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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2022

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

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.)
26 Main Street, Suite 101 **Chatham, New Jersey**	**07928**
(Address of principal executive office)	(Zip Code)

(862) 799-8599

(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, 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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and an "emerging growth company" in Rule 12b-2 of the Exchange Act

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, based on the closing sales price of the common stock as quoted on The NASDAQ Global Market was $50,022,154. For purposes of this computation, all officers and directors 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 13, 2023, there were 62,539,497 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 or will file with the SEC, which, among other places, can be found on the SEC's website at http://www.sec.gov, as well as on our corporate website at www.tonixpharma.com).

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.

Business Overview

We are a clinical-stage biopharmaceutical company focused on developing therapeutics and vaccines to treat and prevent human disease and alleviate suffering. We have a rich pipeline of products in development that has been curated from internal discovery, as well as licenses, acquisitions and collaborations with academic institutions and contract research organizations. We continue to build capabilities in synthetic biology, precision medicine, protein engineering, medicinal chemistry, molecular biology, pharmacogenomics and clinical-scale manufacturing. Our therapeutics under development include both small molecules and biologics.

Our portfolio consists of central nervous system, or CNS, rare disease, immunology, and infectious disease product candidates. The CNS portfolio includes small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Our rare disease portfolio focuses on developing novel therapies for patients with rare diseases, including those caused by genetic disorders which are characterized by complex symptoms and for which no drug is approved. Our immunology portfolio includes biologics to address organ transplant rejection, autoimmune diseases and cancer. Our infectious disease portfolio includes a vaccine in development to prevent smallpox and mpox (formerly known as monkeypox), next-generation vaccines to prevent COVID-19, a platform to make fully human monoclonal antibodies, or mAbs, to treat COVID-19 and humanized anti-SARS-CoV-2 mAbs. Our vaccine in development to prevent smallpox and mpox also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases.

Our latest stage CNS product candidate is TNX-102 SL*, a proprietary sublingual tablet formulation of cyclobenzaprine (CBP) designed for bedtime administration. TNX-102 SL has active INDs for fibromyalgia, or FM, FM-type Long COVID or PASC (post-acute sequelae of SARS-CoV-2 infection), posttraumatic stress disorder, or PTSD, agitation in Alzheimer's disease, or AAD, and alcohol use disorder, or AUD.

TNX-102 SL is in mid-Phase 3 development for the management of FM, a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. In December 2020, we reported positive results from the Phase 3 RELIEF study of TNX-102 SL 5.6 mg for the management of FM. In July 2021, we reported pre-planned interim analysis results from a second Phase 3 study, RALLY. Based on the recommendation from the independent data monitoring committee (IDMC) that the RALLY trial was unlikely to demonstrate a statistically significant improvement in the primary endpoint, we stopped enrollment of new participants but allowed those participants who were already enrolled to complete the study. We reported topline data from the completed study in March of 2022. As expected, based on interim analysis results, TNX-102 SL did not achieve statistical significance over placebo on the primary endpoint of reduction in daily pain, and relative to the previous positive Phase 3 Study (RELIEF), RALLY had an unexpected

increase in study participant adverse event-related discontinuations in both drug and placebo groups. In April 2022, we started a new potentially confirmatory Phase 3 study of TNX-102 SL in FM, RESILIENT. Interim analysis results are expected in the second quarter of 2023 and topline results are expected in the fourth quarter of 2023. Following a positive outcome of the RESILIENT study, Tonix believes we would be positioned to file a New Drug Application (NDA) for TNX-102 SL for the management of FM.

TNX-102 SL is also being developed as a potential treatment for a type of Long COVID, the symptoms of which overlap with FM, that we term FM-type Long COVID. We initiated enrollment in the Phase 2 study PREVAIL, in August 2022. The primary endpoint is a change in daily pain scores from baseline.

For TNX-102 SL in PTSD, we completed the Phase 3 RECOVERY trial and reported topline results in the fourth quarter of 2020 in which TNX-102 SL did not meet the primary efficacy endpoint. PTSD is a serious psychiatric condition that develops in response to experiencing a traumatic event. We subsequently completed a meeting with the FDA to discuss potential new endpoints going forward for the indication of treatment of PTSD. Future studies will employ the one month look-back CAPS-5 as the primary endpoint rather than the one week look-back as used in prior studies.

The AAD program is Phase 2 ready with an active IND and FDA Fast Track designation. AAD, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of the behavioral complications of Alzheimer's disease. Tonix does not have any near-term plans to start a Phase 2 study in AAD.

The AUD program is also Phase 2 ready with an active IND. 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 alcohol. Tonix does not have any near-term plans to start a Phase 2 study in AUD.

TNX-1900* (intranasal potentiated oxytocin) is in development for the treatment of chronic migraine and obesity-associated binge eating disorder, or BED. TNX-1900 was acquired from Trigemina, Inc. and licensed from Stanford University in 2020. The potentiated formulation includes magnesium, which has been shown in animal studies to potentiate binding of oxytocin to the oxytocin receptor. We received IND clearance from the FDA in the fourth quarter of 2021 to study TNX-1900 in chronic migraine and we initiated a Phase 2 study in migraine in the first quarter of 2023. We expect interim analysis results from the first 50 percent of patients enrolled in the fourth quarter of 2023. In March 2022, we announced an agreement with Massachusetts General Hospital, a teaching hospital of Harvard Medical School, to conduct an investigator-initiated Phase 2 clinical trial to study TNX-1900 in BED. The Phase 2 clinical trial is expected to start in the second quarter of 2023. We do not own an IND for BED. We also licensed technology to use TNX-1900 for the treatment of insulin resistance from the University of Geneva and also have rights to develop it as a treatment for craniofacial pain, but we are not imminently pursuing clinical trials in either of these indications at this time.

TNX-601 ER* (tianeptine hemioxalate extended-release tablets) is a CNS product candidate in development as a treatment for major depressive disorder, or depression, and with possible additional indications of PTSD, and neurocognitive dysfunction associated with corticosteroid use. TNX-601 ER represents a novel approach to treating depression in the U.S., since the active ingredient tianeptine induces a neuroprotective and resilient phenotype in both neurons and microglia under conditions of stress in animals. The dramatic and unique effects of tianeptine are illustrated in animal models by the restoration of dendritic arborization of pyramidal neurons of CA3 region of hippocampus and the dentate gyrus region new neuron formation and integration into hippocampal networks. In contrast, antidepressants that are marketed in the U.S. act by modulating the levels or receptor binding of neurotransmitters in the synapse. We have completed a Phase 1 trial for formulation development outside of the U.S. We expect to initiate a potentially pivotal Phase 2 study in the first quarter of 2023 for the treatment of major depressive disorder and we expect interim analysis results from the first 50 percent of patients enrolled in the fourth quarter of 2023.

Another CNS candidate in development is TNX-1300* (double-mutant cocaine esterase) which is in Phase 2 for the treatment of life-threatening cocaine intoxication. TNX-1300 has been granted Breakthrough Therapy designation, or BTD, by the U.S. Food and Drug Administration, or FDA. TNX-1300 was licensed from Columbia University in 2019 after a Phase 2 study showed that it rapidly and efficiently disintegrates cocaine in the blood of volunteers who received intravenous, or i.v., cocaine. In August of 2022, we received a Federal Grant from the National Institute on Drug Abuse (NIDA) to advance the development of TNX-1300 as a treatment for cocaine intoxication. We expect to initiate a potentially pivotal Phase 2 study of TNX-1300 in emergency rooms in the second quarter of 2023.

Finally, our CNS pipeline includes TNX-1600*, an inhibitor of the reuptake of neurotransmitters serotonin, norepinephrine and dopamine, or a triple reuptake inhibitor. TNX-1600 was licensed from Wayne State University in 2019 and is expected to be developed as a treatment for PTSD, depression and attention-deficit/hyperactivity disorder, or ADHD. TNX-1600 is in the preclinical stage of development.

Our rare disease portfolio consists of TNX-2900*, another magnesium-potentiated intranasal oxytocin-based therapeutic in development for the treatment of Prader-Willi syndrome, or PWS. The technology for TNX-2900 was licensed from Inserm, the French National Institute of Health and Medical Research. PWS, an orphan condition, is a rare genetic disorder of failure to thrive in infancy, associated with uncontrolled appetite beginning in childhood with complications of obesity and diabetes. We have sponsored a research

program at Inserm to study oxytocin on suckling behavior in mice that have been engineered to express one of the Prader-Willi genes. TNX-2900 has been granted Orphan-Drug Designation for the treatment of PWS and is in the pre-IND stage of development.

Our lead candidate in the immunology pipeline is TNX-1500*, a humanized mAb, directed against CD40-ligand, or CD40L (also known as CD154), engineered to modulate binding to Fc receptors, that is being developed as a prophylaxis against organ transplant rejection as well as to treat autoimmune conditions. In experiments at the Massachusetts General Hospital or MGH, a teaching hospital of Harvard Medical School, TNX-1500 is being studied as monotherapy or in combination with other immunosuppressive agents in heart and kidney allogeneic organ transplants in non-human primates. Preliminary results from ongoing experiments in kidney and heart transplants indicate that TNX-1500 appears to have comparable efficacy to historical experiments using the chimeric mouse/human IgG1 version (5c8H1) of the anti-CD40L mAb 5c8. First generation anti-CD40L mAb therapies were associated with an increased risk of blood clots or thrombosis. In the non-human primate studies with TNX-1500 for the prevention of rejection in allogeneic organ transplants, no evidence of thrombosis has been observed so far. We expect to start a Phase 1 study of TNX-1500 in the second quarter of 2023. TNX-1500 also is being studied in combination with other immunosuppressive agents in xenogeneic organ transplants in non-human primates at MGH and at the University of Maryland at Baltimore or UMB. In experiments at UMB, TNX-1500 is being studied to prevent rejection of xenogeneic hearts from genetically engineered pigs developed by the Revivicor division of United Therapeutics Corporation.

Our immunology pipeline also includes TNX-1700*, a recombinant Trefoil Factor Family 2, or rTFF2, fusion protein that was licensed from Columbia University in 2019. TNX-1700 consists of TFF2 fused to human serum albumin or HSA and is a biologic being developed to treat gastric and colorectal cancers by an immune-oncology mechanism, in combination with PD1 blockers, and is in the preclinical stage of development. We recently presented data that show a murine version of TNX-1700 consisting of a fusion protein with murine serum albumin or MSA was able to evoke anti-tumor immunity in the MC38 mouse model of colorectal cancer as monotherapy and that TNX-1700 augmented the efficacy of anti-PD1 therapy in both the MC38 model and the CT26.wt mouse models of colorectal cancer.

Our infectious disease portfolio includes vaccines based on our live virus vaccine or recombinant pox vaccine, "RPV" platform. Live virus vaccines are believed to protect against poor clinical outcomes of infectious diseases by eliciting T cell responses in addition to antibody responses. TNX-801*, a live attenuated vaccine based on synthesized horsepox, is in the pre-IND stage of development to protect against smallpox and mpox. Non-human primates vaccinated with TNX-801 were protected from mpox in studies reported in the first quarter of 2020. A Phase 1 study of TNX-801 in humans is expected to start in the second half of 2023. TNX-801 also serves as the live virus vaccine platform for other infectious diseases for which subsequent products will be designed by expressing other viral antigens in the horsepox vector.

TNX-1850* is a live virus vaccine that expresses the SARS-CoV-2 spike protein from the BA.2 strain that has not yet been tested in animals. TNX-1800* is a live virus vaccine that expresses the SARS-CoV-2 spike protein from the ancestral Wuhan strain, which has shown encouraging results in non-human primates. Because the subsequent omicron variant out-competed the ancestral Wuhan strain, we began work on new vaccine versions, TNX-1840* and TNX-1850*, that are designed to express spike protein from the omicron variant and from the BA.2 variant, respectively. Of those, based on the trajectory of COVID-19, the focus is now on TNX-1850. The COVID-19 vaccines that are approved for use, or have emergency use authorization, or EUA, in the U.S. have provided significant health benefits to the vaccinated population; however, they have shown limitations in the durability of protection conferred and in their ability to block forward transmission. Live virus vaccines that protect against other viral diseases by eliciting T cell responses have shown durability of protection that lasts years to decades and some live virus vaccines have significantly inhibited forward transmission. With respect to TNX-1800 vaccination, we reported positive efficacy data from animal challenge studies using live SARS-CoV-2 in the first quarter of 2021. In this study, TNX-1800 vaccinated, SARS-CoV-2 challenged animals had undetectable SARS-CoV-2 in the upper airways, which we believe relates to potential inhibition of forward transmission of this respiratory pathogen.

