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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2019

Commission File Number 001-36019

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**26-1434750**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
509 Madison Avenue, Suite 1608 **New York, New York**	**10022**
(Address of principal executive office)	(Zip Code)

(212) 980-9155
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	TNXP	The NASDAQ Stock Market LLC

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒
(Do not check if a smaller reporting company)	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 13(a) of the Exchange Act. ☐

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2019, based on the closing sales price of the common stock as quoted on The NASDAQ Global Market was $7,272,618. For purposes of this computation, all officers, directors, and 5 percent beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed an admission that such directors, officers, or 5 percent beneficial owners are, in fact, affiliates of the registrant.

As of March 23, 2020, there were49,353,134, shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

ITEM 1 - BUSINESS

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

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

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

Tonix Pharmaceuticals®, Tonmya®*, Protectic™, Angstro-Technology™ and other trademarks and intellectual property of ours appearing in this report are our property. This report contains additional trade names and trademarks of other companies. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for posttraumatic stress disorder, or PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

Business Overview

We are a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Our current portfolio includes biologics to prevent infectious diseases and small molecules and biologics to treat pain, psychiatric and addiction conditions. In 2020, we announced a program to develop a potential vaccine to protect against the novel coronavirus disease emerging in 2019, or COVID-19. Our most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. FM is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. PTSD is a psychiatric condition characterized by the re-experiencing of trauma through intrusive and vivid recollections, nightmares and flashbacks. Both FM and PTSD are associated with chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. In addition, our product pipeline includes other clinical stage and pre-clinical stage programs.

We are led by a management team with significant industry experience in drug development. We complement our management team with a network of scientific, clinical, and regulatory advisors that includes recognized experts in their respective fields.

On February 26, 2020, Tonix announced a strategic collaboration with the Southern Research Institute, or Southern Research, to support the development of TNX-1800 (live modified horsepox virus vaccine for percutaneous administration), a potential vaccine to protect against COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform, which we believe can be engineered to express relevant protein antigens from different infectious diseases to make a variety of vaccines. The collaboration with Southern Research will develop and test TNX-1800, which is designed to express the spike protein from the virus that causes COVID-19, which is called SARS-CoV-2. Our plan is to test whether vaccination with TNX-1800 will elicit an immune response to the SARS-CoV-2 spike protein and if so, whether such an immune response will protect against COVID-19. SARS-CoV-2 is reportedly highly contagious. There are currently no vaccines approved by the U.S. Food and Drug Administration, or FDA, to protect against COVID-19. Multiple companies and research institutions are developing potential COVID-19 vaccines. TNX-1800 is in the pre-clinical, pre-Investigational New Drug application, or pre-IND, stage of development and has not been approved for any indication.

TNX-801 (live synthesized horsepox virus vaccine for percutaneous administration) is a potential vaccine to protect against and treat smallpox and monkeypox. TNX-801 was synthesized by Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada in collaboration with us. TNX-801 has demonstrated protective vaccine activity in mice, using a model of lethal vaccinia virus infection. In addition, the tolerability of TNX-801 compared favorably with a vaccinia virus vaccine in mice. In January, 2020 at the American Society of Microbiology Biothreats conference, we reported the results of experiments on TNX-801 performed in collaboration with Southern Research, that showed TNX-801 vaccinated macaques were protected against monkeypox challenge. TNX-801 is in the pre-IND stage and is not approved for any indication.

Our most advanced product candidate, TNX-102 SL, is a proprietary sublingual tablet formulation of cyclobenzaprine, or CBP, designed for bedtime administration. TNX-102 SL is in development for FM, PTSD, agitation in Alzheimer's disease, or AAD, and alcohol use disorder, or 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 a potential bedtime treatment for the management of FM, and for the treatment of PTSD, AAD, and AUD. In FM, we are enrolling patients into the Phase 3 RELIEF trial (F304) and expect to report results from an interim analysis in the third quarter of 2020. In PTSD, we are completing the Phase 3 RECOVERY trial and expect to report topline results in the second quarter of 2020, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of topline results. Moreover, the RECOVERY study is unlikely to show an effect of TNX-102 SL, because at a pre-planned interim analysis in February of 2020, an Independent Data Monitoring Committee, or IDMC, reported that the a drug effect, if any, was below the pre-specified criteria for futility, based on the results of the first 50% of enrolled participants. Based on the IDMC's recommendation to stop the study, the RECOVERY study stopped enrolling new patients in February 2020. Patient who were already enrolled in RECOVERY are being followed to completion. The AAD program is Phase 2 ready with an active IND and FDA Fast Track designation. The AUD program is in the pre- IND stage, and we intend to submit an IND application in the first half of 2020, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of our IND submission. Upon receiving FDA clearance of an IND application, the AUD program is expected to be ready for a Phase 2 proof-of-concept study. TNX-102 SL is an investigational new drug and is not approved for any indication.

TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for major depressive disorder, or depression, as well as for PTSD and neurocognitive dysfunction associated with corticosteroid use. TNX-601 CR is a new, controlled release formulation of a novel salt of tianeptine. An immediate release form of tianeptine, with three times a day dosing, has been marketed outside of the U.S. for the treatment of depression for several decades. We reported the results of a pharmacokinetic study in the fourth quarter of 2019, performed outside of the U.S., that was the basis for selecting the TNX-601 CR formulation with controlled release characteristics suitable for once-daily dosing. We are planning to conduct the first efficacy study outside of the U.S. in the first half of 2021, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of this efficacy study. TNX-601 CR is expected to be U.S. IND-ready in 2021. TNX-601 CR is an investigational new drug in the pre-IND stage of development and is not approved for any indication.

TNX-1300 (double-mutant cocaine esterase) is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. TNX-1300 was licensed from Columbia University in 2019 after a Phase 2 study showed that it efficiently disintegrates cocaine in the blood of volunteers who had received intravenous, or *i.v*., cocaine. TNX-1300 is an investigational new biological drug and is not approved for any indication.

Finally, in addition to TNX-1800 and TNX-801, our preclinical pipeline includes TNX-1600, TNX-1500, TNX-701 and TNX-1200. TNX-1600 is an inhibitor of the reuptake of neurotransmitters serotonin, norepinephrine and dopamine (a triple reuptake inhibitor). TNX-1600 was licensed from Wayne State University in 2019 and is being developed as a daytime treatment for PTSD, depression and attention deficit hyperactivity disorder, or ADHD. TNX-1500 is monoclonal antibody or mAb, directed against CD40L, discovered in Tonix internal research and is being developed to prevent and treat organ transplant rejection and autoimmune conditions. TNX-1700 is a recombinant modified form of Trefoil Family Factor 2, or rTFF2, that was licensed from Columbia University in 2019, and is a biologic being developed to treat gastric and pancreatic cancers. TNX-701 is an undisclosed small molecule, which is being developed to prevent radiation effects which has the potential to be used as a medical countermeasure to improve biodefense. TNX-1200 (live synthesized vaccinia virus vaccine for percutaneous administration) was synthesized by Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada and is another potential vaccine to protect against and treat smallpox and monkeypox. In addition, new vaccines based on our proprietary horsepox vaccine vector platform are also anticipated.

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 common stock is listed on The NASDAQ Global Market under the symbol "TNXP". 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.

TNX-1800 – Potential COVID-19 Vaccine

TNX-1800 is a potential vaccine for the novel coronavirus disease, COVID-19, based on a modified version of live horsepox virus grown in cell culture. TNX-1800 is designed to express the spike protein from SARS-CoV-2 virus, which causes COVID-19. Our plan is to test whether vaccination with TNX-1800 will elicit an immune response to the SARS-CoV-2 spike protein and if so, whether such an immune response will protect against COVID-19.

TNX-1800 is based on Tonix's proprietary horsepox vector platform. Horsepox is closely related to vaccinia vaccines, which are a group of orthopoxviruses that have been used as smallpox vaccines and as experimental vectors for certain other disease-related antigens. Under the terms of the research collaboration, Southern Research will test TNX-1800 for its ability to express the SARS-CoV-2 spike protein and elicit immune responses to SARS-CoV-2. We expect to receive data from these experiments in the second quarter of 2020. The further development of TNX-1800 for human clinical trials will require manufacturing according to Good Manufacturing Practice, or GMP, standards and sufficient animal testing.

Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. Orthopoxviruses, like vaccinia, can be engineered to express foreign genes and have been explored as platforms for vaccine development because they possess: (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) potential to be manufactured at industrial scale, and (7) ability to provide direct antigen presentation. Although vaccinia vectors are available, different orthopoxvirus strains may behave differently as vectors in part because of their different repertoire of genes that modulate immune responses and host range. Potential advantages of horsepox-based vaccines include the strong immunogenicity we observed for TNX-801 in macaques and mice with good tolerability. The protein synthesis connected with a replicating live virus vaccine provides direct antigen presentation, which can stimulate cellular immunity in addition to humoral immunity.

There is much effort currently being invested into methods of providing vaccines to protect against COVID-19, but there is still much unknown about the biology of the SARS-CoV-2 virus and the methods, if any, of producing a protective immune response. For example, based on studies of a related coronavirus diseases, Severe Acute Respiratory Syndrome, or SARS, from 2003, and Middle East Respiratory Syndrome, or MERS, from 2012, there is potential risk that antibodies to SARS-CoV-2 may potentiate, rather than protect against, infection in some individuals. This phenomenon is called antibody-mediated enhancement. Safety tests will be required to ensure that antibody mediated enhancement, if present, does not compromise protection for any potential COVID-19 vaccine.

We recently filed a provisional patent on TNX-1800's technology. In addition, we expect TNX-1800 to be eligible for 12 years of non-patent-based exclusivity under the Patient Protection and Affordable Care Act, or PPACA.

TNX-801 – Potential Smallpox and Monkeypox Vaccine

TNX-801 is a novel potential smallpox-preventing vaccine based on a synthetic version of live horsepox virus, grown in cell culture. Though it shares structural characteristics with vaccinia-based vaccines, TNX-801 has unique properties that we believe indicate potential safety advantages over existing live replicating vaccinia virus vaccines, which have been associated with adverse side effects such as myopericarditis in some individuals. Emergent BioSolutions' ACAM2000® is the only replicating vaccinia virus vaccine currently approved by the FDA to protect against smallpox. We believe replicating virus vaccines have potential efficacy advantages over non-replicating vaccines, relating to the stimulation of cell mediated immunity. Bavarian Nordic's Jynneos® is the only non-replicating virus vaccine currently approved by the FDA to protect against smallpox and monkeypox. We believe TNX-801 has the potential to have improved tolerability relative to replicating vaccinia vaccines and the potential to have improved efficacy relative to non-replicating vaccinia vaccines.

Smallpox was eradicated by a World Health Organization program that vaccinated individuals with live replicating vaccinia vaccines wherever smallpox appeared. In the 1970s, vaccination of civilians to protect against smallpox was discontinued in the U.S.; however, smallpox remains a material threat to national security and a proportion of military personnel, including members of the Global Response Force, continue to be vaccinated. We are developing TNX-801 as a potential smallpox-preventing vaccine for the U.S. strategic national stockpile and for potential widespread immunization in the event of malicious reintroduction of variola, the virus that causes smallpox. Monkeypox is a growing problem in certain regions of Africa. Some cases of monkeypox have been reported outside of Africa in patients who had been infected while in Africa.

In January 2020 at the American Society of Microbiology Biothreats conference, we reported the results of experiments on TNX-801 that were performed in collaboration with Southern Research, that showed TNX-801 vaccinated macaques were protected against monkeypox challenge. The TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge. Furthermore, eight of eight animals vaccinated with two different doses of TNX-801 showed no lesions after monkeypox challenge.

We have filed a patent to protect the TNX-801 vaccine. In addition, we expect that TNX-801 will be eligible for 12 years of non-patent-based exclusivity under the PPACA. Following the passage of the 21st Century Cures Act, a law designed to help accelerate medical product development, we believe TNX-801 will qualify as a medical countermeasure, and would therefore be eligible for a Priority Review Voucher upon receiving FDA approval. 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 approval 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 by the FDA.

We intend to meet with the FDA to discuss the most efficient and appropriate investigational plan, to establish the safety and effectiveness evidence to support the licensure TNX-801.We are currently working to develop a vaccine that meets cGMP quality to support an IND study.

TNX-102 SL – Fibromyalgia (FM)

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. 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 potentially 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 higher doses of TNX-102 SL, 5.6 mg, in PTSD, we restarted 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, or IA, pending the FDA's agreement, and we expect interim analysis results from this study in the third quarter of 2020 and topline data in the first half of 2021, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of our interim analysis and topline results.

TNX-102 SL – Posttraumatic Stress Disorder (PTSD)

We are developing TNX-102 SL for the treatment of PTSD, which has been designated as a Breakthrough Therapy by the FDA 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 IA indicated the study met a pre-defined threshold p-value for futility. 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 within nine years after the index trauma that resulted in PTSD. This retrospective analysis guided the design of the Phase 3 RECOVERY (P302) study, which was initiated in March 2019. Based on interim analysis results of the first 50% of enrolled participants of the Phase 3 RECOVERY trial (P302), an Independent Data Monitoring Committee recommended stopping the study for futility as TNX-102 SL was unlikely to demonstrate a statistically significant improvement over placebo in the primary endpoint after 12 weeks. We stopped enrollment of new participants, but continue to study those participants currently enrolled until completion. We will proceed with a full analysis of the unblinded data to determine the next steps in this program. Topline data are expected in the second quarter of 2020, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of our topline results.

TNX-102 SL – Agitation in Alzheimer's Disease (AAD)

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 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 (AUD)

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 half of 2020, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of our IND submission.

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

We are developing TNX-601 CR (tianeptine oxalate controlled release tablets) for the treatment of major depressive disorder, or depression, PTSD, and 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 by the FDA 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. Tonix's proprietary, 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. In animals, tianeptine has been shown to reverse the adverse neuroplastic changes that are observed during periods of extreme stress and elevated corticosteroid exposure. Tianeptine and its major metabolite MC5 are weak agonists of the mu-opioid receptor. 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. Several preliminary clinical studies conducted by others have suggested that tianeptine immediate release tablets have activity in combat and military-related PTSD.

TNX-601 CR is in the pre-IND stage and we intend to request a pre-IND meeting with the FDA in 2020. Tonix recently completed a Phase 1 study for formulation development ex-U.S. and we are planning for a Phase 2 study in depression ex-U.S. in the first half of 2021, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of this study.

TNX-1300 – Cocaine Intoxication

We licensed TNX-1300 from Columbia University in May 2019. We are developing TNX-1300 for the treatment of cocaine intoxication. 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 a bacterium (*Rhodococcus*) that uses cocaine as its sole source of carbon and nitrogen and that grows in soil surrounding coca plants. The gene encoding CocE was identified and the protein was extensively characterized. CocE catalyzes the breakdown of cocaine into metabolites 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 shows activity for approximately 6 hours at body temperature. In a Phase 2 study, of volunteer cocaine abusers conducted prior to Tonix licensing the program, TNX-1300 was well tolerated at 100 mg or 200 mg *i.v.* doses and rapidly, within a few minutes, interrupted cocaine effects after cocaine 50 mg *i.v.* challenge. TNX-1300 has been granted Breakthrough Therapy designation by the FDA for the treatment of cocaine intoxication. In August 2019, we met with the FDA to seek guidance on the nonclinical study plans to support the clinical development of TNX-1300.

Other Preclinical Product Candidates

- **TNX-1600 – PTSD, Depression and Attention Deficit Hyperactivity Disorder, or ADHD**

  TNX-1600 was licensed from Wayne State in August 2019 in a transaction that included an asset acquisition agreement with TRImaran, a biopharmaceutical company that had previously licensed the technology from Wayne State. TNX-1600 is a triple reuptake inhibitor, which inhibits the reuptake of dopamine, norepinephrine, and serotonin. TNX-1600 is in development to treat PTSD, depression and ADHD 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-CD40-L or anti-CD154) is a third-generation monoclonal antibody, or mAb, currently in preclinical development as a potential first line monotherapy for autoimmunity and as an adjunctive therapy for preventing and treating organ transplant rejection. Several studies have shown mAbs that react with the same molecular target as TNX-1500 to be active in the treatment of human systemic lupus erythematosus and in transplant rejection. TNX-1500 is specifically designed to retain the efficacy of anti-CD40L mAbs while mitigating potential side effects. In August 2019, we announced a research collaboration with the Massachusetts General Hospital in Boston for the testing of TNX-1500 for the prevention of organ transplant rejection.

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

  TNX-1700 (rTFF2) was licensed from Columbia University in September 2019. TNX-1700 is a biologic molecule 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 mucosal tissue. TFF2 is also expressed at low levels in splenic immune cells and is now appreciated to have intravascular roles in spleen and in the microenvironment of tumors. 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 Tonix is studying rTFF2 to determine whether there are additive or synergistic effects of combining rTFF2 with other anti-neoplastic treatments in gastric and pancreatic cancers.

- **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 preclinical 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.

