies, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have one product candidate, TNX-102 SL, in Phase 3 development for the treatment of PTSD and FM. The success of our business currently depends on the successful development, approval and commercialization of TNX-102 SL. 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.

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

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

We are largely dependent on the success of our clinical-stage product candidate, TNX-102 SL for PTSD and FM, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

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 for PTSD and FM may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or foreign regulatory authorities because our clinical studies fail to demonstrate to their satisfaction that this product candidate is safe and effective or a clinical program may be put on hold due to unexpected safety issues. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical study process. Any failure or delay in completing clinical studies or obtaining regulatory approvals for TNX-102 SL for PTSD and FM in a timely manner would have a material adverse impact on our business and our stock price.

Successful development of our products is uncertain.

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

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

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

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

The results from early clinical studies are not necessarily predictive of results obtained in later clinical studies. Accordingly, even if we obtain positive results from early clinical studies, we may not be able to confirm the results in future clinical studies. For example, in the Phase 3 AFFIRM trial for a product candidate for FM, we were not able to replicate the results we had in the Phase 2b BESTFIT trial using TNX-102 SL 2.8 mg dose in September 2016, and as a result temporarily discontinued this program but subsequently resumed the clinical development using the 5.6 mg dose in March 2019. In addition, clinical studies may not demonstrate sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates.

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

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

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and nonclinical testing and clinical studies, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of biopharmaceutical products. The FDA regulates small molecule chemical entities as drugs, subject to an NDA under the FDCA. The FDA applies the same standards for biologics, requiring an IND application, followed by a Biologic License Application, or BLA, prior to licensure. Other products, such as vaccines, are also regulated under the Public Health Service Act. The FDA has conflated the standards for approval of NDAs and BLAs so that they require the same types of information on safety, effectiveness, and CMCs. 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 the FDA's approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

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

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

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

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

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

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

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

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

We initiated a Phase 3 study in civilian and military-related PTSD in the first quarter of 2019, and we initiated a Phase 3 study in FM in the fourth quarter of 2019. As both of these studies are intended to provide efficacy and safety evidence to support marketing approval by the FDA, they are considered a pivotal, confirmatory or registration studies. The conduct of pivotal clinical studies and the submission of a successful NDA is a complicated process. Although members of our management team have extensive industry experience, including in the development and clinical testing of drug candidates and the commercialization of drug, we have conducted only two pivotal clinical studies before (the HONOR study in PTSD participants and the AFFIRM study in FM participants), have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete this planned clinical study in a way that leads to NDA submission and approval of TNX-102 SL and other product candidates we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical studies would prevent or delay commercialization of TNX-102 SL and other product candidates we are developing.

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

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

If TNX-102 SL or any of our other product candidates cause SAEs or undesirable side effects or suffer from quality control issues:

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

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

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

Our current plans for filing NDAs for our lead product candidate, TNX-102 SL, include efforts to minimize the data we will be required to generate in order to obtain marketing approval and therefore reduce the development time. We intend to file Section 505(b)(2) NDAs for TNX-102 SL for PTSD, FM, and for other proposed indications, that might, if accepted by the FDA, save time and expense in the development and testing of TNX-102 SL.

The TNX-102 SL for PTSD and FM are our most advanced development programs which are in the Phase 3 stages. For the PTSD program, following the results of the Phase 2 AtEase Study, we held an End-of-Phase 2/Pre-Phase 3 meeting with the FDA in August 2016 to discuss the study results and the design of the first Phase 3 study (HONOR). We had our initial Cross-disciplinary Breakthrough Therapy meeting in March 2017 with the FDA to discuss ways to expedite the development and NDA submission of TNX-102 SL after the FDA granted the Breakthrough Therapy designation (BTD) status for TNX-102 SL for the treatment of PTSD in December 2016. Following the interim analysis (IA) of the Phase 3 HONOR Study, we met with the FDA in October 2018 to seek agreement on the design of the currently ongoing Phase 3 study (RECOVERY). In December 2018, the FDA issued an Intent-to-Rescind letter for BTD status for TNX-102 SL for the treatment of PTSD because the IA results of the HONOR study did not meet the criteria for the BTD. In March 2019, the FDA rescinded the BTD, but subsequently withdrew the BTD rescission in April 2019 and granted a meeting in August 2019 to discuss the continuation of BTD. The BTD for TNX-102 SL for PTSD remains in effect and the FDA's intent-to-rescind BTD for TNX-102 SL for PTSD also remains in effect. FDA agreed to consider the additional data and information presented at the August 2019 meeting. The FDA's decision whether to maintain BTD for TNX-102 SL for PTSD is pending. The FDA will inform us of the BTD decision but no timeframe was given.

For the FM program, we held an End-of-Phase 2 meeting with the FDA in February 2013 to discuss the development and NDA submissions of TNX-102 SL for the management of FM. In late 2014, following the results of the Phase 2 BESTFIT study, we corresponded with the FDA to discuss the results and the development of the first Phase 3 study (AFFIRM) and our registration program. In September 2016, following the results of the AFFIRM study, we temporarily discontinued the FM program to focus on the development of the PTSD program. In March 2019, we resumed the clinical development of the FM program and held a Clinical Guidance Meeting with the FDA to discuss the study design of the currently ongoing Phase 3 study (RELIEF).

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

We may not be able to realize a shortened development timeline for TNX-102 SL for PTSD or FM (or other proposed indications under TNX-102 SL), and the FDA may not approve our NDA based on their review of the submitted data. If cyclobenzaprine-containing products are withdrawn from the market by the FDA for any safety reason, we may not be able to reference such products to support a 505(b)(2) NDA for 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 lead product candidate.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure approval of our product candidates by the FDA. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for TNX-102 SL for the treatment of agitation in Alzheimer's disease and may seek fast track designation for other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional procedures of the FDA. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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 monitoring and reporting obligations by the FDA, 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 the FDA's approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical studies.

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

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

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

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

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

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.

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

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

RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS; COMPETITION

We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2018 with respect to our ability to continue as a going concern.

In their report dated March 18, 2019, 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, 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

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

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

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

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

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

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

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

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

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current drug product candidate, TNX-102 SL, can extend up to three and one-half years.

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

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

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same or similar 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.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY RIGHTS AND REGULATORY EXCLUSIVITY

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

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

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

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

In addition, the 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 innovations specifically exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

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

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

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

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

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

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

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

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

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

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

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

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

GENERAL COMPANY-RELATED RISKS

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

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical study;
- reaching agreement on acceptable terms with prospective CROs and study sites;
- developing a stable formulation of a product candidate;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site.

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

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

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

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

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

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

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical studies. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities which could harm our competitive position.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

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

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

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

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

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

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

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

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

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

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

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

We have no manufacturing facilities, and we have no experience in the clinical or commercial-scale manufacture of drugs or in designing drug manufacturing processes. We intend to rely on CMOs to manufacture some or all of our product candidates in clinical studies and our products that reach commercialization. Completion of our clinical studies and commercialization of our product candidates requires the manufacture of a sufficient supply of our product candidates. We have contracted with outside sources to manufacture our development compounds, including 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 studies or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for nonclinical, preclinical, clinical, and commercial purposes. Although we are in discussions with other manufacturers we have identified as potential alternative CMOs of 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 nonclinical testing and clinical studies. Some of these materials are available from only one supplier or vendor. Any interruption in or termination of service by such sole source suppliers could result in a delay or interruption in manufacturing until we locate an alternative source of supply. Any delay or interruption in manufacturing operations (or failure to locate a suitable replacement for such suppliers) could materially adversely affect our business, prospects, or results of operations. We do not have any short-term or long-term manufacturing agreements with many of these manufacturers. If we fail to contract for manufacturing on acceptable terms or if third-party manufacturers do not perform as we expect, our development programs could be materially adversely affected. This may result in delays in filing for and receiving FDA approval for one or more of our products. Any such delays could cause our prospects to suffer significantly.

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

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

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

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

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

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

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

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

Our product candidates may face competition sooner than expected.

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

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

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

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

Our strategy with our product candidates is to control, directly or through contracted third parties, all or most aspects of the product development process, including marketing, sales and distribution. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidates that receive regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts.

To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution channels, or enter into arrangements with third parties, we will experience delays in product sales and incur increased costs.

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

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

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

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other health care laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers, and their respective business associates;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Coverage and adequate reimbursement may not be available for our current or any future drug candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any drug candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future drug candidates that we develop.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the PPACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. The Budget Resolution is not a law, however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The PPACA remains subject to legislative efforts to repeal, modify or delay the implementation of the law. Recent efforts to repeal, modify or delay implementation of the ACA have resulted in some level of success. If the PPACA is repealed or further modified, or if implementation of certain aspects of the PPACA are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the PPACA on us at this time. Due to the substantial regulatory changes that will need to be implemented by CMS and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

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

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

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

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

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

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

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

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

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

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

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

We carry insurance for most categories of risk that our business may encounter, however, we may not have adequate levels of coverage. We currently maintain general liability, clinical study, property, workers' compensation, products liability and directors' and officers' insurance, along with an umbrella policy, which collectively costs approximately \$1,000,000 per annum. We cannot provide any assurances that we will be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

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

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

In 2016, the 21st Century Cures Act, or the Act, was signed into law to support ongoing biomedical innovation. One part of the Act, Section 3086, is aimed at “Encouraging Treatments for Agents that Present a National Security Threat.” The Act created a new priority review voucher program for “material threat medical countermeasures.” The Act defines such countermeasures as drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat or to treat harm from a condition that may be caused by administering a drug or biological product against such an agent. The Department of Homeland Security has identified 13 such threats, including anthrax, smallpox, Ebola/Marburg, tularemia, and botulism. A priority review voucher can be applied to any other product; it shortens the FDA review timeline for a new application from 10-12 months to 6 months. The recipient of a priority review voucher may transfer it.

We intend to seek a priority review voucher for TNX-801 as a material threat medical countermeasure. However, the structure of voucher programs limits the number of medical countermeasures eligible for a priority review voucher. Further, the medical countermeasure must qualify for priority review in order to be eligible and may not include any commercially approved indication. Moreover, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed. As such, the market for the TNX-801 will be limited if we are successful in obtaining a priority review voucher, assuming that the Priority Review Voucher Program is in effect at the time TNX-801 is available for licensing.

There may not be market interest in TNX-801.

The government is the only market for most medical countermeasures. This is because unlike other drugs and vaccines, these products are not sold to doctors, hospitals, or pharmacies. The BioShield Special Reserve Fund, or SRF, has been the sole medical countermeasures market for the last decade; a 10 year advance appropriation of \$5.6 billion was available to procure successful candidate medical countermeasures. The SRF expired in 2013 and all funds were used to add 12 new medical countermeasures to the national stockpile. Congress reauthorized the SRF but adequate funding has not yet followed; the SRF is now appropriated annually and has not kept pace with the need for purchasing products ready for stockpiling. Further, similar products are being developed or marketed by other companies, such as Emergent BioSolutions and Bavarian Nordic. Emergent BioSolutions markets ACAM-2000, which is approved as a vaccine for the prevention of smallpox. Bavarian Nordic developed Modified Virus Ankara, or MVA, which received approval from the FDA in 2019 as a vaccine for the prevention of smallpox and monkeypox and is marketed under the tradename JYNNEOS[®]. As such, even if TNX-801 were to receive FDA licensure, the commercial success of TNX-801 remains uncertain.

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

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

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

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

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

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

RISKS RELATED TO OUR SECURITIES AND THE OFFERING

If we sell securities in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any of our securities sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders could experience additional dilution and, as a result, our stock price may decline.

We will have broad discretion in how we use the net proceeds of this offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section entitled “Use of Proceeds.” We intend to use the net proceeds from this offering to fund clinical development of our product candidates, to repurchase shares of our common stock pursuant to a stock buyback program, and for working capital and other general corporate purposes. As a result, investors will be relying upon management’s judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the NASDAQ Global Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock may impair investors’ ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

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

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

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

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

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

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, 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.

There is no active, public market for the Series B Preferred Shares being offered in this offering.

There is no established public trading market for the Series B Preferred Shares being offered in this offering. We do not intend to apply to list the Series B Preferred Shares on a securities exchange. Without an active trading market, the liquidity of the Series B Preferred Shares will be limited.

The Series B Preferred Shares have limited voting rights.

Holders of Series B Preferred Shares generally will not have the right to vote on any matters brought before the Company's stockholders, either as a separate class or on an as-converted-to-common stock-basis, and will not have the right to vote on members of the Company's board of directors. The holders of Series B Preferred Shares will have the right to vote only on certain material changes in the terms of the Series B Preferred Stock and on other matters as may be required by Nevada law.

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

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

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

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

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

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our bylaws designate the Eighth Judicial District Court of Clark County, Nevada as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our bylaws require that, to the fullest extent permitted by law, and unless the Company consents in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada, will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following:

- any derivative action or proceeding brought in the name or right of the Company or on its behalf,
- any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders,
- any action arising or asserting a claim arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of our articles of incorporation or bylaws, or
- any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws.

Because the applicability of the exclusive forum provision is limited to the extent permitted by law, we believe that the exclusive forum provision would not apply to suits brought to enforce any duty or liability created by the Securities Exchange Act of 1934, as amended (Exchange Act), or any other claim for which the federal courts have exclusive jurisdiction, and that federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act of 1933, as amended (Securities Act). We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Nevada law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus contain, and our officers and representatives may from time to time make, “forward-looking statements,” which include information relating to future events, future financial performance, financial projections, strategies, expectations, competitive environment and regulation. Words such as “may,” “should,” “could,” “would,” “predicts,” “potential,” “continue,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” “goal,” “seek,” “project,” “strategy,” “likely,” and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements are neither historical facts, nor should they be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of operating losses and expectation that we will continue to incur operating losses for the foreseeable future;
- our current and future capital requirements to support our development efforts and our ability to satisfy our capital needs;
- our ability to obtain FDA approval for any of our product candidates;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executives and medical and science personnel;
- the timing and progress of clinical development of our product candidates;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein and in the documents incorporated by reference herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see “Risk Factors” for additional risks which could adversely impact our business and financial performance.

Moreover, new risks regularly emerge and it is not possible for our management to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, do not protect any forward-looking statements that we make in connection with this offering. All forward-looking statements included in this prospectus and in the documents incorporated by reference in this prospectus are based on information available to us on the date of this prospectus or the date of the applicable document incorporated by reference. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout this prospectus and in the documents incorporated by reference in this prospectus. We qualify all of our forward-looking statements by these cautionary statements.

IN ADDITION TO THE ABOVE RISKS, BUSINESSES ARE OFTEN SUBJECT TO RISKS NOT FORESEEN OR FULLY APPRECIATED BY OUR MANAGEMENT. IN REVIEWING THIS PROSPECTUS AND THE DOCUMENTS INCORPORATED BY REFERENCE IN THIS PROSPECTUS, POTENTIAL INVESTORS SHOULD KEEP IN MIND THAT THERE MAY BE OTHER POSSIBLE RISKS THAT COULD BE IMPORTANT.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$9.0 million from the sale of the shares offered in this offering, or approximately \$10.4 million if the underwriter exercises its over-allotment option in full, based on an assumed public offering price of \$1.55 per share of common stock (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020) and \$1,000 per Series B Preferred Share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred Shares are sold in the offering, each \$0.10 increase (decrease) in the assumed public offering price of \$1.55 per share of common stock (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020) would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$0.6 million.

We currently expect to use the net proceeds from this offering to fund Phase 3 development for our lead product candidate, TNX-102 SL, to advance the development of our other product candidates, including in-licensed product candidates, to repurchase shares of our common stock pursuant to a stock buyback program, and for working capital and other general corporate purposes.

Although we may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, or for other strategic investments or opportunities, we have no current understandings, agreements or commitments to do so.

We may also increase or decrease the total number of shares of common stock and Series B Preferred Shares we are offering. Assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred Shares are sold in the offering, an increase (decrease) of 1,000,000 in the total number of shares of common stock we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$1.4 million, assuming the public offering price stays the same. Assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred Shares are sold in the offering, an increase of 1,000,000 in the total number of shares of common stock we are offering, together with a \$0.10 increase in the assumed public offering price of \$1.55 per share of our common stock (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020), would increase the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$2.1 million. Assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred Shares are sold in the offering, a decrease of 1,000,000 in the total number of shares of common stock we are offering, together with a \$0.10 decrease in the assumed public offering price of \$1.55 per share of our common stock (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020), would decrease the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$1.9 million. We do not expect that a change in the offering price or the total number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Price Range of Common Stock

Our common stock is listed on The NASDAQ Global Market under the symbol “TNXP”. The last reported closing price of our common stock on The Nasdaq Global Market was on January 17, 2020 was \$1.55 per share.

Holders

As of January 17, 2020, we had 105 registered holders of record of our common stock. A substantially greater number of holders of our common stock are “street name” or beneficial holders, whose shares of record are held through banks, brokers, other financial institutions and registered clearing agencies.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our Board of Directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and other factors that our Board of Directors may deem relevant. In addition, the terms of our revolving credit facility place certain limitations on the amount of cash dividends we can pay, even if no amounts are currently outstanding.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2019:

- on an actual basis; and
- on an as-adjusted basis to reflect the issuance and sale by us of (i) 6,451,613 shares of our common stock in this offering at the assumed public offering price of \$1.55 per share (the last reported sale price of our common stock on The Nasdaq Capital Global Market on January 17, 2020), and (ii) no Series B Preferred Shares, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale.

You should read this information together with the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes contained in this prospectus.

	As of September 30, 2019	
	Actual	As Adjusted
	(unaudited)	
	(in thousands, except per share data)	
Cash and cash equivalents	\$ 10,024	\$ 19,014
Other long-term liabilities	\$ 51	\$ 51
Stockholders’ equity (deficit):		
Common stock, \$0.001 par value; 15,000,000 authorized, 1,575,246 issued and outstanding (actual); 8,026,859 issued and outstanding, as adjusted	2	8
Preferred stock, \$0.001 par value; 5,000,000 authorized, zero issued and outstanding (actual), 5,000,000 authorized, zero issued and outstanding, as adjusted	—	—
Additional paid-in capital	218,258	227,242
Accumulated deficit	(208,363)	(208,363)
Accumulated other comprehensive loss	(42)	(42)
Total shareholders’ equity	9,855	18,845
Total capitalization	\$ 9,906	\$ 18,896

* On January 16, 2020, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 15,000,000 to 150,000,000.

To the extent we sell any Series B Preferred Shares in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred Shares.

Assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred shares are sold in this offering, each \$0.10 increase (or decrease) in the assumed public offering price of \$1.55 per share (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020) would increase (or decrease) the amount of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization on an as adjusted basis by approximately \$0.6 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred shares are sold in this offering, each increase (decrease) of 1,000,000 shares offered by us would increase (decrease) cash and cash equivalents, total stockholders' equity and total capitalization on an as adjusted basis by approximately \$1.4 million, assuming the assumed public offering price of \$1.55 per share (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020) remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred shares are sold in this offering, each 1,000,000 share increase in the number of shares offered by us together with a concomitant \$0.10 increase in the assumed public offering price of \$1.55 per share (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020) would increase each of cash and cash equivalents and total stockholders' equity by approximately \$2.1 million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. Conversely, assuming 6,451,613 shares of common stock are sold in the offering and no Series B Preferred shares are sold in this offering, each 1,000,000 share decrease in the number of shares offered by us together with a concomitant \$0.10 decrease in the assumed public offering price of \$1.55 per share (the last reported sale price of our common stock on The Nasdaq Global Market on January 17, 2020) would decrease each of cash and cash equivalents and total stockholders' equity by approximately \$1.9 million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of our common stock to be outstanding upon completion of this offering is based on 1,575,246 shares of our common stock outstanding as of September 30, 2019 and excludes:

- shares of common stock that may be issued upon conversion of the Series B Preferred Shares to be issued in this offering;
- 6,956,258 shares of common stock issued in connection with the November 2019 Financing (as defined below), including shares of common stock issued upon (i) the conversion of Series A Convertible Preferred Stock; and (ii) the cashless exercise of the common warrants;
- 109,036 shares of common stock issuable upon exercise of stock options outstanding at a weighted-average exercise price of \$199.57 per share;
- 496,486 shares of common stock issuable upon exercise of warrants outstanding at a weighted-average exercise price of \$42.14 per share;
- 55,825 shares of common stock reserved and available for issuance under our equity compensation plan; and
- 12,619 shares of common stock reserved and available for issuance under our employee stock purchase plan.

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

The following management's discussion and analysis should be read in conjunction with our historical financial statements and the related notes included in this prospectus. Management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, including those we detail under "Risk Factors," "Forward-Looking Statements" and elsewhere in this prospectus, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this prospectus. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this prospectus.

Business Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Our most advanced drug development programs are focused on delivering safe and effective long-term treatments for posttraumatic stress disorder, or PTSD, and FM. PTSD is a psychiatric condition characterized by the reliving of trauma through intrusive and vivid recollections, nightmares and flashbacks. FM is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. Both PTSD and FM are associated with chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden.

We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in their respective fields.

Our lead product candidate, TNX-102 SL, is a proprietary sublingual tablet formulation of cyclobenzaprine, or CBP, designed for bedtime administration. TNX-102 SL is an investigational new drug that has not been approved for any indication. TNX-102 SL is in development for PTSD, FM, agitation in Alzheimer's disease (AAD) and alcohol use disorder (AUD). TNX-102 SL has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD and Fast Track designation by the FDA for the treatment of AAD.

TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD. The FDA has conditionally accepted the proposed trade name Tonmya[®] for TNX-102 SL for the treatment of PTSD. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling patients. RECOVERY is a double-blind, placebo-controlled study evaluating daily bedtime administration of TNX-102 SL in individuals with PTSD resulting from trauma that occurred within nine years of screening. Results from an interim analysis for a potential sample size adjustment are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. We are also developing TNX-102 SL as a bedtime treatment for the management of FM. We have started enrollment in the Phase 3 RELIEF trial (F304) in FM and expects to report results from an interim analysis in the second half of 2020. The AAD program is Phase 2 ready. The AUD program is in the pre-Investigational New Drug (IND) application stage, and we intend to submit an IND application in first quarter of 2020. Upon receiving the FDA's clearance of an IND application, the AUD program is expected to be Phase 2 proof-of-concept ready. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression, as well as for PTSD and neurocognitive dysfunction associated with corticosteroid use. The first efficacy study will be performed outside of the U.S. and is expected to be IND-ready in 2020. Our programs for treating addiction conditions also include TNX-1300 (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has been granted Breakthrough Therapy designation by the U.S. FDA.

Finally, our preclinical pipeline includes TNX-1600 (a triple reuptake inhibitor) which is a third product candidate being developed for PTSD, as a daytime treatment. TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers are also in the preclinical stages. Each of TNX-801 (live virus vaccine for percutaneous [scarification] administration), which is being developed to potentially prevent smallpox, and TNX-701 (undisclosed small molecule), which is being developed to potentially prevent radiation effects are being advanced as medical countermeasures to improve biodefense.

Current Operating Trends

Our current research and development efforts are focused on developing TNX-102 SL for the treatment of PTSD and for the treatment of FM, AAD and AUD, but we also expend effort on our other pipeline programs, primarily related to TNX-1300, TNX-601, TNX-701, TNX-801, TNX-1500 and TNX-1700. Our research and development expenses consist of manufacturing work and the cost of drug ingredients used in such work, fees paid to consultants for work related to clinical trial design and regulatory activities, 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 and safety of our study 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 expect that all of our research and development expenses in the near-term 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, contracts or other agreements. 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 participant recruitment, lack of funding 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.

Three Months Ended September 30, 2019 Compared to Three Months Ended September 30, 2018

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2019 were \$5.1 million, an increase of \$1.8 million, or 55%, from \$3.3 million for the three months ended September 30, 2018. This increase is predominately due to timing of development activities related to the PTSD RECOVERY study, which resulted in a \$1.0 million increase in clinical expenses in 2019, ramp up of work related to TNX-601, resulting in a \$0.3 million increase in manufacturing expenses in 2019, and an increase in non-clinical of \$0.3 million in 2019 related to our development pipeline.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2019 were \$2.8 million, an increase of \$0.5 million, or 22%, from \$2.3 million incurred in the three months ended September 30, 2018. The increase is primarily due to an increase in legal fees of \$0.3 million due to increased patent prosecution costs and an increase in insurance expenses of \$0.2 million due to higher premiums in 2019.

Net Loss. As a result of the foregoing, the net loss for the three months ended September 30, 2019 was \$7.8 million, compared to a net loss of \$5.5 million for the three months ended September 30, 2018.

Nine Months Ended September 30, 2019 Compared to Nine Months Ended September 30, 2018

Research and Development Expenses. Research and development expenses were \$12.5 million for both the nine months ended September 30, 2019 and the nine months ended September 30, 2018. Costs incurred in 2019 are predominately due to the PTSD RECOVERY study while costs incurred in 2018 are predominately due to the PTSD HONOR study.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2019 were \$7.6 million, an increase of \$1.4 million, or 23%, from \$6.2 million incurred in the nine months ended September 30, 2018. The increase is primarily due to an increase in legal fees of \$0.4 million due to increased patent prosecution costs, an increase in investor and public relations expenses of \$0.2 million due to increased investor meetings and an increase in insurance expenses of \$0.5 million due to higher premiums in 2019.

Net Loss. As a result of the foregoing, the net loss for the nine months ended September 30, 2019 was \$19.9 million, compared to a net loss of \$18.5 million for the nine months ended September 30, 2018.

License Agreements with Columbia University

On September 16, 2019, we entered into an exclusive License Agreement (the “September License Agreement”) with the Trustees of Columbia University in the City of New York (“Columbia”) pursuant to which Columbia granted to us an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the “TFF2 Technology”) related to a recombinant Trefoil Family Factor 2 (TFF2), and to develop and commercialize products thereunder (each, a “TFF2 Product”). Pursuant to the terms of the September License Agreement, Columbia has reserved for itself the right to practice the TFF2 Technology for academic research and educational purposes.

We have agreed to pay a five-digit license fee to Columbia as consideration for entering into the September License Agreement. The Company is obligated to use Commercially Reasonable Efforts, as defined in the September License Agreement, to develop and commercialize the TFF2 Product, and to achieve specified developmental milestones.

We have agreed to pay Columbia single-digit royalties on net sales of (i) TFF2 Products sold by us or a sublicensee and (ii) any other products that involve material or technical information related to the TFF2 Product and transferred to us pursuant to the License Agreement (“Other Products”) or sold by us or a sublicensee. Royalties on each particular TFF2 Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the September License Agreement, and (ii) a specified period of time after the first commercial sale of a TFF2 Product in the country in question. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until a specified period of time after the first commercial sale of such particular Other Product in such country. Royalties payable on net sales of the TFF2 Product and Other Products may be reduced by 50% of the royalties payable by us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us under the September License Agreement, provided that the royalty payable on a TFF2 Product or Other Product may not be reduced by more than 50%.

We are also obligated to make contingent milestone payments to Columbia totaling \$4.1 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a TFF2 Product. In addition, we shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to us by a sublicensee. As of September 30, 2019, no milestone payments have been accrued or paid in relation to this agreement.

On May 20, 2019, we entered into an exclusive License Agreement (the “May License Agreement”) with Columbia pursuant to which Columbia, for itself and on behalf of the University of Kentucky and the University of Michigan (collectively, the “Institutions”) granted to us an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the “Technology”) related to a double-mutant cocaine esterase, and to develop and commercialize products thereunder (each, a “Product”). Pursuant to the terms of the May License Agreement, Columbia has reserved for itself and the Institutions the right to practice the Technology for academic research and educational purposes.

We have agreed to pay a six-digit license fee to Columbia as consideration for entering into the May License Agreement. We are obligated to use Commercially Reasonable Efforts, as defined in the May License Agreement, to develop and commercialize the Product, and to achieve specified developmental milestones. The first 50% of the license fee was paid by June 30, 2019, while the remaining 50% license fee has been accrued for within accrued expenses and other current liabilities as of September 30, 2019.

We have agreed to pay Columbia single-digit royalties on net sales of (i) Products sold by us or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to us pursuant to the May License Agreement (“Other Products”) sold by us or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the May License Agreement, (ii) a specified period of time after the first commercial sale of a Product in the country in question, or (iii) expiration of any market exclusivity period granted by a regulatory agency. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until the later of (i) a specified period of time after the first commercial sale of such particular Other Product in such country or (ii) expiration of any market exclusivity period granted by a regulatory agency. Royalties payable on net sales of the Product and Other Products may be reduced by 50% of the royalties payable by us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us under the May License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

We are also obligated to make contingent milestone payments to Columbia totaling \$3 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a Product. In addition, we shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to us by a sublicensee. As of September 30, 2019, no milestone payments have been accrued or paid in relation to this agreement.

Liquidity and Capital Resources

As of September 30, 2019, we had working capital of \$9.2 million, comprised primarily of cash and cash equivalents of \$10.0 million and prepaid expenses and other of \$1.5 million, which was offset by \$1.1 million of accounts payable, \$0.9 million of accrued expenses and other current liabilities and \$0.4 million of current operating lease liabilities. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our ongoing Phase 3 RECOVERY study of TNX-102 SL for the treatment of PTSD. For the nine months ended September 30, 2019 and 2018, we used approximately \$20.0 million and \$17.2 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The increase in cash used in operations is due primarily to close-out costs for the Phase 3 HONOR study and costs related to the current Phase 3 RECOVERY study. Additionally, our annual insurance premiums also increased over the prior year, the payments for which all occur in the first quarter. For the nine months ended September 30, 2019, net proceeds from financing activities were from the sale of our common stock of approximately \$4.9 million and approximately \$70,000 through the exercise of warrants into common stock. In the comparable 2018 period, approximately \$6.4 million was raised through the sale of shares of common stock.

Cash used in investing activities for the nine months ended September 30, 2019 and 2018, was \$12,000 and \$7,000 respectively, related to the purchase of property and equipment.

November 2019 Financing

On November 14, 2019, we entered into an underwriting agreement with Alliance Global Partners (“AGP”) pursuant to which we sold securities consisting of 547,420 Class A Units at a public offering price of \$1.94 per unit, with each unit consisting of one share of common stock, one warrant to purchase one share of common stock and a one-half of one common warrant to purchase one share common stock, and 7,938 Class B Units at a public offering price of \$1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of \$1.94 per share, warrants to purchase 515,464 shares of common stock, and common warrants to purchase 257,732 shares of our common stock. The warrants have an exercise price of \$1.94, are exercisable and expire five years from the date of issuance. The common warrants have an exercise price of \$1.94, are exercisable and expire 12 months from the date of issuance. The common warrants are exercisable on a cashless basis at the option of the holder on the earlier of 30 days from issuance and the date by which an aggregate of \$9.0 million of our securities were traded.

The November 2019 Financing closed on November 19, 2019. AGP purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately \$0.63 million. We received net proceeds from the November 2019 Financing of approximately \$8.1 million, after deducting the underwriting discount and other offering expenses of approximately \$0.6 million.

As of January 17, 2020, all 7,938 previously issued shares of Series A Convertible Preferred Stock have been converted into common stock.

2019 Lincoln Park Transaction

On August 20, 2019, we entered into a purchase agreement (the “2019 Purchase Agreement”) and a registration rights agreement (the “2019 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2019 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2019 Purchase Agreement. Pursuant to the terms of the 2019 Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2019 Purchase Agreement.

Pursuant to the terms of the 2019 Purchase Agreement, at the time we signed the 2019 Purchase Agreement and the 2019 Registration Rights Agreement, we issued 35,529 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2019 Purchase Agreement. The commitment shares were valued at \$200,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2019 Purchase Agreement.

We did not sell any shares of common stock under the 2019 Purchase Agreement during the nine months ended September 30, 2019.

July 2019 Financing

On July 16, 2019, we entered into an underwriting agreement with Aegis Capital Corp., as representatives of the underwriters (“Aegis”), relating to the issuance and sale of 900,000 shares of our common stock, in an underwritten public offering (the “July 2019 Financing”). The public offering price for each share of common stock was \$6.00. We granted Aegis a 45-day option to purchase up to an additional 135,000 shares of common stock to cover over-allotments, if any.

The July 2019 Financing closed on July 18, 2019. Aegis purchased the shares at an eight percent discount to the then current public price, for an aggregate discount of \$0.4 million (or \$0.48 per share). We incurred offering expenses of approximately \$0.5 million. We received net proceeds of approximately \$4.5 million.

December 2018 Financing

On December 7, 2018, we entered into an underwriting agreement with AGP and Dawson James Securities, Inc. (collectively, the “Underwriters”) pursuant to which we sold securities consisting of 86,171 Class A Units at a public offering price of \$35.00 per unit, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock, and 11,984 Class B Units at a public offering price of \$1,000 per unit, with each unit consisting of one share of 2018 Series A Convertible Preferred Stock, with a conversion price of \$35.00 per share, and warrants to purchase 28.5714 shares of Common Stock. The warrants have an exercise price of \$35.00, are exercisable and expire five years from the date of issuance.

We also granted the Underwriters a 45-day option to purchase up to 64,286 shares of common stock and/or additional warrants to purchase up to 64,286 additional shares of common stock.

The December 2018 Financing closed on December 11, 2018. The Underwriters purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately \$1.1 million (or \$2.40 per share). We received net proceeds from the December 2018 Financing of approximately \$13.6 million, after deducting the underwriting discount and other offering expenses of approximately \$0.4 million. Additionally, the Underwriters fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 64,000 shares of common stock for net proceeds of approximately \$6,000.

On December 13, 2018, the Underwriters partially exercised the over-allotment option and purchased 25,000 shares of common stock for net proceeds of approximately \$0.8 million, net of an aggregate discount of \$0.1 million (or \$2.40 per share).

As of January 17, 2020, all shares of 2018 Series A Convertible Preferred Stock have been converted into common stock and the certificate of designation relating to the 2018 Series A Convertible Stock has been withdrawn.

2018 At-the-Market Offering

On May 1, 2018, we entered into a sales agreement (the “Sales Agreement”), with Cowen and Company, LLC., (“Cowen”), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$9.5 million in at-the-market offerings (“ATM”) sales. On the same day, we filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen acted as sales agent and was paid a 3% commission on each sale under the Sales Agreement. Our common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied.

During the nine months ended September 30, 2019, we sold an aggregate of 2,106 shares of common stock under the ATM for net proceeds of approximately \$33,000.

During the quarter ended June 30, 2018, we sold an aggregate of approximately 16,000 shares of common stock using the ATM, resulting in net proceeds of \$4.1 million, net of expenses of approximately \$0.1 of Cowen’s commission.

2018 Lincoln Park Transaction

On October 18, 2018, we entered into a purchase agreement (the “2018 Purchase Agreement”) and a registration rights agreement (the “2018 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2018 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2018 Purchase Agreement. Pursuant to the terms of the 2018 Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2018 Purchase Agreement.

Pursuant to the terms of the 2018 Purchase Agreement, at the time we signed the 2018 Purchase Agreement and the 2018 Registration Rights Agreement, we issued 3,500 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2018 Purchase Agreement. The commitment shares were valued at \$245,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2018 Purchase Agreement.

During the nine months ended September 30, 2019, we sold an aggregate of approximately 22,700 shares of common stock under the 2018 Purchase Agreement, for gross proceeds of approximately \$0.4 million.

Under applicable rules of the NASDAQ Global Market, we could not issue or sell more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the 2018 Purchase Agreement (approximately 26,200 shares) to Lincoln Park under the 2018 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of our common stock to Lincoln Park under the 2018 Purchase Agreement equals or exceeds a threshold amount. As we have issued approximately 26,200 shares to Lincoln Park, by June 30, 2019, under the 2018 Purchase Agreement at less than the threshold amount, we will not sell any additional shares under the 2018 Purchase Agreement without shareholder approval.

2017 Lincoln Park Transaction

On September 28, 2017, we entered into a purchase agreement (the “2017 Purchase Agreement”) and a registration rights agreement (the “Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2017 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of its common stock (subject to certain limitations) from time to time during the term of the 2017 Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2017 Purchase Agreement.

Pursuant to the terms of the 2017 Purchase Agreement, at the time we signed the 2017 Purchase Agreement and the Registration Rights Agreement, we issued 731 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of its common stock under the 2017 Purchase Agreement. The commitment shares were valued at \$300,000, recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2017 Purchase Agreement.

During the nine months ended September 30, 2018, we sold an aggregate of approximately 11,000 shares of common stock under the 2017 Purchase Agreement, for gross proceeds of approximately \$2.3 million.

Under applicable rules of the NASDAQ Global Market, we could not issue or sell more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the 2017 Purchase Agreement (approximately 15,000 shares) to Lincoln Park under the 2017 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of our common stock to Lincoln Park under the 2017 Purchase Agreement equals or exceeds a threshold amount. As we had issued approximately 15,000 shares to Lincoln Park, by December 31, 2018, under the 2017 Purchase Agreement at less than the threshold amount, we will not sell any additional shares under the 2017 Purchase Agreement without shareholder approval.

Future Liquidity Requirements

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 will not have enough resources to meet our operating requirements for the one-year period from the filing date of this prospectus.

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 will need to obtain additional capital in order to fund future 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, shareholders 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.

Stock Compensation

Stock Options

On June 8, 2018, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2018 Stock Incentive Plan (the “2018 Plan”). The 2018 Plan provided for the issuance of up to 13,200 shares of common stock. With the adoption of the 2019 Plan (as defined below), no further grants may be made under the 2018 Plan.

On May 3, 2019, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the “2019 Plan”, and together with the 2018 Plan, the “Plans”).

Under the terms of the 2019 Plan, we may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2018 Plan provides for the issuance of up to 140,000 shares of common stock, which amount will be increased to the extent that awards granted under the 2019 Plan and the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2019 Plan). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2019 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. 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 expiration period of grants under the 2019 Plan may not more than ten years. As of September 30, 2019, 55,825 shares were available for future grants under the 2019 Plan.

The weighted average fair value of options granted during the nine months ended September 30, 2019 was \$16.54 per share. The weighted average fair value of options granted during the three and nine months ended September 30, 2018 was \$82.64 per share and \$277.77 per share, respectively.

We measure the fair value of stock options on the date of grant, based on the Black Scholes option pricing model using certain assumptions discussed in the following paragraph, and the closing market price of our common stock on the date of the grant. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. Most stock options granted pursuant to the Plans typically vest 1/3rd 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, we issue options to directors which vest over a one-year period. In addition, we also issue performance-based options to executive officers, which options vest when the target parameters are met, subject to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

Stock-based compensation expense relating to options granted of \$0.4 million and \$1.1 million was recognized for the three and nine-month periods ended September 30, 2019, respectively, and \$0.4 million and \$1.2 million was recognized for the three and nine-month periods ended September 30, 2018, respectively.

As of September 30, 2019, we had approximately \$2.1 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 1.85 years.

Employee Stock Purchase Plan

On May 3, 2019, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2019 Employee Stock Purchase Plan (the “2019 ESPP”). As a result of adoption of the 2019 ESPP by the stockholders, no further grants may be made under the Tonix Pharmaceuticals Holdings Corp. 2018 Employee Stock Purchase Plan (“2018 ESPP”).

The 2019 ESPP allows eligible employees to purchase up to an aggregate of 15,000 shares of our common stock. Under the 2019 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of our common stock at the end of the offering period. Each offering period under the 2019 ESPP is for six months, which can be modified from time-to-time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee’s accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2019 ESPP, subject to the statutory limit under the Code. As of September 30, 2019, 12,619 shares were available for future grants under the 2019 ESPP.

The 2019 ESPP and 2018 ESPP are considered compensatory plans with the related compensation cost written off over the six-month offering period. The compensation expense related to the 2019 ESPP and 2018 ESPP for the nine months ended September 30, 2019 and 2018 was \$28,000 and \$32,000, respectively. As of December 31, 2018, approximately \$38,000 of employee payroll deductions, which have been withheld since July 1, 2018, the commencement of the offering period ending December 31, 2018, are included in accrued expenses in the accompanying balance sheet. In January 2019, 177 shares that were purchased as of December 31, 2018, were issued under the 2018 ESPP, and approximately \$3,000 of employee payroll deductions accumulated at December 31, 2018, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$35,000 was returned to the employees. In August 2019, 2,381 shares that were purchased as of June 30, 2019, were issued under the 2019 ESPP, and approximately \$29,000 of employee payroll deductions accumulated at June 30, 2019, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$16,000 was returned to the employees. As of September 30, 2019, approximately \$9,000 of employee payroll deductions, which have been withheld since July 1, 2019, the commencement of the offering period ending December 31, 2019, are included in accrued expenses in the accompanying balance sheet.