TNX-2300* is a live virus vaccine based on bovine parainfluenza virus in development to protect against COVID-19. In April 2022, Tonix extended a sponsored research agreement with Kansas State University to develop a vaccine candidate, TNX-2300, for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform based on bovine parainfluenza virus. The efficacy of co-expression of the CD40-ligand, also known as CD154, to stimulate T cell immunity will also be tested. Attenuated bovine parainfluenza virus has previously been shown to be an effective antigen delivery vector in humans. Previous work by others has shown that attenuated BPI3V is well tolerated and immunogenic in non-human primates and human infants and children. We believe the vector is well suited for mucosal immunization using a nasal atomizer, and can also be delivered parenterally. TNX-2300 is in the preclinical stage of development.

TNX-3600* and TNX-3800* are mAbs directed against SARS-CoV-2 which are in development as potential therapeutic or preventative agents for COVID-19. Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants, we seek to contribute a broad set of anti-SARS-CoV-2 mAbs, that can be scaled up quickly and potentially combined with other mAbs. We envision the future of mAb therapy for COVID-19 to be cocktails of mAbs with specificity to variants of concern. TNX-3600 refers to a series of fully human mAbs generated by human-human hybridomas from COVID-19 convalescent volunteers. We are collaborating with Columbia University to produce these fully human mAbs to SARS-CoV-2 spike proteins from variants such as delta, omicron and XBB1.5 and to other viral targets. TNX-3800 refers to three humanized murine mAbs which we licensed exclusively in December 2022 from Curia

Global, Inc. for the treatment or prophylaxis of SARS-CoV-2 infection. The initial focus is to develop COVID-19 therapeutic mAbs. We plan to seek indications similar to previously EUA-approved therapeutic mAbs for treating individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease or for prophylaxis in individuals with compromised immune systems who are at high risk for severe COVID-19 disease. None of the previously EUA-approved therapeutic or preventative mAbs are still available, because each has become obsolete since the SARS-CoV-2 virus has mutated to evade their binding. TNX-3600 and TNX-3800 mAbs may also be used in combination therapy with other COVID-19 therapeutic mAbs. Combination therapies with other anti-SARS-CoV-2 mAbs may reduce the emergence of resistant viral strains. TNX-3600 and TNX-3800 are in the preclinical stage of development.

TNX-3700* is a COVID-19 mRNA vaccine candidate employing a zinc nanoparticle (ZNP) formulation. In collaboration with Kansas State University, we are developing this ZNP technology as a potential replacement for the lipid nanoparticle (LNP) technology used in current mRNA vaccines. ZNP technology potentially allows for improved stability which facilitates shipping and storage and addresses the limitations in current mRNA vaccines which require ultra-cold storage and shipping. This current requirement limits the use of mRNA vaccines in less developed countries. We plan to seek initial indications as a booster, similar to the current FDA approved mRNA vaccines for COVID-19. We intend to conduct research with Kansas State University on ZNP SARS-CoV-2 spike based vaccines in tissue culture and animals in the first half of 2023. TNX-3700 is in the preclinical stage of development.

Relating to our COVID-19 and other infectious disease development programs, we are developing the resources necessary to enable internal research, development and manufacturing capabilities necessary to meet the goal of producing new vaccine candidates within 100 days of recognition within weeks of obtaining sequence information from a novel pathogen. We seek to be a leader in the movement to re-build domestic U.S. research, development and manufacturing capabilities. Because this movement follows a protracted period when domestic research, development and manufacturing were moved out of the U.S., or "off-shore" by other companies to save on labor and other costs, the movement to reverse that trend has been described as "on-shoring" or "re-domestication". The COVID-19 pandemic taught that national borders may close during a health emergency. Therefore, domestic capabilities are essential for the health security of the U.S., which has also been described as pandemic preparedness and biodefense. As articulated in the American Pandemic Preparedness Plan, or AP3, released by the U.S. Office of Science and Technology Policy, this 100-day goal for vaccines is a key component of preparedness for future pandemics. We believe we have established the infrastructure necessary to support the pandemic preparedness goals established in the AP3, specifically with respect to our RPV vaccine and potentially to other vaccine and therapeutic platforms. This infrastructure consists of (i) our R&D Center, or "RDC", (ii) our Advanced Development Center, or "ADC", and (iii) our Commercial Manufacturing Center, or "CMC". We acquired the RDC in Frederick, Maryland consisting of one building totaling approximately 48,000 square feet. The acquisition closed in October 2021 and the facility is operational. The RDC facility focuses on our development of vaccines and antiviral drugs against SARS-CoV-2, its variants, and other infectious diseases. The RDC also conducts research on central nervous systema and immunology drugs. The RDC facility is mostly biosafety level 2 (BSL-2), with some components designated BSL-3. We completed the substantial renovation of the ADC located in the New Bedford business park in Dartmouth, Massachusetts, which became operational as of the fourth quarter 2022. This approximately 45,000 square foot BSL-2 facility is intended to accelerate development and clinical scale manufacturing of live-virus vaccines and biologics to support clinical trials. We also plan to build the CMC in Hamilton, Montana, where we purchased approximately 44 acres of land and have built a field office to manage construction of the facility. The CMC will focus on developing and manufacturing commercial scale live-virus vaccines and biologics and is also intended to be BSL-2. Site enabling work is expected to be initiated for the CMC in 2023. Together, we expect these facilities may qualify the RPV vaccine platform for programs that are designed to carry out the goals of AP3.

*All of our product candidates are investigational new drugs or biologics and have not been approved for any indication.

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.

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 Capital Market under the symbol "TNXP". Our principal executive offices are located at 26 Main Street, Suite 101, Chatham, New Jersey 07928, and our telephone number is (862) 799-8599. Our website address is www.tonixpharma.com.

Our Strategy

Our strategy is to use our integrated development engine to advance innovative programs across multiple therapeutic areas into the clinic while maximizing asset potential, with the objective of developing and commercializing our product candidates. The principal components of our strategy are to:

- ***Pursue CNS, rare disease, immunology, and infectious disease indications with high unmet medical need and significant commercial potential.*** Within the therapeutic areas that Tonix is focusing on, we are pursuing multiple indications that are underserved with limited, effective treatment options. One of our latest stage product candidates, TNX-102 SL for the management of FM, a condition which affects between 6-12 million adults in the U.S. and fewer than half of those treated for FM receive relief from the three FDA-approved drugs.

  We are also pursuing a treatment using TNX-102 SL for FM-type Long COVID, a condition for which there is no currently approved therapy. Our broader development strategy is to leverage the patented formulation and proven mechanism of action to explore the clinical potential of TNX-102 SL in multiple other, psychiatric, and addiction conditions, including PTSD, Agitation in Alzheimer's disease and Alcohol Use Disorder (AUD), all of which are underserved by currently approved medications or have no approved treatment thus representing large unmet medical needs. Within CNS, Tonix is also developing TNX-1900 to treat chronic migraine, TNX-601 ER to treat major depressive disorder and TNX-1300 to treat cocaine intoxication. Although a number of drugs are approved for chronic migraine and major depressive disorder, there remains dissatisfaction with available options. Cocaine intoxication is one of the leading causes of overdose deaths and for which there is no currently approved drug. With TNX-1500, we are pursuing a treatment to prevent organ transplant rejection as well as autoimmune conditions. TNX-1500 is a third generation humanized mAb targeting the CD40L that has the potential to deliver efficacy without compromising safety, based on modulated binding to Fc receptors. At this time, no mAb against CD40L has been licensed anywhere in the world. Within infectious diseases, we are currently focusing on the development of TNX-801 to prevent smallpox and mpox, and TNX-1850 to protect against COVID-19. While there are FDA-approved vaccines to prevent smallpox and mpox, we believe TNX-801 has potential to provide durable protection. While there are FDA-approved COVID-19 vaccines which use mRNA technology, or other technologies, we believe that there are limitations to these vaccines relating to durability of protection and their relative inability to block forward transmission.

- ***Maximize the commercial potential of our lead product candidates***. We plan to commercialize each of our lead product candidates, including our latest stage candidate, TNX-102 SL, either on our own or through collaboration with partners. We believe our lead candidates can be marketed to U.S. physicians either by an internal sales force that we would 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 commercialization.

- ***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 case 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. In the case of TNX-801 and TNX-1850, we own patent applications protecting their composition-of-matter and certain methods of use. We also own patents through in-licensing transactions for TNX-1300, TNX-1900, TNX-2900, and TNX-1700. We own patents outright for TNX-601 ER and have filed patent applications for TNX-1500 and TNX-3700. We plan to opportunistically apply for new patents to protect our product candidates.

- ***Pursue additional indications and commercial opportunities for our product candidates.*** We will seek to maximize the value of 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 TNX-102 SL for generalized anxiety disorder, depression, and fatigue related to disordered sleep. For TNX-1900, we own the rights to develop this for craniofacial pain, episodic migraine, acute migraine and insulin resistance, in addition to chronic migraine. For TNX-601 ER, we own the rights to develop this for PTSD and neurocognitive disorder from corticosteroid use, in addition to major depressive disorder. Finally, our live virus platform using our RPV technology may be developed as vaccines for future pandemics, infectious diseases generally and oncology, in addition to smallpox and mpox.

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 product candidates in or nearing the clinical-stage is set forth below.

Central Nervous System

Fibromyalgia (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.

Long COVID

Long COVID, or PASC, is a condition that some survivors of COVID-19 infection experience in varying degrees of severity. It is a chronic disabling condition that is expected to result in a significant global health and economic burden. We are focusing development of TNX-102 SL on FM-type Long COVID. The symptoms include intense fatigue, sleep problems, multi-site pain, and cognitive issues ("brain fog"). The proposed indication is for the management of multi-site pain associated with PASC.

Post infection, many patients experience one or many of the symptoms of Long COVID: some patients have initial symptoms that become prolonged; others manifest entirely new syndromes that impact more than one system or organ. According to a 2021 publication in the Journal of American Medical Association (JAMA), over 1 in 10 healthcare workers who had recovered from COVID-19 were still coping with at least one moderate to severe symptom eight months later. Research shows that Long COVID occurs in approximately 13% of recovered COVID-19 patients. There is currently no approved drug for the treatment of Long COVID.

Migraine Headaches

Migraine is a primary headache disorder characterized by recurrent headaches that are moderate to severe. Typically, episodes affect one side of the head, are pulsating in nature, and last from a few hours to three days. Associated symptoms may include nausea, vomiting, and sensitivity to light, sound, or smell. The pain is generally made worse by physical activity, although regular exercise may have prophylactic effects. Up to one-third of people affected have aura, typically a short period of visual disturbance that signals that the headache will soon occur. Occasionally, aura can occur with little or no headache following it. Approximately one billion individuals worldwide suffer from migraine (~14% of the population). Migraine is the second leading cause of years lived with disability. Chronic migraine (≥ 15 headache/migraine days per month) affects about 1-2% of individuals (~75-150 million individuals worldwide; 3-7 million in the U.S.). CGRP antibodies are the only migraine specific prophylaxis drugs approved in decades, but they require parenteral administration and there are long term safety concerns with prolonged systemic blockade of CGRP or its receptor.

Major Depressive Disorder

According to the Substance Abuse and Mental Health Services Administration, an estimated 21.0 million adults in the U.S. in 2020 experienced at least one major depressive episode, representing 8.4% of all U.S. adults. According to the National Institute of Mental Health, depression affects approximately 17 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 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, cocaine-involved deaths rose nearly 54% from 2019 to 2021, resulting in over 24,486 deaths total.

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.

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 several have significant safety liabilities and dependence risk.