Our Strategy

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

- ***Develop TNX-1800 for COVID-19.*** We currently are focusing on the development of TNX-1800 for protection against COVID-19. We expect to be engaged in laboratory experiments and then animal experiments to determine whether TNX-1800 protects against effects of SARS-CoV-2 virus infection. There are no vaccines available to prevent COVID-19 and thus this program may address a large unmet medical need;

- ***Develop TNX-801 for preventing smallpox and monkeypox.*** We currently are focusing on the development of TNX-801 to protect against smallpox and monkeypox. Based on the results of TNX-801 in an experiment which showed protection of macaques against monkeypox, we are focused on manufacturing TNX-801 vaccine at GMP standard, for further studies;

- ***Develop TNX-102 SL for FM and TNX-102 SL for PTSD and Other Indications.*** We currently are developing TNX-102 SL for the management of FM and the treatment of PTSD. Our broader development strategy is to leverage the patented formulation to explore the clinical potential of TNX-102 SL in multiple other pain, psychiatric, 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-801 and TNX-1800, we own patent applications protecting their composition-of-matter and certain methods of its use. 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.

COVID-19

On December 31, 2019 the Wuhan Health Commission reported a cluster of atypical pneumonia cases in the city of Wuhan, China. The first patients began experiencing symptoms of illness in mid-December 2019. Clinical isolates were found to contain a novel coronavirus. The novel coronavirus is currently referred to as SARS-CoV-2 and is related to SARS coronavirus (SARS-CoV), although with only approximately 80% similarity at the nucleotide level. There are currently no vaccines to protect against COVID-19. The SARS-CoV-2 virus is reportedly highly contagious.

COVID-19 is a respiratory disease. Symptoms may appear 2-14 days after exposure and include fever, cough and shortness of breath. This is an emerging, rapidly evolving situation and it is expected that the U.S. Centers for Disease Control and Prevention, or CDC, and the World Health Organization, or WHO, will continue to provide updated information as it becomes available, in addition to updated guidance. WHO declared COVID-19 a global pandemic.

Coronaviruses are a large family of viruses that are common in people and many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (SARS-CoV-2). The sequences from U.S. patients are similar to the one that China initially posted, suggesting a likely single, recent emergence of this virus from an animal reservoir.

The complete clinical picture with regard to COVID-19 is not fully understood. Reported illnesses have ranged from mild to severe, including illness resulting in death. Information so far suggests that most COVID-19 illness is mild, with serious illness occurring in a proportion of cases. Older people and people with certain underlying health conditions like heart disease, lung disease and diabetes, for example, seem to be at greater risk of serious illness.

Currently, there is no vaccine to protect against COVID-19 and no antiviral medications approved to treat it. Individuals with COVID-19 receive supportive care to help relieve symptoms, and for severe cases, treatment includes care to support vital organ functions. Currently, the best way to prevent illness due to COVID-19 is to avoid exposure.

COVID-19 was discovered only recently, so it is difficult to forecast a market. Much of what we posit about COVID-19 is based on SARS and MERS, which are coronavirus-related contagious diseases. If the number of COVID-19 cases evolve like SARS, then the number of cases could increase dramatically and then decrease dramatically over the next months. If the number of COVID-19 cases evolve like MERS, then COVID-19 could persist for many years and continue to resurface in new outbreaks. Some coronavirus illnesses can also appear seasonally, but it is not currently known if this will be a characteristic of COVID-19 epidemiology.

Smallpox and Monkeypox

Smallpox is an acute contagious disease caused by the variola virus, or VARV, which is a member of the orthopoxvirus family. Smallpox was declared eradicated in 1980 following a global immunization campaign. Smallpox is transmitted from person to person by infective droplets during close contact with infected symptomatic people. Monkeypox is an acute contagious disease caused by the monkeypox virus or MPXV, which is also a member of the orthopoxvirus family. Monkeypox symptoms are similar to those of smallpox, although less severe. Monkeypox is emerging as an important zoonotic infection in humans in Central and West Africa.

Smallpox was eradicated by a World Health Organization program that vaccinated individuals with live replicating vaccinia vaccines wherever smallpox appeared. In the 1970s, vaccination of civilians to protect against smallpox was discontinued in the U.S.; however, smallpox remains a material threat to national security and a proportion of military personnel, including members of the Global Response Force continue to be vaccinated. We are developing TNX-801 as a potential smallpox-preventing vaccine for the U.S. strategic national stockpile and for potential widespread immunization in the event of malicious reintroduction of variola, which is the virus that causes smallpox. Monkeypox is a growing problem in certain regions of Africa. Some cases of monkeypox have been reported outside of Africa in patients who had been infected while in Africa.

Currently, there are two FDA approved smallpox vaccines, one of which is also indicated for monkeypox. ACAM2000® (Smallpox [Vaccinia] Vaccine, Live) was approved in 2007 and is indicated for active immunization against smallpox disease in persons determined to be at high risk for smallpox infection. Jynneos® (Smallpox and Monkeypox Vaccine, Live, Non-replicating) or MVA-BN is indicated for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

These two smallpox vaccines are FDA approved and purchased by the U.S. Strategic National Stockpile. The US Strategic National Stockpile currently stores more than 300 million doses of smallpox vaccine to protect the U.S. population in the event of reintroduction of variola. We believe that the Strategic National Stockpile will continue to be stocked primarily with a live replicating virus vaccine and secondarily with a non-replicating virus. ACAM2000® is the only replicating vaccinia virus vaccine currently approved by the FDA to protect against smallpox. Jynneos® is the only non-replicating virus vaccine currently approved by the FDA to protect against smallpox. In the post-eradication world, the risk of variola infection is low, so non-replicating vaccines like Jynneos have an appropriate ratio of risk and benefit. However, in a potential post-reintroduction world, we believe live replicating virus vaccines like TNX-801 would be administered to healthy, immunocompetent, non-pregnant adults without risk factors such as eczema or heart disease. The assessment of efficacy of modern smallpox vaccines and the expected benefit of vaccination policy are based on the historical success of predicate live replicating vaccinia vaccines to control smallpox during the time the disease was endemic. We believe TNX-801 has the potential to have improved safety and tolerability relative to replicating vaccinia vaccines and the potential to have improved efficacy relative to non-replicating vaccinia vaccines.

Fibromyalgia, or 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, 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.

Posttraumatic Stress Disorder, or PTSD

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 a 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.

Agitation in Alzheimer's Disease, or AAD

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 U.S..

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 in Alzheimer's 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, or AUD

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. Three drugs have been approved by the FDA, but AUD remains an unmet need due to compliance and safety issues.

Major Depressive Disorder, or Depression

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 that is related to 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, or 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.

Attention Deficit Hyperactivity Disorder or ADHD

Previously called hyperkinetic syndrome, ADHD is defined by a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. Symptoms of ADHD must have been present prior to 12 years of age and must have been present in two or more settings, e.g. at home, school, work; with friends or relatives; in other activities. And there must be clear evidence that the symptoms interfere with, or reduce the quality of, social, academic, or occupational functioning. ADHD is a chronic condition that begins in childhood and is one of the most common mental disorders among children. While high activity levels and short attention spans are generally observed in young children, children with ADHD have greater hyperactivity and inattention relative to children their same age. The consequences of ADHD can cause distress for the individual and result in behavioral problems in structured environments such as school, as well as in less structured environments which occur in social settings or in the home. For a majority of these individuals, the diagnosis will carry into adulthood, and symptoms may only partially remit. The American Psychiatric Association estimates that 8.4 percent of children and 2.5 percent of adults have ADHD.

Our Product Candidates

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-1800	COVID-19 vaccine	Pre-clinical	Worldwide
TNX-801	Smallpox and monkeypox vaccine	Pre-clinical	Worldwide
TNX-102 SL	Fibromyalgia	Phase 3	Worldwide
TNX-102 SL	Posttraumatic stress disorder	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, Neurocognitive Dysfunction from Corticosteroids	Pre-IND	Worldwide
TNX-1300	Cocaine Intoxication	Phase 2	Worldwide
TNX-1600	PTSD, ADHD, Depression	Pre-IND	Worldwide

TNX-1800 – Potential COVID-19 Vaccine

Overview

We are developing TNX-1800 (live modified horsepox virus vaccine for percutaneous administration), a potential vaccine to protect against COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform, which we believe can be engineered to express relevant protein antigens from different infectious diseases to make a variety of vaccines. On February 26, 2020, Tonix announced a strategic collaboration with the Southern Research Institute to support the development of TNX-1800. The collaboration with Southern Research will develop and test TNX-1800, which is designed to express the spike protein from the virus that causes COVID-19, which is called SARS-CoV-2. Under the terms of the research collaboration, Southern Research will test TNX-1800 for its ability to express the SARS-CoV-2 spike protein, elicit immune responses to it and test whether such an immune response will protect against COVID-19. We expect to receive preliminary data from the first of these experiments in small animals in the second quarter of 2020. The further development of TNX-1800 for human clinical trials will require manufacturing according to Good Manufacturing Practice, or GMP, standards and sufficient animal testing in small animals and in non-human primates.

There are currently no vaccines approved by the U.S. Food and Drug Administration, or FDA, to protect against COVID-19. Multiple companies and research institutions are developing potential COVID-19 vaccines. TNX-1800 is in the pre-clinical, pre-Investigational New Drug application, or pre-IND, stage of development and has not been approved for any indication.

We intend to meet with the FDA to discuss the most efficient and appropriate investigational plan to establish the safety and effectiveness evidence to support the licensure of TNX-1800. We recently filed a patent on the COVID-19 vaccine. In addition, 12 years of non-patent-based exclusivity is expected under the Patient Protection and Affordable Care Act, or PPACA.

TNX-801 – Potential Smallpox and Monkeypox Vaccine

Overview

TNX-801 (live horsepox virus vaccine for percutaneous administration), Investigational Smallpox and Monkeypox Vaccine, consists of a live replicating horsepox virus. The investigational product formulation for nonclinical GLP and clinical studies has not been finalized but is expected to be a sterile liquid for administration by percutaneous scarification. TNX-801 is being developed for the prevention of smallpox and monkeypox disease for immunocompetent, non-pregnant adults at high risk for infection, who lack risk factors such as eczema or heart disease.

Tonix is developing TNX-801 as a prophylactic vaccine for active immunization against smallpox and monkeypox disease for individuals at high risk for infection. Tonix believes the efficacy and safety data generated in the course of the proposed studies would facilitate a biologics license application (BLA) for both smallpox and monkeypox vaccine indications.

Smallpox is an acute contagious disease caused by the variola virus, or VARV, which is a member of the orthopoxvirus family. Smallpox was declared eradicated in 1980 following a global immunization campaign. Smallpox is transmitted from person to person by infective droplets during close contact with infected symptomatic people. Monkeypox is an acute contagious disease caused by the monkeypox virus or MPXV, which is also a member of the orthopoxvirus family. Monkeypox symptoms are similar to those of smallpox, although less severe. Monkeypox is emerging as an important zoonotic infection in humans in Central and West Africa. Monkeypox is a growing problem in certain regions of Africa. Some cases of monkeypox have been reported outside of Africa in patients who had been infected while in Africa.

Smallpox was eradicated by a World Health Organization program that vaccinated individuals with live replicating vaccinia vaccines wherever smallpox appeared. In the 1970s, vaccination of civilians to protect against smallpox was discontinued in the U.S.; however, smallpox remains a material threat to national security and a proportion of military personnel, including members of the Global Response Force continue to be vaccinated. We are developing TNX-801 as a potential smallpox-preventing vaccine for the U.S. strategic national stockpile and for potential widespread immunization in the event of malicious reintroduction of variola, the virus that causes smallpox.

Currently, there are two FDA approved smallpox vaccines, one of which is also indicated for monkeypox. Smallpox (Vaccinia) Vaccine, Live (ACAM2000®) was approved in 2007 and is indicated for active immunization against smallpox disease in persons determined to be at high risk for smallpox infection. In September 2019, the FDA approved J Jynneos® (or MVA-BN), Smallpox and Monkeypox Vaccine, Live, Non-replicating. Jynneos® is indicated for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. Certain potential limitations of ACAM2000 and MVA-BN have prompted Tonix to pursue the development of TNX-801 based on evidence suggesting TNX-801 could provide an alternative to the two approved vaccines. TNX-801 may have advantages for use in healthy, immunocompetent non-pregnant individuals, without a history of eczema or cardiac disease, and as part of a public health vaccination policy to respond to an event of variola reintroduction. The assessment of efficacy of modern smallpox vaccines and the expected benefit of vaccination policy are based on the historical success of predicate live replicating vaccinia vaccines to control smallpox during the time the disease was endemic.

The FDA-approved label for ACAM2000 carries a boxed warning related to suspected cases of myocarditis and/or pericarditis in healthy adult primary vaccinees and other safety concerns. The rate of cardiac adverse events (AEs) was estimated at 5.7 per 1000 [95% Confidence Interval (CI): 1.9-13.3]. The molecular mechanism of ACAM2000 associated cardiotoxicity remains unclear.

Since the eradication of smallpox in 1980, the risk and reward ratio of vaccination against smallpox has changed. At the present time, the risks associated with universal ACAM2000 vaccination of the general population outweigh the potential benefits. In addition, ACAM2000 vaccination is not indicated even for first responders. In most of the U.S., routine vaccination against smallpox ended in the early 1970s. In the military, routine vaccinations were limited to recruits entering basic training starting in 1984. In 1990, the Department of Defense (DoD) discontinued routine vaccination of recruits, primarily due to its cardiotoxicity risks. ACAM2000 is currently used primarily in US military personnel deployed to areas that the US government has determined to be at increased risk of malicious smallpox reintroduction and in laboratory workers at potential occupational risk for exposure to orthopoxviruses. According to the Military Health System Smallpox Vaccine Q&A's, more than 2.6 million service members received a smallpox vaccination between December 2002 and December 2017. Currently, it is believed that approximately 60,000 US military personnel are vaccinated each year, mostly in the global response force. This represents hundreds of potential cases of myocarditis and pericarditis among vaccinated troops. Since the threat of intentional or accidental release of VARV and the reemergence of smallpox has not completely disappeared, we believe efforts to develop safer smallpox vaccines must continue.

In the post-eradication world, the risk of variola infection is low, so non-replicating vaccines like Jynneos have an appropriate ratio of risk and benefit. However, in a potential post-reintroduction world, we believe live replicating virus vaccines like TNX-801 would be administered to healthy, immunocompetent, non-pregnant adults without risk factors such as eczema or heart disease. The assessment of efficacy of modern smallpox vaccines and the expected benefit of vaccination policy are based on the historical success of predicate live replicating vaccinia vaccines to control smallpox during the time the disease was endemic. We believe TNX-801 has the potential to have improved tolerability relative to replicating vaccinia vaccines and the potential to have improved efficacy relative to non-replicating vaccinia vaccines.

The FDA approved Jynneos in 2019 based on the demonstration of immunologic non-inferiority to ACAM2000 in humans (peak serum neutralizing antibody titers) and protection against monkeypox virus (MPXV) challenge in a non-human primate (NHP) model. While live replicating vaccinia virus vaccines are administered by a single percutaneous scarification procedure, Jynneos is administered by subcutaneous injection and requires two injections separated by a month or more to induce acceptable neutralizing antibodies.

We intend to meet with the FDA to discuss the most efficient and appropriate investigational plan to establish the safety and effectiveness evidence to support the licensure TNX-801. 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-102 SL

Overview

TNX-102 SL, in clinical development for registration in four indications. 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 FM and PTSD. 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 FM and PTSD, 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 M_1 and histaminergic H_1 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 U.S. We believe that TNX-102 SL has the potential to provide clinical benefit to FM and PTSD patients and possibly other CNS (central nervous system) indications that are underserved by currently marketed products or have no approved treatment.

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

Ongoing Phase 3 RELIEF Study (F304)

We are enrolling patients into the Phase 3 RELIEF study. We 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 by an IDMC 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 third quarter of 2020 and topline results from this study in the first half of 2021, assuming the target population remains 470 patients, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of our interim analysis and topline results.

Completed 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 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.

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.

Completed 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 and unexpected adverse events were reported.

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.

Other NDA Requirements

The Agreed Initial Pediatric Study Plan, or Agreed iPSP, was accepted by the FDA in September 2015). Updates to the Agreed iPSP will be submitted after we confirm the therapeutic dose in adults from the ongoing Phase 3 RECOVERY study, which was initiated in December 2019.

Based on our discussions with the FDA and the FDA official meeting minutes, we will not have to conduct special populations, such as geriatric and renal/hepatic impaired patients, 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 reference listed drug, or RLD, has been successfully completed. Due to the well-established safety profile of CBP at much higher doses than we proposed for FM and the long-term safety data in PTSD, up to 15 months, on TNX-102 SL 5.6 mg, the FDA has not requested a risk management plan or medication guide for this product.

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.

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 RECOVERY study is being conducted at approximately 30 U.S. sites. The study planned to enroll 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. Based on interim analysis results of the first 50% of enrolled participants, an Independent Data Monitoring Committee recommended stopping the Phase 3 RECOVERY trial (P302) in PTSD for futility as TNX-102 SL was unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms between those treated with TNX-102 SL and those receiving placebo. New enrollment for the RECOVERY study was stopped in February 2020, but we intend to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data to determine the next steps in this program. Topline data are expected in the second quarter of 2020.