Restricted Stock Units

In May 2017, a total of 57 restricted stock units (“RSUs”) vested that were granted to our non-employee directors for board services in 2016, in lieu of cash, with a one-year vesting from the grant date and a fair value of \$2,290 at the date of grant. 49 shares of our common stock were issued upon the vesting of such RSUs during the year ended December 31, 2017. The remaining 8 shares of common stock were issued during the three months ended March 31, 2018.

During the nine months ended September 30, 2019 and 2018, no stock-based compensation expense related to RSU grants was expensed.

Commitments

Research and development contracts

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$7.2 million at September 30, 2019 for future work to be performed.

Operating leases

As of September 30, 2019, future minimum lease payments are as follows (in thousands):

Year Ending December 31,		
2019	\$	113
2020		358
2021		6
	\$	<u>477</u>

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. 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.

Leases. We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (“ROU”) assets, other current liabilities and operating lease liabilities in our consolidated balance sheets. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our leases do not provide an implicit rate, we use an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. This is the rate we would have to pay if borrowing on a collateralized basis over a similar term to each lease. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Research and Development. We outsource our research and development efforts and expense the 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.

We estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants and clinical research organizations and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We account for trial expenses according to the progress of the trial as measured by participant progression and the timing of various aspects of the trial. We determine accrual estimates that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us at that time. Our clinical trial accruals and prepaid assets are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

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 condensed 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.

Recent Accounting Pronouncements

In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. We adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. We have elected the ‘package of practical expedients’, which permit us not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. We did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to us.

The new standard has had a material effect on our financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

The new standard also provides practical expedients for an entity’s ongoing accounting. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Beginning in 2019, we expect changes to our disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. The standard did not have a material impact on our results of operations or liquidity.

Upon adoption, we recognized operating lease liabilities of approximately \$0.3 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. We recognized corresponding ROU assets of approximately \$0.3 million.

Off-Balance Sheet Arrangements

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retain or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Our most advanced drug development programs are focused on delivering safe and effective long-term treatments for posttraumatic stress disorder, or PTSD, and fibromyalgia, or FM. PTSD is a psychiatric condition characterized by the reliving of trauma through intrusive and vivid recollections, nightmares and flashbacks. FM is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. Both PTSD and FM are associated with chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden.

We have assembled a management team with significant industry experience to lead the development of our product candidates. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in their respective fields.

Our lead product candidate, TNX-102 SL, is a proprietary sublingual tablet formulation of cyclobenzaprine, or CBP, designed for bedtime administration. TNX-102 SL is an investigational new drug that has not been approved for any indication. TNX-102 SL is in development for PTSD, FM, agitation in Alzheimer's disease (AAD) and alcohol use disorder (AUD). TNX-102 SL has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD and Fast Track designation by the FDA for the treatment of AAD.

TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD. The FDA has conditionally accepted the proposed trade name *Tonmya*[®] for TNX-102 SL for the treatment of PTSD. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling patients. RECOVERY is a double-blind, placebo-controlled study evaluating daily bedtime administration of TNX-102 SL in individuals with PTSD resulting from trauma that occurred within nine years of screening. Results from an interim analysis for a potential sample size adjustment are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. We are also developing TNX-102 SL as a bedtime treatment for the management of FM. We have started enrollment in the Phase 3 RELIEF trial (F304) in FM and expects to report results from an interim analysis in the second half of 2020. The AAD program is Phase 2 ready. The AUD program is in the pre-Investigational New Drug (IND) application stage, and we intend to submit an IND application in first quarter of 2020. Upon receiving FDA clearance of an IND application, the AUD program is expected to be Phase 2 proof-of-concept ready. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression, as well as for PTSD and neurocognitive dysfunction associated with corticosteroid use. The first efficacy study will be performed outside of the U.S. and is expected to be IND-ready in 2020. Our programs for treating addiction conditions also include TNX-1300 (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA.

Finally, our preclinical pipeline includes TNX-1600 (a triple reuptake inhibitor) which is a third product candidate being developed for PTSD, as a daytime treatment. TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers are also in the preclinical stages. Each of TNX-801 (live virus vaccine for percutaneous [scarification] administration), which is being developed to potentially prevent smallpox, and TNX-701 (undisclosed small molecule), which is being developed to potentially prevent radiation effects are being advanced as medical countermeasures to improve biodefense.

TNX-102 SL – Posttraumatic Stress Disorder

TNX-102 SL is a small, rapidly disintegrating tablet containing CBP for sublingual administration. TNX-102 SL employs a proprietary protective eutectic formulation of CBP, *Protectic*[™], which enables rapid systemic exposure and increased bioavailability through transmucosal absorption. Based on the results of a Phase 2 study with TNX-102 SL 2.8 mg and 5.6 mg in military-related PTSD, TNX-102 SL 5.6 mg was studied in the first Phase 3 study which was discontinued after the results of the interim analysis, or IA, indicated a pre-defined threshold p-value for continuing enrollment was not achieved. Retrospective analysis of this Phase 3 study revealed a treatment effect in participants who experienced trauma less than or equal to nine years prior to screening. This analysis defined an optimal treatment window for treatment with TNX-102 SL for PTSD of the first nine years after the index trauma that resulted in PTSD and guided the design of the Phase 3 RECOVERY (P302) study.

The RECOVERY study was initiated in March 2019 and is currently enrolling. Only those participants who have experienced trauma within nine years of screening are included in the study. Both civilian and military-related PTSD are being studied in RECOVERY. Based on guidance from a Breakthrough Therapy Type B Clinical Guidance meeting with the FDA, we plan to conduct an interim analysis which will have three possible recommendations: 1) keep the current sample size and continue as planned; 2) provide the opportunity to increase the sample size to include up to a maximum of 120 additional participants, based on certain criteria; and 3) stop the study early for futility. We expect results from this interim analysis in the first quarter of 2020. Topline data are expected in the second quarter of 2020 if the sample size remains the same. TNX-102 SL has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD.

TNX-102 SL – Fibromyalgia

We are developing TNX-102 SL for the management of FM. TNX-102 SL for FM is a non-opioid, centrally-acting analgesic that could provide a new therapeutic option for FM patients. In September 2016, we interrupted the development of TNX-102 SL for the management of FM to focus on the treatment of PTSD. Our previous development efforts for TNX-102 SL in FM studied the 2.8 mg dose in a Phase 2 and a Phase 3 study. Based on our experience with TNX-102 SL 5.6 mg in PTSD, we are restarting the clinical program in FM using TNX-102 SL 5.6 mg. We met with the FDA in March 2019 to discuss the clinical development plan and the next Phase 3 study design to support the FM indication. We received clear guidance from the FDA to advance FM using TNX-102 SL 5.6 mg and are currently testing this dose in the Phase 3 RELIEF (F304) study which started enrolling patients in December 2019. We plan to conduct an interim analysis pending the FDA's agreement; we expect interim analysis results from this study in the second half of 2020 and topline data in the first half of 2021.

TNX-102 SL – Agitation in Alzheimer’s Disease

We are developing TNX-102 SL for the treatment of AAD, which has been designated as a Fast Track development program by the FDA. The FDA’s comments on the Phase 2 potential pivotal efficacy study protocol have been received and, based on the feedback, the program is ready for a Phase 2 study which could potentially serve as a pivotal efficacy study to support NDA approval.

TNX-102 SL – Alcohol Use Disorder

We are developing TNX-102 SL for the treatment of alcohol use disorder (AUD). We had a pre-IND meeting with the FDA in October 2019 in which we discussed a 505(b)(2) development plan for TNX-102 SL as a treatment for AUD. The FDA official meeting minutes confirmed the agreement received on the study design of the Phase 2 proof-of-concept study; we plan to submit an IND application in the first quarter of 2020.

TNX-601 CR – Major Depressive Disorder, PTSD and Neurocognitive Dysfunction from Corticosteroids

We are developing TNX-601 CR (tianeptine oxalate oral controlled release formulation) for the treatment of major depressive disorder (depression), for the daytime treatment of PTSD, and for the management of neurocognitive dysfunction from corticosteroids. TNX-601 CR is a novel, oral formulation of tianeptine oxalate designed for once-daily, daytime dosing. Currently there is no tianeptine-containing product approved in the U.S., but tianeptine sodium is approved in Europe, Asia, and Latin America for the treatment of depression with three times a day dosing. Tianeptine oxalate is crystalline and has improved pharmaceutical properties, including improved stability, consistency, and manufacturability, as compared to tianeptine sodium, which is amorphous. Tianeptine is believed to work in depression as a modulator of the glutamatergic system. Tianeptine modulates the glutamatergic system indirectly since it does not interact with NMDA, AMPA or kainate receptors. In animals, tianeptine has been shown to reverse the adverse neuroplastic changes that are observed during periods of stress and elevated corticosteroid exposure. Tianeptine and its MC5 metabolite are weak mu-opioid receptor (MOR) agonists. Neither tianeptine nor MC5 have been shown to bind other neurotransmitter receptors. Tianeptine’s reported pro-cognitive and anxiolytic effects as well as its ability to attenuate the neuropathological effects of excessive stress responses suggest that it may be used to treat PTSD by a different mechanism of action than TNX-102 SL.

TNX-601 CR is in the pre-IND stage in the U.S. and we intend to request a pre-IND meeting with the FDA in the first half of 2020. Outside of the U.S., a Phase 1 study for formulation development was recently completed and we are planning for a Phase 2 study in depression ex-U.S. in the second half of 2020.

TNX-1300 – Cocaine Intoxication

We in-licensed TNX-1300 from Columbia University in May 2019. We are developing TNX-1300 for the treatment of cocaine intoxication or overdose. TNX-1300 has been granted Breakthrough Therapy designation by the FDA for the treatment of cocaine intoxication. TNX-1300 is in mid-Phase 2, having been previously studied in a Phase 2 study consisting of volunteer cocaine abusers. In August 2019, we met with the FDA to seek guidance on the nonclinical study plans to support the clinical development of TNX-1300.

TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is a recombinant protein enzyme produced through rDNA technology in a non-disease-producing strain of E. coli bacteria. Cocaine Esterase (CocE) was identified in bacteria (Rhodococcus) that use cocaine as its sole source of carbon and nitrogen and that grow in soil surrounding coca plants. The gene encoding CocE was identified and the protein was extensively characterized. CocE catalyzes the breakdown of cocaine into metabolite ecgonine methyl ester and benzoic acid. Wild-type CocE is unstable at body temperature, so targeted mutations were introduced in the CocE gene and resulted in the T172R/G173Q double-mutant CocE, which is active for approximately 6 hours at body temperature. TNX-1300 is a new molecular entity and a biologic. In a Phase 2 study, TNX-1300 at 100 mg or 200 mg i.v. doses was well tolerated and interrupted cocaine effects after cocaine 50 mg i.v. challenge.

Preclinical Product Candidates

- **TNX-1600 – PTSD**

TNX-1600 was acquired through a license agreement with Wayne State and an asset acquisition agreement with TRImaran. TNX-1600 is a triple reuptake inhibitor in development to treat posttraumatic stress disorder (PTSD) and potentially other central nervous system disorders. TNX-1600 is a new chemical entity and is being developed as first line monotherapy, as an oral daytime treatment.

- **TNX-1500 - Prevention and Treatment of Organ Transplant Rejection; treatment for autoimmune conditions including systemic lupus erythematosus, rheumatoid arthritis and multiple sclerosis**

TNX-1500 (monoclonal antibody anti-CD154) is a third generation monoclonal antibody (mAb), currently in preclinical development as a potential first line monotherapy for autoimmunity and as an add-on therapy for preventing and treating organ transplant rejection. Several studies have shown mAbs that react with the same target as TNX-1500 to be active in the treatment of human systemic lupus and transplant rejection. TNX-1500 is designed to retain the efficacy of anti-CD154 mAbs, but with fewer potential side effects.

- **TNX-1700 – Gastric and Pancreatic Cancers**

TNX-1700 (rTFF2) was in-licensed from Columbia University in September 2019. TNX-1700 is a biologic currently in preclinical development as a treatment for gastric and pancreatic cancers. TFF2 is a small secreted protein, encoded by the TFF2 gene in humans, that is expressed in gastrointestinal mucosa where it functions to protect and repair mucosa. TFF2 is also expressed at low levels in splenic immune cells and is now appreciated to have intravascular roles in spleen and in the tumor microenvironment. In gastric cancer, TFF2 is epigenetically silenced, and TFF2 is suggested to be protective against cancer development through several mechanisms. The mechanism of action of rTFF2 is different from anti-PD-1 or anti-PD-L1 monoclonal antibodies and rTFF2 is being studied to determine whether there is synergy with other treatments for cancer.

Biodefense Product Candidates

- ***TNX-801***

TNX-801 is a novel potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, or HPXV, grown in cell culture. TNX-801 was synthesized by Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada in collaboration with us. An article describing the work was published (Noyce RS, Lederman S, Evans DH (2018) Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. *PLoS ONE* 13(1): e0188453. <https://doi.org/10.1371/journal.pone.0188453>). HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection. Discussions regarding vaccine manufacturing activities have been initiated to support further nonclinical testing of TNX-801. We are developing TNX-801 as a potential smallpox-preventing vaccine for widespread immunization and for the U.S. strategic national stockpile. Though it shares structural characteristics with vaccinia-based vaccines, TNX-801 has unique virulence properties that we believe may suggest lower toxicity and potential safety advantages over existing vaccinia-based vaccines, which have been associated with adverse side effects such as myopericarditis.

We intend to meet with the FDA to discuss the most efficient and appropriate investigational plan, e.g., the application of the FDA Animal Efficacy Rule, or Animal Rule, or conducting active comparator studies using ACAM2000, the current licensed live vaccinia virus vaccine, to establish the safety and effectiveness evidence to support the licensure TNX-801. In the 1970s, vaccination against smallpox was discontinued in the U.S.; however, smallpox remains a material threat to national security. We recently filed a patent on the novel virus vaccine. In addition, 12 years of non-patent-based exclusivity is expected under the Patient Protection and Affordable Care Act, or PPACA. Following the recent passage of the 21st Century Cures Act, we believe TNX-801 qualifies as a medical countermeasure, and therefore should be eligible for a Priority Review Voucher upon receiving FDA licensure. However, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed. We are currently working to develop a vaccine that meets cGMP quality to support an IND study.

- ***TNX-701***

We own rights to intellectual property on a biodefense technology relating to the development of protective agents against radiation exposure, which we refer to as TNX-701. We have begun nonclinical research and development on TNX-701. We plan to develop TNX-701 under the Animal Rule, which is applicable when human efficacy studies are not ethical or feasible. We expect significant reduction in development costs and risks compared to the development of other NCEs or new biologic candidates.

Our Strategy

Our objective is to develop and commercialize our product candidates. The principal components of our strategy are to:

- **Develop TNX-102 SL for PTSD and TNX-102 SL for FM and Other Indications.** We currently are focusing on the development of TNX-102 SL for PTSD and TNX-102 SL for FM. Our broader development strategy is to leverage the patented formulation to explore the clinical potential of TNX-102 SL in multiple other psychiatric, pain and addiction conditions, including AAD and AUD, that are either underserved by currently approved medications or have no approved treatment thus representing large unmet medical needs;
- **Maximize the commercial potential of TNX-102 SL.** We plan to commercialize TNX-102 SL, either on our own or through collaboration with partners. We believe TNX-102 SL can be marketed to U.S. physicians either by an internal sales force that we will build or by a contract sales organization, which we would engage. An alternative strategy would be to enter into partnership agreements with drug companies that already have significant marketing capabilities in the same, or similar, therapeutic areas. If we determine that such a strategy would be more favorable than developing our own sales capabilities, we would seek to enter into collaborations with pharmaceutical or biotechnology companies for the commercialization of TNX-102 SL;
- **Pursue a broad intellectual property strategy to protect our product candidates.** We are pursuing a broad patent strategy for our product candidates, and we endeavor to generate new patent applications as supported by our innovations and conceptions as well as to advance their prosecution. In the cases of TNX-102 SL, we own patents and patent applications protecting its composition-of-matter, certain methods of its use, its formulation, and its pharmacokinetic properties. We plan to opportunistically apply for new patents to protect TNX-102 SL and our other product candidates;
- **Provide value propositions to merit market demand and reimbursement for our product candidates.** We are designing the development programs for our product candidates to demonstrate their value propositions to patients, prescribers, and third-party payors. In the case of TNX-102 SL, we have been engaged in market research and commercial assessment activities, the results of which we may use to inform future commercial strategy. We plan to continue these activities in tandem with our clinical development of TNX-102 SL and to conduct similar work in relation to our other product candidates as they advance in their development; and
- **Pursue additional indications and commercial opportunities for our product candidates** We will seek to maximize the value of TNX-102 SL, and our other product candidates by pursuing other indications and commercial opportunities for such candidates. For example, we own rights related to the development and commercialization of CBP for generalized anxiety disorder, depression, and fatigue related to disordered sleep.

Disease and Market Overview

Our product candidates address disorders that are not well served by currently available therapies or have no approved treatment which represent large potential commercial market opportunities. Background information on the disorders and related commercial markets that may be addressed by our clinical-stage product candidates is set forth below.

Posttraumatic Stress Disorder

PTSD is a chronic condition that may develop after a person is exposed to one or more traumatic events, such as warfare, sexual assault, serious injury, or threat of imminent death. The core symptom clusters of PTSD are avoidance, emotional numbing, hyperarousal, and intrusion, where the triggering traumatic event is commonly re-experienced by the individual through intrusive, recurrent recollections, flashbacks, and nightmares. People with PTSD suffer significant impairment in their daily functioning, including occupational activities and social relations, and are at elevated risk for impulsive violent behaviors toward others and themselves, including suicide. Of those who experience significant trauma, approximately 20% of women and 8% of men develop PTSD. An estimated 12 million adults annually in the U.S. suffer from PTSD. According to the U.S. Department of Veterans Affairs, the prevalence rate of PTSD in the military population is higher than that among civilians. As of 2012, there were approximately 638,000 veterans receiving treatment for PTSD in the Veterans Health Administration, or VHA. Based on March 2015 VHA data, more than 19% of military veterans involved in recent conflicts in Iraq and Afghanistan were seen at VHA facilities for potential or provisional PTSD.

Many patients fail to adequately respond to the medications approved for PTSD and approved medications show little evidence of a treatment effect in men, lack evidence of efficacy in those for whom the traumatic event was combat-related, and carry suicidality warnings. Sleep disturbances are central features of PTSD and are predictive of disease severity, depression, substance abuse, and suicidal ideation, yet are resistant to the approved medications and present a difficult therapeutic challenge. Current PTSD treatments include off-label use of anxiolytics, sedative-hypnotics, and antipsychotics, many of which lack reliable evidence of efficacy, and many have significant safety liabilities and dependence risk.

FM

FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. The peak incidence of FM occurs between 20-50 years of age, and 80-90% of diagnosed patients are female. FM may have a substantial negative impact on social and occupational function, including disrupted relationships with family and friends, social isolation, reduced activities of daily living and leisure activities, avoidance of physical activity, and loss of career or inability to advance in career or education. According to the American Chronic Pain Association, an estimated six to twelve million adults in the U.S. have FM.

According to a report by Frost and Sullivan that we commissioned, despite the availability of approved medications, the majority of patients fail therapy due to either insufficient efficacy or poor tolerability, or both. Prescription pain and sleep medications are frequently prescribed off-label for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic benefit, and many of these medications carry significant safety risks and risk of dependence. For example, approximately 30% of patients diagnosed with FM take chronic opioids, despite the lack of evidence for their effectiveness and the risk of addiction and toxicity, including overdose.

Agitation in Alzheimer's Disease

Alzheimer's disease is a chronic neurodegenerative disease in which behavioral symptoms are a major clinical complication. Sleep disturbances and agitation are common and co-morbid features of Alzheimer's disease. Agitation, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of these behavioral complications of Alzheimer's disease. AAD is likely to affect more than half of the 5.3 million Americans who currently suffer from Alzheimer's disease, and this number is expected to nearly triple by 2050. The presence of agitation nearly doubles the cost of caring for patients with Alzheimer's disease, and agitation is estimated to account for more than 12 percent of the \$256 billion in healthcare and societal cost of associated with Alzheimer's disease for the year 2017 in the United States.

Agitation in Alzheimer's disease is associated with significant negative consequences for both patients as well as their caregivers. Development of agitation, or its worsening, is one of the most common reasons for patients having to transition to nursing homes and other long-term care settings.

Currently, there is no treatment approved by the FDA for behavioral symptoms such as agitation and aggression which affect the quality of life of both the patients and caregivers. Off-label use of atypical anti-psychotic medications for behavioral symptoms in Alzheimer's disease is a common practice, despite the lack of evidence for their effectiveness and significant morbidity and mortality risks associated with their use in this population.

Alcohol Use Disorder

An estimated 36 million adults in the U.S. have AUD. AUD is a chronic relapsing brain disease characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using. Sleep disturbance is extremely common in alcohol recovery and it significantly impacts daytime cognition, mood, and ability to participate in alcohol treatment, and, importantly, is associated with increased risk of relapse. There are three medications approved by the FDA but AUD remains an unmet need due to compliance and safety issues.

Major Depressive Disorder

According to the National Institute of Mental Health, depression affects approximately 16 million adults in the U.S., with approximately 2.5 million adults treated with adjunctive therapy. Depression is a condition characterized by symptoms such as a depressed mood or loss of interest or pleasure in daily activities most of the time for two weeks or more, accompanied by appetite changes, sleep disturbances, motor restlessness or retardation, loss of energy, feelings of worthlessness or excessive guilt, poor concentration, and suicidal thoughts and behaviors. These symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. The majority of people who suffer from depression do not respond adequately to initial antidepressant therapy.

Cocaine Intoxication

Cocaine is an illegal recreational drug which is taken for its pleasurable effects and associated euphoria. Pharmacologically, cocaine blocks the reuptake of the neurotransmitter dopamine from central nervous system synapses, resulting in the accumulation of dopamine within the synapse and an amplification of dopamine signaling and its role in creating positive feeling. With the continued use of cocaine, however, intense cocaine cravings occur resulting in a high potential for abuse and addiction (dependence), as well as the risk of cocaine intoxication. Cocaine intoxication refers to the deleterious effects on other parts of the body, especially those involving the cardiovascular system. Common symptoms of cocaine intoxication include tachyarrhythmias and elevated blood pressure, either of which can be life-threatening. As a result, individuals with known or suspected cocaine intoxication are sent immediately to the emergency department, preferably by ambulance in case cardiac arrest occurs during transit. There are approximately 505,000 emergency room visits for cocaine abuse each year in the U.S., of which 61,000 require detoxification services. According to the National Institute on Drug Abuse, over 13,900 individuals died of cocaine overdose in 2017. According to a recent report by the U.S. Centers for Disease Control and Prevention, and covered by news reports, among all 2017 U.S. drug overdose deaths, approximately 20% involved cocaine. Overdose deaths involving cocaine increased 34 percent from 2016 to 2017.

Our Product Candidates

We currently are focused on developing a portfolio of product candidates, including one candidate, TNX-102 SL, in clinical development for registration in four indications. We believe that our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to available therapies. The following table summarizes our most advanced product candidates, for which we plan to complete the required clinical studies to support their NDA approvals:

Product Candidate	Indication	Stage of Development	Commercialization Rights
TNX-102 SL	Posttraumatic stress disorder	Phase 3	Worldwide
TNX-102 SL	FM	Phase 3	Worldwide
TNX-102 SL	Agitation in Alzheimer's disease	Phase 2 ready	Worldwide
TNX-102 SL	Alcohol Use Disorder	Pre-IND	Worldwide
TNX-601 CR	Depression, PTSD	Pre-IND in U.S.; Phase 2-ready ex-US	Worldwide
TNX-1300	Cocaine Intoxication	Phase 2	Worldwide

TNX-102 SL

Overview

TNX-102 SL is a proprietary sublingual tablet formulation of CBP that efficiently delivers CBP across the oral mucosal membrane into the systemic circulation. We are developing TNX-102 SL as a bedtime treatment for PTSD and management of FM. 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. Excipients used in TNX-102 SL are approved for pharmaceutical use. Some of the excipients were specially selected to promote a local oral environment that facilitates mucosal absorption of CBP.

The current TNX-102 SL sublingual tablets contain 2.8 mg of CBP. For the treatment of PTSD and management of FM, TNX-102 SL, 5.6 mg (two 2.8 mg tablets) at bedtime, is in Phase 3 development. We selected this dose with the goal of providing a balance of efficacy, safety, and tolerability that would be acceptable as a first-line therapy and for long-term use, and in patient populations characterized by burdensome symptoms and sensitivity to medications.

The active ingredient in TNX-102 SL, is cyclobenzaprine or CBP, a serotonin-2A and alpha-1 adrenergic receptor antagonist as well as an inhibitor of serotonin and norepinephrine reuptake. In addition, TNX-102 SL acts upon other receptors in the central nervous system not targeted by products approved for PTSD, including the serotonin 2A, adrenergic alpha-1, muscarinic M₁ and histaminergic H₁ receptors.

CBP is the active ingredient of two products that are approved in the U.S. for the treatment of muscle spasm: FLEXERIL® (5 mg and 10 mg oral immediate-release, or IR, tablet) and AMRIX® (15 mg and 30 mg oral extended-release capsule). The FLEXERIL brand of CBP IR tablet has been discontinued since May 2013. There are numerous generic versions of CBP IR tablets on the market. CBP-containing products are approved for short term use (two to three weeks) only as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. IR CBP tablets are recommended for three times per day dosing, which results in relatively stable blood levels of CBP after several days of treatment. Extended-release CBP capsules taken once a day mimic, and flatten, the pharmacokinetic profile of three times per day IR CBP tablets.

We designed TNX-102 SL to be administered once-daily at bedtime and with the intention for long-term use. We believe the selected dose of TNX-102 SL and its unique pharmacokinetic profile will enable it to achieve a desirable balance of efficacy, safety, and tolerability in PTSD and FM. Our Phase 1 comparative trials showed that, on a dose-adjusted basis, TNX-102 SL results in faster systemic absorption and significantly higher plasma levels of CBP in the first hour following sublingual administration relative to oral IR CBP tablets. It also showed that the sublingual route of administration, which largely bypasses the “first pass” hepatic metabolism that swallowed medications undergo, results in a higher plasma ratio of CBP to its main active metabolite, norcyclobenzaprine. In clinical studies, TNX-102 SL 2.8 mg and TNX-102 SL 5.6 mg were generally well-tolerated, with no drug-related serious and unexpected adverse reactions reported in these studies. Some subjects experienced transient numbness of the tongue after TNX-102 SL administration.

We have successfully completed the pivotal exposure bridging study with TNX-102 SL using AMRIX as the reference listed drug or RLD. Results from this study support the approval of TNX-102 SL under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA. In general, the development timeline for a 505(b)(2) NDA is shorter and less expensive than an NDA developed under Section 505(b)(1), which is for new chemical entities, or NCEs, that have never been approved in the United States. We believe that TNX-102 SL has the potential to provide clinical benefit to PTSD and FM patients and possibly other CNS (central nervous system) indications that are underserved by currently marketed products or have no approved treatment.

On May 2, 2017, we were issued U.S. patent 9,636,408 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, which includes compositions of CBP and methods of manufacturing the eutectic. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of our proprietary TNX-102 SL composition. The patent is expected to provide TNX-102 SL with U.S. market exclusivity until 2034. Eutectic tablets containing CBP and mannitol eutectic have good pharmaceutical stability and manufacturability. A solid eutectic is a form of matter in which two solid crystals co-penetrate each other, such that the inter-molecular space between the units of one crystal lattice are occupied by the other crystal’s lattice. The distance between the molecular units is not changed.

On September 13, 2017, we were issued European patent 2,501,234 “Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine”. This patent recites the use of CBP for the treatment of PTSD, which covers the use of TNX-102 SL for the treatment of PTSD, since the active ingredient in TNX-102 SL is CBP. The patent is expected to provide TNX-102 SL with European market exclusivity until 2030.

On December 15, 2017 we were issued Japanese Patent No. 6259452, “Compositions and Methods for Transmucosal Absorption,” by the Japanese Patent Office (JPO) relating to the pharmacokinetic profile of TNX-102 SL.

On March 20, 2018, we were issued U.S. patent 9,918,948 “Methods and compositions for treating symptoms associated with PTSD using Cyclobenzaprine”. This patent protects the use of TNX-102 SL for the treatment of PTSD as well as its active ingredient CBP for the treatment of PTSD. The patent is expected to provide TNX-102 SL with U.S. market exclusivity until 2030. This method of use patent for TNX-102 SL extends upon previously granted patents related to the composition of matter (U.S. Patent No. 9,636,408) and the active ingredient in TNX-102 SL (European Patent No. 2,501,234) as described above.

On March 23, 2018, we were issued Japanese Patent No. 6310542 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride.” This patent recites pharmaceutical compositions comprising the eutectics and methods of manufacturing these eutectic formulations.

On May 1, 2018, we were issued U.S. Patent No. 9,956,188 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”. The patent recites a eutectic of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics. The patent is expected to provide TNX-102 SL with U.S. market exclusivity until 2034.

On November 6, 2018, we were issued U.S. Patent No. 10,117,936 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”. The patent recites pharmaceutical compositions of eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions. The patent is expected to provide TNX-102 SL with U.S. market exclusivity until 2034.

TNX-102 SL – Posttraumatic Stress Disorder Program

We are developing TNX-102 SL as a bedtime treatment of PTSD under an effective IND application. The approval of TNX-102 SL for PTSD will be under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA.

Clinical Development Plan

Phase 3 HONOR Study (P301)

In the third quarter of 2018, we announced the results of a randomized, double-blind, placebo-controlled Phase 3 study of TNX-102 SL, planned for enrollment of approximately 550 participants with military-related PTSD, which we refer to as the HONOR study. The primary efficacy endpoint of the HONOR study was the 12-week mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5, or CAPS-5, between those treated with TNX-102 SL and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. This study was an adaptive design study based on the results of the Phase 2 AtEase study. The study design was very similar to the Phase 2 AtEase study, except there was one planned IA and the involvement of an independent data monitoring committee, or IDMC, which reviewed the unblinded IA results. In addition, only one active dose (5.6 mg administered as 2 x 2.8 mg tablets) was investigated and the baseline severity entrance criterion was a CAPS-5 total score ≥ 33 in this Phase 3 study. The IA was conducted when approximately 50% of the initially planned participant enrollment was evaluable for efficacy. We received the FDA's acceptance of the Phase 3 HONOR study design in January of 2017. The HONOR study was conducted at approximately 40 U.S. sites. HONOR was discontinued after the results of the IA indicated a pre-defined threshold p-value for continuing enrollment was not achieved. The modified Intent-to-Treat (mITT) population analyzed at the time of the IA included 252 participants.

The HONOR study demonstrated that TNX-102 SL was well tolerated and that the 5.6 mg (administered as 2 x 2.8 mg tablets) dose showed meaningful improvement in overall PTSD symptoms at Week 4. At Week 4, the TNX-102 SL treated group separated from placebo in CAPS-5 ($p = 0.019$) and in the Clinical Global Impression – Improvement (CGI-I) scale ($p = 0.015$), a key secondary endpoint. A CGI-I responder analysis, with responder defined as 'much improved' or 'very much improved' on the CGI-I, demonstrated significantly greater responders in the TNX-102 SL group (29.1% v 45.6%; $p=0.007$) at Week 4. Also, at Week 4, sleep quality improved as measured by both the PROMIS sleep disturbance scale ($p=0.015$) and the CAPS-5 sleep disturbance item ($p=0.002$), supporting the proposed mechanism of action of TNX-102 SL. And the CAPS-5 reckless or self-destructive behavior item at Week 4 was significantly more improved ($p=0.013$). Safety data from these participants did not reveal any serious and/or unexpected adverse events. The most common adverse events were mostly related to local administration site reactions, such as oral hypoesthesia (37.3%), abnormal product taste (11.9%), and oral paraesthesia (9.7%). The most common systemic adverse event was somnolence (15.7%).

Retrospective analysis of the HONOR study revealed a treatment effect in participants who experienced trauma less than or equal to nine years prior to screening. In the participants who experienced trauma within nine years, the p-value of the primary endpoint at Week 12, using mixed model repeated measures with multiple imputation (MMRM with MI), was 0.039, with a least-squares mean difference from placebo of -5.9 units. In contrast, there was no benefit in the participants who experienced trauma more than nine years prior to screening. This analysis defined an optimal treatment window for treatment with TNX-102 SL for PTSD of the first nine years after the index trauma that resulted in PTSD and guided the design of the currently ongoing Phase 3 RECOVERY study.

Phase 2 AtEase Study (P201)

In the second quarter of 2016, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 2 study of TNX-102 SL in participants with military-related PTSD, which we refer to as the AtEase study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat military-related PTSD at a dose of 2.8 mg or 5.6 mg (2 x 2.8 mg tablets). The AtEase study demonstrated that TNX-102 SL was well tolerated and that the 5.6 mg dose of TNX-102 SL had a therapeutic effect as assessed by the CAPS-5 scale, a standardized structured clinician interview considered the gold standard in clinical research and regulatory approval for measuring the symptom severity of PTSD, which was statistically significant by MMRM with MI analysis (p -value = 0.031). The AtEase study also demonstrated that although the 2.8 mg dose trended in the direction of a therapeutic effect, it did not reach statistical significance on the primary endpoint, a 12-week mean change from baseline in the severity of PTSD symptoms as measured by the CAPS-5 scale.

Four distinct SAEs were reported in the AtEase study; three were in the placebo group, and one (proctitis/peri-rectal abscess) in the TNX-102 SL arm, which was determined to be unrelated to TNX-102 SL. The most common non dose-related adverse events were mild and transient local administration site conditions. Systemic adverse events that were potentially dose-related and occurred in greater than or equal to 5% of participants treated with the 2.8 mg or 5.6 mg dose included: somnolence (drowsiness), dry mouth, headache, insomnia, and sedation. For the participants treated with the 2.8 mg dose, the incidence of the most common systemic adverse events reported above were less frequent than participants treated with the 5.6 mg dose with the exception of insomnia, which was 8.5% in placebo, 7.5% in TNX-102 SL 2.8 mg, and 6.0% in TNX-102 SL 5.6 mg.

The primary MMRM analysis of the AtEase study, which controlled for baseline severity, indicated greater response to TNX-102 SL 5.6 mg in those with greater PTSD severity by CAPS-5 at baseline. As the first industry PTSD trial to employ the CAPS-5 (based on the DSM-5 published in 2013), it was not clear what was the ideal severity threshold for randomization into the study comparable to the standard threshold used in precedent studies that employed prior versions of the CAPS. Retrospective analysis imputing scores for all participants assuming a prior version of CAPS suggested a CAPS-5 baseline threshold for randomization of 33 or higher was equivalent to the threshold used in precedent PTSD studies on prior CAPS versions.

A retrospective analysis of the subgroup of participants in AtEase with baseline CAPS-5 score of 33 or higher supported the hypothesized mechanism of sleep quality improvement, since sleep improvement at Week 4, measured by the PROMIS Sleep Disturbance instrument, predicted treatment response (by improvement in total CAPS-5 score without the sleep item) at Week 12 in the TNX-102 SL 5.6 mg group ($p = 0.01$, linear regression), whereas these measures were not related in placebo.

Open-label Extension Study for AtEase

Participants who completed the AtEase study were eligible to enroll into a 12-week open-label extension (OLE) study with TNX-102 SL 2.8 mg. We conducted this open-label extension study to obtain additional safety information from participants in the AtEase study. TNX-102 SL 2.8 mg was well tolerated for up to six months of treatment and no new safety signals were revealed in this open-label extension study.

Ongoing Phase 3 RECOVERY Study (P302)

We initiated the RECOVERY study (P302) in March 2019. The RECOVERY Phase 3 study is a double-blind, randomized, placebo-controlled study of TNX-102 SL 5.6 mg (2 x 2.8 mg sublingual tablets) over 12 weeks of treatment. The study will include approximately 250 participants with civilian and military-related PTSD. The design of this study was guided based on the results of the Phase 3 HONOR study and Phase 2 AtEase study. RECOVERY restricts enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening. The two previous PTSD studies of TNX-102 SL (P201 and P301) restricted enrollment to participants who experienced traumas during military service since 2001. The primary efficacy endpoint is the Week 12 mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with TNX-102 SL and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. A formal unblinded interim analysis will be completed when about 50 percent (n=125) of participants have been randomized and have completed or discontinued the 12-week course of treatment with daily bedtime TNX-102 SL 5.6 mg or placebo sublingual tablets. The three possible recommendations from the interim analysis Independent Data Monitoring Committee are: 1) keep the current sample size and continue as planned; 2) provide the opportunity to increase the sample size to include up to a maximum of 120 additional participants, based on certain criteria; and 3) stop the study early for futility. The Company expects to report the results of the interim analysis and the recommendation of the IDMC in the first quarter of 2020. If the current projected population of 250 study participants remains unchanged, the Company expects to report topline data in the second quarter of 2020. The RECOVERY study is being conducted at approximately 30 U.S. sites.

Long-Term Safety Exposure Study for TNX-102 SL

In October 2019, we completed long-term safety exposure studies in participants with PTSD to evaluate the tolerability of TNX-102 SL 5.6 mg to support an NDA for the treatment of PTSD. The data provide us with exposure data of daily dosing of TNX-102 SL 5.6 mg for at least 12 months in more than 50 individuals, and daily dosing of TNX-102 SL 5.6 mg for at least 6 months in more than 100 individuals. The data was collected in OLE studies of the PTSD program. Based on the FDA's guidance, the long-term safety exposure studies in PTSD are also expected to support an NDA for the management of FM.

Regulatory Update

In May 2014, we submitted an IND for TNX-102 SL indicated for the treatment of PTSD.

In December 2016, the FDA granted Breakthrough Therapy designation, or BT, to TNX-102 SL for the treatment of PTSD. The Breakthrough Therapy designation request was based on the preliminary clinical evidence of TNX-102 SL 5.6 mg on military-related PTSD in the AtEase study.

In March 2017, we held the Initial Cross-Disciplinary Breakthrough Therapy Type B meeting with the FDA to discuss the opportunity to accelerate the development and submission of the TNX-102 SL NDA for the treatment of PTSD. Due to the lack of evidence of potential abuse in clinical studies of TNX-102 SL, the FDA agreed that studies in assessing abuse and dependency potential of TNX-102 SL are not required to support the TNX-102 SL NDA filing.

In June 2017, the FDA conditionally accepted the proposed trade name Tonmya[®] for TNX-102 SL for the treatment of PTSD.

In September 2017, we had a Breakthrough Therapy Chemistry, Manufacturing and Controls ("CMC") guidance meeting with the FDA regarding the CMC data required to support the TNX-102 SL NDA and commercial product. We received the FDA official meeting minutes from that meeting in October 2017 that reflect our readiness to manufacture TNX-102 SL commercial product at production scale if an NDA could have been submitted based on the HONOR study. In principle, our proposed CMC data package to support TNX-102 SL's NDA approval and commercial manufacturing plans was acceptable to the FDA.

In April 2018, we held a Breakthrough Therapy Type B Statistical Guidance teleconference meeting with the FDA to reach an agreement on the statistical methods in the Statistical Analysis Plan (SAP) and Interim SAP (ISAP) for the Phase 3 HONOR study. The final SAP and ISAP was accepted by the FDA in June 2018.

In October 2018, subsequent to reporting the Phase 3 HONOR study IA results, we held a Type B Clinical Guidance Meeting with the FDA in October 2018 to discuss the Phase 3 HONOR study results and the proposed design of the new Phase 3 RECOVERY study to support the registration of TNX-102 SL for the treatment of PTSD and the remaining data package for the NDA filing. We received the FDA's acceptance of the RECOVERY trial design in November 2018, including the expansion to study both civilian and military-related PTSD, enrollment restricted to index traumas within nine years of screening, and primary endpoint of improvement of CAPS-5 from baseline as assessed at Week 4, with the first key secondary endpoint at Week 12. Topline data from the RECOVERY trial is expected in the first half of 2020.

In October 2018, we held a Breakthrough Therapy Type B CMC Guidance teleconference meeting with the FDA to seek acceptance of the proposed regulatory specifications for TNX-102 SL commercial product.