Rare Disease

Prader-Willi Syndrome

Prader-Willi syndrome (PWS) is recognized as the most common genetic cause of life-threatening childhood obesity and affects males and females with equal frequency and all races and ethnicities. The hallmarks of PWS are lack of suckling in infants and, in children and adults, severe hyperphagia, an overriding physiological drive to eat, leading to severe obesity and other complications associated with significant morbidity and mortality. PWS is an orphan disease that occurs in approximately one in 15,000 births. There is currently no approved treatment for obesity and hyperphagia in adults and older children associated with PWS.

Immunology

Organ Transplant Rejection

Organ transplant rejection occurs when the immune system of the organ recipient attacks the new organ as if it was an infection or tumor. Often transplantation is the last resort for most end-stage organ failure patients, affecting either kidneys, liver, heart, lungs, and/or pancreas. Genetic disparity between organ donor and recipient is often at the root of the rejection. Mismatched or not closely matched organs triggers an immune reaction that leads to rejection. Overcoming this difficulty is paramount to a patient's survival as organ donations are in limited supply.

Gastric and Colorectal cancers

Gastric or stomach cancer is a disease in which malignant cancer cells line the inner lumen of the stomach. Development of this form of cancer is often influenced by age, diet and other stomach diseases. This type of cancer begins to form in the mucosa, the surface of the lumen that is in direct contact with the contents of the stomach, and spreads through the outer layers of the stomach as the tumor grows.

Currently, per the National Cancer Institute, the 5-year relative survival for stomach cancer is 33.3%. According to 2017-2019 data, approximately 0.8 percent of men and women will be diagnosed with stomach cancer during their lifetime. In 2019, there were an estimated 123,920 people living with stomach cancer in the U.S.

Colorectal cancer includes cancers in the colon and the rectum, organs that are crucial to absorption of water by the body and the elimination of food-waste. Most colorectal cancers start as a growth or polyp on the inner lining of the colon or rectum. Some types of polyps can change into cancer over time (usually many years), but not all polyps become cancer. Adenomatous polyps are the ones that turn malignant with time. Similar to gastric cancer, the malignancy begins in the mucosal layer and spreads outwards.

The 5-year relative survival rate is 65.1%, per the National Cancer Institute. According to 2017-2019 data, approximately 4.1 percent of men and women will be diagnosed with colorectal cancer during their lifetime. In 2019, there were an estimated 1,369,005 people living with colorectal cancer in the United States.

Infectious Diseases

Smallpox and Mpox

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. Mpox is an acute contagious disease caused by the monkeypox virus or MPXV, which is also a member of the orthopoxvirus family. Mpox symptoms are similar to those of smallpox, although less severe. Mpox is emerging as an important zoonotic infection in humans in Central and West Africa. Until 2022, only a few cases of mpox had been reported outside of Africa in patients who had been infected while in Africa. Starting in May of 2022, mpox cases spread rapidly in the U.S. and other countries. More than 30,000 cases in the U.S. have been reported according to the U.S. Centers for Disease Control and Prevention.

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. Vaccines for smallpox and mpox are stockpiled by the U.S. government in the strategic national stockpile and for potential widespread immunization in the event of malicious reintroduction of VARV.

COVID-19

SARS-CoV-2 is a contagious virus causing the disease COVID-19 that became a global pandemic in 2019 and has resulted in more than three million deaths. While the infection and mortality rates have slowed in regions of the world with high vaccination rates, the struggle with the pathogen is ongoing and evolving since SARS-CoV-2 is mutating into new variants. COVID-19 is characterized by fever, sore throat, acute shortness of breath, cough, and oxygen desaturation in the blood. At least three major variants have swept across the world in successive waves and overwhelmed healthcare systems during these waves. With new variants of the virus emerging, therapeutic research is addressing the challenge of keeping up with this rapidly mutating virus. The early vaccines have been effective in limiting the severity of disease in vaccinated individuals. Vaccines that elicit strong T cell responses are believed to have the potential to provide long-term or durable protection.

Lead Product Candidates

We believe that our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to available therapies. We have worldwide commercialization rights to all of our product candidates listed below. The following table summarizes our later stage product candidates that are in or nearing the clinic:

Product Candidate	Indication	Stage of Development
TNX-102 SL	Fibromyalgia	Mid-Phase 3, >50% enrolled
TNX-102 SL	FM-type Long COVID	Phase 2 enrolling
TNX-1900	Chronic migraine	Phase 2, enrolling
TNX-601 ER	Depression	Phase 2, targeted 1Q 2023 start
TNX-1300	Cocaine Intoxication	Mid-Phase 2, targeted 2Q 2023 start
TNX-1500	Kidney Transplant Rejection	Phase 1, targeted 2Q 2023 start
TNX-801	Smallpox and Mpox vaccine	Phase 1, targeted 2H 2023 start
TNX-2900	Prader-Willi Syndrome	Phase 1

TNX-102 SL

Overview

TNX-102 SL, in clinical development for registration in five 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, PTSD, PASC or Long Covid, AAD and AUD. 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 cyclobenzaprine or CBP.

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

The active ingredient in TNX-102 SL, is 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 including muscarinic M1 and histaminergic H1 receptors.

CBP is the active ingredient of two products that are approved in the U.S. for the treatment of muscle spasm: Flexeril® (5 mg and 10 mg oral immediate-release, or IR, tablet) and Amrix® (15 mg and 30 mg oral extended-release capsule). The Flexeril brand of CBP IR tablet has been discontinued since May 2013. There are numerous generic versions of CBP IR tablets on the market. CBP-containing products are approved for short term use (two to three weeks) only as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. CBP IR 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 CBP IR 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. 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 compared to Amrix. 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, with Amrix as the reference listed drug, or RLD. 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, Long COVID, 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 active IND application. The potential approval of TNX-102 SL for FM is expected to be under Section 505(b)(2) of the FDCA.

Clinical Development Plan

Phase 3 RESILIENT (F307)

The first patient was enrolled in the potentially pivotal Phase 3 RESILIENT study in April 2022. The RESILIENT 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 two-arm trial is expected to enroll approximately 470 participants in the U.S. and was 50% enrolled as of December 2022. The first two weeks of treatment consist of a run-in period in which participants start on TNX-102 SL 2.8 mg (1 tablet) or placebo. Thereafter, all participants increase their dose to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks. The primary endpoint is the daily diary pain severity score change (TNX-102 SL 5.6 mg vs. placebo) 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. An interim analysis by an IDMC will be conducted on the primary endpoint based on the first 50% of enrolled participants for a potential sample size adjustment or early stop for futility. Interim data is expected in the second quarter of 2023. Topline data is expected in the fourth quarter of 2023.

Completed Phase 3 RALLY Study (F306)

We reported pre-planned interim analysis results from a Phase 3 study, RALLY (F306), in July 2021. Based on the recommendation from the independent data monitoring committee that the RALLY trial was unlikely to demonstrate a statistically significant improvement in the primary endpoint, we stopped enrollment of new participants but allowed those participants who were already enrolled to complete the study. We reported topline data from the completed study in March of 2022. As expected based on interim analysis results, TNX-102 SL did not achieve statistical significance over placebo on the primary endpoint of reduction in daily pain, and relative to the previous positive Phase 3 Study (RELIEF), RALLY had an unexpected increase in study participant adverse event-related discontinuations in both drug and placebo groups. The RALLY study was a double-blind, randomized, placebo-controlled adaptive design trial intended to evaluate the efficacy and safety of TNX-102 SL in FM. The trial was expected to enroll approximately 670 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there was a run-in period in which patients started on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients had 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 was 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.

Completed Phase 3 RELIEF Study (F304)

In the fourth quarter of 2020, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 3 study of TNX-102 SL in 503 participants with FM, which we refer to as the RELIEF 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 5.6 mg, administered sublingually once daily at bedtime for 12 weeks. The primary endpoint of the RELIEF trial was the 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 achieved statistical significance on the primary efficacy endpoint: change from baseline in the weekly average of daily diary pain severity numerical rating scale (NRS) scores for TNX-102 SL 5.6 mg (LS mean [SE]: -1.9 [0.12] units) versus placebo (-1.5 [0.12] units), analyzed by mixed model repeated measures with multiple imputation (LS mean [SE] difference: -0.4 [0.16] units, p=0.010).

The statistically significant improvement in pain is further substantiated when diary pain was analyzed by another standard statistical approach, a 30 percent responder analysis, with 46.8% on active and 34.9% on placebo having a 30 percent or greater reduction in pain (logistic regression; odds ratio [95% CI]: 1.67 [1.16, 2.40]; p=0.006). Consistent with the proposed mechanism that TNX-102 SL acts in fibromyalgia through improving sleep quality, TNX-102 SL showed nominal improvement of sleep by several measures. For daily diary sleep quality ratings, TNX-102 SL (-2.0 [0.12] units) compared to placebo (-1.5 [0.12] units) was nominally significant (LS mean difference: -0.6 [0.17] units; p<0.001). For the PROMIS Sleep Disturbance instrument, TNX-102 SL was also nominally significant over placebo on T-scores (LS mean difference: -2.9 [0.82] units; p<0.001). The effect sizes on the diary sleep ratings and PROMIS Sleep Disturbance instrument were 0.31 and 0.32, respectively.

In the RELIEF study, TNX-102 SL was similarly well tolerated as in the Phase 2 BESTFIT and Phase 3 AFFIRM studies, which both studied TNX-102 SL at a lower dose of 2.8 mg daily. There were no new safety signals observed in the RELIEF study at the 5.6 mg daily dose. Among participants randomized to the TNX-102 SL and placebo arms, 82.3% and 83.5%, respectively, completed the 14-week dosing period. As expected, based on prior TNX-102 SL studies, administration site reactions are the most commonly reported adverse events and were higher in the TNX-102 SL treatment group, including rates of oral numbness (17.3% vs. 0.8%), oral pain/discomfort (11.7% v. 2.0%), taste impairment (6.5% vs. 0.4%), and oral tingling (5.6% v. 0.4%). Oral numbness or tingling and taste impairment were local administration site effects nearly always temporally related to dose administration and transiently expressed (<60 minutes) in almost all occurrences. The only systemic treatment-emergent adverse events that occurred at a rate of 5.0% or greater in either arm was somnolence/sedation at 5.6% in the TNX-102 SL arm vs. 1.2% in placebo, which was consistent with known side effects of marketed oral cyclobenzaprine. Adverse events resulted in premature study discontinuation in 8.9% of those who received TNX-102 SL compared with 3.9% of placebo recipients. There was a total of seven serious adverse events reported during the study, none of which were deemed related to investigational product; five in placebo arm, and two in TNX-102 SL arm. Of the two in the TNX-102 SL arm, one was a motor vehicle accident with multiple bone fractures, and the other was a pneumonia secondary to an infection.

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 Fibromyalgia 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).

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.

Other NDA Requirements

The Agreed Initial Pediatric Study Plan, or Agreed iPSP, was accepted by the FDA in September 2015. An amendment to the Agreed iPSP will be submitted for FDA agreement prior to marketing application.

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.

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

We have completed the required Phase 1 bioequivalence, multi-dose bridging pharmacokinetic, and food effect and dose-proportionality studies.

Cyclobenzaprine Hydrochloride Nonclinical Development

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. 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 potential is not required to support the TNX-102 SL NDA filing.

We are planning to develop TNX-102 SL for the treatment of FM in Japan. Cyclobenzaprine, the active ingredient of TNX-102 SL, has not been approved in Japan, and is considered a NCE (new chemical entity). In February 2022, we held an End of Phase 2 Consultation with the Pharmaceuticals and Medical Devices Agency, or PMDA, an independent administrative institution responsible for ensuring the safety, efficacy and quality of pharmaceuticals and medical devices in Japan, to discuss the Japan development plan. Agreement was reached on the design of a Phase 1 bridging study (TNX-CY-F108/F108) in ethnic Japanese healthy volunteers to enable clinical studies of TNX-102 SL in Japan. PMDA also provided guidance on the overall nonclinical package to support a Japan NDA filing for TNX-102 SL for the treatment of FM.

The F108 Phase 1 study was initiated in March 2022 and the clinical phase was completed in May 2022 and we are awaiting the final study report at the time of this filing.