Discontinued 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 conducted at approximately 40 U.S. sites, which we refer to as the HONOR study. 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 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 $\geq$ 33 in this Phase 3 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. The IA was conducted when approximately 50% of the initially planned participant enrollment was evaluable for efficacy. 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 unexpected adverse events. The most common adverse events were mostly related to local administration site reactions, such as oral hypoaesthesia (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 CAPS-5 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 difference in CAPS-5 in the participants who experienced trauma more than nine years prior to screening compared to placebo. 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.

Completed 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, 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 serious adverse events, or 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.

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 BTD, 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.

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 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 granted in December 2016.

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 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 BTD for TNX-102 SL for PTSD is pending. The FDA will inform us of the BTD 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. In February 2020, based on interim analysis results of the first 50% of enrolled participants, an Independent Data Monitoring Committee recommended stopping the Phase 3 RECOVERY trial (P302) in PTSD for futility as TNX-102 SL was unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms between those treated with TNX-102 SL and those receiving placebo. New enrollment for the RECOVERY study was stopped in February 2020, but we intend to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data to determine the next steps in this program. Topline data from the RECOVERY trial is expected in the second quarter of 2020.

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 reference listed drug, or 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 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 5.6 mg 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 has been completed (TNX-CY-F110). Preliminary results from this study confirmed that the rate and extent of absorption of cyclobenzaprine and its long-lived metabolite, norcyclobenzaprine, increased in a dose-proportional manner from 2.8 mg to 5.6 mg of TNX-102 SL. No food effect was observed for cyclobenzaprine or norcyclobenzaprine for TNX-102 SL 5.6 mg.

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 – 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. 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 half of 2020, however, we cannot predict whether the global COVID-19 pandemic will impact the timing of our IND submission. Upon receiving FDA clearance of an IND application, this program will be Phase 2 proof-of-concept ready and is expected to qualify for the 505(b)(2) pathway for approval.

Additional Product Candidates

We also have a pipeline of other drug and biologic candidates, including, TNX-601 CR, a pre-IND daytime treatment for depression, PTSD and Neurocognitive Dysfunction from Corticosteroids; TNX-701, a preclinical drug for radioprotection; TNX-1200, a preclinical smallpox vaccine, TNX-1300, a Phase 2 treatment for cocaine intoxication, TNX-1500 a preclinical treatment for transplant organ rejection and autoimmune conditions, TNX-1600, a preclinical treatment for PTSD, ADHD and depression and TNX-1700 a preclinical treatment for cancers of the gastrointestinal system.

TNX-601 CR

TNX-601 is a novel oral controlled release, or CR, formulation of tianeptine oxalate in the pre-IND stage of development for the once-daily treatment for depression and PTSD. Currently there is no tianeptine-containing product approved in the U.S., but tianeptine sodium (amorphous) immediate release tablets have been marketed in Europe, Asia, and Latin America as a three-times-a-day treatment for depression since 1987. Tianeptine sodium is reportedly effective in various depressive states and also improves depression-associated anxiety and somatic complaints. We have discovered a novel oxalate salt and polymorph, which we believe may provide improved stability, consistency, and manufacturability relative to the known forms of tianeptine. Like CBP, tianeptine shares structural similarities with classic tricyclic antidepressants, but it has unique pharmacological and neurochemical properties. Tianeptine modulates the glutamatergic system indirectly and reverses the neuroplastic changes that are observed during periods of stress and corticosteroid use. It is a weak mu-opioid receptor agonist, but does not have significant affinity for other known neurotransmitter receptors. Due to its decades of use in Europe, Asia, and Latin America, tianeptine has an established safety profile. In addition to being used to treat depression, several published studies support the potential of tianeptine as an effective and safe therapy for patients with PTSD. Leveraging our development expertise in PTSD, TNX-601 CR is being developed for daytime usage as a first-line monotherapy for depression, PTSD and neurocognitive dysfunction from corticosteroids use. 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.

We intend to develop TNX-601 CR under Section 505(b)(1) of the FDCA as a potential daytime treatment for depression and PTSD. TNX-601 CR will also be developed as a treatment for a potential indication, neurocognitive dysfunction associated with corticosteroid use. Pharmaceutical development work on TNX-601 CR has been initiated. We completed a non-IND formulation selection pharmacokinetic study ex-U.S. in the fourth quarter of 2019.

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.

TNX-1200

TNX-1200 is a live, replicating vaccinia virus vaccine that we are developing for the protection against smallpox. Currently, there are two smallpox vaccines approved by the FDA, one of which is also indicated for monkeypox. Smallpox (Vaccinia) Vaccine, Live (ACAM2000®) was approved in 2007 and is indicated for active immunization against smallpox disease in persons determined to be at high risk for smallpox infection. In September 2019, the FDA approved Jynneos® (MVA-BN), Smallpox and Monkeypox Vaccine, Live, Non-replicating. Jynneos is indicated for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. TNX-1200 may be indicated for healthy, immunocompetent non-pregnant individuals, without a history of eczema or cardiac disease, and as part of a public health vaccination policy to respond to an event of variola reintroduction. The assessment of efficacy of modern smallpox vaccines and the expected benefit of vaccination policy are based on the historical success of predicate live replicating vaccinia vaccines to control smallpox during the time the disease was endemic.

Both of the FDA approved smallpox vaccines are purchased by the Strategic National Stockpile or SNS. We believe that the SNS will continue to be stocked primarily with a live replicating virus vaccine and secondarily with a non-replicating virus. The U.S. SNS currently keeps more than 300 million doses to protein the U.S. population in the event of reintroduction of variola. In the post-eradication world, the risk of variola is low, so non-replicating vaccines have a favorable risk to benefit ratio. However, in a potential post-reintroduction world, we believe live replicating virus vaccines like TNX-1200 would have a positive benefit/risk ratio.

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.

COVID-19 Vaccine Development Projects

The activity for developing vaccines for COVID-2019 is competitive and includes companies and academic institutions. Sanofi, Johnson & Johnson, Geovax Labs / BravoVax, CanSino Biologics, Greffex, and Codagenix are working on viral vector based vaccines. Moderna, CureVac, Inovio, Applied DNA Sciences / Takis Biotech, Zydus Cadlia, Stermina Therapeutics and the Imperial College London are working on RNA or DNA based vaccines. GlaxoSmithKline (GSK) / Clover Biopharmaceuticals, Novavax, Altimmune, Vaxart, Generex Biotechnology, Vaxil Bio, iBio, Baylor College of Medicine / New York Blood Center, University of Queensland, University of Saskatchewan, University of Oxford / Advent Srl are working on protein-based vaccines.

Smallpox vaccines and antivirals

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 ACAM2000, which is a replicating vaccinia vaccine for the prevention of smallpox. Bavarian Nordic received FDA approval and markets Jynneos® (or Modified Virus Ankara, strain BN or MVA-BN), 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.

CNS Condition Therapeutics

The market for therapies to treat FM, PTSD and other CNS conditions is well developed and populated with established drugs marketed by large and small pharmaceutical, biotechnology and generic drug companies.

Fibromyalgia

Three drugs have been approved by the FDA for the management of FM: Pfizer's Lyrica®, Lilly's Cymbalta (duloxetine) and Forest's Savella (Milnacipran). Each of these products has subsequently lost patent protection and is available in generic forms.

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 (esreboxetine) was licensed by Axsome from Pfizer and already includes non-clinical and clinical data supporting its use in FM.

PTSD

In PTSD GlaxoSmithKline (Paxil®) and Pfizer (Zoloft®) developed and 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). Bionomics' 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 which comprises a treatment regimen starting with ketamine, and followed by a proprietary combination of 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 and the high blood pressure medicine, prazosin.

Agitation in Alzheimer's Disease

Additionally, a number of companies are developing prescription medicines for AAD, including Otsuka/Lundbeck (Rexulti® or brexpiprazole), Avanir/Otsuka (deudextromethorphan), Axsome (dextromethorphan/buproprion) 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.

Major Depressive Disorder

A number of companies are marketing prescription drugs for depression, including Johnson & Johnson's Janssen division. Janssen markets Spravato® (intranasal esketamine). Many antidepressant medications are beyond their patent life and are generally produced by generic drug companies, including several compounds in the tricyclic class (e.g., amitriptyline), the serotonin-selective reuptake inhibitor class (e.g, fluoxetine, paroxetine and sertraline), the serotonin-norepinephrine reuptake inhibitor class (e.g., venlafaxine), as well as the norepinephrine-dopamine reuptake inhibitor, bupropion. A number of companies are developing novel prescription medicines for depression including Johnson & Johnson, Sage, Axsome, Relmada, BlackThorn, Clexio, Acadia, Allergan and Otsuka. Janssen is developing JNJ-61393215, a selective orexin receptor type-1 antagonist, Sage Therapeutics is developing SAGE-217 or zuranolone, a neurosteroid. Axsome is developing AXS-05 or dextromethorphan/bupropion combination. Relmada is developing REL-1017 or dextromethadone. BlackThorn is developing BTRX-335140, a selective kappa opioid receptor antagonist. Clexio is developing adjunctive CLE-100, an oral NMDA modulator. Acadia is developing adjunctive pimavanserin for inadequate response to antidepressant treatment. Allergan is developing adjunctive cariprazine for inadequate response to antidepressant treatment. Otsuka is developing adjunctive brexpiprazole. Several academic institutions are studying ketamine as a fast-acting antidepressant, alone or in combination.

Attention Deficit Hyperactivity Disorder or ADHD

Currently there are two main types of medication indicated by the FDA for managing the symptoms of ADHD: stimulants and non-stimulants. Stimulants exert their effect by increasing central dopamine and norepinephrine activity, thereby improving motivation, attention and movement. Commonly used stimulants include amphetamine-based stimulants (Adderall®, Dexedrine®, Dextrostat®), dextromethamphetamine (Desoxyn®), dextromethylphenidate (Focalin®), lisdeamfetamine demesylate (Vyvanse®), and several formulations of the stimulant methylphenidate (Concerta®, Daytrana®, Metadate®, Ritalin®). Non-stimulants act by increasing levels of norepinephrine, which is thought to improve attention and memory. FDA approved non-stimulants include the norepinephrine reuptake inhibitor atomoxetine (Strattera®) as well as the α_2-adrenergic agonists guanfacine (Intuniv®) and clonidine (Kapvay®). The stimulants are notoriously difficult for balancing efficacy against common adverse events that include anorexia and weight loss, mood lability and anxiety, insomnia, and addiction (dependence). A number of companies are developing drugs for the treatment of ADHD. Companies with late stage (Phase 3) studies on-going include Otsuka Pharmaceuticals (centanafadine, a triple reuptake inhibitor) and Supernus Pharmaceuticals (SPN-812 or viloxazine hydrochloride, a norepinephrine reuptake inhibitor).

Intellectual Property

We believe that we have an extensive patent portfolio and substantial know-how relating to TNX-1800, TNX-801, 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 March 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 180 issued non-U.S. patents. We are actively pursuing an additional 22 U.S. patent applications, of which 7 are provisional and 15 are non-provisional, 4 international patent applications, and 102 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 U.S. 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 March 9, 2020 are summarized below.

TNX-1800 – Live HPXV Vaccine for Prevention of COVID-19

We are developing TNX-1800, a live HPXV that is being developed as a new COVID-19 preventing vaccine. We have a patent application directed to synthetic poxviruses comprising a SARS-CoV-2 protein, poxvirus delivery vectors for SARS-CoV-2 proteins and methods of using these modified poxviruses to protect individuals against COVID-19. This patent application is U.S. Provisional Patent Application No. 62/981,997.

TNX-801 — Live Horsepox Vaccine for Prevention of Smallpox

We own the rights to develop a potential biodefense technology, TNX-801, a live horsepox 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 horsepox 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-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 — Depression, Posttraumatic Stress Disorder, 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 disfunction 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-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 the treatment of cocaine intoxication. 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 — anti-CD40L Therapeutics

We are collaborating with Harvard Medical School, to develop TNX-1500, a humanized monoclonal antibody (mAb) that targets CD40L 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.

TNX-1200 — Smallpox Vaccine Technology

We own the rights to develop a potential biodefense technology, TNX-1200, a live vaccinia virus 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. We believe that this technology, after further development, may be of interest to biodefense agencies in the U.S. and other countries.

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
I590820	Compositions and Methods for Transmucosal Absorption	Taiwan	June 14, 2033
2013274003	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
I642429	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
6,541,523	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)	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
HK1176235	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
I661825	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 - Albania,Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Republic of Macedonia, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	March 14, 2034
241353	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Israel	March 14, 2034
370021	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico	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
42020003105.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
P00201808623	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia
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/2017/003644	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Mexico
MX/a/2019/014200	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitryptiline 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
202010024102.2	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

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

CBP - Fatigue

Application No.	Title	Country / Region
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

Application No.	Title	Country / Region
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

Application No.	Title	Country / Region
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

Application No.	Title	Country / Region
16/630,832	Analogs of Cyclobenzaprine and Amitryptilene	U.S.A.
CA3069699	Analogs of Cyclobenzaprine and Amitryptilene	Canada
(not yet assigned)	Analogs of Cyclobenzaprine and Amitryptilene	China
EP18831505.5	Analogs of Cyclobenzaprine and Amitryptilene	European Patent Office
(not yet assigned)	Analogs of Cyclobenzaprine and Amitryptilene	Japan

Tianeptine Oxalate – Salts and Crystalline Forms

Application No.	Title	Country / Region
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

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

Novel Smallpox Vaccines

Application No.	Title	Country / Region
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
62020003684.1	Synthetic Chimeric Poxviruses	Hong Kong
62020003675.9	Synthetic Chimeric Poxviruses	Hong Kong

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

Poxvirus vaccine against COVID-19

Application No.	*Title*	*Country / Region*
62/981,997	*Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus*	*U.S.A.*

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-diethylcarbamolyl) glutathione	U.S.A.
62/941,533	Salt forms of S-(N, N-diethylcarbamolyl) 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 a 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 horsepox. 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 U.S. 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 U.S. 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 FM and PTSD, 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 FM and PTSD. The FDA may not agree that this product candidate is approvable for FM and PTSD 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 FDA 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), FDA approval of the Section 505(b)(2) NDA may be made effective immediately upon successful FDA review of the application, in the absence of marketing exclusivity delays, which are discussed below. If the applicant files a certification to the effect of clause (3), the Section 505(b)(2) NDA approval may not be made effective until the expiration of the relevant patent and the expiration of any marketing exclusivity delays.

If the Section 505(b)(2) NDA applicant provides a certification to the effect of clause (4), referred to as a paragraph IV certification, the applicant also must send notice of the certification to the patent owner and the holder of the NDA for the reference drug. The filing of a patent infringement lawsuit within 45 days of the receipt of the notification may prevent the FDA from approving the Section 505(b)(2) NDA for 30 months from the date of the receipt of the notification unless the court determines that a longer or shorter period is appropriate because either party to the action failed to reasonably cooperate in expediting the action. However, the FDA may approve the Section 505(b)(2) NDA before the 30 months have expired if a court decides that the patent is invalid 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, FDA 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 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 FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or a Section 505(b)(2) NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

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

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 BTD, 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 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 granted in December 2016. 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 for TNX-102 SL. 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. The 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.

In October 2014, the FDA granted BTD 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 approved "material threat medical countermeasure applications." The Act defines such countermeasures as drug or biological products, including 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, botulinum toxin, and pandemic influenza, which includes the SARS coronavirus 2, known as SARS-CoV-2. 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 if and when a TNX-801 Biologics License Application is approved 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 FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

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

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

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

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.

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 March 23, 2020, we had 16 full-time employees, of whom fivehold 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.

Item 1A. Risk Factors

RISKS RELATED TO OUR BUSINESS

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

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

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 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 and 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 FM and PTSD. 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 FM and PTSD;
- 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 FM and PTSD 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 COMMERCILAIZATION

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-1800, TNX-801 and 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 FM and PTSD , 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 FM and PTSD 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 FM and PTSD in a timely manner would have a material adverse impact on our business and our stock price.

We may not commence or advance clinical trials for TNX-1800 if the COVID-19 disease outbreak subsides.

Disease outbreaks are unpredictable. For example, the SARS virus disappeared just four months after it caused a global panic. In the event that COVID-19 has a similar disease cycle, we may be forced to abandon or delay the development of TNX-1800 due to a lack of patients or government funding.

Successful development of our products is uncertain.

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

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

Clinical 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. 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. 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 FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes preclinical 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 FDA approval of the product and authorization to commence commercial marketing. In responding to an NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study 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 FDA review and action varies greatly but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Product sales in the United States may commence only when an NDA 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 FM in the fourth quarter of 2019. As this study is intended to provide efficacy and safety evidence to support marketing approval by the FDA, it is considered a pivotal, confirmatory or registration studies. We initiated a Phase 3 study in civilian and military-related PTSD in the first quarter of 2019 and stopped new enrollment in February 2020 after the IDMC recommended stopping the study for futility after reviewing the IA results. Reception of the futility recommendation by the IDMC suggests this study is unlikely to provide the evidence required to support marketing approval by the FDA.