In December 2018, the FDA issued an Intent-to-Rescind letter for BT status for TNX-102 SL for the treatment of PTSD because the IA results of the HONOR study did not meet the criteria for the BT granted in December 2016.

In March 2019, the FDA rescinded the BT, but subsequently withdrew the BT rescission in April 2019 and granted a meeting in August 2019 to discuss the continuation of BT for TNX-102 SL.

In August 2019, we held a Breakthrough Therapy Type B Meeting for continuing BT designation with the FDA. FDA agreed to consider the Phase 3 HONOR study additional data and information we presented at the meeting. The FDA's decision for whether to maintain BT for TNX-102 SL for PTSD is pending. The FDA will inform us of the BT decision, but no timeframe was given.

In October 2019, we held of Breakthrough Therapy Type B Clinical Guidance meeting with the FDA to discuss the timing of the primary endpoint in the currently ongoing RECOVERY study. Based on guidance from the FDA, the timing of the primary endpoint analysis of improvement of CAPS-5 from baseline was changed from Week 4 to Week 12, and the interim analysis allowing for a potential sample size adjustment was added to the study.

Other NDA Requirements

An Agreed Initial Pediatric Study Plan, or Agreed iPSP, is required for the initial NDA submission. We submitted a revised iPSP in the first quarter of 2017, which incorporated the FDA comments received on our iPSP submitted in the third quarter of 2016. Additional comments from the FDA were received in second quarter of 2017 on our revised iPSP. We plan to submit an Agreed PSP once a therapeutic dose in adults is established. An acceptable Pediatric Study Plan will be determined at the time of the NDA approval.

Based on our discussions with the FDA and the FDA official meeting minutes, we will not have to conduct special populations (geriatric and renal/hepatic impaired), drug-drug interaction or cardiovascular safety studies to support the TNX-102 SL NDA filing since the pivotal systemic exposure bridging study using AMRIX as the RLD has been successfully completed. Due to the well-established safety profile of CBP at much higher doses than we proposed for PTSD and the long-term safety data (up to 15 months) on TNX-102 SL 2.8 mg in a prior FM program, the FDA has not requested a risk management plan or medication guide for this product.

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

Completed Bioequivalence Study

We completed a Phase 1 bioequivalence study that compared the pharmacokinetic profiles of a single-dose of TNX-102 SL 2.8 mg tablets manufactured at two facilities: (i) the facility used to produce TNX-102 SL 2.8 mg tablets for the Phase 2 AtEase study; and (ii) the facility used to produce TNX-102 SL 2.8 mg tablets for our clinical studies required to support the PTSD NDA submission and the to-be-marketed product. This bioequivalence study demonstrated that TNX-102 SL, 2.8 mg tablets manufactured at these two facilities were bioequivalent, supporting the use of the AtEase study to support the Phase 3 studies.

Completed Multi-dose Bridging PK Study

We intend to seek the FDA's marketing approval for TNX-102 SL pursuant to Section 505(b)(2) of the FDCA using AMRIX[®] extended-release, or ER, capsules (30 mg) as our reference listed drug, or RLD. We completed a study of TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) in comparison to AMRIX 30 mg ER capsules in a randomized, open-label, parallel, multiple-dose bridging PK study to provide a systemic exposure bridge. The TNX-102 SL initial dose and at steady state exposures were less than the RLD maximum approved dose (30 mg) and the metabolic profile was similar to AMRIX. The results of this study provide the necessary systemic exposure bridge of TNX-102 SL to AMRIX. The approval of TNX-102 SL for PTSD can thus rely on the safety findings (clinical and nonclinical) and relevant labeling information in the approved AMRIX prescribing information.

Food Effect and Dose-proportionality Study

To support the TNX-102 SL product registration, a randomized, open-label, 3-way crossover, food-effect, dose-proportionality, comparative bioavailability study of TNX-102 SL following a single dose in healthy subjects under fasting and fed conditions, and comparing TNX-102 SL 2.8 mg to TNX-102 SL 5.6 mg (administered as 2 x 2.8 mg tablets) in healthy subjects under fasting conditions is ongoing (TNX-CY-F110).

Cyclobenzaprine Hydrochloride Nonclinical Development

The FDA has accepted our proposed nonclinical data package to support our PTSD NDA filing. In October 2016, we completed the six-month repeated-dose toxicology study of the active ingredient, CBP, in rats and a nine-month repeated-dose toxicology study in dogs required for the NDA filing and to support Phase 3 clinical studies outside the U.S., if necessary. These chronic toxicity studies were requested by the FDA to augment the nonclinical information in the AMRIX prescribing information, or labeling, which is necessary to support the TNX-102 SL labeling for long-term use. Due to the lack of evidence of potential abuse in clinical studies of TNX-102 SL, the FDA agreed that nonclinical study to assess CBP abuse and dependency potential is not required to support the TNX-102 SL NDA filing.

Manufacturing

TNX-102 SL drug product for Phase 3 and the associated registration batches for the NDA are manufactured at a commercial cGMP facility. We currently have in excess of 24 months stability data in a number of packaging configurations ready for commercialization. The FDA has accepted our proposed CMC data package to support TNX-102 SL's NDA approval and commercial manufacturing plans, reflecting our readiness to manufacture TNX-102 SL commercial product at production scale.

TNX 102 SL – FM program

We are developing TNX-102 SL as a bedtime treatment for FM under an effective IND application. The approval of TNX-102 SL for FM will be under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA.

Clinical Development Plan

Phase 3 AFFIRM Study (F301)

In the third quarter of 2016, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 3 study of TNX-102 SL in 519 participants with FM, which we refer to as the AFFIRM study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 2.8 mg, administered sublingually once daily at bedtime for 12 weeks. The primary endpoint of the AFFIRM trial was the FDA-agreed upon 30% pain responder analysis in which a responder is defined as a subject for whom pain intensity was reduced by at least 30% at Week 12 as compared to baseline. AFFIRM did not achieve statistical significance at the primary endpoint ($p=0.095$). Yet, statistical significance was achieved when pain was analyzed instead as a continuous variable, either by MMRM ($p<0.001$) or by MMRM with multiple imputation for missing data ($p=0.005$), a generally accepted approach to pain data. TNX-102 SL also showed statistically significant improvements in the declared secondary analyses of the Patient Global Impression of Change, or PGIC ($p=0.038$) and the FM Impact Questionnaire-Revised, or FIQ-R ($p<0.001$). The study also showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, Sleep Disturbance instrument ($p<0.001$). We believe that given the consistent results of the analyses of pain as a continuous endpoint, as well as the nominal significance shown on multiple key secondary endpoints, TNX-102-SL 2.8 mg taken daily at bedtime for 12 weeks showed meaningful clinical benefit in this typical FM population. Although, in light of improved results in PTSD with the higher TNX-102 SL 5.6 mg dose, and also better effects on pain in PTSD of 5.6 mg over 2.8 mg, it was predicted that TNX-102 SL 5.6 mg would have a stronger effect on pain in FM. Upon the re-initiation of the FM program in Fall of 2018, the next Phase 3 study (RELIEF) in FM was initiated with the TNX-102 SL 5.6 mg dose.

TNX-102 SL was well tolerated in the AFFIRM trial. Among patients randomized to the active and control arms, 78% and 86%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 40% of participants on TNX-102 SL vs. 1% on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Phase 2b BESTFIT Study (F202)

In the third quarter of 2014, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 2b study of TNX-102 SL in 205 participants with FM, which we refer to as the BESTFIT study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 2.8 mg, administered sublingually once daily at bedtime for 12 weeks. The primary outcome measure of the BESTFIT trial was the mean change in week 12 average daily pain intensity from baseline on the 11-point Numeric Rating Scale (NRS), using a daily telephonic diary. BESTFIT did not achieve statistical significance in the primary outcome measure ($p=0.172$), whereas TNX-102 SL 2.8 mg did show a statistically significant effect on pain as measured by a 30% responder analysis of the primary pain data ($p=0.033$). The 30% response rate in the final analysis was 34.0% in the active treatment arm as compared to 20.6% in the control arm. The BESTFIT trial also showed statistically significant improvements with TNX-102 SL in the declared secondary analyses of the PGIC ($p=0.025$) and the FIQ-R ($p=0.015$). The study showed statistically significant improvement with TNX-102 SL on measures of sleep quality, including the PROMIS, Sleep Disturbance instrument ($p=0.004$). In addition, statistically significant improvements with TNX-102 SL were observed on several FIQ-R items (pain, sleep quality, anxiety, stiffness, and sensitivity) as well as on the overall symptom subdomain.

TNX-102 SL was well tolerated in the BESTFIT trial. Among patients randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period. The most common adverse events were local in nature, with transient tongue or mouth numbness occurring in 44% of participants on TNX-102 SL vs. 2% on placebo, and bitter taste in 8% on TNX-102 SL compared to none on placebo. These local adverse events did not appear to affect either rates of retention of study participants or their compliance with taking TNX-102 SL. Systemic adverse events were similar between TNX-102 SL and placebo. No serious adverse events were reported.

Ongoing Phase 3 RELIEF Study (F304)

We have initiated the RELIEF study and enrolled the first patient in December 2019. The RELIEF study is a double-blind, randomized, placebo-controlled adaptive design trial designed to evaluate the efficacy and safety of TNX-102 SL in FM. The trial is expected to enroll approximately 470 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there will be a run-in period in which patients will start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients will have the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint is daily diary pain severity score change from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

The RELIEF study is expected to have one unblinded interim analysis when the study has results from approximately the first 50% of efficacy-evaluable patients, pending agreement with the FDA. We expect results from the interim analysis in the second half of 2020 and topline results from this study in the first half of 2021.

Regulatory Update

In October 2011, we filed the first IND for TNX-102 SL 2.8 mg indicated for the management of FM.

In February 2013, we had a Type B End-of-Phase 2/Pre-Phase 3 meeting with the FDA to discuss the study design of the Phase 2b BESTFIT study and the proposed 505(b)(2) NDA package to support the approval of TNX-102 SL for FM. In June 2013, we received the FDA's acceptance of the final Phase 2b BESTFIT study design, which was positioned as a pivotal efficacy study.

In April 2015, we received the FDA's acceptance on the Phase 3 AFFIRM study design and in August 2016, we reached an agreement with the FDA on the AFFIRM statistical analysis plan.

In May 2015, we received FDA conditional acceptance of the proposed proprietary name, Tonmya, for TNX-102 SL for FM.

In September 2015, we reached an agreement with the FDA on the Initial Pediatric Study Plan for FM. The FDA has accepted our request to waive studies in pediatric patients from birth to 12 years of age.

In February 2016, we had a Type B End-of-Phase 2 CMC meeting with the FDA to review our proposed CMC data to support the NDA submission and discuss our plan to establish regulatory specifications for the commercial product. Based on the FDA official meeting minutes received on in March 2016, FDA accepted our NDA CMC plan and proposal to establish regulatory specifications for commercial product.

In December 2016, we notified FDA in our IND annual update that the FM development program was put on hold for business reasons after the Phase 3 AFFIRM study topline data was reported in September 2016.

In April 2017, we withdrew the proposed proprietary name, Tonmya, for TNX-102 SL for FM.

In March 2019, we had a Type C Clinical Guidance meeting with the FDA to discuss the clinical development plan for TNX-102 SL 5.6 mg and obtained the FDA's agreement on the Phase 3 RELIEF study design to support the FM indication.

TNX 102 SL – Agitation in Alzheimer's Disease

Regulatory Update

In November 2017, we held a pre-IND meeting with the FDA to discuss our proposed development of TNX-102 SL for the treatment of AAD. We received the formal minutes from that meeting in December 2017 that reflect that we have the data needed to file an IND to support a Phase 2 study which can potentially be one of the pivotal efficacy studies. In April 2018, the FDA cleared our IND to support a Phase 2 potential pivotal efficacy study

In July 2018, the FDA granted Fast Track Therapy designation to TNX-102 SL for the treatment of AAD.

In September 2018, we received the FDA's comments on our proposed Phase 2 potential pivotal efficacy study protocol. Based on their feedback, the proposed Phase 2 study can potentially serve as a pivotal efficacy study to support NDA approval.

TNX 102 SL – Alcohol Use Disorder

Regulatory Update

In October 2019, we held a Type B pre-IND meeting with the FDA to discuss our proposed 505(b)(2) development plan for TNX-102 SL as a treatment of alcohol use disorder (AUD). We received the formal minutes from that meeting in November 2019 which provided guidance and feedback supportive of our clinical development plans.

Based on this feedback, we plan to submit an IND application in the first quarter of 2020. Upon receiving FDA clearance of an IND application, this program will be Phase 2 proof-of-concept ready as it is expected to qualify for the 505(b)(2) pathway for approval.

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 the FDA's 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 market for therapies to treat PTSD and other CNS conditions is well developed and populated with established drugs marketed by large and small pharmaceutical, biotechnology and generic drug companies. GlaxoSmithKline (Paxil[®]) and Pfizer (Zoloft[®]) market Paxil[®] and Zoloft[®], respectively for PTSD that are approved by the FDA. Paxil and Zoloft lost their U.S. patent exclusivities in 2003 and 2006, respectively.

Certain other companies and institutions are known to be developing prescription medications for PTSD, including Bionomics (BNC-201), Otsuka/Lundbeck (Rexulti[®] [brexpiprazole]), Uniformed Services University of the Health Sciences (riluzole), the Multidisciplinary Association of Psychedelic Studies (methylenedioxymethamphetamine [MDMA]) and Aptinyx (NYX-783).

BNC-201 completed a Phase 2 for PTSD and Bionomics announced that after reformulation a new Phase 2 will be started. BNC-201 is an allosteric modulator of the alpha 7 nicotinic acetylcholine receptor. Rexulti is in Phase 3 for PTSD and is an atypical antipsychotic. Aptinyx drug (NYX-783) is Phase 2 for PTSD and is a modulator of the NMDA receptor. Riluzole is in a Phase 2 trial for active duty military members and veterans with PTSD and is a blocker of certain sodium channels and a modulator of the glutamatergic system. MDMA is in Phase 3 for PTSD and is a DEA schedule 1 hallucinogen that is being studied for drug-assisted psychotherapy. MDMA was granted Breakthrough Therapy designation by the FDA in August 2017. Brainsway Ltd., a medical device company, is currently recruiting patients for a pivotal Phase 3 trial using a deep transcranial magnetic stimulation device for treatment of PTSD. A number of other companies and institutions have or may be developing prescription medications for PTSD, including: Mt. Sinai Hospital and Medical School in New York City is developing ketamine which is in Phase 2 and targets the NMDA receptor, Azevan Pharmaceuticals is developing SRX246 which is in Phase 2 and targets the vasopressin V1A receptor, University of California, San Diego (UCSD) is developing losartan which is in Phase 2 and is an angiotensin receptor blocker (ARB), Massachusetts General Hospital (MGH), University of California, San Francisco (UCSF) are developing oxytocin which is in Phase 2 and targets the oxytocin receptor, Nobilis Therapeutics is developing NBTX-001, a noble gas, which is in Phase 2, EpiVario is developing inhibitors of Acetyl CoA synthetase, which is in Phase 1 and Seelos Therapeutics (recently merged with Apricus Biosciences) is developing an intranasal racemic ketamine to treat PTSD and major depressive disorder (MDD).

Several companies have clinical candidates for which PTSD is being considered as a secondary indication. Johnson and Johnson is developing CERC-501 which is in Phase 2 for depression, targeting the kappa opioid receptor, Merck is studying Belsomra[®] (suvorexant) for PTSD, which is already approved for insomnia, NeuroRx is developing NRX-101 which is in Phase 2 for bipolar depression and is a combination of ketamine, lurasidone, and *d*-cycloserine, Roche is developing RG7314 which is in Phase 3 for Autism and was granted Breakthrough Therapy designation by the FDA in August 2017, Rodin Therapeutics has a preclinical candidate for Alzheimer's disease that targets histone deacetylase 2 (HDAC2 gene product), SpringWorks Therapeutics is developing PF-04457845 which is in Phase 2 for osteoarthritis and targets fatty acid amide hydrolase (FAAH).

In addition, approved medications that are used off-label 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.

A number of companies are developing prescription medicines for FM, including Aptinyx (NYX-2925), Innovative Medical Concepts (celecoxib and famciclovir or IMC-1) and Axsome (eseboxetine or AXS-14). NYX-2925 is in Phase 2 for the treatment of FM and painful diabetic peripheral neuropathy (DPN) and has been granted a Fast Track Designation by the FDA for DPN. IMC-1 has completed a successful Phase 2 trial and has been granted a Fast Track Designation by the FDA for the treatment of FM. AXS-14 was licensed by Axsome from Pfizer and already includes non-clinical and clinical data supporting its use in FM.

Additionally, a number of companies are developing prescription medicines for AAD, including Otsuka/Lundbeck (Rexulti[®] or brexpiprazole), Avanir/Otsuka (deudextromethorphan), Axsome (dextromethorphan/bupropion) and InterCellular (lumateperone). Rexulti[®] has completed two pivotal studies in AAD. Deudextromethorphan is in Phase 3 for the treatment of agitation in patients with dementia of the Alzheimer's type. Dextromethorphan/bupropion is in Phase 3 for the treatment of resistant depression and agitation in patients with Alzheimer's disease. Lumateperone is in Phase 3 for treating behavioral disturbances associated with dementia and was recently approved as CAPLYTA for the treatment of schizophrenia.

Although a number of companies are marketing or developing prescription medicines for sleep disorders, including Merck & Co, Purdue Pharma, Eisai, GlaxoSmithKline, Johnson & Johnson and Sage Therapeutics, none of these sleep disorders drugs are approved for PTSD or AAD. Merck is marketing Belsomra[®] (suvorexant) and Eisai is marketing Dayvigo[®] (lemborexant) which are dual orexin receptor antagonists indicated for insomnia. GlaxoSmithKline is developing SB-649868 which is also a dual orexin receptor antagonist. Johnson & Johnson and Minerva Neurosciences are developing seltorexant which is a selective orexin-2 antagonist. Sage Therapeutics is developing SAGE-217 which is a neurosteroid derivative that acts as a positive allosteric modulator of synaptic and extrasynaptic GABA receptors and was shown to increase sleep efficiency in a 5-hour phase advance model of insomnia.

Additionally, a number of companies are marketing or developing vaccines and treatments for smallpox, including Emergent BioSolutions, Bavarian Nordic, SIGA Technologies and Chimerix. Emergent BioSolutions markets ACAM-2000, which is a replicating vaccinia vaccine for the prevention of smallpox. Bavarian Nordic received FDA approval and markets JYNNEOS[®] (or Modified Virus Ankara or MVA), which is a non-replicating vaccinia virus vaccine for the prevention of smallpox and monkeypox. SIGA received FDA approval and markets TPOXX[®] (tecovirimat), which is an antiviral for smallpox. Chimerix is developing brincidofovir (CMX001), which is an antiviral.

Intellectual Property

We believe that we have an extensive patent portfolio and substantial know-how relating to TNX-102 SL and our other product candidates. Our patent portfolio, described more fully below, includes claims directed to TNX-102 SL compositions and methods of use. As of January 9, 2020, the patents we are either the owner of record of or own the contractual right to include 21 issued U.S. patents and 143 issued non-U.S. patents. We are actively pursuing an additional 20 U.S. patent applications, of which 6 are provisional and 14 are non-provisional, 5 international patent applications, and 98 non-U.S./non-international patent applications.

We strive to protect the proprietary technology that we believe is important to our business, including our proprietary technology platform, our product candidates, and our processes. We seek patent protection in the United States and internationally for our products, their methods of use and processes of manufacture, and any other technology to which we have rights, where available and when appropriate. We also rely on trade secrets that may be important to the development of our business.

Our success will depend on 1) the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, 2) the validity and enforceability of our patents, 3) the continued confidentiality of our trade secrets, and 4) our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be certain that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors — Risks Relating to Our Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the first non-provisional priority application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the PTO in granting a patent or may be shortened if a patent is terminally disclaimed over another patent.

The term of a U.S. patent that covers a drug approved by the FDA or methods of making or using that drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, is a federal law that encourages new drug research by restoring patent term lost to regulatory delays by permitting a patent term extension of up to five years beyond the statutory 20-year term of the patent for the approved product or its methods of manufacture or use if the active ingredient has not been previously approved in the U.S. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and some other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of an NDA, we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

The patent portfolios for our proprietary technology platform and our five most advanced product candidates as of January 9, 2020 are summarized below.

TNX-102 SL – Central Nervous System Conditions

Our patent portfolio for TNX-102 SL includes patent applications directed to compositions of matter of CBP, formulations containing CBP, and methods for treating CNS conditions, such as TNX-102 SL for PTSD, and TNX-102 SL for agitation in neurodegenerative conditions, e.g. AAD, utilizing these compositions and formulations.

Certain eutectic compositions were discovered by development partners and are termed the “Eutectic Technology.” The patent portfolio for TNX-102 SL relating to the Eutectic Technology includes patent applications directed to eutectic compositions containing CBP, eutectic CBP formulations, methods for treating PTSD and other CNS conditions utilizing eutectic CBP compositions and formulations, and methods of manufacturing eutectic CBP compositions. The Eutectic Technology patent portfolio includes U.S. patent applications, such as U.S. Patent Application No. 14/214,433 (now U.S. Patent No. 9,636,408). If U.S. and non-U.S. patents claiming priority from those applications issue, those patents would expire in 2034 or 2035, excluding any patent term adjustments or extensions.

The unique pharmacokinetic profile of TNX-102 SL, or the PK Technology, was discovered by Tonix and its development partners. The patent portfolio for TNX-102 SL relating to the PK Technology includes patent applications directed to compositions of matter of CBP, formulations containing CBP, methods for treating PTSD, agitation in neurodegenerative conditions, and other CNS conditions utilizing these compositions and formulations. The PK Technology patent portfolio includes U.S. Patent Application No. 13/918,692. If U.S. and non-U.S. patents claiming priority from those applications issue, those patents would expire in 2033, excluding any patent term adjustments or extensions.

On May 2, 2017, U.S. Patent No. 9,636,408 entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride” issued. The patent claims recite pharmaceutical compositions comprising the eutectic. The patent claims also recite methods of manufacturing the eutectic. Tablets containing CBP and mannitol eutectic have good pharmaceutical stability and manufacturability. A solid eutectic is a form of matter in which two solid crystals co-penetrate each other, such that the inter-molecular space between the units of one crystal lattice are occupied by the other crystal lattice. The distance between the molecular units is not changed.

On September 13, 2017, European patent 2,501,234, entitled “Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine”, issued. This patent recites the use of CBP for the treatment of PTSD, which covers the use of TNX-102 SL for the treatment of PTSD, since the active ingredient in TNX-102 SL is CBP and provides TNX-102 SL with European market exclusivity until 2030 and may be extended based on the timing of the European marketing authorization of TNX-102 SL for PTSD. In response to an opposition filed in June 2018, the European Patent Office’s Opposition Division in October 2019 upheld the patent in unamended form. Opponent has appealed.

On December 15, 2017, Japanese Patent No. 6259452, entitled “Compositions and Methods for Transmucosal Absorption”, issued. These claims relate to the pharmacokinetic profile of TNX-102 SL.

On March 20, 2018, U.S. Patent No. 9,918,948 entitled “Methods and Compositions for Treating Symptoms Associated with PTSD Using Cyclobenzaprine”, issued. The claims recite a method of using TNX-102 SL’s active ingredient cyclobenzaprine to treat PTSD and provides TNX-102 SL with US market exclusivity until 2030, excluding any patent term extensions.

On March 23, 2018, Japanese Patent No. 6310542 entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, issued. The claims recite pharmaceutical compositions comprising the eutectics and methods of manufacturing these eutectic formulations.

On May 1, 2018, U.S. Patent No. 9,956,188, entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, issued. The claims recite a eutectic of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics.

On November 6, 2018, U.S. Patent No. 10,117,936, entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, issued. The claims recite pharmaceutical compositions of eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions.

On July 23, 2019, U.S. Patent No. 10,357,465 entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride”, issued. The claims recite pharmaceutical compositions comprising eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those compositions.

On November 15, 2019, Japanese Patent No. 6614724 entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride”, issued. The claims recite pharmaceutical compositions comprising CBP:delta-mannitol eutectics and methods of making the same.

On December 11, 2019, European patent 2968992, entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride”, issued. This patent recites pharmaceutical compositions comprising a eutectic of mannitol and Cyclobenzaprine HCl and methods of making the same.

On December 25, 2019, European patent 2,683,245, entitled “Methods and Compositions for Treating Depression Using Cyclobenzaprine”, issued. The claims recite the use of CBP for the treatment of depression in a FM patient. This patent provides TNX-102 SL with European market exclusivity until March 2032 and may be extended based on the timing of the European marketing authorization of TNX-102 SL for depression in a FM patient.

TNX-601 — Posttraumatic Stress Disorder and Neurocognitive Dysfunction

Our patent portfolio for tianeptine oxalate includes European Patent No. 2,299,822, entitled “Method for Treating Neurocognitive Dysfunction”, which issued on July 26, 2017. The '822 patent recites pharmaceutical compositions comprising various compounds (which include tianeptine) and uses thereof. This patent provides TNX-601 with European market exclusivity until April 2029 and may be extended based on the timing of the European marketing authorization of TNX-601 for neurocognitive side effects associated with the use of corticosteroids.

On February 27, 2019, European Patent No. 3,246,031 entitled “Method for Treating Neurodegenerative Dysfunction”, issued. The claims recite the use of TNX-601, or tianeptine oxalate and other salts, for treating neurocognitive dysfunction associated with corticosteroid treatment. This patent provides TNX-601 with European market exclusivity until April 2029 and may be extended based on the timing of the European market authorization of TNX-601 for neurocognitive dysfunction associated with corticosteroid treatment.

On October 22, 2019, U.S. Patent No. 10,449,203 issued. The claims recite anhydrous crystalline oxalate salts of tianeptine and provides TNX-601 with US market exclusivity until 2037, excluding any patent term extensions.

Our patent portfolio for TNX-601 also includes International Patent Application PCT/IB2017/001709 (now nationalized in 15 countries). It includes claims directed to crystalline tianeptine oxalate and compositions of those crystal forms, and disclosures directed to methods of using those crystalline forms and their compositions.

TNX-801 — Live HPXV Vaccine for Prevention of Smallpox

We own the rights to develop a potential biodefense technology, TNX-801, a live HPXV that is being developed as a new smallpox preventing vaccine, we have patent applications directed to synthetic chimeric poxviruses and methods of using these poxviruses to protect individuals against smallpox. These applications include U.S. non-provisional Patent Application No. 15/802,189 and International Patent Application No. PCT/US2017/059782. We also own the rights to develop other vaccine candidates against smallpox. With respect to these vaccine candidates, we own U.S. Patent Application No. 14/207,727 and related intellectual property rights. The smallpox vaccine technologies relate to proprietary forms of live HPXV and vaccinia vaccines which may be safer than ACAM2000, the only currently available replication competent, live vaccinia vaccine to protect against smallpox disease. We believe that this technology, after further development, may be of interest to biodefense agencies in the U.S. and other countries.

TNX-1300 — Cocaine Intoxication Treatment

We have licensed rights from Columbia University, University of Michigan, and The Kentucky Research Foundation to develop a potential product, TNX-1300, for cocaine intoxication treatment. The licensed patents are directed to mutant cocaine esterase polypeptides and methods of using these polypeptides as anti-cocaine therapeutics. They include U.S. Patent Nos. 8,318,156 and 9,200,265, entitled “Anti-Cocaine Compositions and Treatment” and various counterpart patents outside of the U.S. These patents provide TNX-1300 with US market exclusivity until February 2029. They provide market exclusivity outside of the U.S. until July 10, 2027. These dates may be subject to patent term extensions.

TNX-1500 — CD154 Therapeutics

We are collaborating with Harvard Medical School, to develop TNX-1500, a humanized monoclonal antibody (mAb) that targets CD154 for the prevention and treatment of organ transplant rejection. In this regard, we filed U.S. Provisional Patent Application No. 62/869,489, entitled “Anti-CD154 antibodies and uses thereof” on July 1, 2019. We also filed U.S. Provisional Patent Application No. 62/833,473, entitled “Inhibitors of CD40-CD154 Binding” on April 12, 2019. This application is directed to small molecule inhibitors of CD154.

TNX-1600 — Triple Reuptake Inhibitor to Treat PTSD

We have licensed rights from Wayne State University to develop a potential product, TNX-1600, for PTSD treatment. The licensed patents directed to pyran based derivatives and analogues. They include U.S. Patent Nos. 7,915,433, 8,017,791, 8,519,159, 8,841,464, and 8,937,189, entitled “Tri-substituted 2-benzhydryl 5-benzlamino-tetrahydro-pyran-4-OL and 6-benzhydryl-4-benzylamino-tetrahydro-pyran-3-OL analogues, and novel 3,6 disubstituted pyran derivatives” and U.S. Patent No. 9,458,124, entitled “Substituted Pyran Derivatives”. These patents provide TNX-1600 with US market exclusivity between April 2024 and February 2034, respectively, subject to any patent term extensions.

TNX-1700 — Recombinant Trefoil Family Factor 2 (rTFF2) to Treat Gastric and Pancreatic Cancers

We have licensed rights from Columbia University to develop a potential product, TNX-1700, for the treatment of gastric and pancreatic cancers. The licensed patent and patent application are directed to TFF2 compositions and methods of treatment. The licensed patent is U.S. Patent No. 10,124,037. The licensed patent application is U.S. Patent Application No. 16/189,868 entitled “Trefoil Family Factor Proteins and Uses Thereof”. We have also filed U.S. Patent Application No. 62/892,520, entitled “PEGylated TFF2 Polypeptides” on August 27, 2019. The licensed patent provides TNX-1700 with US market exclusivity until April 2033, subject to any patent term extensions.

On August 27, 2019, we filed U.S. Patent Application No. 62/892,520, entitled “PEGylated TFF2 Polypeptides” and on December 4, 2019, we filed U.S. Patent Application No. 62/943,803, entitled “Modified TFF2 Polypeptides”.

TNX-701 — Radioprotection Biodefense Technology

We own the rights to develop a potential biodefense technology, which is a potential radioprotective therapy. For protection of our intellectual property, we have not disclosed the identity of the new development candidate.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary technology platform are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to rights in related or resulting inventions and know-how.

Issued Patents

Our current patents owned include:

Sublingual CBP/Amitriptyline

Patent No.	Title	Country / Region	Expiration Date
6259452	Compositions and Methods for Transmucosal Absorption	Japan	June 14, 2033
631144	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033
1590820	Compositions and Methods for Transmucosal Absorption	Taiwan	June 14, 2033
2013274003	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
1642429	Compositions and Methods for Transmucosal Absorption	Taiwan	June 14, 2033
726488	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033

CBP – Depression

Patent No.	Title	Country / Region	Expiration Date
2012225548	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia	March 6, 2032
2016222412	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia	March 6, 2032
614725	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand	March 6, 2032
714294	Methods and Compositions for Treating Depression Using Cyclobenzaprine	New Zealand	March 6, 2032
2683245	Methods and Compositions for Treating Depression Using Cyclobenzaprine	European Patent Office – Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, and Turkey	March 6, 2032

Low Dose CBP

Patent No.	Title	Country / Region	Expiration Date
6,395,788	Methods for Treating Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	U.S.A.	August 11, 2020
16,541,523	Methods for Treating or Preventing Fibromyalgia Using Very Low Doses of Cyclobenzaprine	U.S.A.	August 11, 2020
1202722; ATE299369T1 in Austria; 60021266.1 in Germany; ES 2245944 T3 in Spain	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	European Patent Office – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	August 11, 2020
1047691	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	Hong Kong	August 11, 2020
516749	Uses Compositions for Treating or Preventing Sleep Disturbances Using Very Low Doses of Cyclobenzaprine	New Zealand	August 11, 2020

Low Dose CBP – GAD

Patent No.	Title	Country / Region	Expiration Date
6,358,944	Methods and Compositions for Treating Generalized Anxiety Disorder	U.S.A.	August 23, 2020

CBP – PTSD

Patent No.	Title	Country / Region	Expiration Date
9,918,948	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	U.S.A.	November 18, 2030
2501234 (AL/P/17/691 in Albania; 602010045270.0 in Germany; 3094254 in Greece; 502017000142469 in Italy; MK/P/17/000807 in Macedonia; 56634 in Serbia; SM-T-201700578 in San Marino; 201717905 in Turkey) HK1176235	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	European Patent Office – Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, Turkey	November 16, 2030
	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	Hong Kong	November 16, 2030

CBP Fatigue

Patent No.	Title	Country / Region	Expiration Date
9,474,728	Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine	U.S.A.	June 9, 2031

Tianeptine – Neurocognitive Dysfunction

Patent No.	Title	Country / Region	Expiration Date
9,314,469	Method for Treating Neurocognitive Dysfunction	U.S.A.	September 24, 2030
2723688	Method for Treating Neurodegenerative Dysfunction	Canada	April 30, 2029
2299822 (602009047361.1 in Germany)	Method for Treating Neurodegenerative Dysfunction	Europe – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	April 30, 2029
3246031 (602009057284.9 in Germany)	Method for Treating Neurodegenerative Dysfunction	Europe – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	April 30, 2029

Eutectic CBP/Amitriptyline

Patent No.	Title	Country / Region	Expiration Date
631152	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand	March 14, 2034
9,636,408	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
9,956,188	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
10,117,936	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
10,322,094	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
10,357,465	Eutectic Formulations of Cyclobenzaprine Hydrochloride	U.S.A.	September 18, 2035
6310542	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan	March 14, 2034
6614724	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan	September 18, 2035
6088	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Saudi Arabia	March 14, 2034
ZL201480024011.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	China	March 14, 2034
2014233277	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Australia	March 14, 2034
1661825	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan	March 14, 2034
IDP000055516	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia	March 14, 2034
IDP000063221	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Indonesia	September 18, 2035
2968992	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	European Patent Office	March 14, 2034

Tianeptine Oxalate – Salts and Crystalline Forms

Patent No.	Title	Country / Region	Expiration Date
10,449,203	Tianeptine Oxalate Salts and Polymorphs	U.S.A	December 28, 2037

Anti-Cocaine Therapeutics

Patent No.	Title	Country / Region	Expiration Date
8,318,156	Anti-Cocaine Compositions and Treatment	U.S.A	February 14, 2029
9,200,265	Anti-Cocaine Compositions and Treatment	U.S.A.	December 30, 2027
2007272955	Anti-Cocaine Compositions and Treatment	Australia	July 10, 2027
2014201653	Anti-Cocaine Compositions and Treatment	Australia	July 10, 2027
2657246	Anti-Cocaine Compositions and Treatment	Canada	July 10, 2027
612929	Anti-Cocaine Compositions and Treatment	New Zealand	July 10, 2027
2046368 (602007045044.6 in Germany; 502016000056543 in Italy)	Anti-Cocaine Compositions and Treatment	Europe – (Germany, Spain, France, United Kingdom, and Italy)	July 10, 2027
2009/00197	Anti-Cocaine Compositions and Treatment	South Africa	July 10, 2027
305483	Anti-Cocaine Compositions and Treatment	Mexico	July 10, 2027
196411	Anti-Cocaine Compositions and Treatment	Israel	July 10, 2027

Triple reuptake inhibitor therapeutics

Patent No.	Title	Country / Region	Expiration Date
7,915,433	Tri-substituted 2-benzhydryl 5-benzlamino-tetrahydro-pyran-4-OL and 6-benzhydryl-4-benzylamino-tetrahydro-pyran-3-OL analogues, and novel 3,6 disubstituted pyran derivatives	U.S.A	March 10, 2028
8,017,791	Tri-substituted 2-benzhydryl 5-benzlamino-tetrahydro-pyran-4-OL and 6-benzhydryl-4-benzylamino-tetrahydro-pyran-3-OL analogues, and novel 3,6 disubstituted pyran derivatives	U.S.A.	April 14, 2024
8,519,159	Tri-substituted 2-benzhydryl 5-benzlamino-tetrahydro-pyran-4-OL and 6-benzhydryl-4-benzylamino-tetrahydro-pyran-3-OL analogues, and novel 3,6 disubstituted pyran derivatives	U.S.A	December 7, 2025
8,841,464	Tri-substituted 2-benzhydryl 5-benzlamino-tetrahydro-pyran-4-OL and 6-benzhydryl-4-benzylamino-tetrahydro-pyran-3-OL analogues, and novel 3,6 disubstituted pyran derivatives	U.S.A	April 15, 2025
8,937,189	Tri-substituted 2-benzhydryl 5-benzlamino-tetrahydro-pyran-4-OL and 6-benzhydryl-4-benzylamino-tetrahydro-pyran-3-OL analogues, and novel 3,6 disubstituted pyran derivatives	U.S.A	January 12, 2027
9,458,124	Substituted Pyran Derivatives	U.S.A	February 6, 2034

TFF2 therapeutics

Patent No.	Title	Country / Region	Expiration Date
10,124,037	Trefoil family factor proteins and uses thereof	U.S.A	April 2, 2033

Pending Patent Applications

Our current pending patent applications are as follows:

CBP/Amitriptyline Eutectic Formulations

Application No.	Title	Country / Region
16/140,090	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
16/429,852	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A
16/518,338	Eutectic Formulations of Cyclobenzaprine Hydrochloride	U.S.A
16/140,105	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
2015317336	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Australia
BR112015022095-9	Pharmaceutical Composition, Method of Fabrication, Eutectic Composition and Use of Compositions Containing Cyclobenzaprine HCl and Mannitol	Brazil
BR112017005231-8	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Brazil
2,904,812	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Canada
2,961,822	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Canada
201580050140.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China
201910263541.6	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	China
15841528.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride	European Patent Office
19214535.7	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	European Patent Office
16106690.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
18101200.4	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Hong Kong
P00201808623	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia
241353	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride (Allowed)	Israel
251218	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Methods of Producing Same	Israel
3392/KOLNP/2015	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	India
201717013182	Eutectic Formulations of Cyclobenzaprine Hydrochloride	India
2019-151766	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan

Application No.	Title	Country / Region
2018-173466	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan
2019-236602	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan
MX/a/2015/012622	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride (Allowed)	Mexico
MX/a/2017/003644	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Mexico
MX/a/2019/014200	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico
PI 2015703142	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Malaysia
PI 2017700889	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Malaysia
730379	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand
747040	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand
517381123	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Saudi Arabia
10201707528W	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Singapore
10201902203V	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Singapore
2015/07443	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride (Allowed)	South Africa
2017/01637	Eutectic Formulations of Cyclobenzaprine Hydrochloride	South Africa
108114946	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan
2014-000391	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Venezuela

Sublingual CBP/Amitriptyline

Application No.	Title	Country / Region
13/918,692	Compositions and Methods for Transmucosal Absorption	U.S.A.
P20130102101	Compositions and Methods for Transmucosal Absorption	Argentina
2018241128	Compositions and Methods for Transmucosal Absorption	Australia
BR112014031394-6	Compositions and Methods for Transmucosal Absorption	Brazil
BR122019024508-8	Compositions and Methods for Transmucosal Absorption	Brazil
2,876,902	Compositions and Methods for Transmucosal Absorption	Canada
201380039522.6	Compositions and Methods for Transmucosal Absorption	China
Not yet assigned	Compositions and Methods for Transmucosal Absorption	China
13804115.7	Compositions and Methods for Transmucosal Absorption	European Patent Office
2013/24661	Compositions and Methods for Transmucosal Absorption	Gulf Cooperation Council
2013/37088	Compositions and Methods for Transmucosal Absorption	Gulf Cooperation Council
15110186.6	Compositions and Methods for Transmucosal Absorption	Hong Kong
P-00 2015 00202	Compositions and Methods for Transmucosal Absorption	Indonesia
236268	Compositions and Methods for Transmucosal Absorption	Israel
139/KOLNP/2015	Compositions and Methods for Transmucosal Absorption	India
2019-91262	Compositions and Methods for Transmucosal Absorption	Japan
MX/a/2014/015436	Compositions and Methods for Transmucosal Absorption	Mexico
PI 2014703784	Compositions and Methods for Transmucosal Absorption	Malaysia
10201605407T	Compositions and Methods for Transmucosal Absorption	Singapore
107117266	Compositions and Methods for Transmucosal Absorption (Allowed)	Taiwan
2013-000737	Compositions and Methods for Transmucosal Absorption	Venezuela
2015/00288	Compositions and Methods for Transmucosal Absorption	South Africa

CBP – PTSD

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
15/915,688	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	U.S.A

CBP - Fatigue

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
16/537,170	Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine	U.S.A.