We are completing nonclinical safety, pharmacology and embryo-fetal development toxicology studies as part of the agreed IND-enabling nonclinical data package to support clinical studies of TNX-102 SL in Japan.

TNX 102 SL – FM-type Long COVID Program

We are developing TNX-102 SL as a bedtime treatment for FM-type Long COVID. The potential approval of TNX-102 SL for Long COVID is expected to be under Section 505(b)(2) of the FDCA.

Phase 2 PREVAIL Study (PA201)

We initiated a Phase 2 study of TNX-102 SL as a treatment for FM-type Long COVID, which is a subset of patients affected by Long COVID whose symptoms overlap with fibromyalgia. The trial initiated in August 2022. The study is a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of TNX-102 SL for FM-type Long COVID.

We completed a pre-IND meeting with the FDA in August 2021 to develop TNX-102 SL as a potential treatment for Long COVID. Long COVID is a protracted syndrome experienced by many people following SARS-CoV-2 infection that can include a number of persistent disabling symptoms, including fatigue, widespread pain, sleep disturbance, brain fog or difficulty concentrating, arthralgias, diffuse myalgia, olfactory dysfunction, and headache. The currently enrolling Phase 2 study focuses on Long COVID patients whose primary symptoms overlap with fibromyalgia, and, therefore, the Long COVID program leverages learnings about the pharmacodynamic activity of TNX-102 SL from more than 1,000 participants who have been or are enrolled in our fibromyalgia trials to date. Long COVID has been compared to fibromyalgia because of the common symptoms of sleep disturbance, persistent widespread pain, fatigue, and brain fog. Additionally, Long COVID, like fibromyalgia, is experienced by women at a rate approximately four times that of men.

TNX-102 SL – Posttraumatic Stress Disorder Program

We are developing TNX-102 SL as a bedtime treatment of PTSD under an active IND application. The potential approval of TNX-102 SL for PTSD is expected to be under Section 505(b)(2) of the FDCA.

Phase 3 RECOVERY Study (P302)

We initiated the RECOVERY study (P302) in March 2019. The RECOVERY Phase 3 study was 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 was conducted at approximately 30 U.S. sites. The study planned to enroll 250 participants with civilian and military-related PTSD. 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 in P302 was 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 (IA) results of the first 50% of enrolled participants, an IDMC 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 continued studying those participants currently enrolled until completion and proceeded with a full analysis of the unblinded data to determine the next steps in this program. Topline data was reported during the fourth quarter of 2020, which revealed that the RECOVERY study did not achieve statistical significance in the prespecified primary efficacy endpoint of change from baseline to Week 12 in the CAPS-5 between TNX-102 SL and placebo (p=0.343; effect size (ES)=0.15). TNX-102 SL separated from placebo in the first key secondary endpoint, CGI-S scale (p=0.024; ES=0.36) and in the PGIC, (p=0.007; ES=0.43). TNX-102 SL also trended for improvement on the PROMIS Sleep Disturbance scale (p=0.055; ES=0.30), consistent with the proposed mechanism of targeting the PTSD sleep disturbance. TNX-102 SL is generally well tolerated and no new safety signals were observed. Tonix met with the FDA to discuss potential new endpoints for the indication of treatment of PTSD. The next PTSD study can use 1 month look-back CAPS-5 as endpoint v. 1 week look-back.

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, i.e. IDMC recommended stopping for futility. The modified Intent-to-Treat (mITT) population analyzed at the time of the IA included 252 participants.

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 next Phase 3 study in PTSD, RECOVERY.

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.

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.

Manufacturing

TNX-102 SL drug product for Phase 3 and the associated registration batches for the NDA were manufactured at commercial cGMP facilities. We currently have 36-month stability data in the proposed packaging configurations ready for commercialization. The FDA has reviewed the proposed CMC data package to support TNX-102 SL's NDA approval and commercial manufacturing plans as part of the IND process. Tonix is ready to manufacture TNX-102 SL commercial product for the forecasted FM market.

TNX-1900 – Migraine, Craniofacial Pain and Obesity-Associated Binge Eating Disorder

TNX-1900 (intranasal potentiated oxytocin) is a proprietary formulation of oxytocin in development for BED, prophylaxis of chronic migraine and for the treatment of craniofacial pain, insulin resistance and related conditions. In 2020, TNX-1900 was acquired from Trigemina, Inc. and licensed from Stanford University. TNX-1900 is a drug-device combination product, based on an intranasal actuator device that delivers oxytocin into the nose.

Oxytocin is a naturally occurring human hormone that acts as a neurotransmitter in the brain. Oxytocin has no recognized addiction potential. It has been observed that low oxytocin levels in the body can lead to an increase in migraine headache frequency, and that increased oxytocin levels can relieve migraine headaches. Certain other chronic pain conditions are also associated with decreased oxytocin levels. Migraine attacks are caused, in part, by the activity of pain-sensing trigeminal nerve cells which, when activated, release CGRP which binds to receptors on other nerve cells and starts a cascade of events that is believed to result in headache. Oxytocin when delivered via the nasal route, concentrates in the trigeminal system resulting in binding of oxytocin to receptors on neurons in the trigeminal system, inhibiting the release of CGRP and transmission of pain signals. Blocking CGRP release is a distinct mechanism compared with CGRP antagonist and anti-CGRP antibody drugs, which block the binding of CGRP to its receptor.

With TNX-1900, the addition of magnesium to the oxytocin formula enhances oxytocin receptor binding as well as its effects on trigeminal neurons and craniofacial analgesic effects in animal models. Intranasal oxytocin has been well tolerated in several clinical trials in both adults and children. Targeted nasal delivery results in low systemic exposure and lower risk of non-nervous system, off-target effects which could potentially occur with systemic CGRP antagonists such as anti-CGRP antibodies. For example, CGRP has roles in dilating blood vessels in response to ischemia, including in the heart. We believe nasally targeted delivery of oxytocin could translate into selective blockade of CGRP release in the trigeminal ganglion and not throughout the body, which could be a potential safety advantage over systemic CGRP inhibition. In addition, daily dosing is more quickly reversible, in contrast to monthly or quarterly dosing, as is the case with anti-CGRP antibodies, giving physicians and their patients greater control.

We initiated a Phase 2 study in chronic migraine in the first quarter of 2023. We also plan to develop TNX-1900 for treatment of episodic migraine, craniofacial pain and insulin resistance. Tonix has a license with the University of Geneva to use TNX-1900 for the treatment of insulin resistance and related conditions. TNX-1900 is also being studied as a potential treatment for BED in an investigator-initiated Phase 2 clinical trial. The Phase 2 clinical trial is expected to start in the second quarter of 2023. In March 2022, we announced an agreement with Massachusetts General Hospital, a teaching hospital of Harvard Medical School, to conduct this study. Tonix does not own this IND.

TNX-601 ER – Depression, PTSD, Neurocognitive Dysfunction from Corticosteroids

We announced the development of TNX-601 ER in July 2022, a potential abuse deterrent, extended-release formulation of tianeptine hemioxalate. TNX-601 ER is designed for once-daily daytime dosing and is being developed as a treatment for major depressive disorder (MDD), posttraumatic stress disorder, and neurocognitive dysfunction associated with corticosteroid use. TNX-601 ER represents a novel approach to treating depression in the U.S., since the active ingredient tianeptine induces a neuroprotective and resilient phenotype in both neurons and microglia under conditions of stress in animals. The dramatic and unique effects of tianeptine are illustrated in animal models by the restoration of dendritic arborization of pyramidal neurons of CA3 region of hippocampus and the dentate gyrus region new neuron formation and integration into hippocampal networks. In contrast, antidepressants that are marketed in the U.S. act by modulating the levels or receptor binding of neurotransmitters in the synapse. Tianeptine sodium (amorphous) immediate release (IR) tablets have been available in Europe and many countries in Asia and Latin America for the treatment of MDD over the more than three decades since it was first marketed in France in 1989. No tianeptine-containing product has been approved by the FDA. The proposed mechanism of action of TNX-601 ER is distinct from traditional monoaminergic antidepressants in the U.S. In addition

to its glutamatergic properties central to its antidepressant effect, tianeptine has weak μ-opioid receptor agonist properties and has been linked to illicit misuse at much higher doses than those reported to be effective in the treatment of MDD (reported to be used daily at 8-80 times the antidepressant daily dose). Previously, we were developing a naloxone-containing tablet, TNX-601 CR (tianeptine oxalate and naloxone controlled-release) for MDD, that was designed to mitigate the risk of parenteral abuse.

We intend to develop TNX-601 ER under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA). Tonix completed a Phase 1 clinical trial for formulation development outside of the U.S in 2019. Based on this study, the final formulation of TNX-601 ER to be used in Phase 2 testing will be 39.4 mg tianeptine hemioxalate for once daily treatment of MDD (which is equivalent in tianeptine content to three 12.5 mg doses of tianeptine sodium). Based on the clearance of IND 152371 by the FDA, we expect to initiate a Phase 2 study in the first quarter of 2023.

The Phase 2 study is planned to be a randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of TNX-601 ER monotherapy compared to placebo in MDD. Treatment duration will be six weeks, preceded by up to five weeks in screening and followed by a two-week safety follow-up period (total up to 13 weeks of participation). We plan to randomize approximately 300 individuals with MDD at a 1:1 ratio to two arms of 150 each for drug and placebo at approximately 30 U.S. sites. The primary efficacy endpoint will be the change from baseline to Week 6 in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score. An IA will be conducted once the first 50 percent of the sample has completed the study, estimated to occur in the fourth quarter of 2023.

TNX-1300 – Cocaine Intoxication

TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is being developed for the treatment of cocaine intoxication. TNX-1300 is a recombinant protein enzyme produced through rDNA technology in a non-disease-producing strain of E. coli bacteria. Cocaine Esterase (CocE) was identified in bacteria (Rhodococcus) that use cocaine as the sole source of carbon and nitrogen and that grow in soil surrounding coca plants. The gene encoding CocE was identified and the protein was extensively characterized. CocE catalyzes the breakdown of cocaine into metabolite ecgonine methyl ester and benzoic acid. Wild-type CocE is unstable at body temperature, so targeted mutations were introduced in the CocE gene and resulted in the T172R/G173Q double-mutant CocE, which is active for approximately 6 hours at body temperature.

Currently there is no specific pharmacotherapy indicated for cocaine intoxication, a state characterized by acute agitation, hyperthermia, tachycardia, arrhythmias, and hypertension, with the potential life-threatening sequalae of myocardial infarction, cerebrovascular accident, rhabdomyolysis, respiratory failure, and seizures. Patients are currently managed only by supportive care for the adverse effects of cocaine overdose on the cardiovascular and central nervous systems. By targeting the cause of cocaine intoxication, rather than the symptoms like other medicines in emergency usage, we believe TNX-1300 may offer significant advantages to the current standard of care for cocaine overdose. TNX-1300 was developed by Columbia University, University of Kentucky and University of Michigan, and in-licensed by Tonix from Columbia University in 2019.

In a Phase 2 randomized, double-blind, placebo-controlled clinical study, TNX-1300 at 100 mg or 200 mg i.v. doses was well tolerated and interrupted cocaine effects after cocaine 50 mg i.v. challenge.

In August 2022, we announced that we received a Cooperative Agreement grant from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), to support development of TNX-1300. The Company expects to initiate a new Phase 2 clinical study of TNX-1300 for the treatment of cocaine intoxication in the second quarter of 2023, pending agreement on protocol design with the U.S. Food and Drug Administration (FDA). The Phase 2 trial is a single-blind, open-label, placebo-controlled, randomized study comparing the safety of a single 200 mg dose of TNX-1300 to standard of care alone in approximately 60 emergency department patients presenting with cocaine intoxication. A positive Phase 2a study of volunteer cocaine users in a controlled laboratory setting has been previously completed. TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

As a biologic and new molecular entity, TNX-1300 is eligible for 12 years of U.S. market exclusivity upon approval by the FDA, in addition to expected patent protection through 2029. Since in-licensing, Tonix has requalified existing inventory, developed a lyophilized drug product to facilitate enhanced stability and handling conditions applicable for an ER treatment, updated the process and analytical methods to current standards and is in the process of manufacturing Phase 2/3 drug product clinical supply.