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 AFFIRM study in FM patients, the HONOR study in PTSD 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 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 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 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 most advanced 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 FM, PTSD, 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.

TNX-102 SL for FM and PTSD are our most advanced development programs which are in the Phase 3 stages. 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).

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.

Our interactions with the FDA have encouraged our efforts to continue to develop TNX-102 SL for FM and PTSD, however, based on interim analysis results of the first 50% of enrolled participants, an Independent Data Monitoring Committee recommended stopping the Phase 3 RECOVERY trial in PTSD for futility as TNX-102 SL was unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms. While we intend to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data to determine the next steps in this program, 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 FM and PTSD 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 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 FM or PTSD (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 FDA approval of our product candidates. 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 FDA procedures. 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 FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical 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 FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

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

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare 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 development of TNX-1800 to protect against COVID-19, TNX-801 to protect against smallpox and monkeypox, and TNX-102 SL for the management of FM and the treatment of PTSD. 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

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future.

In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. For example, we believe our existing capital resources will be insufficient to fund our operations beyond December 31, 2020. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and investors will likely lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

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 on terms that are less favorable to us than might otherwise be available.

We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical 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.

Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.

We may face risks related to health epidemics or outbreaks of communicable diseases. For example, there is now a global pandemic of COVID-19, a highly transmissible pathogenic coronavirus. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries. An outbreak of communicable diseases, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected could adversely affect our business, financial condition or results of operations. For example, an outbreak could significantly disrupt our business by limiting our ability to travel or ship materials within or outside of an affected country and forcing temporary closure of facilities or service providers that we rely upon. An outbreak could also impact our ability to conduct our ongoing multicenter clinical trials if trial participant attendance at requisite study visits is substantially reduced and if a significant percentage of study participants and study staff are adversely affected by coronavirus or other infections and the resulting disease course. Moreover, government or community shutdowns such as those caused by the COVID-19 pandemic, may impair our ability to analyze and submit the results from our clinical and preclinical trials, leading to further delays in the development and approval of our product candidates.

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.

There are risks to our intellectual property based on our international business initiatives.

We may face risks to our technology and intellectual property as a result of our conducting strategic business discussions outside of the United States, and particularly in jurisdictions that do not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know-how and customer information and records. While these risks are common to many companies, conducting business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to joint ventures with foreign partners may have more significant exposure. For example, we have shared intellectual properties with entities in China pursuant to confidentiality agreements in connection with discussions on potential strategic collaborations, which may expose us to material risks of theft of our proprietary information and other intellectual property, including technical data, manufacturing processes, data sets or other sensitive information. For example, our technology may be reverse engineered by the parties or other parties, which could result in our patents being infringed or our know-how or trade secrets stolen. The risk can be by direct intrusion wherein technology and intellectual property is stolen or compromised through cyber intrusions or physical theft through corporate espionage, including with the assistance of insiders, or via more indirect routes.

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 RELIEF study, will require a sufficiently large number of fibromyalgia participants to evaluate the effectiveness and safety of TNX-102 SL in FM. 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 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 we expect there to continue to be, 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.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

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 $1,200,000 per annum. We cannot provide any assurances that we will be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

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

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 approved "material threat medical countermeasures." The Act defines such countermeasures as drug or biologic products, including 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, botulinum toxin, and pandemic influenza, which includes the SARS coronavirus 2 known as SARS-CoV-2. A priority review voucher can be applied to any other product; it shortens the FDA review timeline for a new application from 10 to 12 months to 6 months. The recipient of a priority review voucher may transfer it.

We intend to seek a priority review voucher if and when a TNX-801 Biologics License Application is approved 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 approval 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 approved.

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. The SRF is now appropriated annually and has not kept pace with the need for purchasing products ready for stockpiling. In fiscal year 2020, $735 M was appropriated to SRF. 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.

Our research and development of synthetic poxviruses 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 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 testing, production and storage of our vaccine product candidates.

Developing our TNX-1800 and TNX-801 vaccine candidates each require testing of challenges with monkeypox or SARS-CoV-2 viruses under controlled experimental conditions. The testing of TNX-1800 and TNX-801 may carry risk of infection and harm to individuals.

In addition, our TNX-1800 and TNX-801 vaccine candidates are both live forms of the horsepox. We have initiated vaccine-manufacturing activities to support further nonclinical testing of TNX-801. The production and storage of the synthesized horsepox virus stock and, once initiated, TNX-1800 virus stock, may carry risk of infection and harm to individuals. Any such infection could expose us to product and general liability claims, and may carry risk of infection and harm to individuals.

RISKS RELATED TO OUR STOCK

Sales of additional shares of our common stock could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale, by us or others, including the issuance of common stock upon exercise of outstanding options and warrants, could adversely affect the price of our common stock. We and our directors and officers may sell shares into the market, which could adversely affect the market price of shares of our common stock.

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 common stock could decline in value.

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

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval, disapproval or delay of approval 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 could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.

On November 14, 2019, we received a written notice from the Nasdaq staff indicating that, based on our reported stockholders' equity of $9,855,000 as of September 30, 2019, we no longer met the requirement to maintain a minimum of $10,000,000 in stockholders' equity for continued listing, as set forth in Nasdaq Listing Rule 5450(b)(1)(A). In accordance with Nasdaq listing rules, we were provided a period of 45 calendar days, or until December 30, 2019, in which to regain compliance. In November 2019 we closed a public offering with total net proceeds of approximately $8.1 million; in February 2020 we closed a public offering with total net proceeds of approximately $6.7 million; and in March 2020 we closed a registered direct offering with total net proceeds of approximately $14.8 million. In addition, we generated approximately $7.4 million from the exercise of warrants during the first quarter of 2020. As a result, we believe that we currently satisfy the stockholders' equity standard and submitted a formal plan of compliance on March 6, 2020. If our plan of compliance is not accepted, or if, at the time of our next periodic report, we do not evidence compliance with the stockholders' equity requirement, we may be subject to delisting. If we are unable to maintain compliance with the stockholders' equity standard or other listing requirements, including the minimum share price requirement, we could lose eligibility for continued listing on the Nasdaq Global Market or any comparable trading market.

If we cease to be eligible to trade on Nasdaq:

- We may have to pursue trading on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets."
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a "penny stock," transactions in our stock would be more difficult and cumbersome.
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

The terms of our recent financing may impair our ability to raise necessary funds for our business and may affect the market price of our common stock.

In November 2019, we issued units in an underwritten public offering that included warrants to purchase approximately 4.6 million shares of our common stock. Pursuant to the terms of the warrant, if we issue or are treated as having issued common stock (other than exempt issuances) at a price which is less than the exercise price of the warrant, which is $1.94 per share, the exercise price of the warrant will be reduced to the lowest price at which we sell common stock. The November 2019 warrants also contain a provision that allows the holders to receive the Black-Scholes value of the warrant upon certain fundamental transactions. This may result in the holders receiving a higher per share amount on a fundamental transaction than other shareholders. Our March 2020 registered direct offering of common stock triggered this reset provision, and future financing may result in the potential that a large number of the shares issuable upon exercise of the remaining warrants may be sold in the public market at any given time, which could place downward pressure on the trading price of our common stock. Further, because of this reset provision, investors may be reluctant to invest in our securities and the market price may be affected by the anti-dilution provisions of the warrant and its perceived impact on our ability to obtain additional funding to financing our operations, which may be unavailable on acceptable terms, or at all.

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

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

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

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

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

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

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

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or if we discover material weaknesses and deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

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.

Other companies may have difficulty acquiring us, even if doing so would benefit our stockholders, due to provisions under our corporate charter and bylaws, as well as Nevada law.

Provisions in our articles of incorporation, our bylaws, and under Nevada law could make it more difficult for other companies to acquire us, even if doing so would benefit our stockholders. Our articles of incorporation and bylaws contain the following provisions, among others, which may inhibit an acquisition of our company by a third party:

- advance notification procedures for matters to be brought before stockholder meetings

- a limitation on who may call stockholder meetings
- a limitation on the removal of directors
- the ability of our board of directors to issue up to 5,000,000 shares of preferred stock without a stockholder vote

We are also subject to provisions of Nevada law that prohibit us from engaging in any business combination with any "interested stockholder," meaning generally that a stockholder who beneficially owns 10 percent or more of our stock cannot acquire us for a period of time after the date this person became an interested stockholder, unless various conditions are met, such as approval of the transaction by our board of directors and stockholders.

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.

ITEM 1B – UNRESOLVED STAFF COMMENTS

There are no unresolved staff comments at December 31, 2019.

ITEM 2 – 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, 2019, 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. In February 2020, we extended the lease through August 2021.

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

Year Ending December 31,		
2020	$	358
2021		6
Included interest		(6)
	$	358

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

ITEM 3 - LEGAL PROCEEDINGS

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

ITEM 4 – MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

On March 23, 2020, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was $0.85 per share. On March 23, 2020, there were 105 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Repurchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered securities during the period covered by this Annual Report.

ITEM 6 – SELECTED FINANCIAL DATA

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

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a number of forward-looking statements that reflect Management's current views with respect to future events and financial performance. You can identify these statements by forward-looking words such as "may" "will," "expect," "anticipate," "believe," "estimate" and "continue," or similar words. Those statements include statements regarding the intent, belief or current expectations of us and members of its management team as well as the assumptions on which such statements are based and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report and in other reports we file with the Securities and Exchange Commission, particularly those under "Risk Factors.".

Business Overview

We are a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Our current portfolio includes biologics to prevent infectious diseases and small molecules and biologics to treat pain, psychiatric and addiction conditions. In 2020, we announced a program to develop a potential vaccine to protect against the novel coronavirus disease emerging in 2019, or COVID-19. Our most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. FM is a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. PTSD is a psychiatric condition characterized by the re-experiencing of trauma through intrusive and vivid recollections, nightmares and flashbacks. Both FM and PTSD are associated with chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. In addition, our product pipeline includes other clinical stage and pre-clinical stage programs.

Current Operating Trends

Our current research and development efforts are focused on developing TNX-1800 as a potential COVID-19, TNX-801 as a potential smallpox vaccine, TNX-102 SL for the treatment of FM, PTSD, 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, TNX-1600 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.

Fiscal year Ended December 31, 2019 Compared to Fiscal year Ended December 31, 2018

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2019 were $18.2 million, an increase of $0.6 million, or 3%, from $17.6 million for the fiscal year ended December 31, 2018. This increase is predominately due a ramp up of work related to TNX-601 and the development of our pipeline.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2019 were $10.6 million, an increase of $1.8 million, or 20%, from $8.8 million incurred in the fiscal year ended December 31, 2018. The increase is primarily due to an increase professional fees of $0.7 million, mostly attributable to an increase in legal fees of $0.5 million, due to increased patent prosecution costs, and an increase in investor and public relations expenses of $0.2 million, due to increased investor meetings, and an increase in insurance expenses of $0.7 million due to higher premiums in 2019.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2019 was $28.6 million, compared to a net loss of $26.1 million for the year ended December 31, 2018.

License Agreements

On September 16, 2019, we 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.

We paid a five-digit license fee to Columbia as consideration for entering into the Columbia License Agreement, which was recorded to non-clinical expenses in the statement of operations for the year ended December 31, 2019. 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.

We have 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 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 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 December 31, 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 "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 License Agreement, Columbia has reserved for itself and the Institutions the right to practice the Technology for academic research and educational purposes.

We agreed to pay a six-digit license fee to Columbia as consideration for entering into the License Agreement. We are 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, which was recorded to clinical expenses in the statement of operations for the year ended December 31, 2019, while the remaining 50% license fee, which is expected to be paid during the second quarter of 2020, has been accrued for within accrued expenses and other current liabilities as of December 31, 2019.

We agreed to pay Columbia single-digit royalties on net sales of (i) Products sold by Tonix 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 License Agreement ("Other Products") sold by Tonix 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 us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us under the 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 December 31, 2019, no milestone payments have been accrued or paid in relation to this agreement.

On August 19, 2019, we 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 we acquired TRImaran's assets related to certain pyran-based compounds (the "Assets"). In connection with the acquisition of the Assets, we 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, we paid $100,000 to TRImaran and have assumed certain liabilities of TRImaran totaling $68,500. Upon the achievement of specified development, regulatory and sales milestones, we also agreed to pay TRImaran and the Selling Shareholders, in restricted stock or cash, at our option, a total of approximately $3.4 million. As of December 31, 2019, no milestone payments have been accrued or paid in relation to this agreement.

Pursuant to the terms of the WSU License Agreement, WSU has granted us 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. We are 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.

Pursuant to the WSU License Agreement, we have agreed to pay $75,000 to WSU as reimbursement of certain patent expenses, and, upon the achievement of specified development, regulatory and sales milestones, we also agreed to pay WSU, milestone payments totaling approximately $3.4 million. We have also agreed to pay WSU single-digit royalties on net sales of WSU Products sold by us 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 us to any third party for intellectual property rights which are necessary for the practice of the rights licensed to us 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 December 31, 2019, no milestone payments have been accrued or paid in relation to this agreement.

Liquidity and Capital Resources

As of December 31, 2019, we had working capital of $8.8 million, comprised primarily of cash and cash equivalents of $11.2 million and prepaid expenses and other of $2.7 million, offset by $3.1 million of accounts payable and $1.7 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our Phase 3 clinical trial in FM and PTSD. For the years ended December 31, 2019 and 2018, we used approximately $26.7 million and $24.0 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 outlays principally resulted from an increase in general and administrative activities. For the year ended December 31, 2019 and 2018, net proceeds from financing activities were $12.9 million and $23.5 million, respectively, predominately from the sale of our common stock and warrants.

Cash used by investing activities for the years ended December 31, 2019 and 2018 was approximately $17,000 and $6,000, respectively, related to the purchase of furniture and fixtures.

We believe that our cash resources will be sufficient to meet our projected operating requirements through the end of 2020, but we do not have enough resources to meet our operating requirements for the one-year period from the date of filing of this Form 10-K.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes we may make in our research and development spending plans. These factors raise substantial doubt about our ability to continue as a going concern for the one year period from the date of filing of this Form 10-K. We have 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. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

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 filing date of this report.

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.

Subsequent to December 31, 2019

On February 7, 2020, we entered into an underwriting agreement ("the February 7th Financing") with Alliance Global Partners ("AGP") pursuant to which we sold securities consisting of 3,837,000 Class A Units at a public offering price of $0.57 per unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, and 5,313 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series B Convertible Preferred Stock, with a conversion price of $0.57 per share convertible into 1,754.386 shares of common stock,, warrants to purchase 1,754.386 shares of common stock and warrants to purchase 1,754.386 shares of common stock. The warrants have an exercise price of $0.57, are exercisable and expire five years from the date of issuance.

The February 7th Financing closed on February 11, 2020, AGP purchased the units at a seven-percent discount to the public offering price, for an aggregate discount of approximately $0.5 million. We incurred other offering expenses of approximately $0.3 million. We received net proceeds of approximately $6.7 million, after deducting the underwriting discount and other offering expenses.

As of February 28, 2020, all 5,313 previously issued shares of Series B Convertible Preferred Stock have been converted into common stock.

During February and March 2020, 10.8 million warrants from the February 7th financing, with an exercise price of $0.57, were exercised for proceeds of approximately $6.2 million.

With the February 7th financing, warrants that were issued as part of the November 2019 financing were repriced at $0.57. During February and March 2020, 2.3 million warrants from the November 2019 financing, with an exercise price of $0.57, were exercised for proceeds of approximately $1.3 million.

On February 28, 2020, we entered into an underwriting agreement ("the February 28th Financing") with AGP, relating to the issuance and sale of 14,550,000 shares of its common stock, in a registered direct public offering. The public offering price for each share of common stock was $1.10. The February 28th Financing closed on March 3, 2020. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount of $1.1 million. We incurred other offering expenses of approximately $0.1 million. We received net proceeds of approximately $14.8 million, after deducting the underwriting discount and other offering expenses.

November 2019 Financing

On November 14, 2019, we entered into an underwriting agreement with 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 which converts into 515.464 shares of common stock,, 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 warrants 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 warrants within two years of the date of issuance, with certain exceptions.

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 $0.6 million. We incurred other offering expenses of approximately $0.5 million. We received net proceeds from the November 2019 Financing of approximately $7.9 million, after deducting the underwriting discount and other offering expenses.

As of December 31, 2019, 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 year ended December 31, 2019. As a result of receiving stockholder approval on January 16, 2020, we may sell more than 19.9% of our common stock outstanding pursuant to the 2019 Purchase Agreement without violating Nasdaq Marketplace Rules, including Rule 5635(d), requiring shareholder approval for the sale, issuance or potential issuance by an issuer of common stock (or securities convertible into or exercisable for common stock) at a price less than the greater of book or market value.