CBP - Agitation in Neurodegenerative Condition

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
16/215,952	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	U.S.A.
PCT/IB2018/001509	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	PCT

CBP - Depression

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
13/412,571	Methods and Compositions for Treating Depression Using Cyclobenzaprine	U.S.A.
2018204633	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia
2,829,200	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Canada
19214568.8	Methods and Compositions for Treating Depression Using Cyclobenzaprine	European Patent Office

Analogs of CBP

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
PCT/US2018/042184	Analogs of Cyclobenzaprine and Amitriptylene	PCT

Tianeptine Oxalate – Salts and Crystalline Forms

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
16/597,065	Tianeptine Oxalate Salts and Polymorphs	U.S.A.
2017385958	Tianeptine Oxalate Salts and Polymorphs	Australia
BR112019013244-9	Tianeptine Oxalate Salts and Polymorphs	Brazil
3,048,324	Tianeptine Oxalate Salts and Polymorphs	Canada
201780085697.9	Tianeptine Oxalate Salts and Polymorphs	China
17844642.3	Tianeptine Oxalate Salts and Polymorphs	European Patent Office
P00201906474	Tianeptine Oxalate Salts and Polymorphs	Indonesia
267708	Tianeptine Oxalate Salts and Polymorphs	Israel
201917029300	Tianeptine Oxalate Salts and Polymorphs	India
2019-535330	Tianeptine Oxalate Salts and Polymorphs	Japan
MX/a/2019/007891	Tianeptine Oxalate Salts and Polymorphs	Mexico
PI2019003711	Tianeptine Oxalate Salts and Polymorphs	Malaysia
754797	Tianeptine Oxalate Salts and Polymorphs	New Zealand
519402021	Tianeptine Oxalate Salts and Polymorphs	Saudi Arabia
11201905974W	Tianeptine Oxalate Salts and Polymorphs	Singapore
2019/04185	Tianeptine Oxalate Salts and Polymorphs	South Africa

Tianeptine Neurocognitive Dysfunction

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
15/064,196	Method for Treating Neurocognitive Dysfunction	U.S.A.

Novel Smallpox Vaccines

<u>Application No.</u>	<u>Title</u>	<u>Country / Region</u>
14/207,727	Novel Smallpox Vaccines	U.S.A.

Synthetic Chimeric Poxviruses

Application No.	Title	Country / Region
15/802,189	Synthetic Chimeric Poxviruses	U.S.A.
P 20170103043	Synthetic Chimeric Poxviruses	Argentina
2017/34209	Synthetic Chimeric Poxviruses	Gulf Cooperation Council
106137976	Synthetic Chimeric Poxviruses	Taiwan
2017353868	Synthetic Chimeric Poxviruses	Australia
BR112019008781-8	Synthetic Chimeric Poxviruses	Brazil
3,042,694	Synthetic Chimeric Poxviruses	Canada
201780078546.0	Synthetic Chimeric Poxviruses	China
17868045.0	Synthetic Chimeric Poxviruses	European Patent Office
201917021814	Synthetic Chimeric Poxviruses	India
PID201904682	Synthetic Chimeric Poxviruses	Indonesia
266399	Synthetic Chimeric Poxviruses	Israel
2019-545700	Synthetic Chimeric Poxviruses	Japan
PI2019002462	Synthetic Chimeric Poxviruses	Malaysia
MX/a/2019/005102	Synthetic Chimeric Poxviruses	Mexico
752893	Synthetic Chimeric Poxviruses	New Zealand
11201903893P	Synthetic Chimeric Poxviruses	Singapore
2019/02868	Synthetic Chimeric Poxviruses	South Africa
2017-000418	Synthetic Chimeric Poxviruses	Venezuela

Synthetic Vaccinia Virus

Application No.	Title	Country / Region
PCT/US2019/030486	Synthetic Chimeric Vaccinia Virus	PCT
2019/37492	Synthetic Chimeric Vaccinia Virus	Gulf Cooperation Council
20190101165	Synthetic Chimeric Vaccinia Virus	Argentina
108115290	Synthetic Chimeric Vaccinia Virus	Taiwan

Stem cells-scPV treatment

Application No.	Title	Country / Region
PCT/US2019/030488	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	PCT
2019/37505	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Gulf Cooperation Council
20190101166	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Argentina
108115294	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Taiwan

CBP – ASD and PTSD

Application No.	Title	Country / Region
PCT/IB2019/000940	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	PCT
2019/38140	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Gulf Cooperation Council
108129709	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Taiwan

Salts of glutathione

Application No.	Title	Country / Region
62/824,008	Salt forms of S-(N, N-diethylcarbamoyle) glutathione	U.S.A.
62/941,533	Salt forms of S-(N, N-diethylcarbamoyle) glutathione	U.S.A.

CD154 Therapeutics

Application No.	Title	Country / Region
62/833,473	Inhibitors of CD40-CD154 Binding	U.S.A.
62/869,489	Anti-CD154 antibodies and uses thereof	U.S.A.

TFF2 therapeutics

Application No.	Title	Country / Region
62/892,520	PEGylated TFF2 polypeptide	U.S.A.
62/943,803	Modified TFF2 polypeptides	U.S.A.
16/189,868	Trefoil Family Factor Proteins and Uses Thereof	U.S.A.

Trademarks and Service Marks

We seek trademark and service mark protection in the United States and outside of the United States where available and when appropriate. We are the owner of the following U.S. federally registered marks: TONIX PHARMACEUTICALS (Reg. No. 4656463, issued December 16, 2014) and TONMYA (Reg. No. 4868328, issued December 8, 2015).

We are the owner of the following marks for which applications for U.S. federal registration are currently pending: FYMRALIN (Serial No. 88/064191, filed August 3, 2018), MODALTIN (Serial No. 88/196892, filed November 16, 2018), RAPONTIS (Serial No. 88/196897, filed November 16, 2018), PROTECTIC (Serial No. 88/196912, filed November 16, 2018), TONIX PHARMACEUTICALS (Serial No. 86/400401, filed September 19, 2014) and ANGSTRO-TECHNOLOGY (Serial No. 88/690384, filed November 13, 2019).

Research and Development

We have approximately nine employees dedicated to research and development. Our research and development operations are located in New York, NY, San Diego, CA, Dublin, Ireland and Montreal, Canada. We have used, and expect to continue to use, third parties to conduct our nonclinical and clinical studies.

Manufacturing

We have contracted with third-party cGMP-compliant contract manufacturer organization, or CMOs, for the manufacture of TNX-102 SL drug substances and drug products for investigational purposes, including nonclinical and clinical testing. For TNX-102 SL, we have engaged a cGMP facility for manufacturing of to-be-marketed product for Phase 3 clinical and commercial. Our manufacturing operations are managed and controlled in Dublin, Ireland.

All of our small molecules drug candidates are synthesized using industry standard processes, and our drug products are formulated using commercially available pharmaceutical grade excipients.

Our smallpox-preventing vaccine candidate is a biologic and uses live form of HPXV. Both the drug substance (HPVX and the cell bank) and the drug product (vaccine) will be manufactured by contract cGMP-compliant facilities capable of manufacturing for nonclinical/clinical testing and licensed product.

Government Regulations

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 requirements by the 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;
- 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 for drug products, or a Biologics License Application, or BLA, for biologic products;
- satisfactory completion of a preapproval inspection by the FDA of the manufacturing facilities at which the product is produced to assess compliance with cGMP regulations; and
- the FDA's review and approval of the NDA or BLA 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. 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.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

Clinical testing must satisfy the extensive regulations of the FDA. 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 (or BLA, in the case of a biologic product). An NDA or BLA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA or BLA 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 and BLAs 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 or BLA 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 or BLA 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 or BLA 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 or BLA. 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 or BLA 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) NDAs

There are two types of NDAs: the Section 505(b)(1) NDA, or full NDA, and the Section 505(b)(2) NDA. We intend to file Section 505(b)(2) NDAs for TNX-102 SL for PTSD and FM, and for certain other products, that might, if accepted by the FDA, save time and expense in the development and testing of our product candidates. We may need to file a Section 505(b)(1) NDA for certain other products in the future. 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.

Our drug approval strategy for our new formulations of approved chemical entities is to submit Section 505(b)(2) NDAs to the FDA. As such, we plan to submit an NDA under Section 505(b)(2) for TNX-102 SL for PTSD and FM. The FDA may not agree that this product candidate is approvable for PTSD and FM as a Section 505(b)(2) NDA. If the FDA determines that a Section 505(b)(2) NDA is not appropriate and that a full NDA is required for TNX-102 SL, the time and financial resources required to obtain the FDA's approval for TNX-102 SL could substantially and materially increase, and TNX-102 SL might be less likely to be approved. If the FDA requires a full NDA for TNX-102 SL, 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 a safety 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).

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 in the orange book 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 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), the FDA's approval of the Section 505(b)(2) NDA may be made effective immediately upon successful review by the FDA 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 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 an 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, the FDA's approval of the Section 505(b)(2) NDA may automatically be stayed until 7½ 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 the 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 nonclinical 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 approval by the FDA 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 a "Written Request" issued by the FDA 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.

Breakthrough Therapy Designation

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, was signed. FDASIA Section 902 provides for a new drug designation – Breakthrough Therapy. A Breakthrough Therapy is a drug:

- intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and
- preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

In December 2016, the FDA granted Breakthrough Therapy designation, or BT, to TNX-102 SL for the treatment of PTSD. The Breakthrough Therapy designation was granted based on the preliminary clinical evidence of TNX-102 SL on military-related PTSD in the Phase 2 AtEase study.

Following the interim analysis (IA) of the Phase 3 HONOR Study, we met with the FDA in October 2018 to seek agreement on the design of the next Phase 3 study (RECOVERY). In December 2018, the FDA issued an Intent-to-Rescind letter for BT status for TNX-102 SL for the treatment of PTSD because the IA results of the HONOR study did not meet the criteria for the BT granted in December 2016. In March 2019, the FDA rescinded the BT, but subsequently withdrew the BT rescission in April 2019 and granted a meeting in August 2019 to discuss the continuation of BT for TNX-102 SL. The BT for TNX-102 SL for PTSD remains in effect and the FDA's intent-to-rescind BT for TNX-102 SL for PTSD also remains in effect. The FDA agreed to consider the additional data and information presented at the August 2019 meeting. The FDA's decision whether to maintain BT for TNX-102 SL for PTSD is pending. The FDA will inform us of the BT decision but no timeframe was given.

In October 2014, the FDA granted BT for TNX-1300 for treatment of cocaine intoxication. We in-licensed TNX-1300 from Columbia University in May 2019.

Fast Track Designation

A Fast Track is a designation by the FDA of an investigational drug which:

- intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and
- non-clinical or clinical data demonstrate the potential to address an unmet medical need

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The benefits of a Fast Track designation include rolling submission of portions of the NDA for the drug candidate and eligibility for priority review of the NDA. Additionally, more frequent meetings and written communication with the FDA regarding the development plan and trial design for the drug candidate are encouraged throughout the entire drug development and review process, with the goal of having earlier drug approval and access for patients.

In April 2018, the FDA cleared our IND for TNX-102 SL for treatment of AAD to support a Phase 2, potential pivotal efficacy study, and granted TNX-102 SL for the treatment of AAD Fast Track development program in July 2018.

Material Threat Medical Countermeasures

In 2016, the 21st Century Cures Act, or Act, was signed into law to support ongoing biomedical innovation. One part of the Act, Section 3086, is aimed at “Encouraging Treatments for Agents that Present a National Security Threat.” The Act created a new priority review voucher program for “material threat medical countermeasures.” The Act defines such countermeasures as drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat or to treat harm from a condition that may be caused by administering a drug or biological product against such an agent. The Department of Homeland Security has identified 13 such threats, including anthrax, smallpox, Ebola/Marburg, tularemia, and botulism. A priority review voucher can be applied to any other product application; it shortens the FDA review timeline for a new application from 10-12 months to 6 months. The recipient of a priority review voucher may transfer it. We intend to seek a priority review voucher for TNX-801 licensure as a material threat medical countermeasure. However, the Priority Review Voucher program provision of the 21st Century Cures Act is set to expire in 2023. If TNX-801 does not receive FDA licensure by 2023, we may not be able to capitalize on the incentives contained in the 21st Century Cures Act unless the provision allowing for the Priority Review Voucher Program is extended until such time as TNX-801 is licensed.

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 review by the FDA 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 approvals by the FDA 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.

Coverage and Reimbursement

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

Other Healthcare Laws

Because of our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors, we will also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both. The U.S. laws that may affect our ability to operate, among others, include: the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; certain state laws governing the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

The Impact of New Legislation and Amendments to Existing Laws

The FDCA is subject to routine legislative amendments with a broad range of downstream effects. In addition to new legislation, such as the FDA Reauthorization Act of 2017 or the FDASIA in 2012, Congress introduces amendments to reauthorize drug user fees and address emerging concerns every five years. We cannot predict the impact of these new legislative acts and their implementing regulations on our business. The programs established or to be established under the legislation may have adverse effects upon us, including increased regulation of our industry. Compliance with such regulation may increase our costs and limit our ability to pursue business opportunities. 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. Additionally, the current legislative authority for the Prescription Drug User Fee Act expired in September 2017. The requirements and changes imposed by the legislation to reauthorize the act 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. It is impossible to predict whether additional legislative changes will be enacted, or regulations by the FDA, guidance or interpretations will change, or what the impact of such changes, if any, may be.

We expect that additional federal and state, as well as foreign, healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or additional pricing pressure.

Employees

As of January 17, 2020, we had 15 full-time employees, of whom four hold M.D. or Ph.D. degrees. We have nine employees dedicated to research and development. Our research and development operations are located in New York, NY, San Diego, CA, Dublin, Ireland and Montreal, Canada. We have used, and expect to continue to use, third parties to conduct our nonclinical and clinical studies as well as part-time employees. None of our employees are represented by a collective bargaining agreement, and we believe that our relations with our employees are good.

Corporate Information

We lease the space for our principal executive offices, which are located at 509 Madison Avenue, Suite 1608, New York, New York 10022, and our telephone number is (212) 980-9155. Our website addresses are www.tonixpharma.com, www.tonix.com, and www.krele.com. We do not incorporate the information on our websites into this annual report, and you should not consider such information part of this annual report.

We were incorporated on November 16, 2007 under the laws of the State of Nevada as Tamandare Explorations Inc. On October 11, 2011, we changed our name to Tonix Pharmaceuticals Holding Corp.

Properties

We maintain our principal office at 509 Madison Avenue, Suite 1608, New York, New York 10022. Our telephone number at that office is (212) 980-9155 and our fax number is (212) 923-5700. On December 6, 2018, we entered into a lease amendment, whereby we agreed to lease new office space, commencing January 15, 2019 and expiring on November 30, 2020. In connection therewith, we maintain a letter of credit, which has a remaining balance of \$99,479 as of December 31, 2018, and such amount is deposited into the restricted cash account maintained at the bank that issued the letter of credit. The total square footage of our principal office space is approximately 2,658.

On July 27, 2015, we entered into a lease for approximately 132 square feet of office space in Montreal, Canada, whereby we agreed to lease premises, commencing August 1, 2015 and expiring on July 31 on an annual renewal basis. In connection therewith, we paid a security deposit of \$800.

On August 24, 2015, we entered into a lease for approximately 2,762 square feet of office space in San Diego, California, whereby we agreed to lease premises, commencing September 1, 2015 and expiring on August 31, 2019. In connection therewith, we paid a security deposit of \$11,272. In April 2019, we signed a one-year extension, expiring in August 2020.

On August 22, 2017, we entered into a lease for approximately 450 square feet of office space in Dublin, Ireland, whereby we agreed to lease premises, commencing November 20, 2017 and expiring on November 30, 2018. In connection therewith, we paid a security deposit of \$7,067. In November 2018, we signed a one-year extension, expiring on November 30, 2019. In September 2019, we extended the lease through May 2020.

Future minimum lease payments are as follows (in thousands):

Year Ending December 31,	
2020	\$ 358
2021	6
	<u>\$ 364</u>

We believe that our existing facilities are suitable and adequate to meet our current business requirements.

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, operating results or cash flows.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors and executive officers are as follows:

<u>NAME</u>	<u>AGE</u>	<u>CURRENT POSITION</u>
Seth Lederman	62	President, CEO and Chairman of the Board of Directors
Margaret Smith Bell	60	Director
Daniel Goodman	58	Director
David Grange	72	Director
Adeoye Olukotun	75	Director
John Rhodes	63	Lead Director
James Treco	64	Director
Jessica Morris	42	Chief Operating Officer
Bradley Saenger	46	Chief Financial Officer and Treasurer
Gregory Sullivan	54	Chief Medical Officer and Secretary

Seth Lederman, MD became our President, Chief Executive Officer, Chairman of the Board and a Director in October 2011. Dr. Lederman founded Tonix Pharmaceuticals, Inc., a wholly-owned subsidiary of us (“Tonix Sub”) in 2007 and has acted as its Chairman of the Board of Directors since its inception and as President since 2010. Dr. Lederman is an inventor on key patents and patent applications underlying our programs including: TNX-102 SL’s eutectic composition; TNX-102 SL’s pharmacokinetic profile and related therapeutic properties, and the use of TNX-102 SL for posttraumatic stress disorder (PTSD). Dr. Lederman served as an Associate Professor at Columbia University, between 1996 and 2017. As an Assistant Professor at Columbia, Dr. Lederman discovered and characterized the CD40-ligand, or CD154 and invented therapeutic candidates to treat autoimmune diseases and transplant rejection. TNX-1500 is a monoclonal antibody directed against CD154 invented by Dr. Lederman. Dr. Lederman has been a Manager of L&L Technologies LLC, or L&L, since 1996. In addition, Dr. Lederman has been the Managing Member of Seth Lederman Co, LLC since 2007 and the Managing Member of Lederman & Co, LLC, or Lederman & Co, since 2002, both of which are biopharmaceutical consulting and investing companies. Dr. Lederman has also been the Managing Member of Targent Pharmaceuticals, LLC, or Targent, since 2000, and Managing Member of Plumblin LLC 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 2007 and 2008, Dr. Lederman was Chairman of Validus Pharmaceuticals, Inc. and Fontus Pharmaceuticals, Inc., which were portfolio companies of the Konanda private growth equity funds. Since 2011, Dr. Lederman has served as CEO and Chairman of Leder Laboratories Inc., or Leder Labs, and Starling Pharmaceuticals Inc., or Starling, which are biopharmaceutical development companies. Dr. Lederman was the chairman of Leder Laboratories, Ltd., a wholly-owned subsidiary of Leder Laboratories Inc., between 2013 and 2018, when the entity was dissolved. In 2015, Dr. Lederman served as a member of the US – Japan Business Council. 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’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.

Margaret Smith Bell became a Director in September 2017. Ms. Bell has been retired for the last ten years. Previously, Ms. Bell was a Vice President at Standard Life Investments where she was a portfolio manager and health care equity analyst. Ms. Bell was also a Managing Director at Putnam Investments, and served as a senior health care analyst and a portfolio manager of the Putnam Health Sciences Trust. Ms. Bell was an analyst and vice president at State Street Research and a research analyst at Alex. Brown & Sons, Inc. Ms. Bell is a past member of the Board of Overseers at Beth Israel Deaconess Medical Center. Ms. Bell holds a B.A. from Wesleyan University and an M.B.A. from the Wharton School at the University of Pennsylvania. Ms. Bell’s extensive healthcare and investment banking experience were instrumental in her selection as a member of the Board.

Daniel Goodman became a Director in May 2019. Dr. Goodman founded Riverside Pharmaceuticals, a drug discover company, in 2012 and has been its Chief Executive Officer since inception. Dr. Goodman co-founded PsychoGenics Inc., a preclinical neuropharmacology company, in 1998, was its Chief Executive Officer from 1998 to 2000, and has served on its Board of Directors since 2000. Dr. Goodman graduated from Harvard Medical School and has an M.B.A. from Columbia Business School. Dr. Goodman’s experience in drug discovery and development and psychiatric conditions were critical in his selection as a member of our Board.

Brigadier General David Grange (U.S. Army retired) became a director in February 2018. BG Grange has been President and founder of Osprey Global Solutions, LLC (“OGS”), a Service Disabled Veterans Organization, since 2011. BG Grange was Chief Executive Officer of Pharm-Olam International, Ltd. (“Pharm-Olam”), a contract research organization, from April 2017 to October 2019. Prior to founding OGS, BG Grange was a member of the Board of Pharmaceutical Product Development, Inc. (PPDI), a contract research organization, from 2003 to 2009, and Chief Executive Officer from 2009 to 2011. Prior to PPDI he served in the McCormick Tribune Foundation for 10 years most recently as Chief Executive Officer and President, where he also oversaw the support of Veteran Programs. BG Grange served 30 years in the U.S. Army as a Ranger, Green Beret, Aviator, Infantryman and a member of special operating units. At the Pentagon, he was Director of Army Current Operations, Readiness, and Mobilization. BG Grange commanded the Ranger Regiment and the First Infantry Division (the Big Red One). BG Grange holds a master’s degree in Public Service from Western Kentucky University. BG Grange’s extensive experience in the pharmaceutical industry and service with the U.S. military was instrumental in his selection as a member of our Board.

Adeoye Olukotun, MD became a Director in September 2018. Dr. Olukotun has been the Chief Executive Officer of CR Strategies, LLC, a medical products consulting company, since 2000, and was the Chief Executive Officer of EpiGen Pharmaceuticals, Inc., a pharmaceutical company, from 2014 to January of 2018. Dr. Olukotun served as Vice Chairman of CardioVax, Inc., a pharmaceutical company, from 2012 to 2016, and as its Chief Executive Officer from 2006 to 2012. He is also co-founder of VIA Pharmaceuticals, Inc., a pharmaceutical company, and served as the company’s Chief Medical Officer from 2004 to 2008. Dr. Olukotun’s extensive medical background and experience in the pharmaceutical industry was instrumental in his selection as a member of our Board.

John Rhodes became a Director in October 2011 and Lead Director in February 2014. Mr. Rhodes has served as Chair of the New York State Public Service Commission and Chief Executive Officer of the Department of Public Services since June 2017. Mr. Rhodes served as President and CEO of the New York State Energy Research and Development Authority between September 2013 and June 2017. Between October 2010 and October 2011, Mr. Rhodes served as a director of Tonix Sub. Between 2005 and 2013, Mr. Rhodes was a director of Dewey Electronics Company, a manufacturer of electronic and electromechanical systems for the military and commercial markets. Between January 2013 and September 2013, he served as director of the Center for Market Innovation at Natural Resources Defense Council. 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.

James Treco became a director in February 2019. Mr. Treco has been a Managing Partner at First Chicago Advisors, Inc., a boutique financial advisory firm where he advises executives and boards of directors of a wide range of companies, from global, large-cap companies to emerging companies, from 2009 to 2012 and from 2014 to the present. From 2012 to 2013 Mr. Treco was an investment banker with Gleacher & Company, a company that previously operated an investment banking business, providing corporate and institutional clients with strategic and financial advisory services. Mr. Treco held various positions of increasing responsibility at Salomon Brothers/Citigroup from 1984 to 2008, where he used his extensive experience in the global capital markets to advise a wide range of clients. Mr. Treco holds a B.A. from Yale University and an M.B.A. from the Stanford University Graduate School of Business. Mr. Treco's extensive healthcare and investment banking experience were instrumental in his selection as a member of the Board.

Jessica Morris is our Chief Operations Officer and has worked for the Company since April 2013, first as a consultant (April 2013 – September 2013), then as SVP of Finance (September 2013 – October 2015), followed by Chief Administrative Officer (October 2015 – January 2016), Acting Chief Financial Officer (January 2016 – February 2016), and Executive Vice President, Operations (February 2016 – January 2018). Prior to joining the Company, Ms. Morris was a Vice President in investment management at Zhong Rong Group. Previously, Ms. Morris was a Senior Associate in the Sponsor Finance Group at American Capital, a Vice President of the mezzanine debt fund at Calvert Street Capital Partners, an Associate in the commercial finance department of Silicon Valley Bank, and a Financial Analyst in the investment banking group at Deutsche Bank. Ms. Morris earned a B.S. in Commerce and a B.A. in Music from the University of Virginia, where she was an Echols Scholar.

Bradley Saenger, CPA became our Chief Financial Officer in February 2016. Mr. Saenger has worked for us since May 2014, as the Director of Accounting (May 2014 – December 2015) and VP of Accounting (January 2016 – February 2016). Between June 2013 and March 2014, Mr. Saenger worked for Shire Pharmaceuticals as a consultant in the financial analyst research and development group. Since November 2015, Mr. Saenger has been a director of Tonix Pharma Holdings Limited. Between February 2013 and May 2013, Mr. Saenger worked for Stewart Health Care System as a financial consultant. Between October 2011 and December 2012, Mr. Saenger was an Associate Director of Accounting at Vertex Pharmaceuticals, Inc. Between January 2005 and September 2011, Mr. Saenger worked for Alere Inc., as a Manager of Corporate Accounting and Consolidations (2007 – 2011) and Manager of Financial Reporting (2005 – 2006). Mr. Saenger also worked for PricewaterhouseCoopers LLP, Shifren Hirsowitz, public accountants and auditors in Johannesburg, South Africa, Investec Bank in Johannesburg, South Africa and Norman Sifris and Company, public accountants and auditors in Johannesburg, South Africa. Mr. Saenger received his Bachelor's and Honors' degrees in Accounting Science from the University of South Africa. Mr. Saenger is a Chartered Accountant in South Africa and a Certified Public Accountant in the Commonwealth of Massachusetts.

Gregory Sullivan, MD became our Chief Medical Officer on June 3, 2014 and our Secretary in March 2017. Prior to becoming our Chief Medical Officer, he served on our Scientific Advisory Board since October 2010, and had also provided *ad hoc* consulting services. Previously, Dr. Sullivan had been a member of the faculty of Columbia University since July 1999, where he served as an Assistant Professor of Psychiatry in the Department of Psychiatry at Columbia University Medical Center (CUMC) until June 2014. Between June 1997 and August 2014, Dr. Sullivan maintained a part-time psychiatry practice. He served as a Research Scientist at the New York State Psychiatric Institute (NYSPI) from December 2006 to June 2014. He also served as a member of the Institutional Review Board of the NYSPI from January 2009 to June 2014. As Principal Investigator and Co-Investigator on several human studies of PTSD, Dr. Sullivan has administered the recruitment, biological assessments, treatment, and safety of participants with PTSD in clinical trials of the disorder. He has published more than 50 articles and chapters on research topics ranging from stress and anxiety disorders to abnormal serotonin receptor expression in depression, PTSD and panic disorder. He is a recipient of grants from the National Institute of Mental Health (NIMH), the Anxiety Disorders Association of America, NARSAD, the Dana Foundation, and the American Foundation for Suicide Prevention. Dr. Sullivan received a BA in Biology from the University of California, Berkeley, and received his MD from the College of Physicians & Surgeons at Columbia University. He completed his residency training in psychiatry at CUMC, and then a two-year NIMH-sponsored research fellowship in anxiety and affective disorders before joining the faculty at Columbia.

Directors serve until the next annual meeting of shareholders or until their successors are elected and qualified. Officers serve at the discretion of the board of directors (the "Board").

Board Independence

The Board has determined that (i) Seth Lederman has a relationship which, in the opinion of the Board, 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) Margaret Smith Bell, David Grange, Adeoye Olukotun, John Rhodes and James Treco are each an independent director as defined in the Marketplace Rules of The NASDAQ Stock Market. Prior to his resignation in February 2019, the Board found that Mr. Mather was also an independent director. Prior to their respective resignations, the Board had determined that Patrick Grace and Donald Landry were also independent directors.

Involvement in Certain Legal Proceedings

Except as disclosed below, 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.

In January 2013, the Chief Operating Officer filed for bankruptcy protection under Chapter 7 of Title 11 under the United States Code in the U. S. Bankruptcy Court in New York, New York. The petition was discharged in April 2013.

EXECUTIVE COMPENSATION

Compensation Philosophy and Practices

We believe that the performance of our executive officers significantly impacts our ability to achieve our corporate goals. We, therefore, place considerable importance on the design and administration of our executive officer compensation program. This program is intended to enhance stockholder value by attracting, motivating and retaining qualified individuals to perform at the highest levels and to contribute to our growth and success. Our executive officer compensation program is designed to provide compensation opportunities that are tied to individual and corporate performance.

Our compensation packages are also designed to be competitive in our industry. The Compensation Committee from time-to-time consults with compensation consultants, legal counsel and other advisors in designing our compensation program, including in evaluating the competitiveness of individual compensation packages and in relation to our corporate goals.

Our overall compensation philosophy has been to pay our executive officers an annual base salary and to provide opportunities, through cash and equity incentives, to provide higher compensation if certain key performance goals are satisfied. We believe that many of our key practices and programs demonstrate good governance. The main principles of our fiscal year 2018 compensation strategy included the following:

- *An emphasis on pay for performance.* A significant portion of our executive officers' total compensation is variable and at risk and tied directly to measurable performance, which aligns the interests of our executives with those of our stockholders;
- *Performance results are linked to Company and individual performance.* When looking at performance over the year, we equally weigh individual performance as well as that of the Company as a whole. Target annual compensation is positioned to allow for above-median compensation to be earned through an executive officer's and the Company's extraordinary performance;
- *Equity as a key component to align the interests of our executives with those of our stockholders.* Our Compensation Committee continues to believe that keeping executives interests aligned with those of our stockholders is critical to driving toward achievement of long-term goals of both our stockholders and the Company; and
- *Peer group positioning.* While the Compensation Committee considers the level of compensation paid by the companies in our peer group as a reference point that provides a framework for its compensation decisions, in order to maintain competitiveness and flexibility, the Compensation Committee does not target compensation at a particular level relative to the peer group; nor does the Compensation Committee employ a formal benchmarking strategy or rely upon specific peer-derived targets.

In 2019, we also continued practices that demonstrate good governance and careful stewardship of corporate assets, including:

- *Limited personal benefits.* Our executive officers are eligible for the same benefits as our non-executive salaried employees, and they do not receive any additional perquisites.
- *No retirement benefits.* We do not provide our executive officers with a traditional retirement plan, or with any supplemental deferred compensation or retirement benefits.
- *No tax gross-ups.* We do not provide our executive officers with any tax gross-ups.
- *No single-trigger cash change in control benefits.* We do not provide cash benefits to our executives upon a change in control, absent an actual termination of employment.

At our annual meeting in May 2019, we conducted our tri-annual advisory vote on executive compensation, commonly referred to as a "say-on-pay" vote. At that time, approximately 53% of the votes affirmatively cast on the advisory say-on-pay proposal were voted in favor of the compensation of our named executive officers. The Compensation Committee understood this level of approval to indicate strong stockholder support for our executive compensation policies and programs generally, and as a result, our Compensation Committee made no fundamental changes to our executive compensation programs. We will hold our next say-on-pay vote at the 2022 annual meeting. Our Compensation Committee and our Board will consider shareholder feedback through the say-on-pay vote and remains committed to engaging with shareholders and are open to feedback from shareholders.

Summary Compensation Table

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Chief Executive Officer, and the two next most highly paid executive officers for fiscal years 2019 and 2018.

Name & Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Seth Lederman	2019	585,000	—	—	505,178	—	—	—	1,090,178
Chief Executive Officer	2018	472,500	160,000	—	844,945	—	—	—	1,477,445
Gregory Sullivan	2019	400,000	—	—	168,393	—	—	—	568,393
Chief Medical Officer	2018	335,000	70,000	—	316,855	—	—	—	721,855
Bradley Saenger	2019	385,000	—	—	112,262	—	—	—	497,262
Chief Financial Officer	2018	335,000	70,000	—	211,235	—	—	—	616,235

(1) Represents the aggregate grant date fair value of options granted in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, "Stock Compensation." For the relevant assumptions used in determining these amounts, refer to Note 7 to our audited financial statements.

Grants of Plan-Based Awards in Fiscal 2019

The following table provides information with regard to each grant of plan-based award made to a named executive officer under any plan during the fiscal year ended December 31, 2019.

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 (\$) ⁽¹⁾
Seth Lederman	2/26/2019	2,327	\$ 18.90	\$ 36,680
	2/26/2019	2,327	\$ 23.60 ⁽²⁾	\$ 35,817
	5/6/2019	12,976	\$ 20.50	\$ 219,113
	5/6/2019	12,976	\$ 25.60 ⁽²⁾	\$ 213,568
Bradley Saenger	2/26/2019	517	\$ 18.90	\$ 8,151
	2/26/2019	517	\$ 23.60 ⁽²⁾	\$ 7,959
	5/6/2019	2,884	\$ 20.50	\$ 48,692
	5/6/2019	2,884	\$ 25.60 ⁽²⁾	\$ 47,460
Gregory Sullivan	2/26/2019	776	\$ 18.90	\$ 12,227
	2/26/2019	776	\$ 23.60 ⁽²⁾	\$ 11,939
	5/6/2019	4,326	\$ 20.50	\$ 73,038
	5/6/2019	4,326	\$ 25.60 ⁽²⁾	\$ 71,189

(1) Represents the aggregate grant date fair value of options granted in accordance with FASB ASC Topic 718.

(2) Represents an exercise price at a 125% premium of the closing price of the Company's common stock on the grant date.

Outstanding Equity Awards at December 31, 2019

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2019.

Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$/Sh)	Option Expiration Date
Seth Lederman	35	—	\$ 30,000.00	5/9/2022
	68	—	\$ 10,200.00	2/12/2023
	71	—	\$ 15,880.00	2/11/2024
	100	—	\$ 9,870.00	6/17/2024
	100	—	\$ 6,680.00	10/29/2024
	189	—	\$ 5,950.00	2/25/2025
	8	—	\$ 5,950.00	2/25/2025
	110	—	\$ 5,030.00	2/9/2026
	—	110(1)	\$ 5,030.00	2/9/2026
	148	12(2)	\$ 550.00	3/1/2027
	963	604(3)	\$ 340.00	2/13/2028
	963	604(3)	\$ 425.00	2/13/2028
	—	2,327(4)	\$ 18.90	2/26/2029
	—	2,327(4)	\$ 23.60	2/26/2029
	—	12,976(5)	\$ 20.50	5/6/2029
	—	12,976(5)	\$ 25.60	5/6/2029
Bradley Saenger	11	—	\$ 9,870.00	6/17/2024
	11	—	\$ 6,680.00	10/29/2024
	13	—	\$ 5,950.00	2/25/2025
	15	—	\$ 5,030.00	2/9/2026
	—	60(1)	\$ 2,420.00	5/27/2026
	20	—	\$ 2,420.00	5/27/2026
	45	3(2)	\$ 550.00	3/1/2027
	241	151(3)	\$ 340.00	2/13/2028
	241	151(3)	\$ 425.00	2/13/2028
	—	517(4)	\$ 18.90	2/26/2029
	—	517(4)	\$ 23.60	2/26/2029
	—	2,884(5)	\$ 20.50	5/6/2029
	—	2,884(5)	\$ 25.60	5/6/2029
Gregory Sullivan	27	—	\$ 9,870.00	6/17/2024
	27	—	\$ 6,680.00	10/29/2024
	27	—	\$ 5,950.00	2/25/2025
	30	—	\$ 5,030.00	2/9/2026
	—	30(1)	\$ 5,030.00	2/9/2026
	69	6(2)	\$ 550.00	3/1/2027
	366	222(3)	\$ 340.00	2/13/2028
	366	222(3)	\$ 425.00	2/13/2028
	—	776(4)	\$ 18.90	2/26/2029
	—	776(4)	\$ 23.60	2/26/2029
	—	4,326(5)	\$ 20.50	5/6/2029
	—	4,326(5)	\$ 25.60	5/6/2029

(1) The shares subject to this stock option vest 1/3rd upon the date(s) that certain stock price goals are achieved. The stock price goals are such date(s) when the Company's common stock has an average closing sales price equal to or exceeding each of \$6,000.00, \$7,000.00 and \$8,000.00 per share for 20 consecutive trading days, subject to a one year minimum service period prior to vesting.

(2) The shares subject to this stock option vested as to 1/3 of the shares on March 1, 2018, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(3) The shares subject to this stock option vested as to 1/3 of the shares on February 13, 2019, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(4) The shares subject to this stock option vested as to 1/3 of the shares on February 26, 2020, with the remaining shares vesting on an equal monthly basis over the following 24 months.

(5) The shares subject to this stock option vested as to 1/3 of the shares on May 6, 2020, with the remaining shares vesting on an equal monthly basis over the following 24 months.

Option Exercises and Stock Vested

No options were exercised by any of the named executive officers and no named executive officers held restricted stock units during the fiscal year ended December 31, 2019.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2019.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (A)	Weighted-average exercise price of outstanding options, warrants and rights (B)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column A) ⁽²⁾ (C)
Equity compensation plans approved by security holders ⁽¹⁾	109,036	\$ 199.57	66,866
Equity compensation plans not approved by security holders	—	—	—
Total	109,036	\$ 199.57	66,866

(1) Consists of the 2012 Plan, the 2014 Plan, the 2016 Plan, the 2017 Plan, the 2018 Plan, the 2019 Plan and the 2019 employee stock purchase plan (“ESPP”).

(2) Consists of shares available for future issuance under the 2019 Plan and our ESPP. As of December 31, 2019, 55,825 shares of common stock were available for issuance under the 2019 Plan and 11,041 shares of common stock were available for issuance under the ESPP.

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

Employment Agreement with Seth Lederman

On February 11, 2014, the Company entered into an employment agreement (the “Lederman Agreement”) with Dr. Seth Lederman (“Lederman”) to continue to serve as our President, Chief Executive Officer and Chairman of the Board.

The base salary for Lederman under the Lederman Agreement was \$425,000 per annum and as of January 1, 2019, the base salary is \$585,000. The Lederman Agreement has an initial term of one year and automatically renew for successive one year terms unless either party delivers written notice not to renew at least 60 days prior to the end of the current term.

Pursuant to the Lederman Agreement, if the Company terminates Lederman’s employment without Cause (as defined in the Lederman Agreement) or Lederman resigns for Good Reason (as defined in the Lederman Agreement), Lederman is entitled to the following payments and benefits: (1) his fully earned but unpaid base salary through the date of termination at the rate then in effect, plus all other benefits, if any, under any group retirement plan, nonqualified deferred compensation plan, equity award plan or agreement, health benefits plan or other group benefit plan to which Lederman may be entitled to under the terms of such plans or agreements; (2) a lump sum cash payment in an amount equal to 12 months of his base salary as in effect immediately prior to the date of termination; (3) continuation of health benefits for Lederman and his eligible dependents for a period of 12 months following the date of termination; and (4) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards as to the number of stock awards that would have vested over the 12-month period following termination had Lederman remained continuously employed by the Company during such period.

Pursuant to the Lederman Agreement, if Lederman’s employment is terminated as a result of death or permanent disability, Lederman or his estate, as applicable, is entitled to the following payments and benefits: (1) his fully earned but unpaid base salary through the date of termination at the rate then in effect; (2) a lump sum cash payment in an amount equal to six months of his base salary as in effect immediately prior to the date of termination; and (3) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards.

If Lederman is terminated without Cause or resigns for Good Reason during the period commencing 90 days prior to a Change in Control (as defined below) or 12 months following a Change in Control, Lederman shall be entitled to receive, in lieu of the severance benefits described above, the following payments and benefits: (1) a lump sum cash payment in an amount equal to 36 months of his base salary as in effect immediately prior to the date of termination, except that, if and while Lederman is still entitled to the Sale Bonus (as defined below), it will only be 18 months; (2) continuation of health benefits for Lederman and his eligible dependents for a period of 24 months following the date of termination, except that, if and while Lederman is still entitled to the Sale Bonus it will only be 12 months; and (3) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards.

If during the term of the Lederman Agreement or within 120 days after Lederman is terminated without Cause or resigns for Good Reason, following a Change in Control, the Company consummates a Change in Control transaction in which the Enterprise Value (as defined below) equals or exceeds \$50 million, Lederman shall be entitled to receive a lump sum payment equal to 4.4% of the Enterprise Value (the “Sale Bonus”). The Sale Bonus provision of the Lederman Agreement will terminate upon the Company granting Lederman long-term incentive compensation mutually agreed to by the Board and Lederman.