TNX-2900 – Prader-Willi Syndrome

TNX-2900 is based on our patented intranasal potentiated oxytocin formulation, or TNX-1900, but being developed for Prader-Willi syndrome. Tonix licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from the French National Institute of Health and Medical Research (Inserm). The licensing agreement has been negotiated and signed by Inserm Transfert, the private subsidiary of Inserm, on behalf of Inserm (the French National Institute of Health and Medical Research), Aix-Marseille Université and Centre Hospitalier Universitaire of Toulouse. Prader-Willi syndrome is recognized as the most common genetic cause of life-threatening childhood obesity and affects males and females with equal frequency and all races and ethnicities. There is currently no approved treatment for either the suckling deficit in infants or the obesity and hyperphagia in older children associated with Prader-Willi syndrome. Since Prader-Willi syndrome is an orphan disease that occurs in approximately one in 15,000 births, Tonix has been granted Orphan Drug Designation for TNX-2900 by the FDA. Tonix completed a pre-IND meeting with the FDA in November 2022 to discuss the most efficient and appropriate investigational plan to establish the safety and effectiveness evidence to support the approval of TNX-2900.

In 2022, Tonix entered into a research collaboration with Inserm involving in vitro and in vivo animal studies designed to validate and characterize the role of oxytocin in suckling and in the maturation of feeding behavior during infancy in order to support an intranasal therapeutic approach to restore a normal nutritive suckling. The studies will include mice that have been engineered to precisely recapitulate the genetic issue underlying Prader-Willi in humans.

The mechanisms involved in suckling activity required for normal feeding and the role of oxytocin system in this process will be investigated. The results of this work are expected to be useful in the clinical care of infants requiring support to achieve efficient suckling behavior. Intranasal oxytocin has previously been shown to improve suckling in newborn animals and suppress feeding behaviors in adult animal models.

TNX-1500 – Organ Transplant Rejection/Autoimmune Conditions

TNX-1500 is a humanized mAb directed against CD40-ligand, or CD40L (also known as CD154), engineered to modulate binding to Fc receptors, that is being developed to prevent and treat organ transplant rejection as well as to treat autoimmune conditions. TNX-1500 incorporates the antigen binding fragment (Fab) region of hu5c8, which has been extensively characterized including at the atomic level in complex with CD40-ligand.

In experiments at the Massachusetts General Hospital, a teaching hospital of Harvard Medical School, TNX-1500 is being studied as monotherapy or in combination with immunosuppressive drugs in heart and kidney organ transplants in non-human primates. Preliminary results from ongoing animal experiments in kidney and heart allogeneic transplants indicate that TNX-1500 appears to have comparable efficacy to historical experiments using the chimeric mouse/primate version of the anti-CD40L mAb 5c8, but to date has not shown evidence of the thromboembolic adverse events associated with the first generation mAb directed against CD40L.

CD40-ligand is a protein expressed on the surface of activated T lymphocytes that mediates T cell helper function. CD40-ligand is also known as CD154, the T cell-B cell activating molecule (T-BAM), TRAP and gp39. CD154 is a member of the Tumor Necrosis Factor (TNF) Super Family. No mAb against CD154 has been approved for commercial use anywhere in the world. Other TNF Super Family members have been successfully targeted by antagonist mAbs. Approved mAbs against TNFα include: infliximab (Remicade®), adalimumab (Humira®), certolizumab pegol (Cimzia®), and golimumab (Simponi®) for the treatment of certain autoimmune conditions. Also, etanercept (Enbrel®) is a TNFα antagonist receptor fusion protein. An approved mAb against RANKL (CD254) is denosumab (Prolia® or Xgeva®) for the treatment of osteoporosis, treatment-induced bone loss, metastases to bone, and giant cell tumor of bone.

In January 2021, the World Intellectual Property Organization published a patent application filed under the Patent Cooperation Treaty covering TNX-1500, a humanized mAb directed against CD40-ligand, which is also known as CD154. The patent application is titled "Anti-CD154 Antibodies and Uses Thereof" and published under International Publication No. WO 2021/001458 A1. The application entered national phase in December 2021. The patent applications include claims related to proprietary anti-human CD40-ligand mAbs that were engineered to have modified effector function, including TNX-1500, which have reduced potential for Fc binding to FcγRII. The patent applications also claim uses of TNX-1500 for preventing and treating conditions, such as organ transplant rejection and autoimmune disorders. If claims are granted, a patent issuing from a national stage of this application could potentially provide U.S. patent coverage for the TNX-1500 composition of matter through 2040 excluding possible patent term extensions or patent term adjustments. We also have filed a PCT patent application, PCT/US2022/011404, in January 2022, entitled "Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies." It claims methods of inducing immune tolerance in transplant recipients using anti-CD154 antibodies having modified effector functions. Tonix completed a pre-IND meeting with the FDA in October 2022 to discuss the most efficient and appropriate investigational plan to establish the safety and effectiveness evidence to support the licensure of TNX-1500. We expect to start a Phase 1 study of TNX-1500 in the second quarter of 2023.

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TNX-801 – Potential Smallpox and Mpox Vaccine

TNX-801 is a novel potential smallpox- and mpox-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 mpox. 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- and mpox-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.

Mpox is a growing problem in certain regions of Africa. Starting in May of 2022, cases of mpox have been reported outside of Africa in patients who had not been infected while in Africa. More than 30,000 cases in the U.S. have been reported according to the U.S. Centers for Disease Control and Prevention.

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. Those studies were published as an article in the peer reviewed journal, *Viruses* in 2023.

We hold a U.S. Patent for TNX-801 smallpox and mpox vaccine and Recombinant Pox Virus (RPV) platform technology. This patent is expected to provide Tonix with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments. In addition, we expect that TNX-801 will be eligible for 12 years of non-patent-based exclusivity under the Patient Protection and Affordable Care Act, or PPACA.

We intend to meet with the FDA to discuss the most efficient and appropriate investigational plan for TNX-801, 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 a clinical study. A Phase 1 study of TNX-801 is expected to be initiated in the second half of 2023.

TNX-1850 – Potential COVID-19 Vaccine

Our infectious disease portfolio includes a platform for vaccines for COVID-19. TNX-1800 is live virus vaccine based on our RPV platform that expresses the SARS-CoV-2 spike protein from the ancestral Wuhan strain. Because the subsequent omicron variant has out-competed the ancestral Wuhan strain, we are now planning new versions of this vaccine, TNX-1840 and TNX-1850, that are designed to express spike protein from the omicron variant and from the BA.2 variant, respectively. Each of these RPV vaccines is being developed to protect against COVID-19 primarily by eliciting T cell responses.

The COVID-19 vaccines that are approved for use, or have emergency use authorization, or EUA, in the U.S. have provided significant health benefits to the vaccinated population; however, they are showing limitations in the durability of protection conferred and in their ability to block forward transmission. Live virus vaccines that protect against other viral diseases by eliciting T cell responses have shown durability of protection that lasts years to decades and some live virus vaccines have significantly inhibited forward transmission.

We reported positive efficacy data for the TNX-1800 (spike from Wuhan strain) from animal challenge studies using live SARS-CoV-2 in the first quarter of 2021. In this study, TNX-1800 vaccinated, SARS-CoV-2 challenged animals had undetectable SARS-CoV-2 in the upper airways, which we believe relates to potential inhibition of forward transmission of this respiratory pathogen. This study of non-human primates compared TNX-1800 (modified horsepox virus encoding CoV-2 spike protein) to TNX-801 (horsepox virus, live vaccine) at two doses. A control group received a placebo. Each of these five groups (TNX-1800 high and low dose; TNX-801 high and low dose and placebo) included four animals. At day 41 after vaccination (or placebo), each animal was exposed to SARS-COV-2 by intra-tracheal (1×10^6 TCID50) and intra-nasal (1×10^6 TCID50) administration. Upper airway virus was studied by oropharyngeal swabs and lower airway virus by tracheal lavage using qRT-PCR to determine the number of genome copies of SARS-CoV-2 present in the samples. Six days after challenge, no (0/8) samples taken from animals vaccinated with TNX-1800 showed infection (more than 1,000 genome copies of SARS CoV-2) in either upper or lower airway samples. In contrast, all (8/8)

animals vaccinated with the control vaccine TNX-801 showed infection in either the upper or lower airway samples as did all (4/4) monkeys vaccinated with vehicle control. At day 14 after a single vaccination, all eight of the TNX-1800 vaccinated animals made anti-CoV-2 neutralizing antibodies (≥1:40 titer) and, as expected, none of the eight TNX-801 vaccinated control animals, or any of the four animals in the placebo group made anti-CoV-2 neutralizing antibodies (≤1:10 titer). At 6 days after CoV-2 challenge, TNX-1800 vaccinated animals showed neutralizing antibody titers of (≥1:1280 titer). The level of neutralizing anti-CoV-2 antibody production was similar between the low and high dose TNX-1800 groups (1 x 10^6 Plaque Forming Units [PFU] and 3 x 10^6 PFU, (respectively). For unvaccinated animals challenged with SARS-CoV-2, neutralizing antibodies were measurable after vaccination (≥1:40 titer) that were lower and appeared later than neutralizing antibodies in TNX-1800 vaccinated animals. TNX-1800 and TNX-801 were well tolerated at both doses. Further, as an expected additional outcome, all 16 animals vaccinated with either dose of TNX-1800 or the control TNX-801 manifested a "take", or cutaneous response, signaling that the horsepox vector elicits a strong T cell immune response. These results support the expectation that TNX-1800 at the low dose of 1 x 10^6 PFU is an appropriate dose for a one-shot vaccine in humans and indicate that 100 doses per vial is the target format for commercialization, which is well suited to manufacturing and distribution at large scale.

Together, these data show that TNX-1800 induces protection against SARS-COV-2 infection in non-human primates. These data confirm that "take" is a biomarker of protection of upper and lower airways from SARS-CoV-2 challenge, and a biomarker of immunological response to TNX-1800's cargo COVID-19 antigen, which is the CoV-2 spike protein. Tonix completed a pre-IND meeting 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 believe that the animal data and manufacturing process information that we have developed for TNX-1800 will facilitate expedited development of TNX-1840 and TNX-1850. In addition, we believe the RPV platform can be engineered to express relevant protein antigens from different infectious diseases to make a variety of vaccines.

In June 2020, we announced a partnership with FUJIFILM Diosynth Biotechnologies (FDBT) to provide contract manufacturing and development services to support the manufacturing of our COVID-19 vaccine candidate at the time, TNX-1800, for clinical trial supply. In February 2022, this contract ended. We continue to work with other third party CMOs for the manufacturing and development of TNX-1850, in addition to ultimately planning to utilize our in-house manufacturing capabilities which are currently in development.

Tonix announced the issuance of U.S. Patent for TNX-801 smallpox and mpox vaccine and Recombinant Pox Virus (RPV) platform technology. This patent is expected to provide Tonix with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments, and also expect 12 years of non-patent-based exclusivity under PPACA.

Our preclinical pipeline of drugs and biologic candidates also includes TNX-1600, a preclinical candidate for PTSD, ADHD and depression; TNX-1700 a preclinical candidate for cancers of the gastrointestinal system; TNX-2300, a live-virus vaccine based on bovine parainfluenza virus for COVID-19; TNX-3600, a COVID-19 therapeutic platform; TNX-3700, a COVID-19 vaccine; TNX-3800, a COVID-19 Therapeutic/Preventative.