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 Alliance Global Partners ("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 Series A Convertible Preferred Stock, with a conversion price of $35.00 per share convertible into 28.5714 shares of common stock, 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 incurred other offering expenses of approximately $0.4 million. We received net proceeds from the December 2018 Financing of approximately $13.6 million, after deducting the underwriting discount and other offering expenses. 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 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 year ended December 31, 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 year ended December 31, 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.

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, 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 we signed the 2018 Purchase Agreement and the 2018 Registration Rights Agreement, the 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 year ended December 31, 2019, we sold an aggregate of approximately 22,800 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 its 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 can 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 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 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 our 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 year ended December 31, 2018, we sold approximately 12,000 shares of common stock under the 2017 Purchase Agreement, resulting in net proceeds of $2.3 million, net of expenses of approximately $45,000. We did not sell any shares of common stock under the 2017 Purchase Agreement during the year ended December 31, 2019.

Under applicable rules of the NASDAQ Global Market, we 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 our common stock to Lincoln Park under the 2017 Purchase Agreement equals or exceeds a threshold amount. As we have issued approximately 15,000 shares to Lincoln Park, by December 31, 2018, under the 2017 Purchase Agreement at less than the threshold amount, we can not sell any additional shares under the 2017 Purchase Agreement without shareholder approval

Stock Compensation

Stock Options

We have issued awards under our 2012 Incentive Stock Option Plan, 2014 Stock Incentive Plan, 2016 Stock Incentive Plan, 2017 Stock Incentive Plan and 2018 Stock Incentive Plan (collectively, the "Prior Plans"). No future awards are issuable under these Prior Plans.

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, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the "2019 Plan").

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 December 31, 2019, 55,825 shares were available for future grants under the 2019 Plan.

On January 16, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan (the "2020 Plan"). With the adoption of the 2020 Plan, no further grants may be made under the 2019 Plan. The 2020 Plan provides for the issuance of up to 600,000 shares of common stock.

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 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. 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.

The weighted average fair value of options granted during the years ended December 31, 2019 and 2018, was $16.54 and $277.77 per share, respectively.

Stock-based compensation expense relating to options granted of $1.5 million and $1.6 million was recognized for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the Company had approximately $1.8 million of unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.67 years.

Employee Stock Purchase Plan

On June 8, 2018, our 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.

On May 3, 2019, our 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 December 31, 2019, 11,041 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 year ended December 31, 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 December 31, 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. In January 2020, 1,578 shares that were purchased as of December 31, 2018, were issued under the 2019 ESPP, and approximately $2,000 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 $7,000 was returned to the employees.

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 year ended December 31, 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 $14.6 million at December 31, 2019 for future work to be performed.

Operating Leases

Future minimum lease payments under operating leases were as follows (in thousands):

Year Ending December 31,		
2020	$	358
2021		6
Included interest		(6)
	$	358

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.

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. In addition, for awards that vest immediately and are nonforfeitable, the measurement date is the date the award is issued.

*Accounting for sale of Class B Units in December 2018 and November 2019 including beneficial conversion feature.*In connection with the December 2018 and November 2019 underwritten offerings, we issued warrants to purchase our common stock and convertible preferred stock. To account for the transaction, we had to calculate the relative fair value of each instrument issued in the financing. We also had to determine if a beneficial conversion feature existed. A beneficial conversion feature is defined as a nondetachable conversion feature that is in the money at the commitment date. A conversion feature is in the money if its conversion price is less than the current fair value of the share. For purposes of measuring a beneficial conversion feature, the effective conversion price should be based on the proceeds allocated to the convertible instrument.

We determine the fair value of the warrant, using a Monte Carlo simulation, which is a statistical method used to generate a defined number of share price paths to develop a reasonable estimate of the range of future expected share prices. Estimates and assumptions impacting the fair value measurement include the warrant's callable feature for the December 2018 offering, the number of shares for which the warrants are exercisable, remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying common shares. We estimate expected share volatility based on our historical volatility for a term equal to the contractual term of the warrants adjusted for a discount that a market participant would have taken when pricing the instrument. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We estimated a 0% expected dividend yield based on the fact that we have never paid or declared dividends and do not intend to do so in the foreseeable future. In general, the assumptions used in calculating the fair value of the warrant represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment. We determine the fair value of the convertible preferred stock utilizing the price of the common stock on the commitment date. We then allocated the relative fair value between the preferred shares and the warrants. Since the effective conversion price of the Preferred Stock is less than the fair value of the underlying common stock at the date of commitment, there is a beneficial conversion feature at the commitment 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 beneficial conversion feature was charged to additional paid in capital as a "deemed dividend" and impacted earnings per share.

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. 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.

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.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To 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, 2019 and 2018, 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, 2019 and 2018, 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 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has continuing losses and negative cash flows from operating activities that 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases effective January 1, 2019 due to the adoption of Accounting Standards Codification Topic 842, Leases.

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
Iselin, New Jersey
March 24, 2020

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2019 AND 2018
(In Thousands, Except Par Value and Share Amounts)

	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,249	$ 25,034
Prepaid expenses and other	2,699	1,022
Total current assets	13,948	26,056
Property and equipment, net	34	43
Right to use assets, net	356	—
Restricted cash	100	100
Intangible asset	120	120
Total assets	$ 14,558	$ 26,319
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,070	$ 1,404
Accrued expenses and other current liabilities	1,713	1,251
Lease liability, short term	352	—
Total current liabilities	5,135	2,655
Lease liability, long term	6	—
Total liabilities	5,141	2,655
Commitments (See Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized		
Series A Convertible Preferred stock, $0.001 par value; 7,938 and 11,984 shares designated; as of December 31, 2019 and 2018, respectively 0 and 9,856 shares issued and outstanding as of December 31, 2019 and 2018, respectively	—	—
Common stock, $0.001 par value; 15,000,000 shares authorized;		
8,531,504 and 328,689 shares issued and outstanding as of December 31, 2019 and 2018, respectively, and 1,578 and 177 shares to be issued as of December 31, 2019 and December 31, 2018, respectively	9	—
Additional paid in capital	226,524	212,157
Accumulated deficit	(217,070)	(188,452)
Accumulated other comprehensive loss	(46)	(41)
Total stockholders' equity	9,417	23,664
Total liabilities and stockholders' equity	$ 14,558	$ 26,319

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,	
	2019	2018
COSTS AND EXPENSES:		
Research and development	$ 18,192	$ 17,558
General and administrative	10,636	8,764
	28,828	26,322
Operating Loss	(28,828)	(26,322)
Interest income, net	210	233
Net loss	(28,618)	(26,089)
Preferred stock deemed dividend	2,474	3,266
Net loss available to common stockholders	$ (31,092)	$ (29,355)
Net loss per common share, basic and diluted	$ (19.33)	$ (259.85)
Weighted average common shares outstanding, basic and diluted	1,608,568	112,968

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2019	2018
Net loss	$ (28,618)	$ (26,089)
Other comprehensive loss:		
Foreign currency translation loss	(5)	(29)
Comprehensive loss	$ (28,623)	$ (26,118)

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, 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	9,856	$ —	328,689	$ —	$ 212,157	$ (41)	$ (188,452)	$ 23,664

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
YEAR ENDED DECEMBER 31, 2019
(Dollars In Thousands Except 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
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
Issuance of common stock under 2019 Purchase Agreement, net of transactional expenses of $916	—	—	900,000	1	4,483	—	—	4,484
Issuance of commitment shares in August 2019	—	—	35,529	—	—	—	—	—
Issuance of Series A Convertible preferred stock and common stock warrants in November 2019 ($1,000.00 per share, net of transactional expenses of $957)	7,938	—	—	—	6,980	—	—	6,980
Beneficial conversion feature in connection with issuance of Series A Convertible preferred stock	—	—	—	—	2,474	—	—	2,474
Preferred stock deemed dividend	—	—	—	—	(2,474)	—	—	(2,474)
Issuance of common stock and common stock warrants in November 2019 ($1.94 per share, net of transaction expenses of $128)	—	—	547,420	1	933	—	—	934
Issuance of common stock upon conversion of Series A Convertible preferred stock	(7,938)	—	4,091,753	4	(4)	—	—	—
Issuance of common stock in exchange for exercise of cashless warrants	—	—	2,317,085	2	(2)	—	—	—
Employee stock purchase plan	—	—	2,558	—	31	—	—	31
Stock-based compensation	—	—	—	—	1,457	—	—	1,457
Foreign currency transaction gain	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(28,618)	(28,618)
Balance, December 31, 2019	—	$ —	8,531,504	$ 9	$ 226,524	$ (46)	$ (217,070)	$ 9,417

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (28,618)	$ (26,089)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	26	54
Stock-based compensation	1,457	1,627
Changes in operating assets and liabilities:		
Prepaid expenses	(1,676)	(79)
Accounts payable	1,663	106
Operating lease liabilities and ROU asset, net	3	—
Accrued expenses and other current liabilities	462	410
Net cash used in operating activities	(26,683)	(23,971)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of furniture and fixtures	(17)	(6)
Net cash used in investing activities	(17)	(6)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	70	—
Proceeds, net of $957 and $1,159 expenses, from sale of preferred stock	6,980	10,825
Proceeds, net of $1,045 and $610 expenses, from sale of common stock	5,869	12,714
Net cash provided by financing activities	12,919	23,539
Effect of currency rate change on cash	(4)	(13)
Net decrease in cash, cash equivalents and restricted cash	(13,785)	(451)
Cash, cash equivalents and restricted cash beginning of the year	25,134	25,585
Cash, cash equivalents and restricted cash end of year	$ 11,349	$ 25,134
Supplemental disclosures of cash flow information:		
Taxes paid	$ —	$ 82
Non cash financing activities:		
Beneficial conversion feature in connection with sale of Series A Convertible preferred stock and deemed dividend	$ 2,474	$ 3,266

See the accompanying 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, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. 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, 2019, the Company had working capital of approximately $8.8 million. At December 31, 2019, the Company had an accumulated deficit of approximately $217.0 million. The Company held cash and cash equivalents of approximately $11.2 million as of December 31, 2019.

Subsequent to the year ended December 31, 2019, the Company raised approximately $29.0 million through equity financings and warrant exercises (see Note 14). However, 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

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. 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 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, 2019 and December 31, 2018, cash equivalents, which consisted of money market funds, amounted to $5.4 million and $10.1 million, respectively. Restricted cash at both December 31, 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 11).

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, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	$ 11,249	$ 25,034
Restricted cash	100	100
Total	$ 11,349	$ 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 years ended December 31, 2019 and 2018 was $26,000 and $54,000, respectively. All property and equipment is located in the United States and Ireland.

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, 2019, and 2018, 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.

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.

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, 2019, the Company has not recorded any unrecognized tax benefits. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

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. 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.

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 retroactive effect to the 1-for-10 reverse stock splits, which were effected on November 1, 2019 and November 28, 2018 (see Note 5).

The computation of basic and diluted loss per share for the years ended December 31, 2019 and 2018 excludes potentially dilutive securities when their inclusion would be anti-dilutive, or if their exercise prices were greater than the average market price of the common stock during the period.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share are as follows:

	2019	2018
Series A Convertible Redeemable Preferred Stock	—	281,600
Warrants to purchase common stock	5,138,158	498,510
Options to purchase common stock	109,036	13,740
Totals	5,247,194	793,850

NOTE 3 – OTHER BALANCE SHEET INFORMATION

Components of selected captions in the consolidated balance sheets consist of:

	December 31,	
	2019	2018
	(in thousands)	
Property, plant and equipment, net:		
Office furniture and equipment	$ 334	$ 317
Leasehold improvements	23	23
	357	340
Less: Accumulated depreciation and amortization	(323)	(297)
	$ 34	$ 43
Prepaid expenses and other:		
Contract-related	$ 1,011	$ 525
Other	1,688	497
	$ 2,699	$ 1,022
Accrued expenses and other current liabilities:		
Contract-related	$ 704	$ 475
Compensation and compensation-related	690	614
Professional fees and other	319	162
	$ 1,713	$ 1,251

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, 2019, and December 31, 2018, the Company used Level 1 quoted prices in active markets to value cash equivalents of $5.4 million and $10.1 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. 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, 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. 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.

The Series B Preferred Stock ranks on parity to our common stock with respect to dividends and liquidation rights and does not have any voting rights, subject to limited exceptions.

NOTE 6 – 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 paid $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 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.

Pursuant to the WSU License Agreement, Tonix paid $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 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 December 31, 2019, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 7 – 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 paid a five-digit license fee to Columbia as consideration for entering into the Columbia License Agreement, which was recorded to non-clinical expenses in the statement of operations for the year ended December 31, 2019. 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 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 December 31, 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.

We agreed to pay a six-digit license fee to Columbia as consideration for entering into the License Agreement. We are 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 and the remaining 50% was accrued at December 31, 2019. The entire amount has been recorded to clinical expenses in the Statement of Operations for the year ended December 31, 2019.

The Company 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 December 31, 2019, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 8 – SALE OF COMMON STOCK

November 2019 Financing

On November 14, 2019, the Company entered into an underwriting agreement with Alliance Global Partners ("AGP") pursuant to which the Company 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, convertible into 515.464 shares of common stock, warrants to purchase 515.464 shares of common stock, and common warrants to purchase 257.732 shares of it's 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 $0.6 million. We incurred other offering expenses of approximately $0.5 million. The Company received net proceeds from the November 2019 Financing of approximately $7.9 million, after deducting the underwriting discount and other offering expenses.

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 $2.5 million for the beneficial conversion feature resulting from the intrinsic value of the conversion options of the preferred stock.

As of December 31, 2019, 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, 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 year ended December 31, 2019. As a result of receiving stockholder approval on January 16, 2020, the Company may sell more than 19.9% of its common stock outstanding pursuant to the 2019 Purchase Agreement without violating Nasdaq Marketplace Rules, including Rule 5635(d), requiring shareholder approval for the sale, issuance or potential issuance by an issuer of common stock (or securities convertible into or exercisable for common stock) at a price less than the greater of book or market value.

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.

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 convertible into 28.5714 shares of common stock, 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). We incurred other offering expenses of approximately $0.4 million. The Company received net proceeds from the December 2018 Financing of approximately $13.6 million, after deducting the underwriting discount and other offering expenses.

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).

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 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 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 year ended December 31, 2019, the Company sold an aggregate of approximately 22,800 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 can 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.

During the year ended December 31, 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 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.

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 year ended December 31, 2018, the Company sold approximately 12,000 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 year ended December 31, 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 can not sell any additional shares under the 2017 Purchase Agreement without shareholder approval

NOTE 9 – 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.

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 December 31, 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 years ended December 31, 2019, and 2018 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	4,034	$ 3,998.89	8.35	$ —
Grants	10,206	$ 375.15		—
Exercised	—			
Forfeitures or expirations	(500)	388.44		
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 December 31, 2019	109,036	$ 199.57	8.60	$ —
Vested and expected to vest at December 31, 2019	109,036	$ 199.57	8.60	$ —
Exercisable at December 31, 2019	17,396	$ 1,019.67	5.04	$ —

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 year ended December 31, 2019 and 2018, was $16.54 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. 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.

The assumptions used in the valuation of stock options granted during the year ended December 31, 2019 and 2018 were as follows:

	2019	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' historical stock price volatility.

Stock-based compensation expense relating to options granted of $1.5 million and $1.6 million was recognized for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the Company had approximately $1.8 million of unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.67 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 December 31, 2019, 11,041 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 year ended December 31, 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 December 31, 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. In January 2020, 1,578 shares that were purchased as of December 31, 2019, were issued under the 2019 ESPP, and approximately $2,000 of employee payroll deductions accumulated at December 31, 2019, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $7,000 was returned to the employees.

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 year ended December 31, 2018.

During the year ended December 31, 2019 and 2018, no stock-based compensation expense related to RSU grants was expensed.

NOTE 10 – WARRANTS TO PURCHASE COMMON STOCK

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, 2019.

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2019:

Exercise Price	Number Outstanding	Expiration Date
$ 1.94	2,500	November 2020
$ 1.94	4,639,172	November 2024
$ 35.00	490,571	December 2023
$ 630.00	5,441	October 2021
$ 687.50	474	October 2021
	5,138,158	

During the year ended December 31, 2019, 2,000 warrants with an exercise price of $35.00 were exercised for proceeds of approximately $70,000.

During the year ended December 31, 2019, 24 warrants with a per share exercise price of $25,000 expired. During the year ended December 31, 2018, 11 warrants with an exercise price of $12,000 and 919 warrants with an exercise price of $4,250 expired.

NOTE 11 – 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 December 31, 2019, the Company has right-of-use assets of $0.4 million and a total lease liability for operating leases of $0.4 million of which $6,000 is included in operating lease liabilities, noncurrent and $0.4 million is included in operating lease liabilities, current.

At December 31, 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,	
2020	$ 358
2021	6
Included interest	(6)
	$ 358

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 $0.5 million for year ended December 31, 2019.

Other information related to leases was as follows:

	2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flow from operating leases (in thousands)	$ 455
Weighted Average Remaining Lease Term Operating leases	0.85 years
Weighted Average Discount Rate Operating leases	3.37%

NOTE 12 – COMMITMENTS

Research and Development Contracts

The Company has contracts with various contract research organizations with outstanding commitments aggregating approximately $14.6 million at December 31, 2019 for future work to be performed.