For purposes of the Lederman Agreement, “Cause” generally means (1) commission of an act of fraud, embezzlement or dishonesty or some other illegal act that has a demonstrable material adverse impact on the Company or any successor or affiliate of the Company, (2) conviction of, or entry into a plea of “guilty” or “no contest” to, a felony, (3) unauthorized use or disclosure of the Company’s confidential information or trade secrets or any successor or affiliate of the Company that has, or may reasonably be expected to have, a material adverse impact on any such entity; (4) gross negligence, failure to follow a material, lawful and reasonable request of the Board or material violation of any duty of loyalty to the Company or any successor or affiliate of the Company, or any other demonstrable material willful misconduct by Lederman, (5) ongoing and repeated failure or refusal to perform or neglect of his duties as required by his employment agreement, which failure, refusal or neglect continues for 30 days following Lederman’s receipt of written notice from the Board stating with specificity the nature of such failure, refusal or neglect, provided that such failure to perform is not as a result of illness, injury or medical incapacity, or (6) material breach of any Company policy or any material provision of the Lederman Agreement.

For purposes of the Lederman Agreement, “Good Reason” generally means (1) a material diminution in Lederman’s title, authority, duties or responsibilities, (2) a material diminution in Lederman’s base compensation, unless such a reduction is imposed across-the-board to the Company’s senior management, and such reduction is not greater than 15%, (3) a material change in the geographic location at which Lederman must perform his duties, (4) any other action or inaction that constitutes a material breach by the Company or any successor or affiliate of the Company’s obligations to Lederman under the Lederman Agreement, or (5) the Company elects not to renew the Lederman Agreement for another term.

For purposes of the Lederman Agreement, “Change in Control” generally means:

- A transaction or series of transactions (other than public offerings) that results in any person or entity or related group of persons or entities (other than the Company, its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a person or entity that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of more than 40% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition;
- (1) a merger, consolidation, reorganization, or business combination or (2) the sale, exchange or transfer of all or substantially all of the Company’s assets in any single transaction or series of transactions or (3) the acquisition of assets or stock of another entity, in each case other than a transaction:
 - which results in the Company’s voting securities outstanding immediately before the transaction continuing to represent, directly or indirectly, at least 60% of the combined voting power of the successor entity’s outstanding voting securities immediately after the transaction, and
 - after which no person or group beneficially owns voting securities representing 40% or more of the combined voting power of the Company or its successor; provided, however, that no person or group is treated as beneficially owning 40% or more of combined voting power of the Company or its successor solely as a result of the voting power held in the Company prior to the consummation of the transaction.

For purposes of the Lederman Agreement, “Enterprise Value” generally means (1) in a Change in Control in which consideration is received by the Company, the total cash and non-cash consideration, including debt assumed, received by the Company, net of any fees and expenses in connection with the transaction and (2) in a Change in Control in which consideration is payable to the stockholders of the Company, the total cash and non-cash consideration, including debt assumed, payable to the Company’s stockholders net of any fees and expenses in connection with the transaction. Enterprise Value also includes any cash or non-cash consideration payable to the Company or to the Company’s stockholders on a contingent, earnout or deferred basis.

Employment Agreement with Gregory Sullivan

On June 3, 2014, the Company entered into an employment agreement (the “Sullivan Agreement”) with Dr. Gregory Sullivan (“Sullivan”) to serve as our Chief Medical Officer. The base salary for Sullivan under the Sullivan Agreement was \$225,000 per annum and as of January 1, 2019, the base salary is \$400,000. The Sullivan Agreement had an initial term of one year and automatically renews for successive one year terms unless either party delivers written notice not to renew at least 60 days prior to the end of the current term.

Pursuant to the Sullivan Agreement, if the Company terminates Sullivan’s employment without Cause (as defined below) or Executive resigns for Good Reason (as defined below), Sullivan is entitled to the following payments and benefits: (1) his fully earned but unpaid base salary through the date of termination at the rate then in effect, plus all other benefits, if any, under any group retirement plan, nonqualified deferred compensation plan, equity award plan or agreement, health benefits plan or other group benefit plan to which Sullivan may be entitled to under the terms of such plans or agreements; (2) a lump sum cash payment in an amount equal to 12 months of his base salary as in effect immediately prior to the date of termination; (3) continuation of health benefits for Sullivan and his eligible dependents for a period of 12 months following the date of termination; and (4) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards as to the number of stock awards that would have vested over the 12-month period following termination had Sullivan remained continuously employed by the Company during such period.

Pursuant to the Sullivan Agreement, if Sullivan’s employment is terminated as a result of death or permanent disability, Sullivan or his estate, as applicable, is entitled to his fully earned but unpaid base salary through the end of the month in which termination occurs at the rate then in effect.

For purposes of the Sullivan Agreement, “Cause” generally means (1) commission of an act of fraud, embezzlement or dishonesty or some other illegal act that has a demonstrable material adverse impact on the Company or any successor or affiliate of the Company, (2) conviction of, or entry into a plea of “guilty” or “no contest” to, a felony, (3) unauthorized use or disclosure of the Company’s confidential information or trade secrets or any successor or affiliate of the Company that has, or may reasonably be expected to have, a material adverse impact on any such entity, (4) gross negligence, failure to follow a material, lawful and reasonable request of the Company or material violation of any duty of loyalty to the Company or any successor or affiliate of the Company, or any other demonstrable material misconduct by Sullivan, (5) ongoing and repeated failure or refusal to perform or neglect of his duties as required by his employment agreement, which failure, refusal or neglect continues for 30 days following Sullivan’s receipt of written notice from the Company stating with specificity the nature of such failure, refusal or neglect, or (6) material breach of any Company policy or any material provision of the Sullivan Agreement.

For purposes of the Sullivan Agreement, “Good Reason” generally means (1) a material diminution in Executive’s title, authority, duties or responsibilities, (2) a material diminution in the executive officer’s base compensation, unless such a reduction is imposed across-the-board to the Company’s senior management and such reduction is not greater than 15%, (3) a material change in the geographic location at which the executive officer must perform his duties, (4) any other action or inaction that constitutes a material breach by the Company or any successor or affiliate of the Company’s obligations to Sullivan under the Agreement, or (5) the Company elects not to renew the Agreement for another term.

Directors Compensation Table

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2019 for services to our Company.

Name	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾	Total (\$)
Margaret Smith Bell	\$ —	\$ 49,435	\$ 49,435
Patrick Grace*	\$ —	\$ 8,023	\$ 8,023
Daniel Goodman	\$ —	\$ 49,435	\$ 49,435
David Grange	\$ —	\$ 49,435	\$ 49,435
Donald Landry**	\$ —	\$ 31,373	\$ 31,373
Charles Mather IV***	\$ —	\$ —	\$ —
Adeoye Olukotun	\$ —	\$ 49,435	\$ 49,435
John Rhodes ⁽²⁾	\$ —	\$ 74,152	\$ 74,152
James Treco	\$ —	\$ 64,276	\$ 64,276
Total:	\$ —	\$ 375,564	\$ 375,564

(1) Represents the aggregate grant date fair value of stock options granted in accordance with FASB ASC Topic 718. For the relevant assumptions used in determining these amounts, refer to Note 7 to our audited financial statements. These amounts do not necessarily correspond to the actual value that may be recognized from the stock option grant.

(2) Mr. Rhodes received additional stock options for serving as lead director.

* Mr. Grace resigned from the Board on August 1, 2019.

** Dr. Landry resigned from the Board on May 16, 2019.

*** Mr. Mather resigned from the Board February 16, 2019.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of “related-party transactions.” For purposes of our policy only, a “related-party transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related party” are participants involving an amount that exceeds \$120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related party is any executive officer, director or a holder of more than five percent of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-party transaction, our Chief Compliance Officer must present information regarding the proposed related-party transaction to our Nominating and Corporate Governance Committee for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related parties, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-party transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-party transactions, our Nominating and Corporate Governance Committee will take into account the relevant available facts and circumstances including, but not limited to:

- whether the transaction was undertaken in the ordinary course of our business;
- whether the related party transaction was initiated by us or the related party;
- whether the transaction with the related party is proposed to be, or was, entered into on terms no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us from the related party transaction;
- the approximate dollar value of the amount involved in the related party transaction, particularly as it relates to the related party;
- the related party’s interest in the related party transaction, and
- any other information regarding the related party transaction or the related party that would be material to investors in light of the circumstances of the particular transaction.

The Nominating and Corporate Governance Committee shall then make a recommendation to the Board, who will determine whether or not to approve of the related party transaction, and if so, upon what terms and conditions. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Other than as disclosed below, during the last two fiscal years, there have been no related party transactions.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of January 17, 2020 by:

- each of our stockholders who is known by us to beneficially own 5% or more of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and current officers as a group.

Beneficial ownership is determined based on the rules and regulations of the Securities and Exchange Commission, or the SEC. A person has beneficial ownership of shares if such individual has the power to vote and/or dispose of shares. This power may be sole or shared and direct or indirect. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of our common stock that are subject to options or warrants held by that person and exercisable as of, or within 60 days of, January 17, 2020 are counted as outstanding. These shares, however, are not counted as outstanding for the purposes of computing the percentage ownership of any other person(s). Except as may be indicated in the footnotes to this table and pursuant to applicable community property laws, each person named in the table has sole voting and dispositive power with respect to the shares of our common stock set forth opposite that person's name. Unless indicated below, the address of each individual listed below is c/o Tonix Pharmaceuticals Holding Corp., 509 Madison Avenue, Suite 1608, New York, New York 1022.

Applicable percentage ownership in the following table is based on 8,533,082 shares of our common stock outstanding as of January 17, 2020 and also lists applicable percentage ownership based on 14,984,695 shares of our common stock assumed to be outstanding after completion of the offering, assuming no exercise by the underwriter of its option to purchase additional shares of our common stock.

NAME OF OWNER	NUMBER OF SHARES OWNED(1)	PERCENTAGE OF SHARES BENEFICIALLY OWNED (ASSUMING NO EXERCISE OF THE OVER-ALLOTMENT OPTION)	
		Before Offering (2)	After Offering
Seth Lederman	28,878(3)	*	*
Jessica Morris	1,075(4)	*	*
Bradley Saenger	2,408(5)	*	*
Gregory Sullivan	2,942(6)	*	*
Margaret Smith Bell	400(7)	*	*
David Grange	270(8)	*	*
John Rhodes	900(9)	*	*
Adeoye Olukotun	150(10)	*	*
James Treco	1,000(11)	*	*
Daniel Goodman	6(12)	*	*
Officers and Directors as a Group (10 persons)	38,029(13)	*	*

* Denotes less than 1%

(1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of January 17, 2020 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 8,533,082 shares of common stock issued and outstanding as of January 17, 2020.

(3) Includes 4,582 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 5 shares of common stock underlying warrants, 205 shares of common stock owned by Lederman & Co, 33 shares of common stock owned by L&L, 59 shares of common stock owned by Targent, 30 shares of common stock owned by Leder Laboratories, Inc. (Leder Labs), 30 shares of common stock owned by Starling, 23,267 shares owned through a 401(k) account, 459 shares owned through an IRA account and 31 shares owned by Dr. Lederman's spouse. Seth Lederman, as the Managing Member of Lederman & Co and Targent, the Manager of L&L and the Chairman of Leder Labs and Starling, has investment and voting control over the shares held by these entities.

(4) Includes 1,055 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, and 3 shares of common stock underlying warrants.

(5) Includes 1,011 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(6) Includes 1,537 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(7) Includes 400 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(8) Includes 270 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(9) Includes 652 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, and 13 shares of common stock underlying warrants

(10) Includes 150 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(11) Includes 1,000 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(12) Includes 5 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(13) Includes 10,662 shares of common stock underlying options which are currently exercisable or vested or become exercisable within 60 days, 205 shares of common stock owned by Lederman & Co, 33 shares of common stock owned by L&L, 59 shares of common stock owned by Targent, 30 shares of common stock owned by Leder Labs, 30 shares of common stock owned by Starling, 23,267 shares owned through a 401(k) account of Dr. Lederman, 459 shares owned through an IRA account of Dr. Lederman, 31 shares owned by Dr. Lederman's spouse, and 21 shares of common stock underlying warrants owned directly by the executive officers and directors.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

Other than compensation arrangements for our named executive officers and directors, we have not been a party to any transaction or series of similar transactions, since January 1, 2017, in which:

- the amounts involved exceeded or will exceed the lesser of (i) \$120,000 or (ii) 1% of the average total assets of the Company at year end for the last two completed fiscal years; and
- any of our directors, executive officers, promoters or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in the section titled “Executive Compensation” in this prospectus.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of all material characteristics of our capital stock as set forth in our articles of incorporation and bylaws. The summary does not purport to be complete and is qualified in its entirety by reference to our articles of incorporation and bylaws, each as amended, and to the provisions of Chapters 78 and 92A of the Nevada Revised Statutes, as amended (“NRS”).

Common Stock

We are authorized to issue up to 150,000,000 shares of our common stock, par value \$0.001 per share. As of January 17, 2020, there were 8,533,082 shares of our common stock issued and outstanding. The outstanding shares of our common stock are validly issued, fully paid and nonassessable.

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

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

Exchange Listing

Our common stock is listed on The Nasdaq Global Market under the trading symbol “TNXP.”

Transfer Agent and Registrar.

The Transfer Agent and Registrar for our common stock is vStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock, par value \$0.001 per share, none of which are currently outstanding. The shares of preferred stock may be issued in series, and each such series shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the certificate of designation relating to such series, as approved by the board of directors and filed with the Nevada Secretary of State. Pursuant to our articles of incorporation, the board of directors is expressly vested with the authority, without further action by the stockholders, to determine and fix in the resolution or resolutions providing for the issuances of preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Nevada.

Prior to the issuance of any series of preferred stock, we will further amend our articles of incorporation, as amended, by way of a certificate of designation designating such series and its terms. We will file a copy of the certificate of designation that contains the terms of each such series of preferred stock with the Nevada Secretary of State and the SEC each time we issue a new series of preferred stock. Each certificate of designation will establish the number of shares included in a designated series and fix the designation, powers, privileges, preferences and rights of the shares of each series as well as any applicable qualifications, limitations or restrictions, including, as applicable:

- the designation, stated value and liquidation preference of the series;
- the number of shares within the series;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of the series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;
- the terms and conditions, if any, on which shares of the series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;
- the voting rights, if any, of shares of the series; the status as to reissuance or sale of shares of the series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us or any subsidiary, of the common stock or of any other class of our shares ranking junior to the shares of the series as to dividends or upon liquidation;
- the conditions and restrictions, if any, on the creation of indebtedness by us or by any subsidiary, or on the issuance of any additional stock ranking on a parity with or prior to the shares of the series as to dividends or upon liquidation; and
- any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of the series.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our board of directors to issue preferred stock could discourage, delay or prevent a takeover or other corporate action.

Series A Convertible Preferred Stock

The following is a summary of the material terms of our Series A Convertible Preferred Stock, which we refer to as the Series A Preferred Shares or the Series A Preferred Stock. This summary is not complete. The following summary of the terms and provisions of the Series A Preferred Stock is qualified in its entirety by reference to the certificate of designation for the Series A Convertible Preferred Stock, which has been previously filed.

General

Our board of directors has designated 8,000 shares of the 5,000,000 authorized shares of preferred stock as Series A Preferred Shares, par value \$0.001 per share. When issued, the Series A Preferred Shares will be validly issued, fully paid and non-assessable. Each share of Series A Preferred Shares has a stated value of \$1,000 per share.

As of January 17, 2020, all 7,938 previously issued shares Series A Preferred Stock have been converted into common stock. We have no present intention to issue any of the remaining designated shares of Series A Preferred Stock.

Rank

The Series A Preferred Stock will rank on parity to our common stock with respect to dividends and liquidation rights.

Conversion

Each Series A Preferred Share is initially convertible into shares of our common stock (subject to adjustment as provided in the certificate of designation for the Series A Preferred Stock) at any time at the option of the holder at a conversion price equal to the stated value of the Series A Preferred Shares of \$1,000 divided \$1.94. Holders of Series A Preferred Shares are prohibited from converting the Series A Preferred Shares into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Liquidation Preference

In the event of our liquidation, dissolution or winding-up, holders of Series A Preferred Shares will be entitled to receive the same amount that a holder of our common stock would receive if the Series A Preferred Shares were fully converted into shares of our common stock at the conversion price (disregarding for such purposes any conversion limitations) which amounts shall be paid *pari passu* with all holders of common stock.

Voting Rights

Holders of Series A Preferred Shares generally do not have the right to vote on any matters brought before the Company's common stockholders, either as a separate class or on an as-converted-to-common-stock basis, and do not have the right to vote for members of the Company's board of directors. However, the affirmative vote of the holders of a majority of the then-outstanding Series A Preferred Shares will be required to (a) alter or change adversely the powers, preferences or rights of the Series A Preferred Shares, (b) amend our articles of incorporation or other charter documents in any manner that materially adversely affects any rights of the holders of Series A Preferred Shares, (c) increase the number of authorized Series A Preferred Shares, (c) issue any Series A Preferred Shares other than pursuant to the certificate of designation for the Series A Convertible Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Dividends

The Series A Preferred Stock is not be entitled to receive any dividends, unless and until specifically declared by our board of directors. Holders of the Series A Preferred Shares will participate, on an as-if-converted-to-common stock-basis, in any dividends paid to the holders of common stock.

Redemption

We are not obligated to redeem or repurchase any Series A Preferred Shares. Series A Preferred Shares are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Exchange Listing

The Series A Preferred Shares are not listed on any national securities exchange or other nationally recognized trading system.

Series B Convertible Preferred Stock

The following is a summary of the material terms of the Series B Convertible Preferred Stock, which we refer to as the Series B Preferred Shares or the Series B Preferred Stock. This summary is not complete. The following summary of the terms and provisions of the Series B Preferred Stock is qualified in its entirety by reference to the certificate of designation for the Series B Convertible Preferred Stock, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

General

Our board of directors has designated up to _____ shares of the 5,000,000 authorized shares of preferred stock as Series B Preferred Shares, par value \$0.001 per share. When issued, the Series B Preferred Shares will be validly issued, fully paid and non-assessable. Each share of Series B Preferred Shares will have a stated value of \$1,000 per share.

Rank

The Series B Preferred Stock will rank on parity to our common stock with respect to dividends and liquidation rights.

Conversion

Each Series B Preferred Share is initially convertible into shares of our common stock (subject to adjustment as provided in the certificate of designation for the Series B Preferred Stock) at any time at the option of the holder at a conversion price equal to the stated value of the Series B Preferred Shares of \$1,000 divided by the public offering price of the shares of common stock in this offering. Holders of Series B Preferred Shares will be prohibited from converting the Series B Preferred Shares into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Liquidation Preference

In the event of our liquidation, dissolution or winding-up, holders of Series B Preferred Shares will be entitled to receive the same amount that a holder of our common stock would receive if the Series B Preferred Shares were fully converted into shares of our common stock at the conversion price (disregarding for such purposes any conversion limitations) which amounts shall be paid *pari passu* with all holders of common stock.

Voting Rights

Holders of Series B Preferred Shares generally will not have the right to vote on any matters brought before the Company's common stockholders, either as a separate class or on an as-converted-to-common-stock basis, and will not have the right to vote for members of the Company's board of directors. However, the affirmative vote of the holders of a majority of the then-outstanding Series B Preferred Shares will be required to (a) alter or change adversely the powers, preferences or rights of the Series B Preferred Shares, (b) amend our articles of incorporation or other charter documents in any manner that materially adversely affects any rights of the holders of Series B Preferred Shares, (c) increase the number of authorized Series B Preferred Shares, (c) issue any Series B Preferred Shares other than pursuant to the certificate of designation for the Series B Convertible Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Dividends

Series B Preferred Shares will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. The holders of the Series B Preferred Shares will participate, on an as-if-converted-to-common stock-basis, in any dividends paid to the holders of common stock.

Redemption

We are not obligated to redeem or repurchase any Series B Preferred Shares. Series B Preferred Shares are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Exchange Listing

We do not plan on making an application to list the Series B Preferred Shares on any national securities exchange or other nationally recognized trading system.

November 2019 Warrants

The following is a summary of the material terms of the warrants issued in the November 2019 Financing (the “November 2019 Warrants”). This summary is not complete. The following summary of the terms and provisions of the November 2019 Warrants is qualified in its entirety by reference to November 2019 Warrants and the warrant agency agreement, the forms of which have been previously filed.

Exercisability

The November 2019 Warrants are exercisable at any time after their original issuance and have an expiration date of November 2024. The November 2019 Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the November 2019 Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the November 2019 Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the November 2019 Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the November 2019 Warrants. No fractional shares of common stock will be issued in connection with the exercise of November 2019 Warrants. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation

A holder will not have the right to exercise any portion of the November 2019 Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants.

Exercise Price

The November 2019 Warrants have an exercise price of \$1.94. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise

The exercise price and the number of shares issuable upon exercise of the November 2019 Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The November 2019 Warrant holders must pay the exercise price in cash upon exercise of the November 2019 Warrants, unless such November 2019 Warrant holders are utilizing the cashless exercise provision of the November 2019 Warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the November 2019 Warrants are exercised.

Anti-Dilution

In addition to the adjustments noted above under “Exercise Price,” the November 2019 Warrants also contain anti-dilution protection upon the issuance of any common stock, securities convertible into common stock or certain other issuances at a price below the then-existing exercise price of the November 2019 Warrants within two years of the date of issuance, with certain exceptions. The anti-dilution protection contained in the November 2019 Warrant does not provide for the issuance of additional securities in the event of, or in place of, an adjustment to the then-existing exercise price of the November 2019 Warrants.

Transferability

Subject to applicable laws, the November 2019 Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

The November 2019 Warrants are not listed on any national securities exchange or other nationally recognized trading system.

Fundamental Transactions

In the event of a fundamental transaction, as described in the November 2019 Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the November 2019 Warrants will be entitled to receive upon exercise of the November 2019 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the November 2019 Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board (but not in a fundamental transaction which is not approved by our Board), the holders of the November 2019 Warrants have the right to require us or a successor entity to redeem the November 2019 Warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the November 2019 Warrant on the date of the consummation of the fundamental transaction.

Rights as a Stockholder

Except as otherwise provided in the November 2019 Warrants or by virtue of such holder’s ownership of shares of our common stock, the holder of a November 2019 Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the November 2019 Warrant.

December 2018 Warrants

The following is a summary of the material terms of the warrants issued in the December 2018 Financing (the “December 2018 Warrants”). This summary is not complete. The following summary of the terms and provisions of the warrants is qualified in its entirety by reference to the warrants and the warrant agency agreement, the forms of which have been previously filed.

Exercisability

The December 2018 Warrants are exercisable at any time after their original issuance have an expiration date of December 2023. The December 2018 Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the December 2018 Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the December 2018 Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the December 2018 Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the December 2018 Warrants. No fractional shares of common stock will be issued in connection with the exercise of a December 2018 Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation

A holder will not have the right to exercise any portion of the December 2018 Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the December 2018 Warrants.

Exercise Price

The exercise price of the December 2018 Warrants is \$35.00. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise

The exercise price and the number of shares issuable upon exercise of the December 2018 Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The December 2018 Warrant holders must pay the exercise price in cash upon exercise of the December 2018 Warrants, unless such December 2018 Warrant holders are utilizing the cashless exercise provision of the December 2018 Warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement.

Call Option

If there is a registration statement that covers the resale of the shares underlying the December 2018 Warrants or all of such shares may be sold pursuant to Rule 144 upon cashless exercise without restrictions, including volume restrictions, we have the option to “call” the exercise of any or all of the December 2018 Warrants, from time to time by giving a call notice to the holder only after any 10-consecutive trading day period during which the daily VWAP of the common stock is not less than 300% of the exercise price for the common warrants in effect for such 10-consecutive trading day period. During the call period, the holder may exercise the December 2018 Warrant and purchase the called common stock underlying the December 2018 Warrant. If the holder fails to timely exercise the December 2018 Warrant or a number of shares of common stock equal to number of called shares of common stock during the call period, our sole remedy will be to cancel an amount of called shares of common stock underlying the December 2018 Warrant equal to such shortfall, with the warrant no longer being exercisable with respect to such shares of common stock. The call period is a period of 30 trading days following the date on which the call notice is deemed given and effective.

Transferability

Subject to applicable laws, the December 2018 Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

The December 2018 Warrants are not listed on any national securities exchange or other nationally recognized trading system.

Fundamental Transactions

In the event of a fundamental transaction, as described in the December 2018 Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the December 2018 Warrants will be entitled to receive upon exercise of the December 2018 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the December 2018 Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder

Except as otherwise provided in the December 2018 Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a December 2018 Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the December 2018 Warrant.

October 2016 Warrants

The material provisions of the warrants issued in an underwritten public offering (the "October 2016 Financing") on October 26, 2016 (the "October 2016 Warrants") are set forth herein but are only a summary and are qualified in their entirety by the provisions of the warrant agreement that has been previously filed.

Exercisability

The October 2016 Warrants may be exercised by delivering an exercise notice, appropriately completed and duly signed on or prior to the expiration date at the offices of the warrant agent, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of October 2016 Warrants being exercised, unless such October 2016 Warrant holders are utilizing the cashless exercise provision of the October 2016 Warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. The October 2016 Warrants have an expiration date of October 2021. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the October 2016 Warrants are exercised. The October 2016 Warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their October 2016 Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the October 2016 Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

Because we are prohibited from issuing fractional shares, the October 2016 Warrants can only be exercised in lots of two, which means that each holder must exercise two October 2016 Warrants to receive one share of common stock. No fractional shares of common stock will be issued upon exercise of the October 2016 Warrants. If multiple October 2016 Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the October 2016 Warrants tendered for exercise.

Exercise Price

The exercise price of the October 2016 Warrants is \$630.00. The exercise price and number of shares of common stock issuable upon exercise of the October 2016 Warrants may be adjusted in certain circumstances, including in the event of a stock dividend, extraordinary dividend on or recapitalization, reorganization, merger or consolidation. However, the October 2016 Warrants will not be adjusted for issuances of common stock at a price below the exercise price of the October 2016 Warrants.

Exercise Limitation

Subject to limited exceptions, a holder of the October 2016 Warrants will not have the right to exercise any portion of its October 2016 Warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the holder, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that upon notice to the us, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

Fundamental Transactions

In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the October 2016 Warrants will be entitled to receive upon exercise of the October 2016 Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the October 2016 Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the October 2016 Warrants.

Underwriter Warrants

We also issued to the underwriter or its in the October 2016 Financing warrants to purchase common stock (the "Underwriter Warrants"). The Underwriter Warrants have an exercise price of \$690.00 The Underwriter Warrants are exercisable at any time and from time to time, in whole or in part and have an expiration date of October 2021. The Underwriter Warrants provide for a cashless exercise provision, piggyback registration rights and customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110.

Anti-Takeover Effects of Provisions of the Articles of Incorporation and Bylaws

Articles of Incorporation and Bylaw Provisions. Our articles of incorporation and bylaws include a number of provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. They are intended to enhance long-term value to our stockholders by increasing the likelihood of continued stability in the composition of our board of directors and its policies and may have the effect of discouraging certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. These provisions include the items described below.

Filling Vacancies. Any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board of directors, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

Meetings of Stockholders. Our bylaws provide that our president, our board of directors or a duly authorized committee of the board of directors may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements. Our bylaws include advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in the amended and restated bylaws.

Amendment to Bylaws and Articles of Incorporation. As required by Nevada law, any amendment of our articles of incorporation must first be approved by a majority of our board of directors and, if required by law or our articles of incorporation, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the bylaws, or by the holders of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding voting power of our company, voting together as a single class.

Blank Check Preferred Stock. Our articles of incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may have the effect of discouraging an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the interests of our company or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more offerings or other transactions that might have the effect of diluting the relative voting or other rights of the proposed acquirer or activist stockholder or stockholder group. The issuance of shares of preferred stock with rights preferential to the common stock could have the effect of decreasing the amounts available for distribution to holders of shares of common stock. The issuance may also adversely affect the relative rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring, or preventing a change of control of us.

Exclusive Forum Bylaws Provision. Our bylaws require that, to the fullest extent permitted by law, and unless the Company consents in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada, will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following:

- any derivative action or proceeding brought in the name or right of the Company or on its behalf,
- any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders,
- any action arising or asserting a claim arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of our articles of incorporation or bylaws, or
- any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws.

Because the applicability of the exclusive forum provision is limited to the extent permitted by law, we believe that the exclusive forum provision would not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, and that federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act. We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Nevada law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of the material United States federal income tax consequences to U.S. holders and non-U.S. holders (each as defined below) of their ownership and disposition of our common stock and Series B Convertible Preferred Stock, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon current provisions of the Internal Revenue Code of 1986, as amended, or Code, existing and proposed United States Treasury Regulations promulgated thereunder, current administrative rulings, and judicial decisions, all as in effect as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in United States federal tax consequences different from those set forth below. We have not obtained, and do not intend to obtain, any opinion of counsel or ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any non-United States, state or local jurisdiction or under any non-income tax laws, including United States federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address the potential application of the tax on net investment income or the alternative minimum tax. This discussion may not apply, in whole or in part, to particular U.S. holders and non-U.S. holders in light of their individual circumstances or to holders subject to special treatment under the United States federal income tax laws, including, without limitation:

- insurance companies, banks or other financial institutions;
- tax-exempt organizations;
- pension plans;
- controlled foreign corporations or passive foreign investment companies;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- persons that hold our common stock and Series B Convertible Preferred Stock as a position in a hedging transaction, straddle, conversion transaction, synthetic security or other integrated investment;
- persons that hold or receive our common stock and Series B Convertible Preferred Stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- persons that do not hold our common stock and Series B Convertible Preferred Stock as a capital asset within the meaning of Section 1221 of the Code.

In addition, this discussion does not address the tax treatment of partnerships, including any entity or arrangement treated as a partnership for United States federal income tax purposes. Generally, the tax treatment of a person treated as a partner in such an entity will depend on the status of the partner, the activities of the partner and the partnership, and certain determinations made at the partner level. Accordingly, partnerships that hold our common stock and Series B Convertible Preferred Stock, and partners in such partnerships, should consult their tax advisors.

THIS SUMMARY IS NOT INTENDED TO BE CONSTRUED AS LEGAL ADVICE. WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK AND SERIES B CONVERTIBLE PREFERRED STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY APPLICABLE INCOME TAX TREATIES, OR ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING ESTATE AND GIFT TAX LAWS).

Allocation of Purchase Price

For U.S. federal income tax purposes, each investor must allocate the purchase price paid by such investor among the purchased common stock and Series B Convertible Preferred Stock, as applicable, based on their relative fair market values at the time of issuance. This allocation of the purchase price will establish the holder's initial tax basis for U.S. federal income tax purposes in such investor's purchased common stock or Series B Convertible Preferred Stock, as applicable. The separation (as opposed to the disposition) of common stock or Series B Convertible Preferred Stock pursuant to this offering should not be a taxable event for U.S. federal income tax purposes. Each holder should consult its own tax advisor regarding the allocation of the purchase price described herein.

The foregoing treatment of our common stock and Series B Convertible Preferred Stock and an investor's purchase price allocation are not binding on the IRS or the courts. Because there are no statutory, administrative or judicial authorities that directly address such investment units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, each investor should consult with tax advisors regarding the risks associated with the acquisition of our common stock, and Series B Convertible Preferred Stock pursuant to this offering (including potential alternative characterizations) and regarding an allocation of the purchase price among the purchased common stock and Series B Convertible Preferred Stock, as applicable, that each investor is treated as acquiring. The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

U.S. Holders

Definition of U.S. Holder

For purposes of this discussion, a “U.S. holder” is any beneficial owner of our securities that is, for U.S. federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in the United States or under the laws of the United States or any political subdivision thereof;
- an estate whose income is subject to United States federal income tax regardless of its source; or
- a trust whose administration is subject to the primary supervision of a United States court and which has one or more “United States persons” (as defined in the Code) who have the authority to control all substantial decisions of the trust, or which has made a valid election to be treated as a United States person.

If you are not a U.S. holder, this section does not apply to you. Please see the discussion under “Non-U.S. Holders” below.

Distributions on Common Stock and Series B Convertible Preferred Stock to U.S. Holders

As described in the section captioned “Dividend Policy,” we do not anticipate declaring or paying distributions to holders of our common stock in the foreseeable future. In addition, as described in the section captioned “Description of Capital Stock—Preferred Stock—Series B Convertible Preferred Stock—Dividends,” Series B Convertible Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. However, if we do make distributions of cash or property on our common stock or Series B Convertible Preferred Stock, those payments will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. To the extent those distributions exceed both our current and accumulated earnings and profits, the excess will constitute a return of capital and will first reduce a U.S. holder’s tax basis in our common stock or Series B Convertible Preferred Stock, but not below zero, and then will be treated by a U.S. holder as gain from the sale of stock as described below under “Gain on Dispositions of Our Common Stock or Series B Convertible Preferred Stock by U.S. Holders.”

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided the common shares are held for more than 60 days during the 121-day period beginning 60 days before the exdividend date and certain other holding period requirements are met, dividends we pay to a non-corporate U.S. holder generally will constitute “qualified dividends” that will be subject to tax at the maximum tax rate accorded to long-term capital gains. Dividends paid by us will generally be treated as income from U.S. sources. U.S. holders should consult their own tax advisors regarding the holding period and other requirements that must be satisfied in order to qualify for the reduced maximum tax rate on dividends.

Gain on Disposition of Our Common Stock or Series B Convertible Preferred Stock by U.S. Holders

If a U.S. holder sells or otherwise disposes of our common stock or Series B Convertible Preferred Stock (other than by conversion) in a taxable transaction, the U.S. holder will generally recognize capital gain or loss equal to the difference between the amount realized and the U.S. holder’s adjusted tax basis in the common stock or Series B Convertible Preferred Stock. The capital gain or loss will be long-term capital gain or loss if the U.S. holder’s holding period for the common stock or Series B Convertible Preferred Stock is more than one year at the time of the disposition. Long-term capital gain of a non-corporate U.S. holder is generally taxed at preferential rates. The deductibility of capital losses is subject to limitations.

Conversion of Our Series B Convertible Preferred Stock into Our Common Stock

Generally, a U.S. holder will not recognize any gain or loss in respect of the receipt of our common stock upon the conversion of our Series B Convertible Preferred Stock (except to the extent the U.S. holder receives a cash payment for any fractional share that would otherwise have been issuable upon conversion of the Series B Convertible Preferred Stock). The adjusted tax basis of our common stock that a U.S. holder receives on conversion will equal the adjusted tax basis of the Series B Convertible Preferred Stock converted (decreased by the adjusted tax basis allocable to any fractional share that would otherwise have been issued upon conversion of the Series B Convertible Preferred Stock), and the holding period of such common stock received on conversion will include the period during which the U.S. holder held the Series B Convertible Preferred Stock prior to conversion.

In the event a U.S. holder’s Series B Convertible Preferred Stock is converted pursuant to an election by such U.S. holder in the case of certain acquisitions or fundamental changes or pursuant to certain other transactions (including our consolidation or merger into another person), the tax treatment of such a conversion will depend upon the facts underlying the particular transaction triggering such a conversion. In this regard, it is possible that any related adjustment of the conversion rate would be treated as a constructive distribution to the U.S. holder as described below under “U.S. Holders—Constructive Dividends on Series B Convertible Preferred Stock.” U.S. holders should consult their own tax advisors to determine the specific tax treatment of a conversion under such circumstances.

Constructive Dividends on Series B Convertible Preferred Stock

The conversion rate of our Series B Convertible Preferred Stock is subject to adjustment under certain circumstances, as described above under “Description of Capital Stock—Preferred Stock—Series B Convertible Preferred Stock.” Section 305(c) of the Code and Treasury regulations thereunder may treat a U.S. holder of our Series B Convertible Preferred Stock as having received a constructive distribution includable in such U.S. holder’s income in the manner as described above under “U.S. Holders—Distributions on Common Stock and Series B Convertible Preferred Stock to U.S. Holders,” if and to the extent that certain adjustments in the conversion rate (or failures to make such an adjustment) increase the proportionate interest of such U.S. holder in our earnings and profits. In certain other circumstances, an adjustment to the conversion rate of our Series B Convertible Preferred Stock or a failure to make such an adjustment could potentially give rise to constructive distributions to U.S. holders of our common stock. Thus, under certain circumstances, U.S. holders may recognize income in the event of a constructive distribution even though they may not receive any cash or property.

Information Reporting and Backup Withholding

U.S. holders may be subject to information withholding and/or backup withholding with respect to the gross proceeds from the disposition of our securities, or from payments of dividends. Backup withholding (currently at the rate of 24%) may apply under certain circumstances if a U.S. holder (1) fails to furnish a social security or other taxpayer identification number, or TIN, (2) furnishes an incorrect TIN, (3) fails to report interest or dividends properly or (4) fails to provide a certified statement, signed under penalties of perjury, that the TIN provided is correct, that the U.S. holder is not subject to backup withholding and that the U.S. holder is a U.S. person for U.S. federal income tax purposes on IRS Form W-9. Any amount withheld from a payment under the backup withholding rules is allowable as a credit against (and may entitle a U.S. holder to a refund with respect to) such U.S. holder’s federal income tax liability, provided that the required information is timely furnished to the IRS. Certain persons, including corporations and certain financial institutions, that demonstrate this fact if requested, are exempt from information reporting and backup withholding. U.S. holders should consult with tax advisors as to their qualification for exemption.

Non-U.S. Holders

Definition of Non-U.S. Holder

For purposes of this discussion, you are a non-U.S. holder if you are a beneficial owner of our common stock or Series B Convertible Preferred Stock that is not, for United States federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in the United States or under the laws of the United States or any political subdivision thereof;
- an estate whose income is subject to United States federal income tax regardless of its source; or
- a trust whose administration is subject to the primary supervision of a United States court and which has one or more “United States persons” (as defined in the Code) who have the authority to control all substantial decisions of the trust, or which has made a valid election to be treated as a United States person.

Distributions to non-U.S. Holders

As described in the section titled “Dividend Policy,” we do not anticipate paying any cash dividends or making distributions of other property on our common stock in the foreseeable future. In addition, as described in the section captioned “Description of Capital Stock—Preferred Stock—Series B Convertible Preferred Stock—Dividends,” Series B Convertible Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. However, if we do make distributions of cash or property on our common stock or Series B Convertible Preferred Stock, those payments will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce a non-U.S. holder’s tax basis in our common stock or Series B Convertible Preferred Stock, but not below zero, and then will be treated by a non-U.S. holder as gain from the sale of stock as described below under “Gain on Dispositions of Our Common Stock or Series B Convertible Preferred Stock by Non-U.S. Holders.”

Subject to the discussion below on effectively connected income, backup withholding, and FATCA, any dividend paid to a non-U.S. holder generally will be subject to United States withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. To receive a reduced treaty rate, a non-U.S. holder must provide us with an IRS Form W-8BEN or W-8BEN-E (or applicable successor form) and certify qualification for the reduced rate. If a non-U.S. holder is eligible for a reduced rate of United States withholding tax pursuant to an income tax treaty, such non-U.S. holder may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. If a non-U.S. holder holds our common stock and Series B Convertible Preferred Stock through a financial institution or other agent acting on such non-U.S. holder’s behalf, appropriate documentation will need to be provided to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by a non-U.S. holder that are effectively connected with such non-U.S. holder’s conduct of a trade or business in the United States (and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by such non-U.S. holder in the United States), are generally exempt from the 30% withholding tax if certain certification and disclosure requirements are satisfied. To obtain this exemption, a non-U.S. holder must provide us with an IRS Form W-8ECI (or applicable successor form) properly certifying such exemption. However, such effectively connected dividends, although not subject to withholding tax, generally are taxed at the same United States federal income tax rates applicable to United States persons, net of certain deductions and credits. In addition, dividends received by a corporate non-U.S. holder that are effectively connected with the conduct of a trade or business in the United States may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. Non-U.S. holders should consult with tax advisors regarding any applicable income tax or other treaties that may provide for different rules.

Any documentation provided to an applicable withholding agent may need to be updated in certain circumstances. The certification requirements described above also may require a non-U.S. holder to provide a United States taxpayer identification number.

For additional withholding rules that may apply to dividends, including dividends paid to foreign financial institutions (as specifically defined by the applicable rules) or to certain other foreign entities that have substantial direct or indirect United States owners, see the discussion below under the headings “Information Reporting and Backup Withholding” and “Withholdable Payments to Foreign Financial Institutions and Other Foreign Entities.”