Tonix's Facilities Overview

Relating to our COVID-19 and other infectious disease development programs, we are developing the resources necessary to enable internal research, development and manufacturing capabilities necessary to meet the goal of producing new vaccine candidates within 100 days and new diagnostics within weeks of obtaining sequence information of a novel pathogen. We seek to be a leader in the movement to re-build domestic U.S. research, development and manufacturing capabilities. Because this movement follows a protracted period when domestic research, development and manufacturing were moved out of the U.S., or "off-shore" by other companies to save on labor and other costs, the movement to reverse that trend has been described as "on-shoring" or "re-domestication". The COVID-19 pandemic taught that national borders may close during a health emergency. Therefore, domestic capabilities are essential for the health security of the U.S., which has also been described as pandemic preparedness and biodefense. As articulated in the American Pandemic Preparedness Plan, or AP3 released by the U.S. Office of Science and Technology Policy, this 100-day goal for vaccines is a key component of preparedness for future pandemics. We are establishing the infrastructure necessary to support the pandemic preparedness goals established in the AP3, specifically with respect to our RPV vaccine platform and potentially to other vaccine and therapeutic platforms.

The Research & Development Center (RDC)

We own the approximately 48,000 square foot RDC facility in Frederick, Maryland. The RDC facility is operational and focuses on our development of vaccines and antiviral drugs against COVID-19, its variants, and other infectious diseases. The RDC also conducts research on CNS and immunology drugs. The RDC facility is biosafety level 2 (BSL-2) with BSL-3 components. The RDC currently employs 26 staff. At full capacity, the RDC can employ 80-100 scientists and technical support staff.

The Advanced Development Center (ADC)

The ADC located in the New Bedford business park in Dartmouth, Massachusetts is operational and intended to accelerate development and clinical scale manufacturing of live-virus vaccines and biologics to support Phase 1 and Phase 2 clinical trials. ADC includes single-use bioreactors and purification suites with equipment for Good Manufacturing Practice (GMP) production of vaccines for and biologics clinical trials, including the capability of producing sterile vaccines in glass bottles.

The ADC is an approximately 45,000 square foot BSL-2 facility that currently employs 35 staff. At full capacity, the facility can employ up to 70 researchers, scientists, manufacturing, and technical support staff.

The Commercial Manufacturing Center (CMC)

We intend to build the CMC in Hamilton, Montana where we purchased approximately 44 acres of land. The site is on land designated by Ravalli County as a Target Economic Development District. The CMC will focus on developing and manufacturing Phase 3 and commercial scale live-virus vaccines and biologics and is also intended to be BSL-2. We have constructed a field office on the site to direct construction.

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. Summarized below is the competitive landscape for the indications in which Tonix has product candidates in or nearing the clinical stages of development.

Fibromyalgia

Products approved for the treatment of fibromyalgia include Lyrica® (pregabalin), marketed by Pfizer; Cymbalta® (duloxetine), marketed by Eli Lilly; and Savella® (milnacipran), marketed by Allergan (acquired by AbbVie). Tonix is aware of several other companies developing treatments for fibromyalgia including Virios Therapeutics, Axsome Therapeutics, Tryp Therapeutics, Biomind Labs, Cortene, and Sorrento Therapeutics.

Chronic or Episodic Migraine Prophylaxis

Currently there are several classes of drugs that are approved for the prophylactic treatment of chronic or episodic migraine, including generic beta blockers (propranolol, timolol), and anticonvulsants (divalproex, topiramate). Other drug classes that are used off-label to treat migraine prophylaxis, include tricyclic antidepressants (e.g., amitriptyline). Also, Allergan markets Botox® (onabotulinumtoxinA). More recently, several products have received FDA approval including Aimovig® (erenumab), which is marketed by Amgen/Novartis; Ajovy® (fremanezumab), which is marketed by Teva Pharmaceuticals; Emgality® (galcanezumab) which is marketed by Eli Lilly; and Yvepti® (eptinezumab), which is marketed by Lundbeck. Also, Nurtec ODT® (Rimegepant) was more recently approved as both a preventive and an acute treatment for episodic migraine, marketed by Pfizer; and Qulipta® (atogepant) was approved for prevention of episodic migraine, marketed by AbbVie. We are aware of other companies working to develop therapeutics for the treatment or prophylaxis of migraine including Astrocyte Pharmaceuticals, Protox, Kallyope, Crystec Pharma, Pulmatrix, and Epalex.

Major Depressive Disorder

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. Recently, Auvelity, developed by Axsome Therapeutics, and Vraylar, developed by Allergan, received FDA approval. Tonix is aware of several companies developing novel prescription medicines for depression including Janssen, Neumora Therapeutics (formerly BlackThorn Therapeutics), Sage Therapeutics, Relmada Therapeutics, Clexio Biosciences Ltd., Otsuka, Seelos

Therapeutics, Biomind Labs, FSD Pharma, Bright Minds Biosciences, Vistagen, Alto Neuroscience, Addex Therapeutics, and BetterLife Pharma.

Long COVID (Post-Acute Sequelae of SARS-CoV-2 Infection or PASC)

There currently are no approved products for the treatment of long COVID/PASC. Tonix is aware of several other companies developing therapeutics for long COVID including Direct Biologics, American CryoStem, HopeBiosciences, Axcella Health Inc., Ampio Pharmaceuticals, Pieris Pharmaceuticals, Resolve Therapeutics, PaxMedia, GeNeuro, Organicell, Ampio Pharmaceuticals, Lyramid, Virios Therapeutics, Berlin Cures, and Statera Biopharma.

PTSD

Products approved for the treatment of PTSD include Paxil® (paroxetine), marketed by GlaxoSmithKline and Zoloft® (sertraline), marketed by Pfizer. Tonix is aware of other companies working to develop therapeutics for the treatment of PTSD including Bionomics, Otsuka/Lundbeck, Nobilis Therapeutics, Bright Minds Biosciences, Alto Neuroscience, Addex Therapeutics, Ophidion, Artelo Biosciences, Roche, Boehringer Ingelheim, NRx Pharmaceuticals, Nanomerics, Seelos Therapeutics, and the Multidisciplinary Association of Psychedelic Studies (MAPS). Acadia Pharmaceuticals is testing Nuplazid® (pimavanserin) for the treatment of insomnia in veterans with PTSD.

Cocaine Intoxication

There are no approved antidotes for the treatment of cocaine intoxication. Patients generally receive supportive care. Tonix is not aware of any drugs in development for the treatment of cocaine intoxication.

Anti-CD40-ligand Monoclonal Antibodies

Tonix is aware of several companies developing biologics that target the CD40L molecule and block its interaction with CD40 including UCB/Biogen, Eledon Pharmaceuticals, Horizon Therapeutics Plc. (which is being acquired by Amgen), Lundbeck (in partnership with Aprilbio), and Sanofi. Furthermore, Tonix is aware of several companies developing antagonistic anti-CD40 mAbs including Novartis, Boehringer Ingelheim, Kiniska Pharmaceuticals, Boston Immune Therapies, and NapaJen Pharma, Inc.

Prader-Willi Syndrome

There are no approved products for the treatment of Prader-Willi syndrome. Patients generally receive care to best manage individual symptom presentation. Tonix is aware of two companies developing a therapeutic for Prader Willi Syndrome including Acadia (which purchased Levo Therapeutics in 2022) and OT4B. Several other companies are developing treatments for Prader-Willi syndrome including Aadvark Therapeutics, ConSynance Therapeutics, Soleno Therapeutics, Lipidio Pharma, Helsinn, Inversago Pharma, Saniona, 9 Meters Biopharma, Neuren Pharmaceuticals, Neuracle Science, Harmony Biosciences, and Notitia Biotechnologies.

Gastric and Colorectal Cancer

Tonix is developing a small peptide/biologic for the treatment of gastric and colorectal cancer. Tonix is aware of several other companies developing biologics for the treatment of gastric and colorectal cancer including Bexion Pharmaceuticals Inc., Faeth Therapeutics Inc., PDS Biotechnology Corp, and F-star Alpha Ltd.

COVID-19 Vaccine

Vaccines granted full FDA regulatory approval include Comirnaty® (BNT162b2), marketed by Pfizer-BioNTech and Spikevax® (mRNA-1273), marketed by Moderna. Ad.26.COV2S, developed by Janssen, has FDA approval for limited use. Covovax® (NVX-CoV2373), developed by Novavax, has received EUA from the FDA. Other vaccines have received EUA in international markets.

Smallpox and Mpox Vaccines and Antivirals

Vaccines approved for the prevention of smallpox include ACAM2000®, marketed by Emergent BioSolutions and JYNNEOS®, marketed by Bavarian Nordic. JYNNEOS® is also approved for the prevention of mpox. Approved antivirals for smallpox include TPOXX®, marketed by SIGA and TEMBEXA®, marketed by Chimerix. These antivirals are not FDA approved for the treatment of mpox. Tonix is aware of other companies developing treatments for smallpox and mpox including EpiVax, HK inno.N, BioFactura, Blue Water Vaccines, NightHawk Biosciences, Ascletis, and Hyundai Biosciences.

Intellectual Property

We believe that we have an extensive patent portfolio and substantial know-how relating to TNX-102 SL, TNX-1300, TNX-1500, TNX-601 ER, TNX-801 and our other product candidates. Our patent portfolio, described more fully below, includes claims directed to various compositions and methods of use related to our product candidates. As of March 8, 2023, the patents we are either the owner of record of or own the contractual right to include 34 issued U.S. patents and 271 issued non-U.S. patents. We are actively

pursuing an additional 32 U.S. patent applications, of which 7 are provisional and 25 are non-provisional, 11 international patent applications, and 247 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 most advanced product candidates as of March 8, 2023 are summarized below.

TNX-102 SL — Central Nervous System Conditions

Our patent portfolio for TNX-102 SL includes patent applications directed to compositions of matter of CBP, formulations containing CBP, and methods for treating CNS conditions, such as TNX-102 SL for PTSD, for acute stress disorder, for sleep disturbances in fibromyalgia, for alcohol abuse, for disordered sleep, for sexual dysfunction, for depression in fibromyalgia, fatigue, e.g., CAP rates, post-acute sequelae of SARS-CoV-2 infection, and 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. patents, such as U.S. Patent No. 9,636,408, U.S. Patent No. 9,956,188, U.S. Patent No. 10,117,936, U.S. Patent No. 10,357,465, U.S. Patent No. 10,864,175, and U.S. Patent No. 11,026,898. 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.

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 by a German law firm, the European Patent Office's Opposition Division in October 2019 upheld the patent in unamended form. Opponent has appealed. The Technical Board of the European Patent Office has canceled the April 27, 2023 Oral Proceedings pending the decision of the Enlarged Board of Appeal in G 2/21 (plausibility), which seeks to clarify whether a technical effect can be relied on when proof for the effect rests solely in post-published evidence and what role, if any, plausibility should play in this assessment.

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 August 3, 2022, European Patent No. 2861223, 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 April 16, 2019, Chinese Patent No. ZL 201480024011.1 entitled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride", issued. The claims recite pharmaceutical compositions comprising 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 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. In response to an opposition filed in September 2020 by Hexal AG, the European Patent Office's Opposition Division upheld the patent in unamended form in the January 2022 oral proceedings. The written decision is pending.

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. In September 2020, Hexal AG filed an opposition against this patent. The European Patent Office's Opposition Division upheld the patent claims in unamended form at the February 2022 oral proceedings. The written decision is pending.

On December 15, 2020, U.S. Patent No. 10,864,175 entitled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride", issued. The claims recite a eutectic comprising cyclobenzaprine hydrochloride and beta-mannitol.

On April 8, 2021, U.S. non-provisional Patent Application No. 17/226,058 and International Patent Application No. PCT/US2021/026492, entitled "Cyclobenzaprine Treatment for Sexual Dysfunction" were filed. The PCT application is now nationalized in Australia, Canada, China, European Patent Office and Japan. On October 5, 2022, International Patent Application No. PCT/US2022/045791, entitled "Cyclobenzaprine Treatment for Sexual Dysfunction" was filed. The claims of these applications are

directed to methods using pharmaceutical compositions and combinations for treating sexual dysfunction with cyclobenzaprine or pharmaceutically acceptable salts of cyclobenzaprine.

On October 25, 2016 and July 28, 2020, U.S. Patent No. 9,474,728 and U.S. Patent No. 10,722,478, entitled "Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine", issued, respectively. The claims are directed to a method for monitoring the effectiveness of cyclobenzaprine treatment for disordered sleep and method for reducing CAP rates A2 or A3 by treating a subject with a pharmaceutical composition comprising cyclobenzaprine.