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, 2019 and 2018, the Company charged operations $0.1 million and $0.2 million, respectively, for contributions under the 401(k) Plan.

NOTE 13 – INCOME TAXES

Components of the net loss consist of the following (in thousands):

	Year ended December 31,	
	2019	2018
Foreign	$ (22,630)	$ (21,502)
Domestic	(5,988)	(4,587)
Total	$ (28,618)	$ (26,089)

In 2019, the foreign losses are comprised of $22.2 million related to the Bermudan operations of Tonix International Holding. In 2018, the foreign losses were primarily comprised of $20.9 million related to the Bermudan operations of Tonix International Holding.

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,	
	2019	2018
Statutory federal income tax	(21.0)%	(21.0)%
State income tax, net of federal tax effect	0.0%	0.0%
Permanent difference	0.0%	0.1%
Change in valuation allowance	1.0%	1.7%
Foreign loss not subject to income tax	16.4%	17.0%
Return to provision true-ups	0.0%	(0.1)%
Attribute reduction from control Change	4.1%	3.9%
Other	(0.5)%	(1.6)%
Income Tax Provision	0.0%	0.0%

Deferred tax assets and related valuation allowance as of December 31, 2019 and 2018 were as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforward	$ 770	$ 763
Stock-based compensation	2,951	2,659
Other	507	226
Total deferred assets	4,228	3,648
Valuation allowance	(3,874)	(3,648)
Deferred tax liabilities	(354)	—
Net deferred tax assets	$ —	$ —

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, 2019 have been reduced to $0.0 million to reflect IRC section 383 ownership changes through December 31, 2019 and the resulting inability to utilize a portion of the R&D credit prior to its expiration.

At December 31, 2019, the Company has $5.0 million of Ireland NOL carryforwards that do not expire. As of December 31, 2019, the Company's federal, New York State, and New York City NOL carryforwards are subject to annual limitations in their use in accordance with IRC section 382. The NOL carryforwards at December 31, 2019 have been reduced to reflect IRC section 382 ownership changes through December 31, 2019 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, 2019. 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, 2019 and 2018 were $0.2 million, and $(0.3) million respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2019 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, 2019, the Company's tax returns remain open and subject to examination by the tax authorities for the tax years 2016 and after.

NOTE 14 – SUBSEQUENT EVENTS

On January 16, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan (the "2020 Plan").

On February 25, 2020, the Company granted options to purchase an aggregate of 343,500 shares of the Company's common stock to employees with an exercise price of $0.40, 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 207,000 shares of the Company's common stock to employees with an exercise price of $0.50, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months.

On February 7, 2020, the Company entered into an underwriting agreement ("the February 7th Financing") with AGP pursuant to which the Company sold securities consisting of 3,837,000 Class A Units at a public offering price of $0.57 per unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, and 5,313 Class B Units at a public offering price of $1,000 per unit, with each unit consisting of one share of Series B Convertible Preferred Stock, with a conversion price of $0.57 per share, convertible into 1,754.386 shares of common stock and warrants to purchase 1,754.386 shares of it's common stock. The warrants have an exercise price of $0.57, are exercisable and expire five years from the date of issuance.

The February 7th Financing closed on February 11, 2020, AGP purchased the Units at a seven-percent discount to the public offering price, for an aggregate discount of approximately $0.5 million. We incurred other offering expenses of approximately $0.3 million. The Company received net proceeds of approximately $6.7 million, after deducting the underwriting discount and other offering expenses.

As of February 28, 2020, all 5,313 previously issued shares of Series B Convertible Preferred Stock have been converted into common stock.

During February and March 2020, 10.8 million warrants from the February 7th Financing, with an exercise price of $0.57, were exercised for proceeds of approximately $6.2 million.

With the February 7th Financing, warrants that issued as part of the November 2019 financing were repriced at $0.57 per share. During February and March 2020, 2.3 million warrants from the November 2019 financing, with an exercise price of $0.57 per share, were exercised for proceeds of approximately $1.3 million.

On February 28, 2020, the Company entered into an underwriting agreement ("the February 28th Financing") with AGP, relating to the issuance and sale of 14,550,000 shares of its common stock, in a registered direct public offering. The public offering price for each share of common stock was $1.10. The February 28th Financing closed on March 3, 2020. AGP purchased the shares at a seven percent discount to the then current public price, for an aggregate discount of $1.1 million. We incurred other offering expenses of approximately $0.1 million. The Company received net proceeds of approximately $14.8 million, after deducting the underwriting discount and other offering expenses.

On March 18, 2020, the Company entered into a $1.3 million research collaboration with the Southern Research Institute to conduct animal research on TNX-1800 in mouse and non-human primate animal models of COVID-19.

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

None.

ITEM 9A – CONTROLS AND PROCEDURES

Management's evaluation of disclosure controls and procedures.

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

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

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's principal executive and principal financial officer and effected by the our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

We conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our principal executive officer and principal financial officer conclude that, at December 31, 2019, our internal control over financial reporting was effective.

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

ITEM 9B – OTHER INFORMATION

On November 14, 2019, the Company received a written notice from the Nasdaq staff indicating that, based on its reported stockholders' equity of $9,855,000 as of September 30, 2019, it no longer met the requirement to maintain a minimum of $10,000,000 in stockholders' equity for continued listing, as set forth in Nasdaq Listing Rule 5450(b)(1)(A). In accordance with Nasdaq listing rules, the Company was provided a period of 45 calendar days, or until December 30, 2019, in which to regain compliance. In November 2019 the Company closed a public offering with total net proceeds of approximately $8.1 million; in February 2020 it closed a public offering with total net proceeds of approximately $6.7 million; and in March 2020 it closed a registered direct offering with total net proceeds of approximately $14.8 million. In addition, the Company generated approximately $7.4 million from the exercise of warrants during the first quarter of 2020. As a result, the Company believes that it currently satisfy the stockholders' equity standard and submitted a formal plan of compliance on March 6, 2020. If the plan of compliance is not accepted, or if, at the time of its next periodic report, the Company does not evidence compliance with the stockholders' equity requirement, the Company may be subject to delisting. If we are unable to maintain compliance with the stockholders' equity standard or other listing requirements, including the minimum share price requirement, the Company could lose eligibility for continued listing on the Nasdaq Global Market or any comparable trading market..

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The Board of Directors elects our executive officers annually. A majority vote of the directors who are in office is required to fill vacancies. Each director shall be elected for the term of one year and until his successor is elected and qualified or until his earlier resignation or removal. Our directors and executive officers are as follows:

NAME	AGE	CURRENT POSITION
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	Director
James Treco	64	Lead Director
Jessica Morris	42	Chief Operating Officer
Bradley Saenger	46	Chief Financial Officer and Treasurer
Gregory Sullivan	54	Chief Medical Officer and Secretary

The following information with respect to the principal occupation or employment of each nominee for director, the principal business of the corporation or other organization in which such occupation or employment is carried on, and such nominee's business experience during the past five years, as well as the specific experiences, qualifications, attributes and skills that have led the Board to determine that such Board members should serve on our Board, has been furnished to the Company by the respective director nominees:

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 Plumbline 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, MD 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 CardoVax, 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 served as Lead Director from February 2014 until March 2020. 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 and has been our Lead Director since March 2020. 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.

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, Daniel Goodman, 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.

Board Leadership Structure

Our CEO also serves as the chairman of the Board. An independent director serves as the Board's lead director. This structure allows one person to speak for and lead both the Company and the Board, while also providing for effective independent board oversight through an independent lead director. Having Dr. Lederman, our CEO, serve as Chairman creates clear and unambiguous authority, which is essential to effective management. Our Board and management can respond more effectively to a clearer line of authority. By designating our CEO as its Chairman, our Board also sends as an important signal to our employees and shareholders about who is accountable. Further, since Dr. Lederman is the founder of our Company and is an inventor on key patents and patent applications underlying our programs, we believe that Dr. Lederman is best-positioned to set our Board's agenda and provide leadership.

We have established the position of lead director, which is filled by Mr. Rhodes. The lead director has the following responsibilities, as detailed in the Lead Director charter, adopted by the Board (and also performs any other functions the Board may request):

- **Board leadership** — provides leadership to the Board in any situation where the chairman's role may be, or may be perceived to be, in conflict, and also chairs meetings when the chairman is absent;
- **Leadership of independent director meetings** — leads independent director meetings, which take place without any management directors or Tonix employees present;
- **Additional meetings** — calls additional independent director meetings as needed;
- **Chairman-independent director liaison** — regularly meets with the chairman and serves as liaison between the chairman and the independent directors;
- **Stockholder communications** — makes himself available for direct communication with our stockholders;
- **Board agenda, schedule & information** — works with the chairman regarding meeting agendas, meeting schedules and information sent to directors for Board meetings, including the quality, quantity, appropriateness and timeliness of such information; and
- **Advisors and consultants** — recommends to the Board the retention of outside advisors and consultants who report directly to the Board on Board-wide issues.

Board Role in Risk Oversight

Risk is an integral part of the Board and Board committee deliberations throughout the year. While the Board has the ultimate oversight responsibility for the risk management process, various committees of the Board also have responsibility for risk management. In particular, the Audit Committee focuses on financial risk, including internal controls, and receives financial risk assessment reports from management. Risks related to the compensation programs are reviewed by the Compensation Committee. The Board is advised by these committees of significant risks and management's response through periodic updates.

Stockholder Communications with the Board

The Company's stockholders may communicate with the Board, including non-executive directors or officers, by sending written communications addressed to such person or persons in care of Tonix Pharmaceuticals Holding Corp., Attention: Secretary, 509 Madison Avenue, Suite 1608, New York, New York 10022. All communications will be compiled by the Secretary and submitted to the addressee. If the Board modifies this process, the revised process will be posted on the Company's website.

Meetings and Committees of the Board

During the fiscal year ended December 31, 2019, the Board held eight meetings, the Audit Committee held nine meetings, the Compensation Committee held seven meetings and the Nominating and Corporate Governance Committee held seven meetings. The Board and Board committees also approved certain actions by unanimous written consent.

Board Committees

The Board has standing Audit, Compensation, and Nominating and Corporate Governance Committees. Information concerning the membership and function of each committee is as follows:

Board Committee Membership

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Margaret Smith Bell		**	
Daniel Goodman	*		*
David Grange		*	*
Adeoye Olukotun		*	
John Rhodes	*		
James Treco	**		**

* Member of Committee
** Chairman of Committee

Audit Committee

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

Our Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent auditors, (ii) appointing, replacing and discharging the independent auditor, (iii) pre-approving the professional services provided by the independent auditor, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditor, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditor. The Audit Committee reviewed and discussed with management the Company's audited financial statements for the year ended December 31, 2019.

Compensation Committee

Our Compensation Committee consists of Margaret Smith Bell, David Grange and Adeoye Olukotun, with Ms. Bell elected as Chairman of the Committee. Our Board has determined that all of the members are "independent" under the current listing standards of the NASDAQ Stock Market. Our Board has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee.

Our Compensation Committee has responsibility for, among other things, evaluating and making decisions regarding the compensation of our executive officers, assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy, producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC and periodically evaluating and administering the terms and administration of our incentive plans and benefit programs. In addition, our Compensation Committee reviews and makes recommendations to the Board regarding incentive compensation plans that require shareholder approval, director compensation, the Company's compensation discussion and analysis ("CD&A") and the related executive compensation information for inclusion in the Company's 10-K and proxy statement, and employment and severance agreements relating to the chief executive officer.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Daniel Goodman, David Grange and James Treco, with Mr. Treco elected as Chairman of the Committee. The Board has determined that all of the members are "independent" under the current listing standards of the NASDAQ Stock Market.

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

Nomination of Directors

As provided in its charter and our Company's corporate governance principles, the Nominating and Corporate Governance Committee is responsible for identifying individuals qualified to become directors. The Nominating and Corporate Governance Committee seeks to identify director candidates based on input provided by a number of sources, including (1) the Nominating and Corporate Governance Committee members, (2) our other directors, (3) our shareholders, (4) our Chief Executive Officer or Chairman, and (5) third parties such as professional search firms. In evaluating potential candidates for director, the Nominating and Corporate Governance Committee considers the entirety of each candidate's credentials.

Qualifications for consideration as a director nominee may vary according to the particular areas of expertise being sought as a complement to the existing composition of the Board. However, at a minimum, candidates for director must possess:

- high personal and professional ethics and integrity;
- the ability to exercise sound judgment;
- the ability to make independent analytical inquiries;
- a willingness and ability to devote adequate time and resources to diligently perform Board and committee duties; and
- the appropriate and relevant business experience and acumen.

In addition to these minimum qualifications, the Nominating and Corporate Governance Committee also takes into account when considering whether to nominate a potential director candidate the following factors:

- whether the person possesses specific industry expertise and familiarity with general issues affecting our business;
- whether the person's nomination and election would enable the Board to have a member that qualifies as an "audit committee financial expert" as such term is defined by the SEC in Item 401 of Regulation S-K;
- whether the person would qualify as an "independent" director under the listing standards of the Nasdaq Stock Market;
- the importance of continuity of the existing composition of the Board to provide long term stability and experienced oversight; and
- the importance of diversified Board membership, in terms of both the individuals involved and their various experiences and areas of expertise.

The Nominating and Corporate Governance Committee will consider director candidates recommended by shareholders provided such recommendations are submitted in accordance with the procedures set forth below. In order to provide for an orderly and informed review and selection process for director candidates, the Board has determined that shareholders who wish to recommend director candidates for consideration by the Nominating and Corporate Governance Committee must comply with the following:

- The recommendation must be made in writing to the Corporate Secretary at Tonix Pharmaceuticals Holding Corp.;
- The recommendation must include the candidate's name, home and business contact information, detailed biographical data and qualifications, information regarding any relationships between the candidate and the Company within the last three years and evidence of the recommending person's ownership of the Company's common stock;
- The recommendation shall also contain a statement from the recommending shareholder in support of the candidate; professional references, particularly within the context of those relevant to board membership, including issues of character, judgment, diversity, age, independence, expertise, corporate experience, length of service, other commitments and the like; and personal references; and

- A statement from the shareholder nominee indicating that such nominee wants to serve on the Board and could be considered "independent" under the Rules and Regulations of the Nasdaq Stock Market and the SEC, as in effect at that time.

All candidates submitted by shareholders will be evaluated by the Nominating and Corporate Governance Committee according to the criteria discussed above and in the same manner as all other director candidates.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees.

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.

ITEM 11 - 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 2019 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	198,095	—	505,178	—	—	—	1,288,273
Chief Executive Officer	2018	472,500	160,000	—	844,945	—	—	—	1,477,445
Gregory Sullivan	2019	400,000	84,000	—	168,393	—	—	—	652,393
Chief Medical Officer	2018	335,000	70,000	—	316,855	—	—	—	721,855
Bradley Saenger	2019	385,000	80,850	—	112,262	—	—	—	578,112
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, 2020, the base salary is $614,250. 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, 2020, the base salary is $420,000. 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.

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 23, 2020:

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

Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o Tonix Pharmaceuticals Holding Corp., 509 Madison Avenue, Suite 1608, New York New York 10022.

NAME OF OWNER	TITLE OF CLASS	NUMBER OF SHARES OWNED (1)	PERCENTAGE OF COMMON STOCK (2)
Seth Lederman	Common Stock	37,964 (3)	*
Jessica Morris	Common Stock	3,101 (4)	*
Bradley Saenger	Common Stock	4,434 (5)	*
Gregory Sullivan	Common Stock	5,980 (6)	*
Margaret Smith Bell	Common Stock	3,400 (7)	*
Daniel Goodman	Common Stock	3,006 (8)	*
David Grange	Common Stock	3,270 (9)	*
Adeoye Olukotun	Common Stock	3,150 (10)	*
John Rhodes	Common Stock	5,400 (11)	*
James Treco	Common Stock	4,000 (12)	*
Officers and Directors as a Group (11 persons)	Common Stock	73,705 (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 March 23, 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 49,353,134 shares of common stock issued and outstanding as of March 23, 2020.

(3) Includes 13,668 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 3,081 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 3,037 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(6) Includes 4,575 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(7) Includes 3,400 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(8) Includes 3,005 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(9) Includes 3,270 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(10) Includes 3,150 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(11) Includes 5,152 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, and 13 shares of common stock underlying warrants

(12) Includes 4,000 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(13) Includes 46,338 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.

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.

ITEM 13 - 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.

During the last two fiscal years, there have been no related party transactions.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees billed by our independent registered public accounting firm, for professional services rendered for the audit of our annual financial statements for the years ended December 31, 2019 and 2018, including review of our interim financial statements as well as registration statement filings with the SEC and comfort letters issued to underwriters were $421,720 and $424,380, respectively.

Audit-Related Fees

We did not incur fees to our independent registered public accounting firm for audit related fees during the fiscal years ended December 31, 2019 and 2018.

Tax and Other Fees

We incurred fees to our independent registered public accounting firm for tax services during the fiscal years ended December 31, 2019 and 2018, of $0 and $7,500, respectively, related to a net operating loss study.