Gain on Disposition of Our Common Stock or Series B Convertible Preferred Stock by Non-U.S. Holders

Subject to the discussion below under the headings “Information Reporting and Backup Withholding” and “Withholdable Payments to Foreign Financial Institutions and Other Foreign Entities,” a non-U.S. holder generally will not be required to pay United States federal income tax or withholding tax on any gain recognized upon the sale, exchange or other taxable disposition of our common stock or Series B Convertible Preferred Stock unless:

- the gain is effectively connected with the conduct of a trade or business by such non-U.S. holder in the United States (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or a fixed base maintained by such non-U.S. holder in the United States), in which case the non-U.S. holder will be required to pay tax on the net gain derived from the sale or disposition at the rates and in the manner applicable to United States persons, and an additional branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty) may also apply to a corporate non-U.S. holder;
- such non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met, in which case the non-U.S. holder will be required to pay a flat 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the gain derived from the sale or disposition, which gain may be offset by United States-source capital losses for the taxable year of the sale or disposition; or
- our common stock and Series B Convertible Preferred Stock constitute a United States real property interest by reason of our status as a “United States real property holding corporation”, or USRPHC, for United States federal income tax purposes at any time within the shorter of the five-year period preceding such non-U.S. holder’s disposition of, or holding period for, our common stock or Series B Convertible Preferred Stock, in which case the non-U.S. holder generally will be taxed on net gain derived from the sale or disposition at the rates applicable to United States persons.

We believe that we are not currently and will not become a USRPHC and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as United States real property interests only if a non-U.S. holder actually or constructively holds more than 5% of such regularly traded common stock at any time during the shorter of the five-year period preceding such non-U.S. holder’s disposition of, or holding period for, our common stock or Series B Convertible Preferred Stock. Non- U.S. holders should consult with tax advisors regarding any applicable income tax or other treaties that may provide for different rules.

Conversion of Our Series B Convertible Preferred Stock into Our Common Stock

A non-U.S. holder generally will not recognize any gain or loss in respect of the receipt of our common stock upon the conversion of our Series B Convertible Preferred Stock (except to the extent the non-U.S. holder receives a cash payment for any fractional share that would otherwise have been issuable upon conversion of the Series B Convertible Preferred Stock).

Constructive Dividends on Series B Convertible Preferred Stock

The conversion rate of our Series B Convertible Preferred Stock is subject to adjustment under certain circumstances, as described above under “Description of Capital Stock—Preferred Stock—Series B Convertible Preferred Stock.” In certain circumstances, an adjustment to the conversion rate of our Series B Convertible Preferred Stock or a failure to make such an adjustment could potentially give rise to constructive distributions to non-U.S. holders of our common stock that are treated as dividends for U.S. federal income tax purposes. Any constructive dividend deemed paid to a non-U.S. holder will be subject to U.S. federal income tax or withholding tax in the manner described above under “Distributions to Non-U.S. Holders.” It is possible that U.S. federal tax on the constructive dividend would be withheld, if applicable, from subsequent payments on the Series B Convertible Preferred Stock or our common stock.

Information Reporting and Backup Withholding

We (or the applicable paying agent) must report annually to the IRS the amount of dividends on our common stock or Series B Convertible Preferred Stock paid to non-U.S. holders and the amount of tax withheld, if any. A similar report will be sent to each non-U.S. holder. Copies of this information reporting may also be made available under the provisions of a specific income tax treaty or agreement with the tax authorities in a non-U.S. holder’s country of residence.

Non-U.S. holders will generally be subject to backup withholding (at a current rate of 24%) for dividends on our common stock or Series B Convertible Preferred Stock paid to such non-U.S. holders unless an exemption is established such as by, for example, properly certifying non-United States status on an IRS Form W-8BEN or W-8BEN-E (or applicable successor form). Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that a holder of our common stock or Series B Convertible Preferred Stock is a United States person.

Information reporting and backup withholding generally are not required with respect to the amount of any proceeds from the sale or other disposition of our common stock or Series B Convertible Preferred Stock by a non-U.S. holder outside the United States through a foreign office of a foreign broker that does not have certain specified connections to the United States. However, if a non-U.S. holder sells or otherwise disposes of shares of common stock or Series B Convertible Preferred Stock through a United States broker or the United States offices of a foreign broker, the broker will generally be required to report the amount of proceeds paid to such non-U.S. holder to the IRS and also to backup withhold on that amount unless the broker is provided with appropriate certification of status as a non-United States person or an exemption is otherwise established. Information reporting will also apply if a non-U.S. holder sells shares of common stock or Series B Convertible Preferred Stock through a foreign broker deriving more than a specified percentage of its income from United States sources or having certain other connections to the United States, unless such broker has documentary evidence in its records that such non-U.S. holder is a non-United States person and certain other conditions are met, or an exemption is otherwise established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment may be refunded or credited against a non-U.S. holder’s United States federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS. Non-U.S. holders should consult with tax advisors regarding the application of the information reporting and backup withholding rules to investment in our common stock or Series B Convertible Preferred Stock.

Withholdable Payments to Foreign Financial Institutions and Other Foreign Entities

The Foreign Account Tax Compliance Act, or FATCA, imposes a United States federal withholding tax of 30% on certain payments to “foreign financial institutions” (as specifically defined under these rules) and certain other non-United States persons that fail to comply with certain information reporting and certification requirements pertaining to their direct and indirect United States security holders and/or United States account holders. Such payments generally include dividends on our common stock and Series B Convertible Preferred Stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult with tax advisors regarding the possible implications of this legislation and any applicable intergovernmental agreements on investment in our common stock and Series B Convertible Preferred Stock.

U.S. Federal Estate Tax

Certain securities beneficially owned by an individual who is not a citizen or resident of the United States (as defined for United States federal estate tax purposes) at the time of their death will generally be includable in the decedent’s gross estate for United States federal estate tax purposes and, therefore, may be subject to United States federal estate tax unless an applicable estate tax treaty or other treaty provides otherwise. Investors are urged to consult their own tax advisors regarding the United States federal estate tax consequences of the ownership or disposition of our securities.

THIS SUMMARY IS NOT INTENDED TO BE CONSTRUED AS LEGAL ADVICE. NON-U.S. HOLDERS ARE URGED TO CONSULT WITH TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE UNITED STATES FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK AND SERIES B CONVERTIBLE PREFERRED STOCK ARISING UNDER THE UNITED STATES FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-UNITED STATES OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

UNDERWRITING

Alliance Global Partners is acting as the sole underwriter in this offering. We have entered into an underwriting agreement dated _____, 2020 with the Alliance Global Partners. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares listed next to its name in the following table:

Underwriters	Number of shares of Common Stock	Number of shares of Series B Preferred Stock
Alliance Global Partners		

The underwriter is committed to purchase all the shares offered by us other than those covered by the over-allotment option to purchase additional securities described below, if it purchases any shares. The obligations of the underwriter may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriter's obligations are subject to customary conditions and representations and warranties contained in the underwriting agreement, such as receipt by the underwriter of officers' certificates and legal opinions.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriter may be required to make in respect thereof.

The underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-allotment Option to Purchase Additional Securities

We have granted the underwriter an option to purchase additional shares of common stock. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriter to purchase a maximum of additional shares of common stock (15% of the shares of common stock and the shares of common stock underlying the shares of Series B Preferred sold in this offering) from us, solely to cover over-allotments, if any. If the underwriter exercises all or part of this over-allotment option, it will purchase such common stock covered by the over-allotment option at the public offering price per share of common stock, less the underwriting discounts and commissions. If this over-allotment option is exercised in full, the total offering price to the public will be approximately \$ _____ million and the total net proceeds, after expenses, to us will be approximately \$ _____ million.

Discounts, Commissions and Expense Reimbursement

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriter of its over-allotment option to purchase additional securities.

	Per share of Common Stock	Per share of Series B Preferred Stock	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	\$ _____	\$ _____	\$ _____	\$ _____

The underwriter proposes to offer the shares offered by us to the public at the public offering price per respective share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of up to \$ _____ per share of common stock and \$ _____ per share of Series B Preferred Stock.

If all of the shares offered by us are not sold at the respective public offering prices per share, the underwriter may change the offering price per share and other selling terms by means of a supplement to this prospectus.

We have also agreed to reimburse certain of the underwriter's out of pocket expenses not to exceed \$140,000, including the fees of underwriters' counsel, which will not exceed \$100,000, \$20,000 for IPREO software related expenses, \$5,000 for background check expenses, \$3,000 for tombstones and up to \$12,000 in marketing related expenses including roadshow expenses.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts, commissions and underwriter expense reimbursement will be approximately \$ _____ million.

Lock-Up Agreements

We have agreed with the underwriter not to offer for sale, issue or sell, or register for offer or sale, any of our common stock or securities convertible into our common stock for a period of three months after the date of this prospectus, subject to certain exceptions. In addition, all of our directors and executive officers have entered into lock up agreements with the underwriter prior to the commencement of this offering pursuant to which each of these persons, for a period of three months from the closing date of this offering, without the prior written consent of the underwriter, agree not to (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into or exercisable or exchangeable for shares our common stock owned or acquired on or prior to the closing date of this offering (including any common shares acquired after the closing date of this offering upon the conversion, exercise or exchange of such securities); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common shares or such other securities, in cash or otherwise, except for certain exceptions and limitations; (3) file or caused to be filed any registration statement relating to the offering of any shares of our capital shares; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to such securities.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The underwriter may agree to allocate a number of shares of common stock or Series B Preferred Stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

The Nasdaq Global Market Listing

Our common stock is listed on The Nasdaq Global Market under the symbol “TNXP.”

Stabilization

In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales. Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position that may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any short position by exercising its option to purchase additional shares of common stock and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriter sells more shares than could be covered by exercise of the over-allotment option and, therefore, has a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares or common stock or preventing or retarding a decline in the market price of our shares or common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Global Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, the underwriter and selling group members may engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Certain Relationships

The underwriter and its affiliates have provided, or may in the future provide, various investment banking, commercial banking, financial advisory, brokerage, and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and expense reimbursement.

The underwriters and its affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of our company. The underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction.

LE GAL MATTERS

The validity of the issuance of the shares of common stock and preferred stock offered hereby will be passed upon for us by Brownstein Hyatt Farber Schreck, LLP, Las Vegas, Nevada. Certain legal matters in connection with this offering will be passed upon for the underwriter by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPE RTS

The consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. and subsidiaries as of December 31, 2018 and 2017 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein, which report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. Such financial statements are incorporated herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

DISC LOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our directors and officers are indemnified to the fullest extent permitted under Nevada law. We also maintain insurance which protects our officers and directors against any liabilities incurred in connection with their service in such a capacity.

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

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and our securities, reference is made to our SEC filings and the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the office of the SEC at the Public Reference Room at Station Place, 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the SEC at prescribed rates from the Public Reference Section of the SEC at such address. In addition, registration statements and certain other filings made with the SEC electronically are publicly available through the SEC's web site at <http://www.sec.gov>. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the SEC.

We are subject to the information and periodic reporting requirements of the Exchange Act of 1934, as amended (the "Exchange Act"), and we file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at <http://www.tonixpharma.com>. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus, and any references to this website or any other website are inactive textual references only. You may also request a copy of these filings, at no cost, by writing us at 509 Madison Avenue, Suite 1608, New York, New York 10022 or calling us at (212) 980-9155.

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For the Years Ended December 31, 2018 and 2017

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TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands, Except Par Value and Share Amounts)

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,024	\$ 25,034
Prepaid expenses and other	1,529	1,022
Total current assets	11,553	26,056
Property and equipment, net	34	43
Right to use assets, net	465	—
Restricted cash	100	100
Intangible asset	120	120
Total assets	\$ 12,272	\$ 26,319
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,119	\$ 1,404
Accrued expenses and other current liabilities	832	1,251
Lease liability, short term	415	—
Total current liabilities	2,366	2,655
Lease liability, long term	51	—
Total liabilities	2,417	2,655
Commitments (See Note 10)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized		
Series A Convertible Preferred stock, \$0.001 par value; 11,984 shares designated; 0 and 9,856 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.001 par value; 150,000,000 shares authorized; 1,575,246 and 328,689 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively, and 177 shares to be issued as of December 31, 2018	2	—
Additional paid in capital	218,258	212,157
Accumulated deficit	(208,363)	(188,452)
Accumulated other comprehensive loss	(42)	(41)
Total stockholders' equity	9,855	23,664
Total liabilities and stockholders' equity	\$ 12,272	\$ 26,319

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
COSTS AND EXPENSES:				
Research and development	\$ 5,052	\$ 3,264	\$ 12,502	\$ 12,501
General and administrative	2,839	2,277	7,592	6,171
	<u>7,891</u>	<u>5,541</u>	<u>20,094</u>	<u>18,672</u>
Operating Loss	(7,891)	(5,541)	(20,094)	(18,672)
Interest income, net	53	62	183	171
NET LOSS	<u>\$ (7,838)</u>	<u>\$ (5,479)</u>	<u>\$ (19,911)</u>	<u>\$ (18,501)</u>
Net loss per common share, basic and diluted	<u>\$ (5.69)</u>	<u>\$ (54.99)</u>	<u>\$ (23.93)</u>	<u>\$ (195.51)</u>
Weighted average common shares outstanding, basic and diluted	<u>1,377,857</u>	<u>99,640</u>	<u>832,050</u>	<u>94,628</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In Thousands)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (7,838)	\$ (5,479)	\$ (19,911)	\$ (18,501)
Other comprehensive loss:				
Foreign currency translation (loss) gain	(3)	5	(1)	(17)
Comprehensive loss	\$ (7,841)	\$ (5,474)	\$ (19,912)	\$ (18,518)

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2019
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Series A Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2018	9,856	\$ —	328,689	\$ —	\$ 212,157	\$ (41)	\$ (188,452)	\$ 23,664
Issuance of common stock upon conversion of Series A Convertible preferred stock	(9,856)	—	281,610	1	(1)	—	—	—
Issuance of common stock in exchange for exercise of warrants in March 2019 (\$35.00 per share)	—	—	2,000	—	70	—	—	70
Employee stock purchase plan	—	—	177	—	3	—	—	3
Stock-based compensation	—	—	—	—	305	—	—	305
Foreign currency transaction gain	—	—	—	—	—	2	—	2
Net loss	—	—	—	—	—	—	(6,233)	(6,233)
Balance, March 31, 2019	—	—	612,476	1	212,534	(39)	(194,685)	17,811
Issuance of common stock under 2018 Purchase Agreement	—	—	22,754	—	387	—	—	387
Issuance of common stock under At-the-market offering, net of transactional expenses of \$1	—	—	2,106	—	33	—	—	33
Stock-based compensation	—	—	—	—	431	—	—	431
Foreign currency transaction loss	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(5,840)	(5,840)
Balance, June 30, 2019	—	—	637,336	1	213,385	(39)	(200,525)	12,822
Issuance of common stock under July 2019 Financing, net of transactional expenses of \$484	—	—	900,000	1	4,483	—	—	4,484
Issuance of commitment shares in August 2019 under 2019 Purchase Agreement	—	—	35,529	—	—	—	—	—
Employee stock purchase plan	—	—	2,381	—	28	—	—	28
Stock-based compensation	—	—	—	—	362	—	—	362
Foreign currency transaction gain	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(7,838)	(7,838)
Balance, September 30, 2019	—	\$ —	1,575,246	\$ 2	\$ 218,258	\$ (42)	\$ (208,363)	\$ 9,855

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2018
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Series A Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2017	—	\$ —	82,064	\$ —	\$ 186,991	\$ (12)	\$ (162,363)	\$ 24,616
Issuance of common stock related to restricted stock units	—	—	8	—	—	—	—	—
Issuance of common stock in March (\$321.00 per share), net of transaction expenses of \$45	—	—	1,800	—	532	—	—	532
Stock-based compensation	—	—	—	—	399	—	—	399
Foreign currency transaction loss	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(6,935)	(6,935)
Balance, March 31, 2018	—	—	83,872	—	187,922	(13)	(169,298)	18,611
Issuance of common stock in April (\$321.00 per share)	—	—	4,500	—	1,315	—	—	1,315
Issuance of common stock in June 2018 under At-the-market offering, net of transaction expenses of \$50	—	—	3,592	—	1,615	—	—	1,615
Stock-based compensation	—	—	—	—	409	—	—	409
Foreign currency transaction loss	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(6,087)	(6,087)
Balance, June 30, 2018	—	—	91,964	—	191,261	(34)	(175,385)	15,842
Issuance of common stock under purchase agreement	—	—	4,500	—	409	—	—	409
Issuance of common stock in July, August and September 2018 under At-the-market offering, net of transaction expenses of \$77	—	—	12,115	—	2,481	—	—	2,481
Stock-based compensation	—	—	—	—	451	—	—	451
Foreign currency transaction gain	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	(5,479)	(5,479)
Balance, September 30, 2018	—	\$ —	108,579	\$ —	\$ 194,602	\$ (29)	\$ (180,864)	\$ 13,709

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)
(Unaudited)

	Nine months ended September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (19,911)	\$ (18,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21	43
Stock-based compensation	1,098	1,259
Changes in operating assets and liabilities:		
Prepaid expenses and other	(508)	(149)
Accounts payable	(285)	(249)
Operating lease liabilities	2	—
Accrued expenses and other current liabilities	(386)	450
Net cash used in operating activities	<u>(19,969)</u>	<u>(17,147)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(12)	(7)
Net cash used by investing activities	<u>(12)</u>	<u>(7)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	70	—
Proceeds, net of \$485 and \$172 expenses, from sale of common stock	4,904	6,352
Net cash provided by financing activities	<u>4,974</u>	<u>6,352</u>
Effect of currency rate change on cash	(3)	(10)
Net decrease in cash, cash equivalents and restricted cash	(15,010)	(10,812)
Cash, cash equivalents and restricted cash beginning of the period	25,134	25,585
Cash, cash equivalents and restricted cash end of period	<u>\$ 10,124</u>	<u>\$ 14,773</u>
Supplemental disclosures of cash flow information:		
Non cash financing activities:		
Issuance of common stock under employee benefit plan	<u>\$ 31</u>	<u>\$ —</u>

See the accompanying notes to the condensed consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. (“Tonix Sub”), clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions, to improve biodefense through potential medical counter-measures, to treat transplant rejection and to treat gastric and pancreatic cancers. All drug product candidates are still in development.

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its wholly owned subsidiaries, Tonix Sub, Krele LLC, Tonix Pharmaceuticals (Canada), Inc., Tonix Medicines, Inc., Tonix Pharma Holdings Limited and Tonix Pharma Limited (collectively hereafter referred to as the “Company” or “Tonix”).

On October 31, 2019, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective November 1, 2019. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, \$0.001 par value, whereby 15,717,402 outstanding shares of the Company’s common stock were exchanged for 1,575,246 shares of the Company’s common stock. In connection with the reverse stock split, the Company issued an additional 3,457 shares of the Company’s common stock due to rounding. Furthermore, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 150 million to 15 million. All per share amounts and number of shares in the condensed consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

Going concern

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At September 30, 2019, the Company had working capital of approximately \$9.2 million. At September 30, 2019, the Company had an accumulated deficit of approximately \$208.4 million. The Company held cash and cash equivalents of approximately \$10 million as of September 30, 2019. The Company does not have enough resources to meet its operating requirements for the one-year period from the date of filing of this report. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company continues to face significant challenges and uncertainties and, as a result, the Company’s available capital resources may be consumed more rapidly than currently expected due to changes the Company may make in its research and development spending plans. The Company may seek to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. However, the Company may not be able to raise capital with terms acceptable to the Company. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company’s ability to achieve its development and commercialization goals would be adversely affected. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Interim financial statements

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

The condensed consolidated balance sheet as of December 31, 2018 contained herein has been derived from audited financial statements.

Operating results for the three and nine months ended September 30, 2019 are not necessarily indicative of results that may be expected for the year ending December 31, 2019. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2018 included in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission (“SEC”) on March 18, 2019.

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Recent accounting pronouncements

In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company has elected the 'package of practical expedients', which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

The new standard has had a material effect on the Company's financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for operating leases; and (2) providing new disclosures about its leasing activities.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. In connection with the adoption of this standard, the Company made changes to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. The standard did not have a material impact on the Company's results of operations or liquidity.

Upon adoption, the Company recognized operating lease liabilities of approximately \$0.3 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company recognized corresponding ROU assets of approximately \$0.3 million.

Risks and uncertainties

The Company's primary efforts are devoted to conducting research and development of innovative pharmaceutical and biological products to address public health challenges. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. Further, the Company does not have any commercial products available for sale and has not generated revenues, and there is no assurance that if its products are approved for sale, 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.

Use of estimates

The preparation of financial statements in accordance with GAAP 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 expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets, assumptions used in the fair value of stock-based compensation and other equity instruments, and the percent of completion of research and development contracts.

Cash, cash equivalents and restricted cash

The Company considers cash equivalents to be those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased. At September 30, 2019 and December 31, 2018, cash equivalents, which consisted of money market funds, amounted to \$8.5 million and \$10.1 million, respectively. Restricted cash at both September 30, 2019 and December 31, 2018 of approximately \$100,000 collateralizes a letter of credit issued in connection with the lease of office space in New York City (see Note 9).

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The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statement of cash flow:

	September 30, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	\$ 10,024	\$ 25,034
Restricted cash	100	100
Total	\$ 10,124	\$ 25,134

Property and equipment

Property 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, five years for furniture and all other equipment and term of lease for leasehold improvements. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization expense for the three and nine months ended September 30, 2019 was \$5,000 and \$21,000, respectively, and \$13,000 and \$43,000, respectively, for the three and nine months ended September 30, 2018. All property and equipment is located in the United States and Ireland.

Intangible asset with indefinite lives

During 2015, the Company purchased certain internet domain rights, which were determined to have an indefinite life. Identifiable intangibles with indefinite lives are not amortized but are tested for impairment annually or whenever events or changes in circumstances indicate that its carrying amount may be less than fair value. As of September 30, 2019, the Company believed that no impairment existed.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, operating lease liabilities, current and operating lease liabilities, noncurrent in the Company's condensed consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the transition date and commencement date in determining the present value of lease payments. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Upon adoption, the Company recognized operating lease liabilities of approximately \$0.3 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company also recognized corresponding ROU assets of approximately \$0.3 million. In January 2019, the Company entered into a new operating lease, resulting in the Company recognizing an operating lease liability of approximately \$0.4 million based on the present value of the minimum rental payments. The Company also recognized corresponding ROU assets of approximately \$0.4 million. In April 2019, the Company entered into a lease amendment, resulting in the Company recognizing an additional operating lease liability of approximately \$0.1 million based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately \$0.1 million.

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Research and development costs

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

The Company estimates its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company accounts for trial expenses according to the timing of various aspects of the trial. The Company determines accrual estimates taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed.

During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Stock-based compensation

All stock-based payments to employees and to nonemployee directors for their services as directors, including grants of restricted stock units ("RSUs"), and stock options, are measured at fair value on the grant date and recognized in the condensed 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.

Foreign currency translation

Operations of the Canadian subsidiary are conducted in local currency, which represents its functional currency. The U.S. dollar is the functional currency of the other foreign subsidiaries. Balance sheet accounts of the Canadian subsidiary were translated from foreign currency into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated at the average rate of exchange prevailing during the period. Translation adjustments resulting from this process were included in accumulated other comprehensive income (loss) on the condensed consolidated balance sheets.

Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity of a business during a period from transactions and other events and circumstances from non-owner's sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. Other comprehensive income (loss) represents foreign currency translation adjustments.

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 a 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 September 30, 2019, the Company has not recorded any unrecognized tax benefits.

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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 1-for-10 reverse stock split, which was effected on November 1, 2019 and November 28, 2018 (see Note 1).

As of September 30, 2019, and 2018, there were outstanding warrants to purchase an aggregate of 496,486 and 5,939 shares, respectively, of the Company's common stock. In addition, the Company has issued to employees, directors and consultants, options to acquire shares of the Company's common stock, of which 109,036 and 14,236 were outstanding at September 30, 2019 and 2018, respectively. In computing diluted net loss per share for the three and nine months ended September 30, 2019 and 2018, no effect has been given to such options and warrants (see Note 8) as their effect would be anti-dilutive.

NOTE 3 – FAIR VALUE MEASUREMENTS

Fair value measurements affect the Company's accounting for certain of its financial assets. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured according to a hierarchy that includes:

- Level 1: Observable inputs, such as quoted prices in active markets.
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly. Level 2 assets and liabilities include debt securities with quoted market prices that are traded less frequently than exchange-traded instruments. This category includes U.S. government agency-backed debt securities and corporate-debt securities.
- Level 3: Unobservable inputs in which there is little or no market data.

As of September 30, 2019, and December 31, 2018, the Company had Level 1 quoted prices in active markets of \$8.5 million and \$10.1 million, respectively, consisting entirely of cash equivalents.

NOTE 4 – ASSET PURCHASE AGREEMENT WITH TRIMARAN

On August 19, 2019, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") with TRImaran Pharma, Inc. ("TRImaran") and the selling shareholders named therein (the "Selling Shareholders") pursuant to which Tonix acquired TRImaran's assets related to certain pyran-based compounds (the "Assets"). In connection with the acquisition of the Assets, Tonix entered into a First Amended and Restated Exclusive License Agreement (the "WSU License Agreement") with Wayne State University ("WSU") on August 19, 2019. As consideration for entering into the Asset Purchase Agreement, Tonix has agreed to pay \$100,000 to TRImaran and has assumed certain liabilities of TRImaran totaling \$68,500. Upon the achievement of specified development, regulatory and sales milestones, Tonix also agreed to pay TRImaran and the Selling Shareholders, in restricted stock or cash, at Tonix's option, a total of approximately \$3.4 million. Pursuant to the terms of the Asset Purchase Agreement, TRImaran and the Selling Shareholders are prohibited from disclosing confidential information related to the Assets and are restricted from engaging, for a period of three years, in the development or commercialization of any therapeutic containing any pyran-based drug compound for the treatment of post-traumatic stress disorder, attention deficit hyperactivity disorder or major depressive disorder. Also for a period of three years, if TRImaran or any Selling Shareholder engage in the research or development of any potential therapeutic compound for the treatment of any central nervous system disorder, TRImaran or such Selling Shareholder is obliged to provide notice and opportunity to Tonix to make an offer to acquire or license rights with respect to such product candidate.

Pursuant to the terms of the WSU License Agreement, WSU has granted to Tonix an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the "Technology") related to the Assets. WSU has reserved for itself the right to practice the Technology for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to obtain regulatory approval for one or more products utilizing the Technology ("WSU Products") and to use commercially reasonable marketing efforts throughout the term of the WSU License Agreement. The WSU License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to WSU. Tonix is obligated to substantially manufacture WSU Products in the United States if WSU Products will be sold in the United States.

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Pursuant to the WSU License Agreement, Tonix has agreed to pay \$75,000 to WSU as reimbursement of certain patent expenses, and, upon the achievement of specified development, regulatory and sales milestones, the Company also agreed to pay WSU, milestone payments totaling approximately \$3.4 million. Tonix has also agreed to pay WSU single-digit royalties on net sales of WSU Products sold by Tonix or a sublicensee on a tiered basis based on net sales, and additional sublicense fees on certain consideration received from sublicensees. Royalties on each particular WSU Product are payable on a country-by-country and Product-by-Product basis until the date of expiration of the last valid claim in the last to expire of the issued patents covered by the WSU License Agreement. Royalties payable on net sales of WSU Products may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the WSU License Agreement, provided that the royalty payable on a WSU Product may not be reduced by more than 50%. Each party also has the right to terminate the agreement for customary reasons such as material breach and bankruptcy. The WSU License Agreement contains provisions relating to termination, indemnification, confidentiality and other customary matters for an agreement of this kind.

As of September 30, 2019, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 5 – LICENSE AGREEMENTS WITH COLUMBIA UNIVERSITY

On September 16, 2019, the Company entered into an exclusive License Agreement (the “Columbia License Agreement”) with the Trustees of Columbia University in the City of New York (“Columbia”) pursuant to which Columbia granted to Tonix an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the “TFF2 Technology”) related to a recombinant Trefoil Family Factor 2 (TFF2), and to develop and commercialize products thereunder (each, a “TFF2 Product”). Pursuant to the terms of the Columbia License Agreement, Columbia has reserved for itself the right to practice the TFF2 Technology for academic research and educational purposes.

The Company has agreed to pay a five-digit license fee to Columbia as consideration for entering into the Columbia License Agreement. The Company is obligated to use Commercially Reasonable Efforts, as defined in the Columbia License Agreement, to develop and commercialize the TFF2 Product, and to achieve specified developmental milestones.

The Company has agreed to pay Columbia single-digit royalties on net sales of (i) TFF2 Products sold by Tonix or a sublicensee and (ii) any other products that involve material or technical information related to the TFF2 Product and transferred to Tonix pursuant to the Columbia License Agreement (“Other Products”) sold by Tonix or a sublicensee. Royalties on each particular TFF2 Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the Columbia License Agreement, and (ii) a specified period of time after the first commercial sale of a TFF2 Product in the country in question. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until a specified period of time after the first commercial sale of such particular Other Product in such country. Royalties payable on net sales of the TFF2 Product and Other Products may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the Columbia License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

The Company is also obligated to make contingent milestone payments to Columbia totaling \$4.1 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a TFF2 Product. In addition, the Company shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to the Company by a sublicensee. As of September 30, 2019, no milestone payments have been accrued or paid in relation to this agreement.

On May 20, 2019, the Company entered into an exclusive License Agreement (the “License Agreement”) with Columbia pursuant to which Columbia, for itself and on behalf of the University of Kentucky and the University of Michigan (collectively, the “Institutions”) granted to the Company an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the “Technology”) related to a double-mutant cocaine esterase, and to develop and commercialize products thereunder (each, a “Product”). Pursuant to the terms of the License Agreement, Columbia has reserved for itself and the Institutions the right to practice the Technology for academic research and educational purposes.

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The Company has agreed to pay a six-digit license fee to Columbia as consideration for entering into the License Agreement. The Company is obligated to use Commercially Reasonable Efforts, as defined in the License Agreement, to develop and commercialize the Product, and to achieve specified developmental milestones. The first 50% of the license fee was paid by June 30, 2019, while the remaining 50% license fee has been accrued for within accrued expenses and other current liabilities as of September 30, 2019.

The Company has agreed to pay Columbia single-digit royalties on net sales of (i) Products sold by the Company or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to the Company pursuant to the License Agreement (“Other Products”) sold by the Company or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the License Agreement, (ii) a specified period of time after the first commercial sale of a Product in the country in question, or (iii) expiration of any market exclusivity period granted by a regulatory agency. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until the later of (i) a specified period of time after the first commercial sale of such particular Other Product in such country or (ii) expiration of any market exclusivity period granted by a regulatory agency. Royalties payable on net sales of the Product and Other Products may be reduced by 50% of the royalties payable by the Company to any third party for intellectual property rights which are necessary for the practice of the rights licensed to the Company under the License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

The Company is also obligated to make contingent milestone payments to Columbia totaling \$3 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a Product. In addition, the Company shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to the Company by a sublicensee. As of September 30, 2019, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 6 – SALE OF COMMON STOCK

2019 Lincoln Park Transaction

On August 20, 2019, the Company entered into a purchase agreement (the “2019 Purchase Agreement”) and a registration rights agreement (the “2019 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2019 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of the Company’s common stock (subject to certain limitations) from time to time during the term of the 2019 Purchase Agreement. Pursuant to the terms of the 2019 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2019 Purchase Agreement.

Pursuant to the terms of the 2019 Purchase Agreement, at the time the Company signed the 2019 Purchase Agreement and the 2019 Registration Rights Agreement, the Company issued 35,529 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2019 Purchase Agreement. The commitment shares were valued at \$200,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2019 Purchase Agreement.

The Company did not sell any shares of common stock under the 2019 Purchase Agreement during the nine months ended September 30, 2019.

July 2019 Financing

On July 16, 2019, the Company entered into an underwriting agreement with Aegis Capital Corp., as representatives of the underwriters (“Aegis”), relating to the issuance and sale of 900,000 shares of its common stock, in an underwritten public offering (the “July 2019 Financing”). The public offering price for each share of common stock was \$6.00. The Company granted Aegis a 45-day option to purchase up to an additional 135,000 shares of common stock to cover over-allotments, if any.

The July 2019 Financing closed on July 18, 2019. Aegis purchased the shares at an eight percent discount to the then current public price, for an aggregate discount of \$0.4 million (or \$0.48 per share). The Company incurred offering expenses of approximately \$0.5 million. We received net proceeds of approximately \$4.5 million.

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December 2018 Financing

On December 7, 2018, the Company entered into an underwriting agreement with Alliance Global Partners (“AGP”) and Dawson James Securities, Inc. (collectively, the “Underwriters”) pursuant to which the Company sold securities consisting of 86,171 Class A Units at a public offering price of \$35.00 per unit, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock, and 11,984 Class B Units at a public offering price of \$1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of \$35.00 per share, and warrants to purchase 28,5714 shares of Common Stock. The warrants have an exercise price of \$35.00, are exercisable and expire five years from the date of issuance.

The Company also granted the Underwriters a 45-day option to purchase up to 64,286 shares of common stock and/or additional warrants to purchase up to 64,286 additional shares of common stock.

The December 2018 Financing closed on December 11, 2018. The Underwriters purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately \$1.1 million (or \$2.40 per share). The Company received net proceeds from the December 2018 Financing of approximately \$13.6 million, after deducting the underwriting discount and other offering expenses of approximately \$0.4 million. Additionally, the Underwriters fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 64,000 shares of common stock for net proceeds of approximately \$6,000.

On December 13, 2018, the Underwriters partially exercised the over-allotment option and purchased 25,000 shares of common stock for net proceeds of approximately \$0.8 million, net of an aggregate discount of \$0.1 million (or \$2.40 per share).

During the first quarter of 2019, the remaining 9,856 shares of Series A Convertible Preferred Stock were converted into 281,610 shares of common stock. As of March 11, 2019, all Series A Convertible Preferred Stock has been converted into common stock.

2018 Lincoln Park Transaction

On October 18, 2018, the Company entered into a purchase agreement (the “2018 Purchase Agreement”) and a registration rights agreement (the “2018 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the 2018 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of the Company’s common stock (subject to certain limitations) from time to time during the term of the 2018 Purchase Agreement. Pursuant to the terms of the 2018 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2018 Purchase Agreement.

Pursuant to the terms of the 2018 Purchase Agreement, at the time the Company signed the 2018 Purchase Agreement and the 2018 Registration Rights Agreement, the Company issued 3,500 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2018 Purchase Agreement. The commitment shares were valued at \$245,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2018 Purchase Agreement.

During the nine months ended September 30, 2019, the Company sold an aggregate of approximately 22,700 shares of common stock under the 2018 Purchase Agreement, for gross proceeds of approximately \$0.4 million.

Under applicable rules of the NASDAQ Global Market, the Company could not issue or sell more than 19.99% of the shares of its common stock outstanding immediately prior to the execution of the 2018 Purchase Agreement (approximately 26,200 shares) to Lincoln Park under the 2018 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 2018 Purchase Agreement equals or exceeds a threshold amount. As the Company has issued approximately 26,200 shares to Lincoln Park, by June 30, 2019, under the 2018 Purchase Agreement at less than the threshold amount, the Company will not sell any additional shares under the 2018 Purchase Agreement without shareholder approval.

2018 At-the-Market Offering

On May 1, 2018, the Company entered into a sales agreement (the “Sales Agreement”), with Cowen and Company, LLC., (“Cowen”), pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to \$9.5 million in at-the-market offerings (“ATM”) sales. On the same day, the Company filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen acted as sales agent and was paid a 3% commission on each sale under the Sales Agreement. The Company’s common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied.

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During the nine months ended September 30, 2019, the Company sold an aggregate of 2,106 shares of common stock under the ATM for net proceeds of approximately \$33,000.

During the nine months ended September 30, 2018, the Company sold an aggregate of approximately 16,000 shares of common stock using the ATM, resulting in net proceeds of \$4.1 million, net of expenses of approximately \$0.1 million of Cowen's commission.

2017 Lincoln Park Transaction

On September 28, 2017, the Company entered into a purchase agreement (the "2017 Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to \$15,000,000 of its common stock (subject to certain limitations) from time to time during the term of the 2017 Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2017 Purchase Agreement.

Pursuant to the terms of the 2017 Purchase Agreement, at the time the Company signed the 2017 Purchase Agreement and the Registration Rights Agreement, the Company issued 731 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of its common stock under the Purchase Agreement. The commitment shares were valued at \$300,000, recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the Purchase Agreement.

During the nine months ended September 30, 2018, the Company sold approximately 11,000 shares of common stock under the 2017 Purchase Agreement, resulting in net proceeds of \$2.3 million, net of expenses of approximately \$45,000. The Company did not sell any shares of common stock under the 2017 Purchase Agreement during the nine months ended September 30, 2019.

Under applicable rules of the NASDAQ Global Market, the Company could not issue or sell more than 19.99% of the shares of its common stock outstanding immediately prior to the execution of the 2017 Purchase Agreement (approximately 15,000 shares) to Lincoln Park under the 2017 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 2017 Purchase Agreement equals or exceeds a threshold amount. As the Company has issued approximately 15,000 shares to Lincoln Park, by December 31, 2018, under the 2017 Purchase Agreement at less than the threshold amount, the Company will not sell any additional shares under the 2017 Purchase Agreement without shareholder approval.

NOTE 7 – STOCK-BASED COMPENSATION

2018 Stock Incentive Plan

On June 8, 2018, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2018 Stock Incentive Plan (the "2018 Plan"). The 2018 Plan provided for the issuance of up to 13,200 shares of common stock. With the adoption of the 2019 Plan (as defined below), no further grants may be made under the 2018 Plan.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

2019 Stock Incentive Plan

On May 3, 2019, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the "2019 Plan", and together with the 2018 Plan, the "Plans").

Under the terms of the 2019 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2019 Plan provides for the issuance of up to 140,000 shares of common stock, which amount will be increased to the extent that awards granted under the 2019 Plan and the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2019 Plan). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2019 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. 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 expiration period of grants under the 2019 Plan may not more than ten years. As of September 30, 2019, 55,825 shares were available for future grants under the 2019 Plan.

General

A summary of the stock option activity and related information for the Plans for the nine months ended September 30, 2019 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	13,740	\$ 1,430.90	8.14	\$ —
Grants	95,517	\$ 21.74		\$ —
Exercised	—			
Forfeitures or expirations	(221)	359.86		
Outstanding at September 30, 2019	109,036	\$ 199.57	8.86	\$ —
Vested and expected to vest at September 30, 2019	109,036	\$ 199.57	8.86	\$ —
Exercisable at September 30, 2019	16,723	\$ 1,045.31	5.17	\$ —

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price at the respective dates.

The weighted average fair value of options granted during the nine months ended September 30, 2019 was \$16.54 per share. The weighted average fair value of options granted during the three and nine months ended September 30, 2018 was \$82.64 per share and \$277.77 per share, respectively.

The Company measures the fair value of stock options on the date of grant, based on the Black Scholes option pricing model using certain assumptions discussed below, and the closing market price of the Company's common stock on the date of the grant. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. Most stock options granted pursuant to the Plans typically vest 1/3rd 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, the Company issues options to directors which vest over a one-year period. In addition, the Company also issues performance-based options to executive officers, which options vest when the target parameters are met, and premium options which have an exercise price greater than the grant date fair value, subject in each case to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

The assumptions used in the valuation of stock options granted during the nine months ended September 30, 2019 and 2018 were as follows:

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Risk-free interest rate	2.30% to 2.54%	2.54% to 2.81%
Expected term of option	5.10 to 10.00 years	4.50 to 7.00 years
Expected stock price volatility	107.12% to 109.72%	99.65% to 109.22%
Expected dividend yield	0.0%	0.0%

The risk-free interest rate 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, as provided in an SEC Staff Accounting Bulletin, and the expected stock price volatility is based on the Company's historical stock price volatility.

Stock-based compensation expense relating to options granted of \$0.4 million and \$1.1 million was recognized for the three and nine-month periods ended September 30, 2019, respectively, and \$0.4 million and \$1.2 million was recognized for the three and nine-month periods ended September 30, 2018, respectively.

As of September 30, 2019, the Company had approximately \$2.1 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.85 years.

2018 Employee Stock Purchase Plan

On June 8, 2018, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2018 Employee Stock Purchase Plan (the "2018 ESPP"). As a result of adoption of the 2019 ESPP, as defined below, by the stockholders, no further grants may be made under the 2018 ESPP Plan.