On December 11, 2018, U.S. non-provisional Patent Application No. 16/215,952 and International Patent Application No. PCT/IB2018/001509, entitled "Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions," were filed. The PCT application is now nationalized in 16 countries. The claims are directed to methods for treating or preventing agitation, cognitive decline, psychosis, and associated symptoms thereof using pharmaceutical compositions and combinations with cyclobenzaprine or pharmaceutically acceptable salts of cyclobenzaprine.

On August 20, 2019, International Patent Application No. PCT/IB2019/000940, entitled "Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder," was filed. The PCT application is now nationalized in 18 countries. The claims are directed to methods of treating acute stress disorder or post-traumatic stress disorder in a subject who has experienced a traumatic event using pharmaceutical compositions with cyclobenzaprine, amitriptyline or pharmaceutically acceptable salts of cyclobenzaprine or amitriptyline.

On November 19, 2021, International Patent Application No. PCT/US2021/060011, entitled "Cyclobenzaprine Treatment for Alcohol Use Disorder," was filed. The claims are directed to methods for treating alcohol use disorder and associated symptoms using pharmaceutical compositions with cyclobenzaprine or pharmaceutically acceptable salts of cyclobenzaprine.

On December 7, 2021, International Patent Application No. PCT/US2021/062244, entitled, "Cyclobenzaprine Treatment for Fibromyalgia," was filed. The claims are directed to methods for treating fibromyalgia and its associated symptoms of pain, sleep disturbance and/or fatigue by transmucosally administering a eutectic with cyclobenzaprine hydrochloride and mannitol in dosage units with a basifying agent.

TNX-1900 — Oxytocin-based treatments for Migraine, Pain, Insulin Resistance, Diabetes and Obesity

We have acquired the migraine and pain treatment technologies of Trigemina, Inc., and have assumed its license rights to related technologies from The Board of Trustees of the Leland Stanford Junior University. TNX-1900, an enhanced formulation of nasal oxytocin, has demonstrated activity in several non-clinical studies in pain, including migraine.

As part of our acquisition, we acquired International Patent Application No. PCT/US2016/012512, filed on January 7, 2016, entitled "Magnesium-Containing Oxytocin Formulations and Methods of Use" (nationalized in 13 countries). We also acquired U.S. Patent Nos. 9,629,894 and 11,389,473, entitled "Magnesium-Containing Oxytocin Formulations and Methods of Use", which will expire in January 2036, excluding any patent term extensions. We also have rights to International Patent Application No. PCT/US2019/020419, filed on April 12, 2017, entitled "Labeled Oxytocin and Method of Manufacture and Use" (nationalized in the U.S., European Patent Office and Japan).

We have entered into an exclusive license to the University of Geneva's technology for using oxytocin to treat insulin resistance and related syndromes, including obesity. This license expands our intranasal potentiated oxytocin development program, TNX-1900, into cardiometabolic syndromes. Under the license, we have rights to European Patent No. EP2571511B1, entitled "New Uses of Oxytocin-like Molecules and Related Methods." We also have rights to U.S. Patent No. 9,101,569, entitled "Methods for the Treatment of Insulin Resistance." The U.S. and non-U.S. patents expire in May 2031, excluding any patent term adjustments or extensions.

TNX-2900 — Oxytocin-based therapeutics treatments for Prader-Willi syndrome

We have licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from the French National Institute of Health and Medical Research (INSERM). The co-exclusive license relates to TNX-2900, an intranasal potentiated oxytocin, for the treatment of Prader-Willi syndrome and other feeding disorders. Under the license, we have rights to European Patent No. EP2575853B1, entitled "Methods and Pharmaceutical Composition for the Treatment of a Feeding Disorder with Early-Onset in a Patient"; U.S. Patent No. 8,853,158, entitled "Methods for the Treatment of a Feeding Disorder with Onset During Neonate Development Using an Agonist of the Oxytocin Receptor"; and U.S. Patent No. 9,125,862, entitled "Methods for the Treatment of Prader-Willi-like Syndrome or Non-Organic Failure to Thrive (NOFITT) Feeding Disorder Using an Agonist of the Oxytocin Receptor." The U.S. and non-U.S. patents expire in May 2031, excluding any patent term extensions.

TNX-601 and TNX-601 ER— Depression, Posttraumatic Stress Disorder, Neurocognitive Dysfunction

Our patent portfolio for tianeptine oxalate includes U.S. Patent No. 9,314,469 and European Patent No. 2,299,822, both entitled "Method for Treating Neurocognitive Dysfunction", which issued on April 29, 2016 and July 26, 2017, respectively. 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. The '469 patent claims methods of treating cognitive impairment associated with corticosteroid treatment using compounds, including tianeptine, excluding patent term extensions, the patent provides TNX-601 with US marketing exclusivity until 2028.

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.

On March 16, 2021, U.S. Patent No. 10,946,027 issued. The claims recite pharmaceutical compositions of 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 16 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.

Our patent portfolio for TNX-601 CR includes International Patent Application No. PCT/US2022/020406, entitled "Tianeptine Oxalate and Naloxone Treatment for Major Depressive Disorder," was filed March 15, 2022. It includes claims directed to compositions with tianeptine and naloxone or pharmaceutically acceptable salts of tianeptine and naloxone and methods of preventing or treating major depressive disorder using the compositions.

TNX-1300 — Cocaine Intoxication Treatment

We have licensed rights from The Trustees of Columbia University in the City of New York, The Regents of the University of Michigan, and University of 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 (e.g., European Patent 2046368). These patents provide TNX-1300 with US market exclusivity until February 2029, and market exclusivity outside of the U.S. until July 10, 2027, subject to any patent term extensions.

TNX-1500 — anti-CD40L Therapeutics

We are developing TNX-1500, a humanized mAb that targets CD40L for the prevention and treatment of organ transplant rejection. In this regard, we filed International Application No. PCT/EP2020/068589, entitled "Anti-CD154 antibodies and uses thereof" on July 1, 2020 (nationalized in 15 countries). We also filed International Patent Application No. PCT/US2020/028002 on April 13, 2020, entitled "Inhibitors of CD40-CD154 Binding" (nationalized in U.S., Canada, China, European Patent Office and Japan). We also filed International Patent Application No. PCT/US2022/011404, entitled "Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies" on January 6, 2022.

TNX-801 — Live Horsepox Vaccine for Prevention of Smallpox and Mpox

We own the rights to develop a potential biodefense technology, TNX-801, a live horsepox that is being developed as a new smallpox and mpox preventing vaccine, we have filed 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 (nationalized in 15 countries and filed in 4 non-PCT countries). We also own the rights to develop other vaccine candidates against smallpox. With respect to these vaccine candidates, we own International Patent Application No. PCT/US2019/030486 and the non-convention and national phase applications related thereto (nationalized in 17 countries and filed in 2 non-PCT countries). 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.

On May 31, 2022, U.S. Patent No. 11,345,896 was issued. The claims recite a synthetic chimeric orthopoxvirus (scOPV), a synthetic chimeric horsepox virus (scHPXV), methods of generating the scOPV and scHPXV, and compositions comprising the scOPV or scHPXV.

TNX-1850 — Live Modified Horsepox Vaccine for Prevention of COVID-19

We are developing TNX-1850, a live HPXV that is being developed as a new COVID-19 preventing vaccine. On February 26, 2021, we filed International Patent Application No. PCT/US2021/020119, entitled "Recombinant Poxvirus Based Vaccine Against SARS-CoV-2." On the same date, we also filed applications in Argentina and Taiwan and we filed U.S. Application No. 17/187,678. The PCT application is not nationalized in 18 countries. These applications are 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.

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

We have licensed rights from The Trustees of Columbia University in the City of New York to develop a potential product, TNX-1700, for the treatment of gastric and pancreatic cancers. The licensed patents are directed to TFF2 compositions and methods of treatment. The licensed patents U.S. Patent No. 10,124,037 and U.S. Patent No. 11,167,010. The licensed patents provide TNX-1700 with US market exclusivity until April 2033, subject to any patent term extensions. On August 27, 2020, we filed International Patent Application No. PCT/IB2020/000699 entitled "Modified TFF2 Polypeptides." The PCT application is now nationalized in 12 countries.

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-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.

On May 7, 2021, we filed International Patent Application No. PCT/US2021/031441, entitled "Radio-and Chemo-Protective Compounds," and U.S. non-provisional Patent Application No. 17/315,258, entitled "Radio-Protective and Chemo-Protective Substituted Thiols." The PCT application is now nationalized in 10 countries. The applications claim compounds, compositions and methods of use in radioprotection.

On January 31, 2023, U.S. Patent No. 11,566,032 issued. The claims recite compounds of a formula I or a pharmaceutically acceptable salt thereof or stereoisomer thereof and a pharmaceutical composition comprising a compound of formula I.

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, entitled "Synthetic Chimeric Vaccinia Virus," include U.S. non-provisional Patent Application No. 17/050,946 and International Patent Application No. PCT/US2019/030486 (now nationalized in 16 countries) and applications filed in Argentina, Taiwan and Venezuela. We believe that this technology, after further development, may be of interest to biodefense agencies in the U.S. and other countries.

TNX-2300 — Bovine Parainfluenza 3 Virus vaccine

We have an exclusive field-of-use option agreement with Kansas State University Research Foundation to develop TNX-2300, a bovine parainfluenza virus vaccine, as a new COVID-19 preventing vaccine or treatment. The patent applications in this agreement include International Patent Application No. PCT/US2020/070725, entitled "Broadly Protective Bovine Parainfluenza 3 Virus and Bovine Viral Diarrhea Virus Vaccine" (nationalized in U.S. as Patent Application No. 17/755,359), and International Patent Application No. PCT/US2022/072433, entitled "SARS-Coronavirus 2 (SARS-CoV-2) Spike Protein Subunit Vaccines."

TNX-3700 — Zinc Nanoparticle mRNA vaccine

We have an exclusive field-of-use option agreement with Kansas State University Research Foundation to develop TNX-3700, a zinc nanoparticle mRNA vaccine, as a new COVID-19 preventing vaccine or treatment. The patent applications in this agreement include International Patent Application No. PCT/US2022/070739, entitled "RNA Stabilizing Nanoparticles," and International Patent Application No. PCT/US2022/075944, entitled "mRNA Vaccine Formulations and Methods of Using the Same."

TNX-3900 — antiviral drugs

We have acquired the intellectual property rights of Healion Bio, Inc. to develop antiviral drugs. These rights include International Patent Application No. PCT/US2021/032461 (nationalized in 4 countries) and U.S. Patent Application No. 18/055,596, both entitled "Compositions and Methods for Increasing Efficacy of a Drug," as well as International Patent Application No. PCT/US2021/052664, entitled "Methods and Compositions for the Treatment of Viral Diseases."

TNX-4100 — murine anti-SARS-CoV-2 antibodies

We have exercised the option to obtain an exclusive license from Columbia University to develop, TNX-4100, a series of murine and humanized anti-SARS-CoV-2 mAbs as new COVID-19 preventatives or treatments.