Pre-Approval Policies and Procedures

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(c) Index to Exhibits

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by an asterisk (*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15.

EXHIBIT INDEX

Exhibit No.	Description
1.01	Form of Underwriting Agreement, filed herewith.
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, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on January 17, 2020 and incorporated herein by reference.
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.
4.04	Form of Warrant, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on February 6, 2020 and incorporated herein by reference
4.05	Form of Warrant Agency Agreement, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on February 6, 2020 and incorporated herein by reference.
4.06	Description of Registrant's Securities, filed herewith.
10.01	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.
10.02	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.*
10.03	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.
10.04	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.
10.05	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.*
10.06	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.
10.07	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.
10.08	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.

10.09	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.
10.10	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.
10.11	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.
10.12	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.
10.13	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.
10.14	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.
10.15	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.
10.16	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.
10.17	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.
10.18	Research Collaboration Agreement between Tonix Pharmaceutical, Inc. and Southern Research Institute, dated November 7, 2018, filed herewith.
14.01	Code of Business Conduct and Ethics for Employees, Executive Officers and Directors, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on February 16, 2016 and incorporated herein by reference.
21.01	List of Subsidiaries.
23.01	Consent of Independent Registered Public Accounting Firm, filed herewith.
31.01	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Tonix Pharmaceuticals Holding Corp.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Stockholders' Equity, (v) the Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: March 24, 2020

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

Date: March 24, 2020

By: /s/ BRADLEY SAENGER
Bradley Saenger
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Seth Lederman and Bradley Saenger, jointly and severally, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ SETH LEDERMAN Seth Lederman	Chief Executive Officer, President and Director (Principal Executive Officer)	March 24, 2020
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 24, 2020
/s/ MARGARET SMITH BELL Margaret Smith Bell	Director	March 24, 2020
/s/ DAVID GRANGE David Grange	Director	March 24, 2020
/s/ DANIEL GOODMAN Daniel Goodman	Director	March 24, 2020
/s/ ADEOYE OLUKOTUN Adeoye Olukotun	Director	March 24, 2020
/s/ JOHN RHODES John Rhodes	Director	March 24, 2020
/s/ JAMES TRECO James Treco	Director	March 24, 2020

Exhibit 4.06

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a summary of all material characteristics of our common 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 Chapter 78 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.

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

Transfer Agent and Registrar

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

DESCRIPTION OF PREFERRED STOCK

The following is a summary of all material characteristics of our preferred 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 Chapter 78 of the Nevada Revised Statutes, as amended ("NRS").

Preferred Stock

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

Terms of the Preferred Stock That We May Offer and Sell to You

We summarize below some of the provisions that will apply to the preferred stock that we may offer to you unless the applicable prospectus supplement provides otherwise. This summary may not contain all information that is important to you. You should read the prospectus supplement, which will contain additional information and which may update or change some of the information below. Prior to the issuance of a new series of preferred stock, we will further amend our articles of incorporation, as amended, designating the stock of that series and the terms of that series. We will file a copy of the certificate of designation that contains the terms of each new 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. You should refer to the applicable certificate of designation as well as our articles of incorporation, as amended, before deciding to buy shares of our preferred stock as described in the applicable prospectus supplement.

Our board of directors has the authority, without further action by the stockholders, to issue preferred stock in one or more series and to fix the number of shares, dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking funds, and any other rights, preferences, privileges and restrictions applicable to each such series of preferred stock.

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.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to that particular series of preferred stock, including, where applicable:

- the designation, stated value and liquidation preference of such preferred stock;
- 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 such 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 such 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 such series; the status as to reissuance or sale of shares of such 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 such 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 such 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 such preferred stock.

The description of the terms of a particular series of preferred stock in the applicable prospectus supplement will not be complete. You should refer to the applicable amendment to our articles of incorporation, as amended, for complete information regarding a series of preferred stock.

The preferred stock will, when issued against payment of the consideration payable therefore, be fully paid and nonassessable.

Exhibit 10.18

MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (hereinafter **"Agreement"**) is made this 7th day of November, 2018 (hereinafter **"Effective Date"**) by and between Southern Research Institute (hereinafter **"Southern Research"**), a 501(c)(3) non-profit corporation organized under the laws of the State of Alabama, and Tonix Pharmaceuticals, Inc. (hereinafter **"Client"**) (each singularly a **"Party"** and collectively the **"Parties"**).

RECITALS

WHEREAS, Southern Research has certain expertise in areas related to Client's business; and

WHEREAS, Client hereby desires to establish an agreement in order to engage Southern Research for the purposes described in this Agreement;

THEREFORE, in consideration of the mutual promises and covenants herein contained, both Southern Research and Client agree as follows:

1.0 SERVICES TO BE RENDERED.

1.1 Services. The specific details of any services to be provided by Southern Research for each project under this Agreement (hereinafter **"Services"**) will be separately negotiated and specified in writing in a task order to be agreed upon and executed by the Parties, each of which shall be attached hereto and incorporated herein (each, a **"Task Order"**). Unless otherwise specifically stated in a proposal, all prices quoted by Southern Research in connection with a Task Order are good for ninety (90) days. Further, in the event Client does not release Southern Research to perform a Task Order within ninety (90) days of the date of Southern Research's proposal, Southern Research reserves the right to renegotiate the prices originally quoted. Unless otherwise stated therein, if the performance of a Task Order exceeds one (1) year, all prices set forth therein are subject to renegotiation every twelve months (12) after the effective date of the Task Order.

1.2 Performance Standards. Southern Research shall perform the Services (i) in a professional manner, meeting the standards of diligence, care, timeliness, trust, dependability, safety, efficiency, economy and skill customary in the field, (ii) in compliance with all applicable federal, state and local laws, (iii) in compliance with this Agreement, including using best efforts to meet timelines and schedules as agreed to between the Parties, and (iv) in accordance with all reasonable instructions and requests of Client as mutually agreed upon in writing by the Parties.

1.3 Materials. Client agrees to supply to Southern Research, at no charge to Southern Research, such necessary quantities of the Client's products and/or other materials (collectively, the **"Materials"**) as set forth in each Task Order or at such times and in such quantities as Southern Research may reasonably request in order to complete the Task Order. Client shall also include an appropriate material safety data sheet (MSDS), if available, with the shipment of the Materials in accordance with Code of Federal Regulations 29 CFR 1910. Southern Research shall use the Materials only for the purpose of performing the Task Order and shall not subject the Materials to any analysis or use inconsistent with the Services as described in the applicable Task Order. Client will provide written directions specifying the return or destruction of any remaining Materials within sixty (60) days after completion of the Services as described in the applicable Task Order.

1.4 Retention of Study Materials. Southern Research shall store data and study materials derived as a result of the Services provided to Client for a period of three (3) months following the issuance of the draft report or final experimental data (**"Archival Period"**). At or about the issuance of the draft report or final experimental data, the Client shall be provided with an Archived Materials Report (**"AMR"**) that shall contain options to either continue the Archival Period for an additional fee or have the data and study materials destroyed or shipped to a selected destination, at Client's expense. Client agrees to pay for the elections made and will be subsequently invoiced for each annual AMR. Southern Research shall not discard or destroy any data or other study materials relating to the Services without giving the Client advance written notice of this intention and a reasonable opportunity to have such data or other study materials shipped at Client's expense.

1.5 Client Information. Client agrees to provide to Southern Research all necessary information as is deemed necessary by Southern Research to perform the Services, in a timely manner and in any format which may be reasonably specified by Southern Research. Southern Research shall not be responsible for independently verifying the accuracy or completeness of any such information.

1.6 Authorization, Cancellation, Postponement of Studies. Client shall authorize Southern Research to initiate scheduling of Services in writing, by email, or by other recordable means ("Authorization"), and pay the initial invoice amount as set forth in the proposal. Schedule/s will be provided to Client in writing, by email, or by other recordable means. In the event Client cancels one or more studies following Authorization, and Southern Research is not able to reallocate the scheduled time to another client, Client shall pay a cancellation fee of two and a half percent (2.5%) of the total price of the study, for each study cancelled, plus any actual study costs incurred up to the date of cancellation (such fees and costs constituting the (**"Cancellation Charges"**))**.** The Cancellation Charges shall be in addition to any other remedy available to Southern Research due to such cancellation, and Southern Research's decision to pursue collection of Cancellation Charges shall not be deemed an election of remedies.

In the event Client postpones a study following Authorization and provision of the schedule, and Southern Research is not able to reallocate the scheduled time to another client, Client agrees to payment any actual study costs incurred up to the date of postponement, as well as costs and per diems for extended care and housing of any animals procured at Southern Research's standard rates (such fee and costs constituting the (**"Postponement Charges"**)) until the study is initiated or cancelled by the Client. If Client does not communicate its intent to re-schedule a postponed study within thirty (30) days following the original study initiation date, the Parties may elect to treat the study as cancelled; Cancelation Charges will then go into effect. Following receipt of such notification, Southern Research shall invoice Client for Cancellation Charges incurred up to the date of termination. Southern Research may not unilaterally cancel a Task Order for convenience, but it may cancel a Task Order if Client materially breaches its obligations under the Task Order and fails to cure such breach after thirty (30) days written notice by Southern Research. Client may cancel a Task Order for any reason immediately upon providing written notice to Southern Research.

Upon cancellation or termination of this Agreement or any Task Order for any reason, Southern Research will promptly deliver to Client all work product (in whatever stage of development), including incomplete work product, created by Southern Research for Client pursuant to the Agreement or Task Order. Except in the event of a cancellation or termination by Client for Southern Research's material breach of this Agreement, Client agrees to pay Southern Research for all work product and any authorized Services rendered through the date of termination or cancellation. In the event of cancellation of a Task Order hereunder, Client shall also pay Southern Research any reasonable and justifiable costs directly incurred by Southern Research as a result of the cancellation. In the event Southern Research has received any advance payments for Services which it has not performed, Southern Research shall be obligated to promptly refund such advance payments to Client.

1.7 Subcontracting. Southern Research may from time to time utilize the resources of a Subcontractor to provide specific expertise on a relevant Task Order with prior notice to Client.

2.0 CHARGES AND INVOICING.

2.1 Charges. It is agreed that Client's liability for the payment of Task Order charges (the "Charges") shall be set forth separately in each Task Order.

2.2 Invoicing. Client shall provide payment of the Charges in accordance with the terms of each Task Order. Except for any required prepayments as specified in each Task Order, Client shall pay each invoice within thirty (30) days of receipt thereof. Southern Research shall invoice the Client as identified in the proposal. If no invoicing schedule is identified in the proposal, the following invoicing schedule shall be applied for each study: 30% of the study costs at contract signature, 40% at study initiation (beginning of experimental testing), 20% at study completion (end of experimental testing), and 10% at issuance of the draft report or release of data when a report is not a deliverable associated with the contract.

The Client shall pay invoices submitted within thirty (30) days of receipt. Southern Research will apply a late payment fee of 1 1/2% percent interest on any outstanding payment(s) due and payable calculated as follows: such interest shall begin accrual at 1 1/2% on the 31st day after submission of an invoice where such payment has not yet been received by Southern Research. Interest shall accrue until payment is received.

2 . 2 Prepayment. Prior to the commencement of the Services, Client shall remit any identified prepayment specified on the relevant Task Order (each, a "Prepayment").

3.0 CONFIDENTIAL INFORMATION.

3.1 Client and Southern Research agree that they will exert diligent efforts to ensure their employees, agents, and consultants will not disclose or publish any proprietary information, confidential technical information, confidential financial information, or confidential business information (collectively hereinafter referred to as "Confidential Information") transmitted to one another for use in the performance of Services or new information developed by Client or Southern Research in connection with the Services under this Agreement. The confidentiality obligations herein shall not apply to:

i. Confidential Information, that at the time of disclosure, is lawfully in the public domain; or

ii. Confidential Information, that after disclosure, becomes available to the public or is lawfully made available to Client or Southern Research by a third party without restrictions as to disclosure; or

iii. Confidential Information that Client or Southern Research can establish by reasonable proof was in their possession at the time of disclosure, or was subsequently and independently developed by employees of Client or Southern Research without benefit of the Confidential Information disclosed as evidenced by its written records; or

iv. Confidential Information that Client and Southern Research mutually agree in writing to release from the terms of this Agreement; or

v. Confidential Information required to be disclosed by order of a court or other governmental body after consultation with the Party who owns the Confidential Information.

3.2 Upon request by the discloser, the recipient shall return to discloser all Confidential Information, copies thereof, if any, within thirty (30) days, except recipient may retain one archival copy thereof solely for the purpose of determining any continuing obligation of confidentiality.

3.3 Client's and Southern Research's obligation not to disclose or publish shall continue (1) for a period of five (5) years from completion of each Task Order under this Agreement or (2) for a period of five (5) years from the termination of this Agreement, whichever period is longer. At the end of such period or when the Confidential Information is no longer confidential under the foregoing exceptions said obligations will terminate, except with respect to Confidential Information that is also a trade secret, which shall remain subject to the obligation not to disclose or publish until such time as such Confidential Information ceases to be a trade secret.

3.4 Client and Southern Research may, in their sole discretion, disclose necessary or appropriate Confidential Information to employees, agents, consultants, representatives, or affiliates in order for Client or Southern Research to perform its obligation under this Agreement, provided, however, that such employees, agents, consultants, representatives, or affiliates shall be bound by the terms and conditions of this Article that are applicable to Client and Southern Research.

3.5 Client and Southern Research agree that the Confidential Information disclosed will not be used to provoke an interference with any patent application that the other Party or its employees have filed with respect to Confidential Information, and will not be used to amend any claim in any pending patent application to dominate any invention (whether or not patentable) disclosed as Confidential Information.

3.6 Client and Southern Research have significant economic value in their respective Confidential Information. Confidential Information has independent value from not being generally known to, and not being readily ascertainable through proper means, by others who could also gain economic value from the Confidential Information.

4.0 INTELLECTUAL PROPERTY.

4.1 BACKGROUND Intellectual Property (BIP)shall mean all technology developed prior to or independently of thisAgreement and made available by the Party to conduct Services under this Agreement. BIP includes all patents, designs, copyright (including copyright in software), database rights, and any other intellectual property rights excluding Foreground Intellectual Property, whether tangible or intangible, owned by any of the Parties, in the field and which are necessary for the exploitation of Foreground Intellectual Property in accordance with this Agreement. All BIP used in connection with this Agreement shall remain the property of the Party introducing the same or any other third parties. Each Party shall take responsibility for ensuring that all necessary permissions have been sought to use BIP. Client shall grant to Southern Research a non-exclusive, royalty-free right during the term of this Agreement to use, reproduce, modify, practice and prepare derivative works of any Client BIP solely as necessary for Southern Research to perform its obligations under this Agreement. Southern Research shall grant to Client an irrevocable, non-exclusive, royalty-free worldwide license to use Southern Research BIP only to the extent that such license is required to enable Client to make use of Southern Research's Services under this Agreement.

4.2 FOREGROUND Intellectual Property (FIP) shall mean, with respect to Southern Research, all intellectual property, whether protectable by copyright or patent made, created or conceived and reduced to practice during performance of the Services covered by this Agreement made by Southern Research personnel that relate solely to (i) the characterization or evaluation of compositions, including test methods or models to characterize or evaluate compositions generally, and (ii) methods or processes for testing, analyzing or reporting on tested materials generally and not specifically with respect to the Client's Materials or Client's proprietary protocol shall become the property of Southern Research. FIP, with respect to Client, shall mean all intellectual property, whether protectable by copyright or patent made, created or conceived and reduced to practice during performance of the Services covered by this Agreement that relate to Client Material or Client BIP. Each Party must promptly notify the other Party in writing of any and all inventions, trade secrets, discoveries, developments, know-how, methods, techniques, formulae, processes and compositions of matter, whether or not patentable, resulting from or derived from or directly relating to Southern Research's and/or Client's performance under this Agreement and must provide the other Party with full and complete information so as to enable the Parties to make a patent application or to seek other intellectual property protection for that invention, discovery or development.

4.3 ACCESS RIGHTS AND LICENSES Southern Research shall grant to Client a royalty-free, paid up, worldwide, perpetual, non-exclusive, non-transferable license to use any Southern Research FIP incorporated in any deliverable, solely for Client's use of that deliverable and for its internal business purposes. The preceding paragraphs shall not apply to any Services to the extent their development was funded by the U.S. Government.

5.0 RELATIONSHIP OF PARTIES. For purposes of this Agreement and all Services to be provided hereunder, this is a non-exclusive agreement and the Parties are independent contractors and not agents or employees of the other. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other Party, except as expressly provided herein or in a Task Order. Southern Research shall be responsible for paying all income taxes imposed on it in connection with the compensation received by Southern Research pursuant to this Agreement.

6.0 INSURANCE. Southern Research agrees to procure and maintain, at Southern Research's expense, liability insurance and workers compensation insurance in amounts and with sureties as generally maintained by others rendering similar services under similar conditions as contemplated by this Agreement.