2019 Employee Stock Purchase Plan

On May 3, 2019, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2019 Employee Stock Purchase Plan (the "2019 ESPP").

The 2019 ESPP allows eligible employees to purchase up to an aggregate of 15,000 shares of the Company's common stock. Under the 2019 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of the Company's common stock at the end of the offering period. Each offering period under the 2019 ESPP is for six months, which can be modified from time-to-time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee's accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2019 ESPP, subject to the statutory limit under the Code. As of September 30, 2019, 12,619 shares were available for future grants under the 2019 ESPP.

The 2019 ESPP and 2018 ESPP are considered compensatory plans with the related compensation cost written off over the six-month offering period. The compensation expense related to the 2019 ESPP and 2018 ESPP for the nine months ended September 30, 2019 and 2018 was \$28,000 and \$32,000, respectively. As of December 31, 2018, approximately \$38,000 of employee payroll deductions, which have been withheld since July 1, 2018, the commencement of the offering period ending December 31, 2018, are included in accrued expenses in the accompanying balance sheet. In January 2019, 177 shares that were purchased as of December 31, 2018, were issued under the 2018 ESPP, and approximately \$3,000 of employee payroll deductions accumulated at December 31, 2018, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$35,000 was returned to the employees. In August 2019, 2,381 shares that were purchased as of June 30, 2019, were issued under the 2019 ESPP, and approximately \$29,000 of employee payroll deductions accumulated at June 30, 2019, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$16,000 was returned to the employees. As of September 30, 2019, approximately \$9,000 of employee payroll deductions, which have been withheld since July 1, 2019, the commencement of the offering period ending December 31, 2019, are included in accrued expenses in the accompanying balance sheet.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

Restricted Stock Units

In May 2017, a total of 57 restricted stock units (“RSUs”) vested that were granted to our non-employee directors for board services in 2016, in lieu of cash, with a one-year vesting from the grant date and a fair value of \$2,290 at the date of grant. 49 shares of the Company’s common stock were issued upon the vesting of such RSU’s during the year ended December 31, 2017. The remaining 8 shares of common stock were issued during the three months ended March 31, 2018.

During the nine months ended September 30, 2019 and 2018, no stock-based compensation expense related to RSU grants was expensed.

NOTE 8 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at September 30, 2019:

Exercise Price	Number Outstanding	Expiration Date
\$ 35.00	490,571	December 2023
\$ 630.00	5,441	October 2021
\$ 690.00	474	October 2021
	496,486	

During the nine months ended September 30, 2019, 2,000 warrants with an exercise price of \$35.00 were exercised for proceeds of approximately \$70,000.

During the nine months ended September 30, 2019, 24 warrants with a per share exercise price of \$25,000 expired. During the nine months ended September 30, 2018, 11 and 919 warrants with a per share exercise price of \$12,000 and \$4,250, respectively, expired.

NOTE 9 – LEASES

The Company has various operating lease agreements, which are primarily for office space. These agreements frequently include one or more renewal options and require the Company to pay for utilities, taxes, insurance and maintenance expense. No lease agreement imposes a restriction on the Company’s ability to engage in financing transactions or enter into further lease agreements. At September 30, 2019, the Company has right-of-use assets of \$0.5 million and a total lease liability for operating leases of \$0.5 million of which \$0.1 million is included in operating lease liabilities, noncurrent and \$0.4 million is included in operating lease liabilities, current.

At September 30, 2019, future minimum lease payments for operating leases with non-cancelable terms of more than one year were as follows (in thousands):

Year Ending December 31,	
Remainder of 2019	\$ 113
2020	358
2021	6
	\$ 477

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2019 AND 2018 (UNAUDITED)

In January 2019, the Company entered into a new operating lease, resulting in the Company recognizing an operating lease liability of approximately \$0.4 million based on the present value of the minimum rental payments. The Company also recognized corresponding ROU assets of approximately \$0.4 million. In April 2019, the Company entered into a lease amendment, resulting in the Company recognizing an additional operating lease liability of approximately \$0.1 million based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately \$0.1 million. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the transition date and commencement date in determining the present value of lease payments. Operating lease expense was \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2019. Amortization expense was \$0.1 million and \$0.3 million for the three and nine months ended September 30, 2019.

Other information related to leases was as follows:

	Nine Months Ended September, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flow from operating leases (in thousands)	\$ 333
Weighted Average Remaining Lease Term	
Operating leases	1.09 years
Weighted Average Discount Rate	
Operating leases	3.37%

NOTE 10 – COMMITMENTS

Research and development contracts

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$7.2 million at September 30, 2019 for future work to be performed.

Defined contribution plan

The Company has a qualified defined contribution plan (the "401(k) Plan") pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) Plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 100 percent of each participant's pretax contributions of up to six percent of his or her eligible compensation, and the Company is also required to make a contribution equal to three percent of each participant's salary, on an annual basis, subject to limitations under the Code. The Company charged operations \$8,000 and \$74,000 for the three and nine months ended September 30, 2019, respectively, and \$26,000 and \$88,000 for the three and nine months ended September 30, 2018, respectively, for contributions under the 401(k) Plan.

NOTE 11 – SUBSEQUENT EVENT

On October 31, 2019, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective November 1, 2019. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, \$0.001 par value, whereby 15,717,402 outstanding shares of the Company's common stock were exchanged for 1,575,246 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 3,457 shares of the Company's common stock due to rounding. Furthermore, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 150 million to 15 million. All per share amounts and number of shares in the condensed consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split. On January 16, 2020, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 15,000,000 to 150,000,000.

R E P O R T O F I N D E P E N D E N T R E G I S T E R E D P U B L I C A C C O U N T I N G F I R M

The Board of Directors and Stockholders of
Tonix Pharmaceuticals Holding Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. and subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders’ equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has continuing losses and negative cash flows from operating activities which raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company’s auditor since 2010.

EISNERAMPER LLP
New York, New York

March 18, 2019, except for the second paragraph of Note 5, as to which the date is January 21, 2020

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2018 AND 2017
(In Thousands, Except Par Value and Share Amounts)

	2018	2017
ASSETS		
Current assets:		
Cash	\$ 25,034	\$ 25,496
Prepaid expenses and other	1,022	947
Total current assets	26,056	26,443
Property and equipment, net	43	91
Restricted cash	100	89
Intangible Asset	120	120
Security deposits	—	11
Total assets	\$ 26,319	\$ 26,754
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,404	\$ 1,296
Accrued expenses	1,251	830
Total current liabilities	2,655	2,126
Deferred rent payable	—	12
Total liabilities	2,655	2,138
Commitments (See Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized		
Series A Convertible Preferred stock, \$0.001 par value; 11,984 shares designated; 9,856 and 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	—
Common stock, \$0.001 par value; 150,000,000 shares authorized; 328,689 and 82,064 shares issued and outstanding as of December 31, 2018 and 2017, respectively, and 177 shares to be issued as of December 31, 2018	—	—
Additional paid in capital	212,157	186,991
Accumulated deficit	(188,452)	(162,363)
Accumulated other comprehensive loss	(41)	(12)
Total stockholders' equity	23,664	24,616
Total liabilities and stockholders' equity	\$ 26,319	\$ 26,754

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)

	Year ended December 31,	
	2018	2017
COSTS AND EXPENSES:		
Research and development	\$ 17,558	\$ 13,342
General and administrative	8,764	7,949
	26,322	21,291
Operating Loss	(26,322)	(21,291)
Interest income, net	233	168
Net loss	(26,089)	(21,123)
Preferred stock deemed dividend	3,266	—
Net loss available to common stockholders	\$ (29,355)	\$ (21,123)
Net loss per common share, basic and diluted	\$ (259.85)	\$ (299.99)
Weighted average common shares outstanding, basic and diluted	112,968	70,411

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In Thousands)

	Year ended	
	December 31,	
	2018	2017
Net loss	\$ (26,089)	\$ (21,123)
Other comprehensive loss:		
Foreign currency translation loss	(29)	(5)
Comprehensive loss	<u>\$ (26,118)</u>	<u>\$ (21,128)</u>

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In Thousands, Except Share and Per Share Amounts)

	Series A Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2016	—	\$ —	42,946	\$ —	\$ 166,608	\$ (7)	\$ (141,240)	\$ 25,361
Employee stock purchase plan	—	—	203	—	74	—	—	74
Issuance of common stock related to restricted stock units	—	—	109	—	—	—	—	—
Issuance of common stock in February 2017 (\$509.00 per share), March 2017 (\$450.00 per share) and April 2017 (\$655.00 per share), net of transaction expenses of \$280	—	—	14,868	—	9,062	—	—	9,062
Issuance of common stock in April 2017 (\$445.00 per share, net of transaction expenses of \$888)	—	—	20,700	—	8,325	—	—	8,325
Issuance of commitment shares in September 2017 (\$411.00 per share)	—	—	731	—	—	—	—	—
Issuance of common stock in exchange for exercise of warrants in April 2017 (\$630.00 per share)	—	—	23	—	14	—	—	14
Issuance of common stock in October 2017 (\$456.00 per share, net of transaction expenses of \$15)	—	—	2,484	—	1,118	—	—	1,118
Stock-based compensation	—	—	—	—	1,790	—	—	1,790
Foreign currency translation loss	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(21,123)	(21,123)
Balance, December 31, 2017	—	\$ —	82,064	\$ —	\$ 186,991	\$ (12)	\$ (162,363)	\$ 24,616

See the accompanying notes to the consolidated financial statements

	Series A Convertible Preferred stock		Common stock		Additional Paid in Capital	Accumulated Other Comprehensive loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2017	—	\$ —	82,064	\$ —	\$ 186,991	\$ (12)	\$ (162,363)	\$ 24,616
Issuance of common stock related to restricted stock units	—	—	8	—	—	—	—	—
Issuance of commitment shares in October 2018 (\$70.00 per share)	—	—	3,500	—	—	—	—	—
Issuance of common stock under 2017 Purchase Agreement, net of transactional expenses of \$45	—	—	11,797	—	2,315	—	—	2,315
Issuance of common stock under At-the-market offering, net of transactional expenses of \$212	—	—	59,349	—	6,857	—	—	6,857
Issuance of Series A Convertible preferred stock and common stock warrants in December 2018 (\$1,000.00 per unit, net of transactional expenses of \$1,159)	11,984	—	—	—	10,825	—	—	10,825
Issuance of common stock and common stock warrants in December 2018 (\$35.00 per unit, net of transaction expenses of \$353)	—	—	111,171	—	3,542	—	—	3,542
Beneficial conversion feature in connection with issuance of Series A Convertible preferred stock	—	—	—	—	3,266	—	—	3,266
Preferred stock deemed dividend	—	—	—	—	(3,266)	—	—	(3,266)
Issuance of common stock upon conversion of Series A Convertible preferred stock	(2,128)	—	60,800	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,627	—	—	1,627
Foreign currency transaction loss	—	—	—	—	—	(29)	—	(29)
Net loss	—	—	—	—	—	—	(26,089)	(26,089)
Balance, December 31, 2018	<u>9,856</u>	<u>\$ —</u>	<u>328,689</u>	<u>\$ —</u>	<u>\$ 212,157</u>	<u>\$ (41)</u>	<u>\$ (188,452)</u>	<u>\$ 23,664</u>

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Year ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (26,089)	\$ (21,123)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54	70
Stock-based compensation	1,627	1,790
Changes in operating assets and liabilities:		
Prepaid expenses	(79)	72
Accounts payable	106	424
Accrued expenses and deferred rent	410	(361)
Net cash used in operating activities	<u>(23,971)</u>	<u>(19,128)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(6)	(5)
Maturities of marketable securities	—	7,174
Net cash provided by investing activities	<u>(6)</u>	<u>7,169</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	—	14
Proceeds, net of \$1,159 expenses, from sale of preferred stock	10,825	—
Proceeds, net of \$610 and \$1,183 expenses, from sale of common stock	12,714	18,505
Net cash provided by financing activities	<u>23,539</u>	<u>18,519</u>
Effect of currency rate change on cash	<u>(13)</u>	<u>(5)</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(451)	6,555
Cash, cash equivalents and restricted cash beginning of the year	<u>25,585</u>	<u>19,030</u>
Cash, cash equivalents and restricted cash end of year	<u>\$ 25,134</u>	<u>\$ 25,585</u>
Supplemental disclosures of cash flow information:		
Taxes paid	<u>\$ 82</u>	<u>\$ 65</u>
Non cash financing activities:		
Issuance of common stock under employee benefit plan	<u>\$ —</u>	<u>\$ 74</u>
Beneficial conversion feature in connection with sale of Series A Convertible preferred stock and deemed dividend	<u>\$ 3,266</u>	<u>\$ —</u>

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. (“Tonix Sub”), is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. All drug product candidates are still in development.

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its wholly owned subsidiaries, Tonix Sub, Krele LLC, Tonix Pharmaceuticals (Canada), Inc., Tonix Medicines, Inc., Tonix Pharma Holdings Limited and Tonix Pharma Limited (collectively hereafter referred to as the “Company” or “Tonix”).

Going Concern

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At December 31, 2018, the Company had working capital of approximately \$23.4 million. At December 31, 2018, the Company had an accumulated deficit of approximately \$188.5 million. The Company held cash and cash equivalents of approximately \$25.0 million as of December 31, 2018. The Company does not have enough resources to meet its operating requirements through March 2020. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company continues to face significant challenges and uncertainties and, as a result, the Company’s available capital resources may be consumed more rapidly than currently expected due to changes the Company may make in its research and development spending plans. The Company has the ability to obtain additional funding through public or private financing or collaborative arrangements with strategic partners to increase the funds available to fund operations. However, the Company may not be able to raise capital with terms acceptable to the company. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company’s ability to achieve its development and commercialization goals would be adversely affected. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Consolidation

The consolidated financial statements include the accounts of Tonix Pharmaceuticals Holding Corp. and its direct and indirect wholly owned subsidiaries.

All significant intercompany balances and transactions have been eliminated in consolidation.

Recently Issued Accounting Pronouncements

In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company adopted the new standard on January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company has elected the 'package of practical expedients', which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter is not applicable to the Company.

The new standard will have a material effect on the Company's financial statements. The most significant effects of adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

Upon adoption, the Company will recognize additional operating lease liabilities of approximately \$0.3 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The Company expects to recognize corresponding ROU assets of approximately \$0.3 million.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company will elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Beginning in 2019, the Company expects changes to its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. These revised disclosures will be made in the Company's first quarterly report in 2019.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Risks and Uncertainties

The Company's primary efforts are devoted to conducting research and development of innovative pharmaceutical and biological products to address public health challenges. The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. Further, the Company does not have any commercial products available for sale and has not generated revenues, and there is no assurance that if its products are approved for sale, 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.

Use of Estimates

The preparation of financial statements in accordance with GAAP 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 expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the useful life of fixed assets, assumptions used in the fair value of stock-based compensation and other equity instruments, and the percent of completion of research and development contracts.

Cash Equivalents and Restricted Cash

The Company considers cash equivalents to be those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased. At December 31, 2018 and December 31, 2017, cash equivalents, which consisted of money market funds, amounted to \$10.1 million and \$17.3 million, respectively. Restricted cash at December 31, 2018 and December 31, 2017 of approximately \$100,000 and \$89,000, respectively, collateralizes a letter of credit issued in connection with the lease of office space in New York City (see Note 8).

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statement of cash flow:

	December 31,	December 31,
	2018	2017
	(in thousands)	
Cash and cash equivalents	\$ 25,034	\$ 25,496
Restricted cash	100	89
Total	<u>\$ 25,134</u>	<u>\$ 25,585</u>

Intangible Asset with Indefinite Lives

During the year ended December 31, 2015, the Company purchased certain internet domain rights, which were determined to have an indefinite life. Identifiable intangibles with indefinite lives are not amortized but are tested for impairment annually or whenever events or changes in circumstances indicate that its carrying amount may be less than fair value. As of December 31, 2018, and 2017, the Company believed that no impairment existed.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Research and Development Costs

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

The Company estimates its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company accounts for trial expenses according to the timing of various aspects of the trial. The Company determines accrual estimates taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed.

During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Property and Equipment

Property 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, five years for furniture and all other equipment and term of lease for leasehold improvements. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was \$54,000 and \$64,000, respectively. All remaining property and equipment is located in the United States.

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 a 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, 2018, the Company has not recorded any unrecognized tax benefits.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Stock-Based Compensation

All stock-based payments to employees and to nonemployee directors for their services as directors, including grants of restricted stock units (“RSUs”), and stock options, are measured at fair value on the grant date and recognized in the condensed 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.

Foreign Currency Translation

Operations of the Canadian subsidiary are conducted in local currency, which represents its functional currency. The U.S. dollar is the functional currency of the other foreign subsidiaries. Balance sheet accounts of the Canadian subsidiary were translated from foreign currency into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated at the average rate of exchange prevailing during the period. Translation adjustments resulting from this process were included in accumulated other comprehensive income (loss) on the consolidated balance sheets.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business during a period from transactions and other events and circumstances from non-owners sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. Other comprehensive income (loss) represents foreign currency translation adjustments.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 1-for-10 reverse stock split, which was effected on November 28, 2018 and November 1, 2019 (see Note 6).

As of December 31, 2018, and 2017, there were outstanding warrants to purchase an aggregate of 498,510 and 6,869 shares, respectively, of the Company's common stock (see Note 8). The Company has issued to employees, directors and consultants, options to acquire shares of the Company's common stock, of which 13,740 and 4,034 were outstanding at December 31, 2018 and 2017, respectively. For the year ended December 31, 2018, net loss attributable to common stockholders included preferred stock dividends of \$3.3 million, related to the beneficial conversion feature of the issuance of the Series A convertible preferred stock. The number of preferred shares convertible to common stock that were excluded from the computations of net loss per common share for the year ended December 31, 2018 were 281,600. In computing diluted net loss per share for the years ended December 31, 2018 and 2017, no effect has been given to such convertible preferred stock, options and warrants as their effect would be anti-dilutive.

NOTE 3 – OTHER BALANCE SHEET INFORMATION

Components of selected captions in the consolidated balance sheets consist of:

	December 31,	
	2018	2017
	(in thousands)	
Property, plant and equipment, net:		
Office furniture and equipment	\$ 317	\$ 311
Leasehold improvements	23	23
	340	334
Less: Accumulated depreciation and amortization	(297)	(243)
	\$ 43	\$ 91
Prepaid expenses and other:		
Contract-related	\$ 525	\$ 494
Other	497	453
	\$ 1,022	\$ 947
Accrued expenses:		
Contract-related	\$ 475	\$ 519
Compensation and compensation-related	614	65
Professional fees and other	162	246
	\$ 1,251	\$ 830

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 4 – FAIR VALUE MEASUREMENTS

Fair value measurements affect the Company's accounting for certain of its financial assets. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured according to a hierarchy that includes:

- Level 1: Observable inputs, such as quoted prices in active markets.
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly. Level 2 assets and liabilities include debt securities with quoted market prices that are traded less frequently than exchange-traded instruments. This category includes U.S. government agency-backed debt securities and corporate-debt securities.
- Level 3: Unobservable inputs in which there is little or no market data.

As of December 31, 2018, and December 31, 2017, the Company used Level 1 quoted prices in active markets to value cash equivalents of \$10.1 million and \$17.3 million, respectively.

NOTE 5 – STOCKHOLDERS' EQUITY

On November 26, 2018, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective November 28, 2018. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, \$0.001 par value, whereby 15,293,782 outstanding shares of the Company's common stock were exchanged for 1,529,427 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 2,833 shares of the Company's common stock due to rounding. Furthermore, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 150 million to 15 million. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

On October 31, 2019, the Company filed a Certificate of Change with the Nevada Secretary of State, which was effective November 1, 2019. Pursuant to the Certificate of Change, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock, \$0.001 par value. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split. On January 16, 2020, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 15,000,000 to 150,000,000.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 – SALE OF COMMON STOCK

December 2018 Financing

On December 7, 2018, the Company entered into an underwriting agreement with Alliance Global Partners (“AGP”) and Dawson James Securities, Inc. (“Dawson”) (collectively “the Underwriters”) pursuant to which the Company sold securities consisting of 86,171 Class A Units at a public offering price of \$35.00 per unit, with each unit consisting of one share of Common Stock and a Warrant to purchase one share of Common Stock, and 11,984 Class B Units at a public offering price of \$1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock, with a conversion price of \$35.00 per share, and Warrants to purchase 28.5714 shares of Common Stock. The Warrants have an exercise price of \$35.00, are exercisable and expire five years from the date of issuance.

The Company also granted the underwriters a 45-day option to purchase up to 64,286 shares of common stock and/or additional Warrants to purchase up to 64,286 additional shares of common stock.

The December 2018 Financing closed on December 11, 2018. The Underwriters purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately \$1.1 million (or \$2.40 per share). The Company received net proceeds from the December 2018 Financing of approximately \$13.6 million, after deducting the underwriting discount and other offering expenses of approximately \$0.4 million. Additionally, the Underwriters fully exercised the over-allotment option related to the warrants and purchased additional warrants to acquire 64,000 shares of common stock for net proceeds of approximately \$6,000.

On December 13, 2018, the 2018 Underwriters partially exercised the over-allotment option and purchased 25,000 shares of common stock for net proceeds of approximately \$0.8 million, net of an aggregate discount of \$0.1 million (or \$2.40 per share).

After allocating proceeds to the warrants issued with the Series A convertible preferred stock, the effective conversion price of the Series A convertible preferred Stock, after the bifurcation of the warrants, was determined to be less than the fair value of the underlying common stock at the date of commitment, resulting in a beneficial conversion feature (“BCF”) at that date. Since the Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF was charged to additional paid in capital as a “deemed dividend” and impacted earnings per share. The Company recognized a one-time non-cash deemed dividend of \$3.3 million for the beneficial conversion feature resulting from the intrinsic value of the conversion options of the preferred stock.

During the year ended December 31, 2018, 2,128 shares of Series A convertible preferred stock were converted into 60,800 shares of common stock. As of March 13, 2019, all Series A convertible preferred stock has been converted into common stock.

2018 At-the-Market Offering

On May 1, 2018, the Company entered into a sales agreement (“the Sales Agreement”), with Cowen and Company, LLC., (“Cowen”), pursuant to which the Company may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$9.5 million in at-the-market offerings (“ATM”) sales. On the same day, the Company filed a prospectus supplement under its existing shelf registration relating to the Sales Agreement. Cowen acted as sales agent and was paid a 3% commission on each sale under the Sales Agreement. The Company’s common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

During the year ended December 31, 2018, the Company sold an aggregate of approximately 59,300 shares of common stock using the ATM, resulting in net proceeds of \$6.9 million, net of expenses of approximately \$0.2 million of Cowen's commission.

2018 Lincoln Park Transaction

On October 18, 2018, the Company entered into a purchase agreement (the "2018 Purchase Agreement") and a registration rights agreement (the "2018 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2018 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2018 Purchase Agreement. Pursuant to the terms of the 2018 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2018 Purchase Agreement.

Pursuant to the terms of the 2018 Purchase Agreement, at the time the Company signed the 2018 Purchase Agreement and the 2018 Registration Rights Agreement, the Company issued 3,500 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2018 Purchase Agreement. The commitment shares were valued at \$245,000 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2018 Purchase Agreement.

As of December 31, 2018, no shares of common stock were sold under this agreement.

2017 Lincoln Park Transaction

On September 28, 2017, the Company entered into a purchase agreement (the "2017 Purchase Agreement") and a registration rights agreement (the "2017 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2017 Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to \$15,000,000 of its common stock (subject to certain limitations) from time to time during the term of the 2017 Purchase Agreement. Pursuant to the terms of the 2017 Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the 2017 Purchase Agreement.

Pursuant to the terms of the 2017 Purchase Agreement, at the time the Company signed the 2017 Purchase Agreement and the 2017 Registration Rights Agreement, the Company issued 731 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of its common stock under the 2017 Purchase Agreement. The commitment shares were valued at \$300,000, recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the 2017 Purchase Agreement.

During the year ended December 31, 2018, the Company sold an aggregate of approximately 11,800 shares of common stock under the 2017 Purchase Agreement, for gross proceeds of \$2.4 million, and from inception of the 2017 Purchase Agreement, the Company has sold an aggregate of approximately 14,300 shares of common stock, for gross proceeds of approximately \$3.5 million.

Under applicable rules of the NASDAQ Global Market, the Company could not issue or sell more than 19.99% of the shares of its common stock outstanding immediately prior to the execution of the 2017 Purchase Agreement (approximately 15,000 shares) to Lincoln Park under the 2017 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 2017 Purchase Agreement equals or exceeds a threshold amount. As the Company has issued approximately 15,000 shares to Lincoln Park under the 2017 Purchase Agreement at less than the threshold amount, the Company will not sell any additional shares under the 2017 Purchase Agreement without shareholder approval.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

April 2017 Financing

On March 30, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp., as representative of the several underwriters (collectively, the “2017 Underwriters”), relating to the issuance and sale of 18,000 shares of our common stock, in an underwritten public offering (the “April 2017 Financing”). The public offering price for each share of common stock was \$445.00. We granted the 2017 Underwriters an option to purchase up to an additional 2,700 shares of common stock to cover over-allotments, if any.

The April 2017 Financing closed on April 4, 2017. The 2017 Underwriters purchased the shares at a seven percent discount to the public offering price, for an aggregate discount of \$0.6 million (or \$31.20 per share). The Company incurred offering expenses of approximately \$0.2 million. We received net proceeds of approximately \$7.2 million. On April 13, 2017, the 2017 Underwriters fully exercised the over-allotment option and purchased 2,700 shares of common stock for net proceeds of approximately \$1.1 million, net of an aggregate discount of \$0.1 million (or \$31.20 per share).

2016 At-the-Market Offering

During the year ended December 31, 2017, the Company sold an aggregate of approximately 14,900 shares of common stock using the at the ATM, resulting in net proceeds of \$9.1 million, net of expenses of approximately \$0.3 million of Cowen’s commission. With these sales, the Company sold all \$15 million of shares under the 2016 Sales Agreement, and the 2016 Sales Agreement was terminated.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – STOCK-BASED COMPENSATION

2017 Stock Incentive Plan

On June 16, 2017, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2017 Stock Incentive Plan (the "2017 Plan" and together with the 2012 Incentive Stock Option Plan, 2014 Incentive Stock Option Plan and the 2016 Stock Incentive Plan, the "Prior Plans"). Under the terms of the 2017 Plan, the Company could have issued (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2017 Plan provided for the issuance of up to 12,800 shares of common stock. With the adoption of the 2018 Plan (as defined below), no further grants may be made under the Prior Plans.

2018 Stock Incentive Plan

On June 8, 2018, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2018 Stock Incentive Plan (the "2018 Plan" and together with the Prior Plans, the "Plans"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the Prior Plans.

Under the terms of the 2018 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) SARs, (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The 2018 Plan provides for the issuance of up to 13,200 shares of common stock, which amount was (a) reduced by awards granted under the Prior Plans after March 1, 2018, and (b) will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the 2018 Plan). In terms of calculating how many shares are reduced or increased based on activity under the Prior Plans after March 1, 2018, the calculation shall be based on one share for every one share that was subject to an option or SAR and 1.23 shares for every one share that was subject to an award other than an option or SAR. The Board of Directors determines the exercise price, vesting and expiration period of the grants under the 2018 Plan. However, the exercise price of an incentive stock option may not be less than 110% of fair value of the common stock at the date of the grant for a 10% or more shareholder and 100% of fair value for a grantee who is not a 10% shareholder. 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 expiration period of grants under the 2018 Plan may not more than ten years. The Company reserved 13,200 shares of its common stock for future issuance under the terms of the 2018 Plan. As of December 31, 2018, 11,850 shares were available for future grants under the 2018 Plan.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

General

A summary of the stock option activity and related information for the Plans for the years ended December 31, 2018, and 2017 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	2,196	\$ 9,132.90	7.82	\$ —
Grants	2,600	\$ 463.40		—
Exercised	—			
Forfeitures or expirations	(762)	6,759.24		
Outstanding at January 1, 2018	4,034	\$ 3,998.89	8.35	\$ —
Grants	10,206	\$ 375.15		—
Exercised	—			
Forfeitures or expirations	(500)	\$ 388.44		
Outstanding at December 31, 2018	<u>13,740</u>	\$ 1,430.90	8.14	\$ —
Vested and expected to vest at December 31, 2018	<u>13,740</u>	\$ 1,430.90	8.14	\$ —
Exercisable at December 31, 2018	<u>3,997</u>	\$ 3,768.19	5.84	\$ —

General

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price at the respective dates.

The Company measures the fair value of stock options on the date of grant, based on the Black Scholes option pricing model using certain assumptions discussed below, and the closing market price of the Company's common stock on the date of the grant. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. Most stock options granted pursuant to the Plans typically vest 1/3rd 12 months from the date of grant and 1/36th each month thereafter for 24 months and expire ten years from the date of grant. In addition, the Company issues options to directors which vest over a one-year period. In addition, the Company also issues performance-based options to executive officers, which options vest when the target parameters are met, and premium options which have an exercise price greater than the grant date fair value, subject in each case to a one year minimum service period prior to vesting. Stock-based compensation expense related to awards is amortized over the applicable vesting period using the straight-line method.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The assumptions used in the valuation of stock options granted during the years ended December 31, 2018 and 2017 were as follows:

	2018	2017
Risk-free interest rate	2.54% to 2.81%	1.75% to 2.33%
Expected term of option	4.5 to 7.00 years	5.0 to 7.91 years
Expected stock price volatility	99.65% to 109.22%	76.28% to 77.59%
Expected dividend yield	0%	0%

The risk-free interest rate 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, as provided in an SEC Staff Accounting Bulletin, and the expected stock price volatility is based on the companies' historical stock price volatility.

The weighted-average grant-date fair value of stock options granted was \$277.77 in 2018 and \$292.06 in 2017.

Stock-based compensation expense relating to options granted of \$1.6 million and \$1.7 million was recognized for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company had approximately \$1.8 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.87 years.

2014 Employee Stock Purchase Plan

On June 9, 2014, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2014 Employee Stock Purchase Plan (the "2014 ESPP"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the 2014 ESPP.

2018 Employee Stock Purchase Plan

On June 8, 2018, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2018 Employee Stock Purchase Plan (the "2018 ESPP"). As a result of adoption of the 2018 Plan by the stockholders, no further grants may be made under the Prior Plan.

The 2018 ESPP allows eligible employees to purchase up to an aggregate of 3,000 shares of the Company's common stock. Under the 2018 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of the Company's common stock at the end of the offering period. Each offering period under the 2018 ESPP is for six months, which can be modified from time-to-time. Subject to limitations, each participant will be permitted to purchase a number of shares determined by dividing the employee's accumulated payroll deductions for the offering period by the applicable purchase price, which is equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. A participant must designate in his or her enrollment package the percentage (if any) of compensation to be deducted during that offering period for the purchase of stock under the 2018 ESPP, subject to the statutory limit under the Code. As of December 31, 2018, there were 2,823 shares available for future issuance under the 2018 ESPP, after taking into account the shares issued below.

The 2018 ESPP and 2014 ESPP are considered compensatory plans with the related compensation cost written off over the six-month offering period. The compensation expense related to the 2018 ESPP for the year ended December 31, 2018 was \$32,000. The compensation expense related to the 2014 ESPP for the year ended December 31, 2017 was \$36,000. As of December 31, 2018, approximately \$38,000 of employee payroll deductions, which have been withheld since July 1, 2018, the commencement of the offering period ending December 31, 2018, are included in accrued expenses in the accompanying balance sheet. In January 2019, 177 shares that were purchased as of December 31, 2018, were issued under the 2018 ESPP, and approximately \$3,000 of employee payroll deductions accumulated at December 31, 2018, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining \$35,000 was returned to the employees. In July 2017, 178 shares that were purchased as of June 30, 2017, were issued under the 2014 ESPP, and approximately \$64,000 of employee payroll deductions accumulated at June 30, 2017, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. In January 2017, 25 shares that were purchased as of December 31, 2016, were issued under the 2014 ESPP, and approximately \$10,000 of employee payroll deductions accumulated at December 31, 2016, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. No employee deductions were withheld during 2017.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Restricted Stock Units

In February 2017, a total of 57 RSUs vested that were granted to the Company's non-employee directors for board services in 2016, in lieu of cash, with a one-year vesting from the grant date and a fair value of \$3,810.00 at the date of grant. 57 shares of the Company's common stock were issued upon the vesting of such RSUs during the year ended December 31, 2017.

In May 2017, a total of 57 RSUs vested that were granted to the Company's non-employee directors for board services in 2016, in lieu of cash, with a one-year vesting from the grant date and a fair value of \$2,290.00 at the date of grant. 49 shares of the Company's common stock were issued upon the vesting of such RSUs during the year ended December 31, 2017. The remaining 8 shares of common stock were issued during the year ended December 31, 2018.

The following table summarizes the RSU activity for the years ended December 31, 2018 and 2017:

Unvested restricted stock units as of January 1, 2017	114
Granted	—
Forfeited	—
Vested	<u>(114)</u>
Unvested restricted stock units as of January 1, 2018	—
Granted	—
Forfeited	—
Vested	<u>—</u>
Unvested restricted stock units as of December 31, 2018	—

Stock-based compensation expense related to RSU grants was \$0 and \$0.1 million for the year ended December 31, 2018 and 2017, respectively.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company, all of which were vested and exercisable, at December 31, 2018:

Exercise Price	Number Outstanding	Expiration Date
\$ 35.00	492,571	December 2023
\$ 630.00	5,441	October 2021
\$ 690.00	474	October 2021
\$ 25,000.00	24	January 2019 to February 2019
	<u>498,510</u>	

During the year ended December 31, 2017, 23 warrants with an exercise price of \$630.00 were exercised. During the year ended December 31, 2018, 11 warrants with an exercise price of \$12,000.00 and 919 warrants with an exercise price of \$4,250.00 expired. During the year ended December 31, 2017, 332 and 446 warrants with exercise prices of \$25,000.00 and \$12,000.00, respectively, expired.

**TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 9 – COMMITMENTS

Research and Development Contracts

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$5.5 million at December 31, 2018 for future work to be performed.

Operating Leases

As of December 31, 2018, future minimum lease payments are as follows (in thousands):

Year Ending December 31,		
2019	\$	413
2020		212
2021		6
	<u>\$</u>	<u>631</u>

Rent expense charged to operations, which differs from rent paid due to 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, 2018 and 2017, rent expense was \$0.5 million and \$0.6 million, respectively, and as of December 31, 2018 and 2017, deferred rent payable was \$12,000 and \$32,000, respectively, including the current portion, which at December 31, 2018 and 2017, was \$12,000 and \$20,000, respectively, which is included in accrued expenses in 2018 and 2017.

Defined Contribution Plan

Effective April 1, 2014, the Company established a qualified defined contribution plan (the “401(k) Plan”) pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 100 percent of each participant’s pretax contributions of up to six percent of his or her eligible compensation, and the Company is also required to make a contribution equal to three percent of each participant’s salary, on an annual basis, subject to limitations under the Code. For the years ended December 31, 2018 and 2017, the Company charged operations \$0.2 million and \$0.1 million, respectively, for contributions under the 401(k) Plan.

NOTE 10 – INCOME TAXES

Components of the net loss consist of the following (in thousands):

	Year ended December 31,	
	2018	2017
Foreign	\$ (21,502)	\$ (20,490)
Domestic	(4,587)	(633)
Total	<u>\$ (26,089)</u>	<u>\$ (21,123)</u>

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In 2018, the foreign losses are comprised of \$20.9 million related to the Bermudan operations of Tonix International Holding. In 2017, the foreign losses were primarily comprised of \$18.9 million related to the Bermudan operations of Tonix International Holding, which included a licensing fee of \$2.0 million charged by Tonix subsidiary pursuant to a licensing agreement with Tonix subsidiary.

The operations and management of Tonix Holding Pharma Limited are located in Bermuda, and accordingly, are not subject to income taxes in Ireland, which is its country of incorporation. The operations of Tonix Holding Pharma Limited are not subject to income tax in Bermuda.

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

	Year Ended December 31,	
	2018	2017
Statutory federal income tax	(21.0)%	(34.0)%
State income tax, net of federal tax effect	0.0%	0.0%
Permanent difference	0.1%	0.1%
Change in valuation allowance	1.7%	(65.3)%
Foreign loss not subject to income tax	17.0%	32.1%
Return to provision true-ups	(0.1)%	(2.6)%
Tax rate change	0.0%	22.8%
Attribute reduction from control Change	3.9%	43.8%
Forfeiture of stock options	0.0%	4.8%
Other	(1.6)%	(1.7)%
Income Tax Provision	0.0%	0.0%

Deferred tax assets and related valuation allowance as of December 31, 2018 and 2017 were as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforward	\$ 763	\$ 724
Stock-based compensation	2,659	2,424
Other	226	176
Total deferred assets	3,648	3,324
Valuation allowance	(3,648)	(3,324)
Net deferred tax assets	\$ —	\$ —

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company has incurred research and development (“R&D”) expenses, a portion of which qualifies for tax credits. The Company conducted an R&D credit study to quantify the amount of credits and has claimed an R&D credit on its 2014-2017 tax returns. A portion of these R&D credit carryforwards are subject to annual limitations in their use in accordance with Internal Revenue Service Code (“IRC”) section 383. The R&D credit carryforwards at December 31, 2018 have been reduced to \$0 to reflect IRC section 383 ownership changes through December 31, 2018 and the resulting inability to utilize a portion of the R&D credit prior to its expiration.

At December 31, 2018, the Company had available unused federal net operating loss (“NOL”) carryforwards of approximately \$0.1 million of which do not expire. Additionally, the Company has \$4.7 million of Ireland NOL carryforwards that do not expire, \$0.1 million of Canada NOL which expires between 2036 and 2038 and \$0.1 million of Quebec NOL which expires between 2036 and 2038. A portion of the federal, New York State, and New York City NOL carryforwards is subject to annual limitations in their use in accordance with IRC section 382. The NOL carryforwards at December 31, 2018 have been reduced to reflect IRC section 382 ownership changes through December 31, 2018 and the resultant inability due to annual limitations, to utilize a portion of the NOL prior to its expiration.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2018. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth. As such, 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 full valuation allowance against its gross deferred tax assets. The increase/ (decrease) in the valuation allowance for the years ended December 31, 2018 and 2017 were \$0.3 million, and (\$13.9) million respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2018 there are no unrecognized tax benefits recorded. The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of December 31, 2018, the Company’s tax returns remain open and subject to examination by the tax authorities for the tax years 2015 and after.

The Tax Act also includes a provision to tax global intangible low-taxed income of foreign subsidiaries, a special tax deduction for foreign-derived intangible income (“GILTI”), and a base erosion anti-abuse tax measure that may tax certain payments between a U.S. corporation and its subsidiaries. These additional provisions of the Tax Act are effective for the Company beginning after December 31, 2017. The Company has elected to account for GILTI as a period cost in the year the tax is incurred.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 – SUBSEQUENT EVENTS

On February 14, 2019, the Company granted options to purchase an aggregate of 1,000 shares of the Company's common stock to a director with an exercise price of \$18.60, with a term of ten years, vesting on the date of the Corporation's 2019 annual meeting of shareholders.

On February 26, 2019, the Company granted options to purchase an aggregate of 6,205 shares of the Company's common stock to employees with an exercise price of \$18.90, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months. Additionally, the Company granted options to purchase 4,137 shares of the Company's common stock to employees with an exercise price of \$23.60, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months.

3,225,807 shares of Common Stock
5,000 shares of Series B Convertible Preferred Stock

PROSPECTUS

, 2020

A.G.P

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and Nasdaq listing fee.

Item	Amount to be paid
SEC registration fee	\$ 1,493
FINRA filing fee	*
Printing and engraving expenses	10,000
Legal fees and expenses	110,000
Accounting fees and expenses	40,000
Underwriter's expenses	140,000
Miscellaneous fees and expenses	*
Total	\$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers

Nevada Revised Statutes ("NRS") 78.7502 provides that a corporation may indemnify, pursuant to the provisions of that statute, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with the action, suit or proceeding if the person (i) is not liable pursuant to NRS 78.138 or (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the conduct was unlawful. NRS 78.7502 further provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit if the person (a) is not liable pursuant to NRS 78.138 or (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation. To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any such action, suit or proceeding, or in defense of any claim, issue or matter therein, the corporation shall indemnify him or her against expenses, including attorneys' fees, actually and reasonably incurred by him or her in connection with the defense. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, does not, of itself, create a presumption that the person is liable pursuant to NRS 78.138 or did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, or that, with respect to any criminal action or proceeding, he or she had reasonable cause to believe that the conduct was unlawful. Indemnification pursuant to NRS 78.7502 may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

NRS 78.7502 provides that any discretionary indemnification pursuant to the provisions of that statute (unless ordered by a court or advanced pursuant to NRS 78.751(2)), may be made by the corporation only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances. The determination must be made (i) by the stockholders; (ii) by the board of directors by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding; (iii) if a majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding so orders, by independent legal counsel in a written opinion; or (iv) if a quorum consisting of directors who were not parties to the action, suit or proceeding cannot be obtained, by independent legal counsel in a written opinion. NRS 78.751(2) provides that unless otherwise restricted by the corporation's articles of incorporation or bylaws, or an agreement made by the corporation, the corporation may pay the expenses of officers and directors incurred in defending a civil or criminal action, suit or proceeding as they are incurred and in advance of the final disposition of the action, suit or proceeding, upon receipt of an undertaking by or on behalf of the director or officer to repay the amount if it is ultimately determined by a court of competent jurisdiction that the director or officer is not entitled to be indemnified by the corporation.

Our articles of incorporation provide that our directors or officers shall not be personally liable to us or our stockholders for monetary damages for breach of such director's or officer's fiduciary duty, except for liability (i) for any breach of the duty of loyalty to our company or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, or (iii) for any transaction from which the officer or director derived any improper personal benefit. Our articles of incorporation and our amended and restated bylaws provide for the indemnification of any of our directors and officers who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was a director or officer of the our company, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, subject to certain express limitations and conditions. We believe that these provisions in our articles of incorporation bylaws, as amended, are necessary to attract and retain qualified persons as directors and officers.

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

Item 15. Recent Sales of Unregistered Securities

In the three years preceding the filing of this registration statement, the Registrant has issued the following securities that were not registered under the Securities Act:

On April 10, 2017, we issued 23 shares of common stock to one investor upon the exercise of warrants issued October 26, 2016 for proceeds of \$14,175.

On May 31, 2017, we issued 8 shares of common stock to a non-employee director in settlement for restricted stock units that vested in May 2017.

On June 1, 2017, we issued 8 shares of common stock to a non-employee director in settlement for restricted stock units that vested in May 2017.

On June 5, 2017, we issued 12 shares of common stock to a non-employee director in settlement for restricted stock units that vested in May 2017.

On June 6, 2017, we issued 8 shares of common stock to a non-employee director in settlement for restricted stock units that vested in May 2017.

On June 20, 2017, we issued 8 shares of common stock to a non-employee director in settlement for restricted stock units that vested in May 2017.

On July 11, 2017, we issued 8 shares of common stock to a non-employee director in settlement for restricted stock units that vested in May 2017.

On September 28, 2017, we issued 731 shares of common stock, at a price per share of \$411.00, to Lincoln Park Capital Fund, LLC pursuant to that certain Purchase Agreement dated September 28, 2017.

On October 18, 2018, we issued 3,500 commitment shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock pursuant to that certain Purchase Agreement dated October 18, 2018.

On August 20, 2019, we issued 35,529 commitment shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock pursuant to that certain Purchase Agreement dated August 20, 2019.

Unless otherwise noted, all of the transactions described in Item 15 were exempt from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act in that such sales did not involve a public offering, under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701, or under Rule 506 of Regulation D promulgated under the Securities Act.

Item 16. Exhibits and financial statement schedules

(a) Exhibits

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(b) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

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

(d) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit No.	Description
1.01†	Form of Underwriting Agreement
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	Third Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 3, 2016 and incorporated herein by reference.
3.04	Certificate of Change of Tonix Pharmaceuticals Holding Corp., dated March 13, 2017 and effective March 17, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 16, 2017 and incorporated herein by reference.
3.05	Certificate of Amendment to Articles of Incorporation, effective June 16, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 16, 2017 and incorporated herein by reference.
3.06	Specimen Common Stock Certificate, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 24, 2018 and incorporated herein by reference.
3.07	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.’s Articles of Incorporation, as amended, filed with the Secretary of State of the State of Nevada on May 3, 2019.
3.08	Certificate of Designation of Series A Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on November 15, 2019 and incorporated herein by reference.
3.09	Form of Certificate of Designation of Series B Convertible Preferred Stock.
4.01	Specimen Common Stock Certificate of the Registrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 24, 2018 and incorporated herein by reference.
4.02	Form of Warrant, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on November 14, 2019 and incorporated herein by reference.
4.03	Form of Warrant Agency Agreement, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on November 14, 2019 and incorporated herein by reference.
5.01	Opinion of Brownstein Hyatt Farber Schreck, LLP, filed herewith.
10.01	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.
10.02	Tonix Pharmaceuticals Holding Corp. 2012 Amended and Restated Incentive Stock Option Plan, incorporated herein by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A (File No. 000-54879), filed with the Commission on April 3, 2013.
10.03	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Seth Lederman, dated February 11, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 14, 2014 and incorporated herein by reference.*
10.04	Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on May 2, 2014.
10.05	Lease Amendment and Expansion Agreement, dated February 11, 2014, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on February 27, 2015 and incorporated herein by reference.
10.06	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Gregory Sullivan, dated June 3, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on June 3, 2014 and incorporated herein by reference.*
10.07	Tonix Pharmaceuticals Holding Corp. 2016 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 25, 2016.
10.08	Tonix Pharmaceuticals Holding Corp. 2017 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on May 2, 2017.
10.09	Tonix Pharmaceuticals Holding Corp. 2018 Equity Incentive Plan, incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on April 19, 2018.
10.10	Tonix Pharmaceuticals Holding Corp. 2018 Employee Stock Purchase Plan, incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on April 19, 2018
10.11	Sales Agreement, dated May 1, 2018, by and between Tonix Pharmaceuticals Holding Corp. and Cowen and Company, LLC, filed with the Commission on May 24, 2018 and incorporated herein by reference.
10.12	Registration Rights Agreement, dated October 18, 2018, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 24, 2018 and incorporated herein by reference.

- [10.13](#) Purchase Agreement, dated October 18, 2018, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 24, 2018 and incorporated herein by reference.
- [10.14](#) Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 18, 2019.
- [10.15](#) Tonix Pharmaceuticals Holding Corp. 2019 Employee Stock Purchase Plan, incorporated herein by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 18, 2019.
- [10.16](#) License Agreement, dated May 20, 2019, between Tonix Pharmaceuticals Holding Corp. and The Trustees of Columbia University in the City of New York, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on August 12, 2019 and incorporated herein by reference.
- [10.17](#) Registration Rights Agreement, dated August 20, 2019, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on August 23, 2019 and incorporated herein by reference.
- [10.18](#) Purchase Agreement, dated August 20, 2019, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on August 23, 2019 and incorporated herein by reference.
- [10.19](#) Asset Purchase Agreement, dated August 19, 2019, between Tonix Pharmaceuticals Holding Corp. and TRImaran Pharma, Inc., filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 8, 2019 and incorporated herein by reference.
- [10.20](#) First Amended and Restated Exclusive License Agreement, dated August 19, 2019, between Tonix Pharmaceuticals Holding Corp. and Wayne State University, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 8, 2019 and incorporated herein by reference.
- [10.21](#) Exclusive License Agreement, dated September 16, 2019, between Tonix Pharmaceuticals Holding Corp. and The Trustees of Columbia University in the City of New York, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 8, 2019 and incorporated herein by reference.
- [10.22](#) Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on December 13, 2019.
- [10.23](#) Tonix Pharmaceuticals Holding Corp. 2020 Employee Stock Purchase Plan, incorporated herein by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on December 13, 2019.
- [23.01](#) Consent of Independent Registered Public Accounting Firm, filed herewith.
- [23.02](#) Consent of Brownstein Hyatt Farber Schreck, LLP (included in Exhibit 5.01).
- † To be filed by amendment.
- * Indicates a management contract or compensatory plan or arrangement.

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on January 21, 2020.

TONIX PHARMACEUTICALS HOLDING CORP.

By: /s/ Seth Lederman
Seth Lederman
President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that the undersigned officers and directors of Tonix Pharmaceuticals Holding Corp., a Nevada corporation, do hereby constitute and appoint each of Seth Lederman and Bradley Saenger as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments, exhibits thereto and other documents in connection therewith) to this Registration Statement and any subsequent registration statement filed by the registrant pursuant to Rule 462(b) of the Securities Act of 1933, as amended, which relates to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Seth Lederman</u> Seth Lederman	President, Chief Executive Officer (Principal Executive Officer) and Director	January 21, 2020
<u>/s/ Bradley Saenger</u> Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	January 21, 2020
<u>/s/ Margaret Smith Bell</u> Margaret Smith Bell	Director	January 21, 2020
<u>/s/ Daniel Goodman</u> Daniel Goodman	Director	January 21, 2020
<u>/s/ David Grange</u> David Grange	Director	January 21, 2020
<u>/s/ Adeoye Olukotun</u> Adeoye Olukotun	Director	January 21, 2020
<u>/s/ John Rhodes</u> John Rhodes	Director	January 21, 2020
<u>/s/ James Treco</u> James Treco	Director	January 21, 2020

TONIX PHARMACEUTICALS HOLDING CORP.
CERTIFICATE OF DESIGNATION
OF
SERIES B CONVERTIBLE PREFERRED STOCK
PURSUANT TO NEVADA REVISED STATUTES 78.1955

The undersigned, Seth Lederman, does hereby certify that:

1. Such individual is an officer of Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Corporation").
2. The Corporation is authorized to issue 5,000,000 shares of preferred stock, none of which have been heretofore designated pursuant to Nevada Revised Statutes ("NRS") 78.1955.
3. The following resolutions were duly adopted by the board of directors of the Corporation (the "Board of Directors"):

WHEREAS, the Articles of Incorporation of the Corporation provide for a class of its authorized capital stock known as preferred stock, consisting of 5,000,000 shares, \$0.001 par value per share, issuable from time to time in one or more series;

WHEREAS, the Board of Directors is authorized to provide for the issuance of the shares of preferred stock in series and to establish, from time to time, the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and any qualifications, limitations or restrictions thereon; and

WHEREAS, it is the desire of the Board of Directors, pursuant to such authority, to fix the rights, preferences, restrictions and other matters relating to a series of the preferred stock, which shall consist of [] shares of the Corporation's authorized preferred stock;

NOW, THEREFORE, BE IT RESOLVED, that the Board of Directors does hereby provide for the issuance of a series of preferred stock to be designated as "Series B Convertible Preferred Stock" and does hereby fix and determine the rights, preferences, restrictions and other matters relating to such series of preferred stock as follows:

TERMS OF SERIES B CONVERTIBLE PREFERRED STOCK

Section 1 **Definitions.** For the purposes hereof, the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act.

"Alternate Consideration" shall have the meaning set forth in Section 7(d).

"Beneficial Ownership Limitation" shall have the meaning set forth in Section 6(d).

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Buy-In" shall have the meaning set forth in Section 6(c)(iv).

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the Corporation's common stock, par value \$0.001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Corporation or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Conversion Amount" means the sum of the Stated Value at issue.

"Conversion Date" shall have the meaning set forth in Section 6(a).

"Conversion Price" shall have the meaning set forth in Section 6(b).

"Conversion Shares" means, collectively, the shares of Common Stock issuable upon conversion of the shares of Preferred Stock in accordance with the terms hereof.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Fundamental Transaction" shall have the meaning set forth in Section 7(d).

"GAAP" means United States generally accepted accounting principles.

“Holder” shall have the meaning set forth in Section 2.

“Liquidation” shall have the meaning set forth in Section 5.

“New York Courts” shall have the meaning set forth in Section 8(d).

“Notice of Conversion” shall have the meaning set forth in Section 6(a).

“Original Issue Date” means the date of the first issuance of any shares of the Preferred Stock regardless of the number of transfers of any particular shares of Preferred Stock and regardless of the number of certificates which may be issued to evidence such Preferred Stock.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Preferred Stock” shall have the meaning set forth in Section 2.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Share Delivery Date” shall have the meaning set forth in Section 6(c).

“Stated Value” shall have the meaning set forth in Section 2.

“Subsidiary” means any subsidiary of the Corporation and shall, where applicable, also include any direct or indirect subsidiary of the Corporation formed or acquired after the date hereof.

“Successor Entity” shall have the meaning set forth in Section 7(d).

“Trading Day” means a day on which the principal Trading Market is open for business.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the NYSE American or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means vStock Transfer, LLC, the current transfer agent of the Corporation, with a mailing address of 18 Lafayette Place, Woodmere, NY 11598 and an email address of ariel@vstocktransfer.com and any successor transfer agent of the Corporation.

Section 2 Designation, Amount and Par Value. The series of preferred stock is hereby designated as the Series B Convertible Preferred Stock (the “Preferred Stock”) and the number of shares so designated shall be [] (which shall not be subject to increase without the written consent of a majority of the holders of the Preferred Stock (each, a “Holder” and collectively, the “Holders”). Each share of Preferred Stock shall have a par value of \$0.001 per share and a stated value equal to \$1,000 (the “Stated Value”).

Section 3 Dividends. Except for share dividends or distributions for which adjustments are to be made pursuant to Section 7, Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of Preferred Stock equal (on an as-if-converted-to-Common-Stock basis, without regard to conversion limitations herein) to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends shall be payable or paid on shares of Preferred Stock. The Corporation shall not pay any dividends on the Common Stock unless the Corporation simultaneously complies with this provision.

Section 4 Voting Rights. Except as otherwise provided herein or as otherwise required by law, the Preferred Stock shall have no voting rights and for the avoidance of doubt, to the extent the NRS would nonetheless grant the holders of the Preferred Stock any right to vote or act (including, without limitation, pursuant to NRS 78.2055, 78.207 or 78.390), such right to vote or act is hereby specifically denied, provided, however, that notwithstanding the foregoing, as long as any shares of Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the Holders of a majority of the then outstanding shares of the Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Preferred Stock or alter or amend this Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the Holders, (c) increase the number of authorized shares of Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Section 5 Liquidation. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a “Liquidation”), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation the same amount that a holder of Common Stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations hereunder) to Common Stock which amounts shall be paid pari passu with all holders of Common Stock. The Corporation shall mail written notice of any such Liquidation, not less than 30 days prior to the payment date stated therein, to each Holder.

(a) Conversions at Option of Holder. Each share of Preferred Stock shall be convertible, at any time and from time to time from and after the Original Issue Date at the option of the Holder thereof, into that number of shares of Common Stock (subject to the limitations set forth in Section 6(d)) determined by dividing the Stated Value of such share of Preferred Stock by the Conversion Price. Holders shall effect conversions by providing the Corporation with the form of conversion notice attached hereto as Annex A (a "Notice of Conversion"). Each Notice of Conversion shall specify the number of shares of Preferred Stock to be converted, the number of shares of Preferred Stock owned prior to the conversion at issue, the number of shares of Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable Holder delivers by facsimile such Notice of Conversion to the Corporation (such date, the "Conversion Date"). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion to the Corporation is deemed delivered hereunder. No ink-original Notice of Conversion shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Conversion form be required. The calculations and entries set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error. To effect conversions of shares of Preferred Stock, a Holder shall not be required to surrender the certificate(s) representing the shares of Preferred Stock to the Corporation unless all of the shares of Preferred Stock represented thereby are so converted, in which case such Holder shall deliver the certificate representing such shares of Preferred Stock promptly following the Conversion Date at issue. Shares of Preferred Stock converted into Common Stock or redeemed in accordance with the terms hereof shall be deemed canceled and shall not be reissued.

(b) Conversion Price. The conversion price for the Preferred Stock shall equal \$[], subject to adjustment herein (the "Conversion Price").

(c) Mechanics of Conversion.

i. Delivery of Conversion Shares Upon Conversion. Not later than the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined below) after each Conversion Date (the "Share Delivery Date"), the Corporation shall deliver, or cause to be delivered, to the converting Holder (A) the number of Conversion Shares being acquired upon the conversion of the Preferred Stock, which Conversion Shares shall be free of restrictive legends and trading restrictions and (B) a bank check in the amount of accrued and unpaid dividends, if any. The Corporation shall use its best efforts to deliver the Conversion Shares required to be delivered by the Corporation under this Section 6 electronically through the Depository Trust Company ("DTC") or another established clearing corporation performing similar functions. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Corporation's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Conversion. Notwithstanding the foregoing, with respect to any Notice(s) of Conversion delivered by 12:00 pm (NY time) on the Original Issue Date, the Corporation agrees to deliver the Conversion Shares subject to such notice(s) by 4:00 pm (NY time) on the Original Issue Date.

ii. Failure to Deliver Conversion Shares. If, in the case of any Notice of Conversion, such Conversion Shares are not delivered to or as directed by the applicable Holder by the Share Delivery Date, the Holder shall be entitled to elect by written notice to the Corporation at any time on or before its receipt of such Conversion Shares, to rescind such Conversion, in which event the Corporation shall promptly return to the Holder any original Preferred Stock certificate delivered to the Corporation and the Holder shall promptly return to the Corporation the Conversion Shares issued to such Holder pursuant to the rescinded Notice of Conversion.

iii. Obligation Absolute: Partial Liquidated Damages. The Corporation's obligation to issue and deliver the Conversion Shares upon conversion of Preferred Stock in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by a Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by such Holder or any other Person of any obligation to the Corporation or any violation or alleged violation of law by such Holder or any other person, and irrespective of any other circumstance which might otherwise limit such obligation of the Corporation to such Holder in connection with the issuance of such Conversion Shares; provided, however, that such delivery shall not operate as a waiver by the Corporation of any such action that the Corporation may have against such Holder. In the event a Holder shall elect to convert any or all of the Stated Value of its Preferred Stock, the Corporation may not refuse conversion based on any claim that such Holder or any one associated or affiliated with such Holder has been engaged in any violation of law, agreement or for any other reason, unless an injunction from a court, on notice to Holder, restraining and/or enjoining conversion of all or part of the Preferred Stock of such Holder shall have been sought and obtained, and the Corporation posts a surety bond for the benefit of such Holder in the amount of 150% of the Stated Value of Preferred Stock which is subject to the injunction, which bond shall remain in effect until the completion of arbitration/litigation of the underlying dispute and the proceeds of which shall be payable to such Holder to the extent it obtains judgment. In the absence of such injunction, the Corporation shall issue Conversion Shares and, if applicable, cash, upon a properly noticed conversion. If the Corporation fails to deliver to a Holder such Conversion Shares pursuant to Section 6(c)(i) by the Share Delivery Date applicable to such conversion, the Corporation shall pay to such Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Stated Value of Preferred Stock being converted, \$10 per Trading Day for each Trading Day after the Share Delivery Date until such Conversion Shares are delivered or Holder rescinds such conversion. Nothing herein shall limit a Holder's right to pursue actual damages for the Corporation's failure to deliver Conversion Shares within the period specified herein and such Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief. The exercise of any such rights shall not prohibit a Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

iv. Compensation for Buy-In on Failure to Timely Deliver Conversion Shares Upon Conversion. In addition to any other rights available to the Holder, if the Corporation fails for any reason to deliver to a Holder the applicable Conversion Shares by the Share Delivery Date pursuant to Section 6(c)(i), and if after such Share Delivery Date such Holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by such Holder of the Conversion Shares which such Holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "Buy-In"), then the Corporation shall (A) pay in cash to such Holder (in addition to any other remedies available to or elected by such Holder) the amount, if any, by which (x) such Holder's total purchase price (including any brokerage commissions) for the Common Stock so purchased exceeds (y) the product of (1) the aggregate number of shares of Common Stock that such Holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such Holder, either reissue (if surrendered) the shares of Preferred Stock equal to the number of shares of Preferred Stock submitted for conversion (in which case, such conversion shall be deemed rescinded) or deliver to such Holder the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(c)(i). For example, if a Holder purchases shares of Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted conversion of shares of Preferred Stock with respect to which the actual sale price of the Conversion Shares (including any brokerage commissions) giving rise to such purchase obligation was a total of \$10,000 under clause (A) of the immediately preceding sentence, the Corporation shall be required to pay such Holder \$1,000. The Holder shall provide the Corporation written notice indicating the amounts payable to such Holder in respect of the Buy-In and, upon request of the Corporation, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Corporation's failure to timely deliver Conversion Shares upon conversion of the shares of Preferred Stock as required pursuant to the terms hereof.

v. Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Preferred Stock as herein provided, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holder (and the other holders of the Preferred Stock), not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments and restrictions of Section 7) upon the conversion of the then outstanding shares of Preferred Stock. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid and nonassessable.

vi. Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of the Preferred Stock. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such conversion, the Corporation shall at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share.

vii. Transfer Taxes and Expenses. The issuance of Conversion Shares on conversion of this Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such Conversion Shares, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such Conversion Shares upon conversion in a name other than that of the Holders of such shares of Preferred Stock and the Corporation shall not be required to issue or deliver such Conversion Shares unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid. The Corporation shall pay all Transfer Agent fees required for same-day processing of any Notice of Conversion and all fees to the DTC (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Conversion Shares.

(d) Beneficial Ownership Limitation. Notwithstanding anything to the contrary herein, the Corporation shall not effect any conversion of the Preferred Stock, and a Holder shall not have the right to convert any portion of the Preferred Stock, to the extent that, after giving effect to the conversion set forth on the applicable Notice of Conversion, such Holder (together with such Holder's Affiliates, and any Persons acting as a group together with such Holder or any of such Holder's Affiliates (such Persons, "Attribution Parties")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (i) conversion of the remaining, unconverted Stated Value of Preferred Stock beneficially owned by such Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation subject to a limitation on conversion or exercise analogous to the limitation contained herein (including, without limitation, the Preferred Stock) beneficially owned by such Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 6(d), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. To the extent that the limitation contained in this Section 6(d) applies, the determination of whether the Preferred Stock is convertible (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and of how many shares of Preferred Stock are convertible shall be in the sole discretion of such Holder, and the submission of a Notice of Conversion shall be deemed to be such Holder's determination of whether the shares of Preferred Stock may be converted (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and how many shares of the Preferred Stock are convertible, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder will be deemed to represent to the Corporation each time it delivers a Notice of Conversion that such conversion will not violate the restrictions set forth in this paragraph and the Corporation shall have no obligation to verify or confirm the accuracy of such representation. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 6(d), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (i) the Corporation's most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by the Corporation or (iii) a more recent written notice by the Corporation or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request (which may be via email) of a Holder, the Corporation shall within two Trading Days confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Corporation, including the Preferred Stock, by such Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (except as otherwise specified or provided for to the Corporation prior to the issuance of any Preferred Stock or in the Beneficial Ownership Limitation Adjustment Notice (as defined below)) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Preferred Stock held by the applicable Holder. A Holder may increase or decrease the Beneficial Ownership Limitation applicable to its Preferred Stock by providing written notice to the Corporation (which notice may not be waived) in the form attached hereto as Annex B (the "Beneficial Ownership Limitation Adjustment Notice"); provided that the Beneficial Ownership Limitation in no event may exceed 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of this Preferred Stock held by the Holder and the provisions of this Section 6(d) shall continue to apply; and provided further that a Holder who fails to specify a Beneficial Ownership Limitation in a Beneficial Ownership Limitation Adjustment Notice or who specifies a Beneficial Ownership Limitation in a Beneficial Ownership Limitation Adjustment Notice in excess of 9.99% shall be deemed to have specified a Beneficial Ownership Limitation of 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Preferred Stock held by the applicable Holder. Any such increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such Beneficial Ownership Limitation Adjustment Notice is delivered to the Corporation and shall only apply to such Holder and no other Holder. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 6(d) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of Preferred Stock.

(a) Share Dividends and Stock Splits. If the Corporation, at any time while this Preferred Stock is outstanding: (i) pays a share dividend or otherwise makes a distribution or distributions payable in shares of Common Stock on shares of Common Stock or any other Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of, or payment of a dividend on, this Preferred Stock), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Corporation, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 7(a) above, if at any time the Corporation grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of such Holder's Preferred Stock (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(c) Pro Rata Distributions. During such time as this Preferred Stock is outstanding, if the Corporation declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the first issuance of Preferred Stock, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of this Preferred Stock (without regard to any limitations on conversion hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(d) Fundamental Transaction. If, at any time while any shares of Preferred Stock are outstanding, (i) the Corporation, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Corporation with or into another Person, (ii) the Corporation, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Corporation, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Corporation, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent conversion of the Preferred Stock by the Holder thereof, the Holder shall receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 6(d) on the conversion of the Preferred Stock), the number of shares of common stock (as applicable) of the successor or acquiring corporation or the number of shares of Common Stock of the Corporation (as applicable), if it is the surviving corporation, and all additional securities (equity or debt), cash, property or other consideration (all such additional consideration, the "Alternate Consideration"), receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which such Holder's Preferred Stock is convertible immediately prior to such Fundamental Transaction (without regard to any limitation in Section 6(d) on the conversion of the Preferred Stock). For purposes of any such conversion, the determination of the Conversion Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Corporation shall apportion the Conversion Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are entitled to elect the proportion of securities, cash, property or other consideration to be received by holders of Common Stock in a Fundamental Transaction, then each Holder of Preferred Stock shall be given the same choice as to the proportion of securities, cash, property or other consideration such Holder is entitled to receive upon any conversion of such Holder's shares of Preferred Stock following such Fundamental Transaction. To the extent necessary to effectuate the foregoing provisions, any successor to the Corporation or surviving entity in such Fundamental Transaction shall file a new Certificate of Designation in respect of a new series of preferred stock of the successor or acquiring corporation, or the Corporation, if it is the surviving corporation, setting forth the same rights, preferences, privileges and other terms contained in this Certificate of Designation in respect of the Preferred Stock, including, without limitation, the provisions contained in this Section 7(d) and evidencing, among other things, the Holders' right to convert such new preferred stock into Alternate Consideration. The Corporation shall cause any successor entity in a Fundamental Transaction in which the Corporation is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Corporation under this Certificate of Designation in accordance with the provisions of this Section 7(d) prior to such Fundamental Transaction and shall deliver to such Holder in exchange for such Holder's Preferred Stock a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to the Preferred Stock which is convertible for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon conversion of the Preferred Stock (without regard to any limitations on the conversion of the Preferred Stock) prior to such Fundamental Transaction, and with a conversion price which applies the conversion price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such conversion price being for the purpose of protecting the economic value of the Preferred Stock immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder(s) thereof. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Certificate of Designation referring to the "Corporation" shall refer instead to the Successor Entity), and may exercise every right and power of the Corporation and shall assume all of the obligations of the Corporation under this Certificate of Designation with the same effect as if such Successor Entity had been named as the Corporation herein. For the avoidance of doubt, if, at any time while any shares of Preferred Stock are outstanding, a Fundamental Transaction occurs, pursuant to the terms of this Section 7(d), a Holder of Preferred Stock shall not be entitled to receive any consideration in such Fundamental Transaction in respect of such Holder's shares of Preferred Stock, except as provided for in this Certificate of Designation (or any new Certificate of Designation in respect of a new series of preferred stock issued to the Holders of Preferred Stock as contemplated hereby).

(e) Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

(f) Notice to the Holders.

i . Adjustment to Conversion Price. Whenever the Conversion Price is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder a notice setting forth the Conversion Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Conversion by Holder. If (A) the Corporation shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Corporation shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Corporation shall authorize the granting to all holders of the Common Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Corporation shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Corporation is a party, any sale or transfer of all or substantially all of the assets of the Corporation, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property or (E) the Corporation shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Corporation, then, in each case, the Corporation shall cause to be filed at each office or agency maintained for the purpose of conversion of this Preferred Stock, and shall cause to be delivered to each Holder at its last address as it shall appear upon the stock books of the Corporation, at least ten (10) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange, provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Corporation or any of the Subsidiaries, the Corporation shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to convert the Conversion Amount of this Preferred Stock (or any part hereof) during the 10-day period commencing on the date of such notice through the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 8 Miscellaneous.

(a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile, email address or sent by a nationally recognized overnight courier service, addressed to the Corporation at:

Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 1608
New York, NY 10022
Attention: Bradley Saenger
Facsimile: (212) 923-5700
Email address: bradley.saenger@tonixpharma.com

with a copy (which shall not constitute notice) to:

Lowenstein Sandler LLP
1251 Avenue of the Americas
New York, New York 10020
Attention: Michael Lerner
Email address: mlermer@lowenstein.com
Facsimile: (973) 597-6395

or such other facsimile number or address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section 8. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by facsimile, by email attachment or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, email address or address of such Holder appearing on the books of the Corporation, or if no such facsimile number, email address or address appears on the books of the Corporation, at the principal place of business of such Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile or email attachment at the facsimile number or email address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or email attachment at the facsimile number or email address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the Person to whom such notice is required to be given. Notwithstanding any other provision of this Certificate of Designation, where this Certificate of Designation provides for notice of any event to a Holder, if the Preferred Stock is held in global form by DTC (or any successor depository), such notice may be delivered via DTC (or such successor depository) pursuant to the procedures of DTC (or such successor depository).

(b) Absolute Obligation. Except as expressly provided herein, no provision of this Certificate of Designation shall alter or impair the obligation of the Corporation, which is absolute and unconditional, to pay liquidated damages and accrued dividends, as applicable, on the shares of Preferred Stock at the time, place, and rate, and in the coin or currency, herein prescribed.

(c) Lost or Mutilated Preferred Stock Certificate. If a Holder's Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership hereof reasonably satisfactory to the Corporation.

(d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Certificate of Designation shall be governed by and construed and enforced in accordance with the internal laws of the State of Nevada, without regard to the principles of conflict of laws thereof. Each of the Corporation and each Holder agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by this Certificate of Designation (whether brought against the Corporation, a Holder or any of their respective Affiliates, directors, officers, stockholders, employees or agents) shall be commenced in the state and federal courts sitting in the City of New York, Borough of Manhattan (the "New York Courts"). Each of the Corporation and each Holder hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such New York Courts, or such New York Courts are improper or inconvenient venue for such proceeding. Each of the Corporation and each Holder hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such Person at the address in effect for notices to it under this Certificate of Designation and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. Each of the Corporation and each Holder hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Certificate of Designation or the transactions contemplated hereby. If the Corporation or any Holder shall commence an action or proceeding to enforce any provisions of this Certificate of Designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

(e) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that Person (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

(f) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

(g) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

(h) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

(i) Status of Converted or Redeemed Preferred Stock. If any shares of Preferred Stock shall be converted, redeemed or reacquired by the Corporation, such shares shall resume the status of authorized but undesignated and unissued shares of preferred stock and shall no longer be designated as Series B Convertible Preferred Stock.

RESOLVED, FURTHER, that the executive chairman, the president or any vice-president, and the secretary or any assistant secretary, of the Corporation be and they hereby are authorized and directed to prepare and file this Certificate of Designation of Preferences, Rights and Limitations in accordance with the foregoing resolution and the provisions of Nevada law.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Designations of Series B Convertible Preferred Stock as of this ____ day of _____.

TONIX PHARMACEUTICALS HOLDING CORP.

By: _____
Name: Seth Lederman
Title: Chief Executive Officer

ANNEX A

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER TO CONVERT SHARES OF PREFERRED STOCK)

The undersigned hereby elects to convert the number of shares of Series B Convertible Preferred Stock indicated below into shares of common stock, par value \$0.001 per share (the "Common Stock"), of Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Corporation"), according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a Person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto. No fee will be charged to the Holders for any conversion, except for any such transfer taxes.

Conversion calculations:

Date to Effect Conversion: _____

Number of shares of Preferred Stock owned prior to Conversion: _____

Number of shares of Preferred Stock to be Converted: _____

Stated Value of shares of Preferred Stock to be Converted: _____

Number of shares of Common Stock to be Issued: _____

Applicable Conversion Price: _____

Number of shares of Preferred Stock subsequent to Conversion: _____

Address for Delivery:

or

DWAC Instructions:

Broker no: _____

Account no: _____

[HOLDER]

By: _____
Name:
Title:

ANNEX B

BENEFICIAL OWNERSHIP LIMITATION ADJUSTMENT NOTICE

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER TO INCREASE OR DECREASE THE BENEFICIAL OWNERSHIP LIMITATION APPLICABLE TO SUCH HOLDER'S PREFERRED STOCK)

By checking the box below, the undersigned hereby irrevocably elects to waive the 4.99% Beneficial Ownership Limitation, as designated by the undersigned's election below, applicable to the undersigned's beneficial ownership of Series B Convertible Preferred Stock of Tonix Pharmaceuticals Holding Corp., a Nevada corporation, as such Beneficial Ownership Limitation is defined under Section 6(d) of the Certificate of Designation.

- The undersigned hereby elects to waive the Beneficial Ownership Limitation applicable to the undersigned's beneficial ownership of Series B Convertible Preferred Stock.

The Beneficial Ownership Limitation applicable to the undersigned's Series B Convertible Preferred Stock (effective as of the date that is 61 days following the date of this Beneficial Ownership Limitation Adjustment Notice) shall be:

_____ % (may not be more than 9.99%)

* Notice: Failure to specify a Beneficial Ownership Limitation percentage above will result in the undersigned's being deemed to have specified a Beneficial Ownership Limitation of 9.99%. Specifying a Beneficial Ownership Limitation percentage in excess of 9.99% will result in the undersigned's being deemed to have specified a Beneficial Ownership Limitation of 9.99%.

The undersigned understands and agrees that, as a result of this waiver, the Beneficial Ownership Limitation applicable to the Series B Convertible Preferred Stock beneficially owned by the undersigned shall be (i) the percentage specified by the undersigned above or (ii) 9.99% and, in each case, the provisions of Section 6(d) of the Certificate of Designation shall continue to apply.

The undersigned understands and agrees that by waiving the Beneficial Ownership Limitation, the undersigned may become subject to the reporting requirements and liability provisions of Sections 13 and 16 of the Securities Exchange Act of 1934.

[HOLDER]

By: _____
Name:
Title:



January 21, 2020

Tonix Pharmaceuticals Holding Corp.
509 Madison Avenue, Suite 1608
New York, New York 10022

Ladies and Gentlemen:

We have acted as local Nevada counsel to Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Company"), in connection with the proposed issuance and sale by the Company of the following securities (collectively, the "Securities"), having an aggregate offering price of up to \$11,500,001 (which includes the aggregate offering price of any Securities issued and sold pursuant to an overallotment option granted to the underwriter), as described in the Company's Registration Statement on Form S-1 (the "Registration Statement") and the Prospectus contained therein (the "Prospectus"), as filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Act"): (i) shares (collectively, the "Common Shares") of the Company's common stock, par value \$0.001 per share (the "Common Stock"), and (ii) shares (collectively, the "Preferred Shares") of the Company's Series B Convertible Preferred Stock, par value \$0.001 per share (the "Series B Preferred Stock"), to be issued pursuant to the then-effective Certificate of Designation (as defined below), which Preferred Shares are convertible into shares of Common Stock (collectively, the "Conversion Shares") pursuant to the terms thereof. This opinion letter is being delivered at your request pursuant to the requirements of Item 601(b)(5) of Regulation S-K under the Act.

In our capacity as such counsel, we are familiar with the proceedings taken and proposed to be taken by the Company in connection with the authorization, issuance and sale of the Securities as contemplated by, and as described in, the Registration Statement and the Prospectus. For purposes of this opinion letter, and except to the extent set forth in the opinion below, we have assumed that all such proceedings have been or will be timely completed in the manner presently proposed in the Registration Statement and the Prospectus.

For purposes of issuing the opinion hereinafter expressed, we have made such legal and factual examinations and inquiries, including an examination of originals or copies certified or otherwise identified to our satisfaction as being true copies of (i) the Registration Statement, including the Prospectus, (ii) the Company's articles of incorporation and bylaws, each as amended to date, (iii) the form of the certificate of designation relating to the Series B Preferred Stock as filed as an exhibit to the Registration Statement (the "Certificate of Designation"), and (iv) such other agreements, instruments, corporate records and other documents as we have deemed necessary or appropriate. We have also obtained from officers, representatives and agents of the Company and from public officials, and have relied upon, such certificates, representations, assurances and public filings as we have deemed necessary and appropriate for the purpose of issuing this opinion letter.

100 North City Parkway, Suite 1600
Las Vegas, NV 89106-4614
main 702.382.2101

bhfs.com

Brownstein Hyatt Farber Schreck, LLP

Without limiting the generality of the foregoing, we have, with your permission, assumed without independent verification that (i) each natural person executing any of the documents we reviewed has sufficient legal capacity to do so; (ii) all documents submitted to us as originals are authentic, the signatures on all documents we reviewed are genuine, and all documents submitted to us as certified, conformed, photostatic, electronic or facsimile copies conform to the original document; (iii) all corporate records made available to us by the Company, and all public records we have reviewed, are accurate and complete; (iv) prior to any issuance of any Preferred Shares or Conversion Shares, the Certificate of Designation will have been duly authorized and approved by the Company's board of directors or a duly authorized and constituted committee thereof, signed by an authorized officer of the Company and properly filed with the Nevada Secretary of State, and will be effective (collectively, "Corporate Proceedings"); (v) after any issuance of Common Shares or Conversion Shares, the total number of issued and outstanding shares of Common Stock, together with the total number of shares of Common Stock then reserved for issuance or obligated to be issued by the Company pursuant to any agreement or arrangement or otherwise, will not exceed the total number of shares of Common Stock then authorized under the Company's articles of incorporation; and (vi) after any issuance of Preferred Shares, the total number of issued and outstanding shares of Series B Preferred Stock, together with the total number of shares of such series then reserved for issuance or obligated to be issued by the Company pursuant to any agreement or arrangement or otherwise, will not exceed the total number of shares of Series B Preferred Stock then designated under the Certificate of Designation.

We are qualified to practice law in the State of Nevada. The opinions set forth herein are expressly limited to and based exclusively on the general corporate laws of the State of Nevada, and we do not purport to be experts on, or to express any opinion with respect to the applicability or effect of, the laws of any other jurisdiction. We express no opinion concerning, and we assume no responsibility as to laws or judicial decisions related to any federal laws, rules or regulations, including, without limitation, any federal securities laws, rules or regulations, or any state securities or "blue sky" laws, rules or regulations.

Based on the foregoing, and in reliance thereon, and having regard to legal considerations and other information that we deem relevant, we are of the opinion that:

1. The Common Shares have been duly authorized by the Company.
 2. If and when any Common Shares are issued in accordance with the proceedings described in, and in the manner contemplated by, the Registration Statement and the Prospectus, such Common Shares will be validly issued, fully paid and nonassessable.
 3. If and when all Corporate Proceedings have been undertaken and completed, the Preferred Shares and the Conversion Shares will be duly authorized.
 4. If and when all Corporate Proceedings have been undertaken and completed and any Preferred Shares are issued in accordance with the proceedings described in, and in the manner contemplated by, the Registration Statement and the Prospectus, such Preferred Shares will be validly issued, fully paid and nonassessable.
-

5. If and when all Corporate Proceedings have been undertaken and completed and any Conversion Shares are issued in accordance with the terms of, and in the manner contemplated by, the Certificate of Designation, including the due and proper conversion of such Preferred Share(s) in accordance with the Certificate of Designation, and in accordance with the proceedings described in, and in the manner contemplated by, the Registration Statement and the Prospectus, such Conversion Shares will be validly issued, fully paid and nonassessable.

The opinions expressed herein are based upon the applicable laws of the State of Nevada and the facts in existence on the date of this opinion letter. In delivering this opinion letter to you, we disclaim any obligation to update or supplement the opinions set forth herein or to apprise you of any changes in any laws or facts after such time as the Registration Statement is declared effective. No opinion is offered or implied as to any matter, and no inference may be drawn, beyond the strict scope of the specific issues expressly addressed by the opinions set forth herein.

We hereby consent to the filing of this opinion letter as an exhibit to the Registration Statement and to the reference to our firm in the Prospectus under the heading "Legal Matters". In giving this consent, we do not admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,
/s/ Brownstein Hyatt Farber Schreck, LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement of Tonix Pharmaceuticals Holding Corp. (the “Company”) on Form S-1 to be filed on or about January 21, 2020 of our report dated March 18, 2019, except for the second paragraph of Note 5, as to which date is January 21, 2020, on our audits of the consolidated financial statements as of December 31, 2018 and 2017 and for each of the years then ended. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company’s ability to continue as a going concern. We also consent to the reference to our firm under the caption “Experts” in this Registration Statement.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
January 21, 2020