7.0 INDEMNIFICATION.

7.1 By Southern Research. Southern Research will indemnify, defend and hold harmless Client and its directors, officers, shareholders, employees, representatives and assigns (each, a "Client Indemnified Party"), from and against all losses, damages, judgments, settlements, liabilities, reasonable attorneys' fees, court costs, and expenses (collectively, "Losses") resulting or arising from any third-party claims, as well as third party actions, proceedings, investigations or litigation relating to or arising from or in connection with this Agreement, any Task Order, or the Services rendered hereunder (collectively, an "Action"), to the extent such Losses are caused by the breach of this Agreement by Southern Research or the negligent acts, negligent omissions or intentional misconduct of Southern Research.

7.2 By Client. Client will indemnify, defend and hold harmless Southern Research and its directors, officers, shareholders, employees, representatives and assigns (each, a "Southern Research Indemnified Party"), from and against any and all Losses resulting or arising from any Action, to the extent such Losses are caused by the breach of this Agreement by Client or the negligent acts, negligent omissions or intentional misconduct of Client. Such indemnification shall specifically include all Losses resulting or arising from any Action related to Client's infringement of any third-party intellectual property or proprietary information.

7.3 Requirements. Each Party's indemnification obligations hereunder will be subject to (i) the indemnifying Party (a) receiving prompt written notice of the existence of any Action; (b) being able to, at its option, control the defense of such Action; and (c) receiving full cooperation of the indemnified Party in the defense thereof; and (ii) the indemnified Party not settling any Action without the prior written consent of the indemnifying Party.

8.0 REPRESENTATIONS AND WARRANTIES.

8.1 By Both Parties. Each Party represents and warrants to the other that: (i) it has the requisite power, capacity and authority to enter into this Agreement and to carry out its obligations hereunder; (ii) this Agreement will be executed by its duly authorized representative and once executed shall constitute a legal, valid and binding obligation of each Party; and (iii) it shall comply with all applicable laws and all relevant rules, regulations and issued codes of practice and guidance applicable to such Party's obligations hereunder.

8.2 By Southern Research. Southern Research represents and warrants to Client that neither Southern Research nor any of its employees who will perform any aspect of the Services has: (i) been convicted of any felony, any business crime, or any crime relating to honesty or integrity; (ii) been reprimanded or censured by any federal or state licensing or regulatory agency; or (iii) been disbarred or suspended from participation in any activity regulated by the U.S. Food and Drug Administration or in any federal procurement on non-procurement program. Southern Research will promptly notify Client should any of these events occur.

8.3 By Client. Client represents and warrants to Southern Research that (i) it is authorized to use and transfer all information and Materials to be transferred by Client to Southern Research with respect to its performance of the Services; and (ii) all information provided by Client to Southern Research shall be so provided in accordance with all applicable laws and regulations, including but not limited to HIPAA or the privacy laws of the country of origin if any such information is provided.

9.0 DISCLAIMER; LIMITATION OF LIABILITY.

9.1 Disclaimer of Warranties. Client understands and acknowledges that approvals and clearances of regulatory agencies are subjective, and that Southern Research does not give any warranty as to results, approval or success of any submissions or requests to regulatory agencies. Client further understands and acknowledges that the results of scientific research are inherently unpredictable. While Southern Research will use all reasonable efforts to render the Services in a professional and workmanlike manner, no assurance can be given that any particular result will be achieved. Therefore, SOUTHERN RESEARCH PROVIDES NO REPRESENTATIONS OR WARRANTIES, EITHER IN FACT OR BY OPERATION OF LAW, AS TO THE RESULTS OF ANY SERVICES PROVIDED BY SOUTHERN RESEARCH TO CLIENT, AND SOUTHERN RESEARCH SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE IN RELATION TO THE SERVICES OR ANY PRODUCT(S) PRODUCED THEREFROM. SOUTHERN RESEARCH FURTHER PROVIDES NO REPRESENTATIONS OR WARRANTIES, EITHER IN FACT OR BY OPERATION OF LAW, AS TO NON-INFRINGEMENT WITH RESPECT TO ANY SERVICES PROVIDED BY SOUTHERN RESEARCH TO CLIENT. Acceptance, reliance on, or use of such results or product(s) shall be at the sole risk of Client, and Client does hereby acknowledge that it shall be solely responsible for investigating and addressing any infringement issues related to the Services provided by Southern Research. Client hereby agrees to release, waive and forever discharge any demands, claims, suits or actions against Southern Research arising out of or in connection with Client's acceptance, reliance on, or use of such results or product(s).

9.2 Limitation of Liability. EXCEPT WHEN RESULTING FROM A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES (INCLUDING WITHOUT LIMITATION, LOST PROFITS OR REVENUE; GOVERNMENT FINES OR ASSESSMENT; LOSS OF DATA, TECHNOLOGY, RIGHTS OR SERVICES; INTERRUPTION OF BUSINESS; OR COSTS OF PROCUREMENT OF SUBSTITUTE PRODUCTS OR SERVICES), EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER ARISING UNDER THEORIES OF CONTRACT, TORT, OR ANY OTHER THEORY OF LIABILITY, INCLUDING NEGLIGENCE. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, EXCEPT IN THE EVENT OF SOUTHERN RESEARCH'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, THE AGGREGATE LIABILITY OF SOUTHERN RESEARCH TO CLIENT (INCLUDING CLIENT'S PARENT COMPANY, INVESTORS, SHAREHOLDERS, AFFILIATES, LENDERS, SUBCONTRACTORS, OFFICERS, DIRECTORS, CONSULTANTS, AGENTS OR MEMBERS) WITH RESPECT TO THIS AGREEMENT, WHETHER SUCH LIABILITY ARISES OUT OF BREACH OF CONTRACT, TORT, PRODUCT LIABILITY, CONTRIBUTION, STRICT LIABILITY OR OTHER LEGAL THEORY, SHALL NOT EXCEED AN AMOUNT EQUAL TO CHARGES PAID OR OWED BY CLIENT TO SOUTHERN RESEARCH UNDER THE TASK ORDER THAT GAVE RISE TO THE CLAIM. IT IS AGREED THAT THE LIMITATIONS OF LIABILITY SET FORTH IN THIS SECTION 9.2 ARE AN ESSENTIAL BASIS OF THIS AGREEMENT.

10.0 EXPORT CONTROL.

Exports of data exchanged under the Agreement may be subject to the export laws of the United States including, but not limited to, the U.S. International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations (EAR). The Parties shall not export, disclose or transfer any such data directly or indirectly without compliance with these and any other applicable laws and regulations. The Parties agree to not export or re-export any products, materials, or technical data unless all required licenses, agreements or other authorizations from the U. S. government have been obtained. The Parties agree to cooperate in securing any license which the agency deems necessary in connection with this Agreement. Each Party agrees to notify the other Party if any data or Materials to be supplied are subject to export control license requirements or are listed under export control regulations. Exports of technical data include the sending or taking of any technical data out of the United States in any manner, disclosing or transferring technical data to non-U.S. persons (i.e. any person who is not a U.S. citizen, a lawful permanent resident of the U.S. or a protected individual as defined by 8 U.S.C. section 1101 and 1324), whether in the United States or abroad, or performing services for a foreign client, whether in the United States or abroad.

11.0 PUBLICITY/ENDORSEMENTS.

11.1 Southern Research shall not publish or present any papers based on the specific Services performed for Client without the prior written consent of Client, which consent, in the interest of scientific or educational purposes for the public, shall not be unreasonably withheld. Neither Party, their agents, assigns, nor anyone on their behalf may use the name of the other Party, or any of its affiliates, in any advertising or publicity, express or implied, without the prior written consent of the other Party.

11.2 Client acknowledges that Southern Research neither endorses products or services, nor allows the data or other results of Southern Research work to be used as an endorsement. Therefore, Client agrees that it will not, whether explicitly or through implication, use Southern Research's name, logo, trademarks, the name, title, or statements of Southern Research employees, this Agreement, or the results of work from this Agreement for advertising or other promotional purposes, raising of capital, recommending investments, or in any way that states or implies endorsement by Southern Research. Any exceptions to this Clause will require the advanced written approval of Southern Research, which may be withheld at Southern Research's sole discretion.

12.0 NON-SOLICITATION.

Client agrees not to directly or indirectly employ or engage as an independent contractor any Southern Research employee (whether full or part-time) during the term of this Agreement, and not to directly or indirectly induce any Southern Research employee(s) to leave his or her employment with Southern Research during the term of this Agreement.

13.0 TERM; TERMINATION.

13.1 Term. This Agreement shall be effective as of the Effective Date, and will continue in effect until the later of (i) the completion of the Services as set forth on a Task Order, or (ii) the first anniversary of the Effective Date, unless earlier terminated in accordance with Section 13.2 hereof.

13.2 Termination.

(a) Unless otherwise specifically stated in a Task Order, this Agreement may be terminated by Client upon not less than thirty (30) days' written notice to Southern Research.

(b) Either Party may terminate this Agreement immediately if the other Party is in material breach of this Agreement, after prior written notice from the terminating Party to the other Party describing such material breach in reasonable detail, and the other Party's failure to cure the same within a reasonable period of time (which in no event shall be less than fourteen (14) calendar days). Non- payment by Client shall be deemed a material breach of this Agreement; and in the event of such non- payment, Southern Research shall be entitled to suspend rendering Services to Client until such time as such material breach is cured in full.

(c) Client may terminate this Agreement immediately in the event of Southern Research's breach of Section 8.2 of this Agreement.

13.3 Effect of Termination or Expiration. Except as otherwise stated in a Task Order or in the event of Southern Research's material breach, in the event that this Agreement is terminated prior to the full performance of the Services or full payment of the Charges for the Services, Client shall pay Southern Research solely for Services performed prior to such termination. The following provisions shall survive the termination or expiration of this Agreement: Section 3 Confidential Information, Section 4 Intellectual Property, Section 5 Relationship of Parties, Section 7 Indemnification, Section 8 Representations and Warranties, Section 9 Disclaimer; Limitation of Liability and Section 15 Miscellaneous.

14.0 DISPUTE RESOLUTION

14.1 Process.

14.1.1 Internal Escalation. The primary contact persons named in the Task Order giving rise to the dispute shall use their best efforts to cooperatively and through good faith negotiations resolve disputes and problems that arise in connection with such Task Order. If such contact persons are unable to expeditiously resolve any dispute or problem, they shall promptly refer the matter to executives of the Parties. In the event of such referral, executives for each Party, and any other personnel they designate to assist them, are obligated to meet within ten (10) business days at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to exchange relevant information and to attempt to resolve the dispute. If the matter has not been resolved within thirty (30) days of the initiating referral, or if the Parties fail to meet within ten (10) business days, either Party may initiate mediation of the dispute. Each Party shall be responsible for its own costs, travel and related expenses during the Parties' internal attempt to resolve the dispute.

14.1.2 Mediation. In the event internal escalation procedures cannot resolve the dispute, the Parties will submit the matter to be mediated by a professional mediator mutually acceptable to the Parties. The mediation and all documentation, hearings, and communications relating thereto will be confidential. The Parties will share equally the costs of the mediator and shall be responsible for their own costs, travel and related expenses associated with the mediation. If a good faith attempt of mediation does not settle the dispute after sixty (60) days, either Party may refer the matter to a court of competent jurisdiction.

14.2 Clarification. Neither Party may terminate this Agreement or refer the dispute to a court, except for seeking equitable relief, until the escalation and mediation process has ended. Nothing in the dispute resolution process specified herein shall be deemed to waive the right of either Party to apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm. In any mediation or court action to enforce or interpret this Agreement, the prevailing Party shall be entitled to recover, as part of the agreed settlement, or judgment, reasonable attorneys' fees and associated necessary costs.

15.0 MISCELLANEOUS.

15.1 Entire Agreement. This Agreement, together with any other documents incorporated herein by reference and all related exhibits and schedules, constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein and therein, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter. Any preprinted terms and conditions contained in Client's business forms, including without limitation, purchase orders and invoices, shall be without legal effect in transactions under this Agreement, unless mutually agreed to by the Parties in writing.

15.2 Order of Precedence. In the event of any inconsistent or incompatible provision set forth in any Task Order, this Agreement shall take precedence, unless both Parties specifically agree otherwise and reflect the same in the Task Order and have it signed by both Parties.

15.3 Waiver. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party so waiving. No waiver by any Party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

15.4 Severability. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

15.5 Amendment. No change or modification to this Agreement or any Task Order shall be binding unless in writing and signed by each Party.

15.6 Assignment. Neither Party may assign or transfer its interest hereunder or delegate its duties without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

15.7 No Inducement. Each Party hereby acknowledges that in executing this Agreement, such Party has not been induced, persuaded or motivated by any promise or representation made by any other Party, unless expressly set forth herein.

15.8 No Third Party Beneficiaries. This Agreement is for the sole benefit of the Parties hereto and their respective permitted successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

15.9 Return of Data and Records. At the completion of the Services by Southern Research, all Client work product and other data and records owned by Client, regardless of the method of storage or retrieval, shall be promptly delivered to Client at Client's request and at Client's expense. Southern Research may retain one archival copy of such materials as may be necessary for it to manage its ongoing obligations hereunder.

15.10 Notices. Any notice, request, approval or consent required to be given under this Agreement will be sufficiently given if in writing and delivered to a Party in person, by recognized overnight courier or mailed in the United States Postal Service, postage prepaid to the address set forth below, or at such other address as each Party so designates in accordance with these criteria. Notice shall be deemed effective upon receipt if delivered in person or by overnight courier or five (5) business days after mailing with the United States Postal Service.

In the case of Southern Research to:

Southern Research Institute

Attn: Lillie Ryans-Culclager
Director, Contracts and Proposals
2000 9th Avenue South
Birmingham, AL 35205-2708
lryans-culclager@southernresearch.org

In the case of Client to:

Tonix Pharmaceuticals, Inc.
509 Madison Ave, Suite 306
New York, NY 10022
Attn: Jessica Morris, Chief Operating Officer
Jessica.morris@tonixpharma.com

15.11 Cumulative Remedies. The rights and remedies under this Agreement are cumulative and are in addition to and not in substitution for any other rights and remedies available at law or in equity or otherwise.

15.12 Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction).

15.13 Force Majeure. No Party shall be liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement (except for any obligations to make payments to the other party hereunder), when and to the extent such failure or delay is caused by or results from acts beyond the affected Party's reasonable control, including, without limitation: (a) acts of God; (b) flood, fire, earthquake or explosion; (c) war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest; (d) government order or law; (e) actions, embargoes or blockades in effect on or after the date of this Agreement; (f) action by any governmental authority; (g) national or regional emergency; (h) strikes, labor stoppages or slowdowns or other industrial disturbances; and (i) shortage of adequate power or transportation facilities. The Party suffering a Force Majeure event shall give notice to the other Party, stating the period of time the occurrence is expected to continue and shall use diligent efforts to end the failure or delay and ensure the effects of such Force Majeure event are minimized.

15.14 Interpretation. Whenever used in this Agreement and when required by the context, the singular number shall include the plural and the plural the singular. Pronouns of one gender shall include all genders, masculine, feminine and neuter.

15.15 Headings. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

15.16 Counterparts. This Agreement and Task Orders may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement or a Task Order delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement, by their respective duly authorized representatives, on the day and year hereinafter written.

SOUTHERN RESEARCH INSTITUTE

By: Lillie Ryans
Name:
Title:
Digitally signed by Lillie Ryans
Date: 2018.11.26 10:20:32 -06'00'

TONIX PHARMACEUTICALS, INC

By: Jessica Morris
Name: Jessica Morris
Title: COO

Exhibit 21.01

SUBSIDIARIES OF THE COMPANY

Subsidiary Name	State/ Jurisdiction of Incorporation/Formation
Tonix Pharmaceuticals, Inc.	Delaware
Krele, LLC	Delaware
Tonix Pharmaceuticals (Canada), Inc.	New Brunswick, Canada
Tonix Pharma Holdings Limited	Ireland
Tonix Pharma Limited	Ireland
Tonix Medicines, Inc.	Delaware

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Pharmaceuticals Holding Corp. on Form S-1 (Nos. 333-234263, 333-235976) Form S-3 (Nos. 333-224586) and Form S-8 (Nos. 333-202006, 333-212300, 333-219928, 333-226776, and 333-232137) of our report dated March 24, 2020, on our audit of the consolidated financial statements as of December 31, 2019 and 2018 and for each of the years then ended, which report is included in this Annual Report on Form 10-K. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. Our report includes an explanatory paragraph that refers to a change in the method of accounting for leases due to the adoption of Account Standards Codification Topic 842, *Leases*.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 24, 2020

Exhibit 31.01

CERTIFICATION

I, Seth Lederman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 24, 2020

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

Exhibit 31.02

CERTIFICATION

I, Bradley Saenger, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 24, 2020

/s/ BRADLEY SAENGER

Bradley Saenger
Chief Financial Officer

Exhibit 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: March 24, 2020

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

I, Bradley Saenger, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: March 24, 2020

By: /s/ BRADLEY SAENGER
Name: Bradley Saenger
Title: *Chief Financial Officer*