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 or licensed include:

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

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 R.O.C.	June 14, 2033
2013274003	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
I642429	Compositions and Methods for Transmucosal Absorption	Taiwan R.O.C.	June 14, 2033
726488	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033
I683660	Compositions and Methods for Transmucosal Absorption	Taiwan R.O.C.	June 14, 2033
2018241128	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
2876902	Compositions and Methods for Transmucosal Absorption	Canada	June 14, 2033
IDP000076019	Compositions and Methods for Transmucosal Absorption	Indonesia	June 14, 2033
382516	Compositions and Methods for Transmucosal Absorption	Mexico	June 14, 2033
2861223	Compositions and Methods for Transmucosal Absorption	European Patent Office – Italy, Albania, Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, San Marino, Serbia, Croatia, North Macedonia and Turkey	June 14, 2033
236268	Compositions for Transmucosal Delivery and Uses Thereof	Israel	June 14, 2033
2015/00288	Compositions and Methods for Transmucosal Absorption	South Africa	June 14, 2033
BR112014031394-6	Compositions and Methods for Transmucosal Absorption	Brazil	June 14, 2033
1209361	Compositions and Methods for Transmucosal Absorption	Hong Kong	June 14, 2033
398632	Compositions and Methods for Transmucosal Absorption	Mexico	June 14, 2033
A059897	Compositions and Methods for Transmucosal Absorption	Venezuela	June 14, 2033
MY-194495-A	Compositions and Methods for Transmucosal Absorption	Malaysia	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
2018204633	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Australia	March 6, 2032
2020203874	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
2,829,200	Methods and Compositions for Treating Depression Using Cyclobenzaprine	Canada	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, Republic of North Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, and Turkey	March 6, 2032

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 Republic of North 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, Republic of North 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
10,722,478	Methods and Compositions for Treating Fatigue Associated with Disordered Sleep Using Very Low Dose Cyclobenzaprine	U.S.A.	June 9, 2031

CBP/Amitriptyline Eutectic Formulations

Patent No.	Title	Country / Region	Expiration Date
631152	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	New Zealand	March 14, 2034
747040	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
10,736,859	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
10,864,175	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
10,864,176	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
11,026,898	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
6717902	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
ZL.201580050140.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China	September 18, 2035
2014233277	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Australia	March 14, 2034
2015317336	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Australia	September 18, 2035
I661825	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan R.O.C.	March 14, 2034
I740136	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan R.O.C.	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
IDP000076872	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia	March 14, 2034
2968992 (1211591 in Austria, CZ2014-762323 in Czechia, 602014058260.5 in Germany, E018723 in Estonia, P20200055 in Croatia, 201361792757 P in Ireland, 2020.67 in Monaco, P-2020/0094 in Serbia, 201431487 in Slovenia, 33269 in Slovakia, 2020000045 in San Marino, AL/P/2019/906 in Albania, MK/P/2020/67 in Republic of North Macedonia, 3102655 in Greece, 502020000007756 in Italy)	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	European Patent Office -Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Republic of North Macedonia, Germany, Greece, 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
251218	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Methods of Producing Same	Israel	September 18, 2035
277814	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Methods of Producing Same	Israel	September 18, 2034
370021	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico	March 14, 2034
387402	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Mexico	September 18, 2035
388137	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico	March 14, 2034

Patent No.	Title	Country / Region	Expiration Date
2015/07443	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	South Africa	March 14, 2034
2017/01637	Eutectic Formulations of Cyclobenzaprine Hydrochloride	South Africa	September 18, 2035
BR112015022095-9	Pharmaceutical Composition, Method of Fabrication, Eutectic Composition and Use of Compositions Containing Cyclobenzaprine HCl and Mannitol	Brazil	March 14, 2034
2904812	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Canada	March 14, 2034
HK1218727	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong	March 14, 2034
MY-186047-A	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Malaysia	September 18, 2035
398845	Eutectic Formulations of Cyclobenzaprine Hydrochloride	India	September 18, 2035

Oxytocin therapeutics

Patent No.	Title	Country / Region	Expiration Date
9,629,894	Magnesium-Containing Oxytocin Formulations and Methods of Use	U.S.A.	January 7, 2036
11,389,473	Magnesium-Containing Oxytocin Formulations and Methods of Use	U.S.A.	January 7, 2036
11201705591P	Magnesium-Containing Oxytocin Formulations and Methods of Use	Singapore	January 7, 2036
388286	Magnesium-Containing Oxytocin Formulations and Methods of Use	Mexico	January 7, 2036
253347	Magnesium-Containing Oxytocin Formulations and Methods of Use	Israel	January 7, 2036
7030517	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan	January 7, 2036
ZL201680013809.5	Magnesium-Containing Oxytocin Formulations and Methods of Use	China	January 7, 2036
7093559	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan	April 12, 2037
2575853	Methods and Pharmaceutical Composition for the Treatment of a Feeding Disorder with Early-Onset in a Patient	Europe – (Spain, France, and United Kingdom)	May 25, 2031
8,853,158	Methods for the Treatment of a Feeding Disorder with Onset During Neonate Development Using an Agonist of the Oxytocin Receptor	U.S.A.	May 25, 2031
9,125,862	Methods for the Treatment of Prader-Willi-like Syndrome or Non-Organic Failure to Thrive (NOFITT) Feeding Disorder Using an Agonist of the Oxytocin Receptor	U.S.A.	May 25, 2031
2571511	New Uses of Oxytocin-like Molecules and Related Methods	Europe – (Switzerland, Spain, France, United Kingdom, and Ireland)	May 17, 2031
9,101,569	Methods for the Treatment of Insulin Resistance	U.S.A.	June 22, 2031

Nociceptin/Orphanin FQ therapeutics

Patent No.	Title	Country / Region	Expiration Date
8,551,949	Methods for treatment of pain	U.S.A.	August 11, 2031
9,238,053	Methods for treatment of pain	U.S.A.	October 12, 2030
2010281436	Methods for treatment of pain	Australia	July 27, 2030
ZL 201080042858.4	Methods for treatment of pain	China	July 27, 2030
2459183 (602010028120.5 in Germany)	Methods for treatment of pain	Europe – (Switzerland, Germany, Denmark, France, and United Kingdom)	July 27, 2030
1169804	Methods for treatment of pain	Hong Kong	July 27, 2030
329837	Methods for treatment of pain	Mexico	July 27, 2030
597763	Methods for treatment of pain	New Zealand	July 27, 2030
10201406930U	Methods for treatment of pain	Singapore	July 27, 2030
201200584	Methods for treatment of pain	South Africa	July 27, 2030
2,769,347	Methods for treatment of pain	Canada	July 27, 2030
413642	Methods for treatment of pain	India	July 27, 2030

Tianeptine Hemioxalate – 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
10,946,027	Tianeptine Oxalate Salts and Polymorphs	U.S.A.	December 28, 2037
2019/04185	Tianeptine Oxalate Salts and Polymorphs	South Africa	December 28, 2037
2017385958	Tianeptine Oxalate Salts and Polymorphs	Australia	December 28, 2037
IDP000082485	Tianeptine Oxalate Salts and Polymorphs	Indonesia	December 28, 2037
754797	Tianeptine Oxalate Salts and Polymorphs	New Zealand	December 28, 2037

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 and E911827 in Austria)	Method for Treating Neurodegenerative Dysfunction	European Patent Office – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	April 30, 2029
3246031 (602009057284.9 in Germany)	Method for Treating Neurocognitive Dysfunction	European Patent Office – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, Portugal	April 30, 2029

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
11,167,010	Trefoil family factor proteins and uses thereof	U.S.A	April 2, 2033

Synthetic Chimeric Poxviruses

Patent No.	Title	Country / Region	Expiration Date
11,345,896	Synthetic Chimeric Poxviruses	U.S.A	November 2, 2037
397516	Synthetic Chimeric Poxviruses	Mexico	November 2, 2037
2019/02868	Synthetic Chimeric Poxviruses	South Africa	November 2, 2037

Radioprotection therapeutics

Patent No.	Title	Country / Region	Expiration Date
11,566,032	Radio-Protective and Chemo-Protective Substituted Thiols	U.S.A	May 7, 2041

Pending Patent Applications

Our current pending patent applications are as follows:

CD40 and anti-CD154 Therapeutics

Application No.	Title	Country / Region
17/623,710	Anti-CD154 antibodies and uses thereof	U.S.A.
2020300002	Anti-CD154 antibodies and uses thereof	Australia
BR112021026410-8	Anti-CD154 antibodies and uses thereof	Brazil
3145453	Anti-CD154 antibodies and uses thereof	Canada
202080059891.1	Anti-CD154 antibodies and uses thereof	China
20764933.6	Anti-CD154 antibodies and uses thereof	European Patent Office
202217004870	Anti-CD154 antibodies and uses thereof	India
P00202200763	Anti-CD154 antibodies and uses thereof	Indonesia
289354	Anti-CD154 antibodies and uses thereof	Israel
2021-578262	Anti-CD154 antibodies and uses thereof	Japan
PI 2021007835	Anti-CD154 antibodies and uses thereof	Malaysia
MX/a/2022/000133	Anti-CD154 antibodies and uses thereof	Mexico
784548	Anti-CD154 antibodies and uses thereof	New Zealand

Application No.	Title	Country / Region
11202114433Y	Anti-CD154 antibodies and uses thereof	Singapore
2022/01378	Anti-CD154 antibodies and uses thereof	South Africa
62022063693.5	Anti-CD154 antibodies and uses thereof	Hong Kong
62022062573.0	Anti-CD154 antibodies and uses thereof	Hong Kong
PCT/US2022/011404	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	PCT
3136725	Inhibitors of CD40-CD154 Binding	Canada
20787970.1	Inhibitors of CD40-CD154 Binding	European Patent Office
2021-560713	Inhibitors of CD40-CD154 Binding	Japan
17/603,260	Inhibitors of CD40-CD154 Binding	U.S.A.
202080033531.4	Inhibitors of CD40-CD154 Binding	China

CBP/Amitriptyline Eutectic Formulations

Application No.	Title	Country / Region
17/121,547	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
17/082,949	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
2020289838	Eutectic Formulations of Cyclobenzaprine Hydrochloride (Allowed)	Australia
BR112017005231-8	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Brazil
BR122020020968-2	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Brazil
2,961,822	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Canada
3,119,755	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Canada
201910263541.6	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	China
202011576351.9	Eutectic Formulations of Cyclobenzaprine 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
18101200.4	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Hong Kong
42020003105.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
42020019748.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
42021036749.6	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Hong Kong
3392/KOLNP/2015	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	India
2021-105582	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan
2021-169539	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan
PI 2015703142	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Malaysia
PI 20233000078	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Malaysia
730379	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand
768064	Eutectic Formulations of Cyclobenzaprine 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
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
Not Yet Assigned	Compositions and Methods for Transmucosal Absorption	Argentina
BR122019024508-8	Compositions and Methods for Transmucosal Absorption	Brazil
3,118,913	Compositions and Methods for Transmucosal Absorption	Canada
202010024102.2	Compositions and Methods for Transmucosal Absorption	China
2013/24661	Compositions and Methods for Transmucosal Absorption	Gulf Cooperation Council
2013/37088	Compositions and Methods for Transmucosal Absorption	Gulf Cooperation Council
2013/40660	Compositions and Methods for Transmucosal Absorption	Gulf Cooperation Council
42020020336.2	Compositions and Methods for Transmucosal Absorption	Hong Kong
P-00 2021 01421	Compositions and Methods for Transmucosal Absorption	Indonesia
2021-100154	Compositions and Methods for Transmucosal Absorption	Japan
10201605407T	Compositions and Methods for Transmucosal Absorption	Singapore

CBP – PTSD

Application No.	Title	Country / Region
17/951,723	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	U.S.A.

Assessing Clinical Response – PTSD

Application No.	Title	Country / Region
PCT/US2022/015327	An Improved Method of Assessing Clinical Response in the Treatment of PTSD Symptoms	PCT

CBP – Fatigue

Application No.	Title	Country / Region
16/903,965	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.
2018383098	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Australia
BR112020011345-0	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Brazil
3,083,341	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Canada
201880079917.1	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	China
18847270.8	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	European Patent Office
P00202004178	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Indonesia
275289	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Israel
202017023747	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	India
2020-531611	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Japan
MX/a/2020/006140	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Mexico
PI2020002800	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Malaysia
765792	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	New Zealand
520412146	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Saudi Arabia
11202004799T	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Singapore
2020/03243	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	South Africa
6202002246.2	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Hong Kong
62021029558.5	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Hong Kong

CBP – Depression

Application No.	Title	Country / Region
13/412,571	Methods and Compositions for Treating Depression Using Cyclobenzaprine	U.S.A.
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 Amitriptyline	U.S.A.
CA3069699	Analogs of Cyclobenzaprine and Amitriptyline	Canada
201880050758.2	Analogs of Cyclobenzaprine and Amitriptyline	China
EP18831505.5	Analogs of Cyclobenzaprine and Amitriptyline Analogs of Cyclobenzaprine and Amitriptyline	European Patent Office
2020-526592	Analogs of Cyclobenzaprine and Amitriptyline	Japan

CBP – ASD and PTSD

Application No.	Title	Country / Region
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 R.O.C.
17/269,106	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	U.S.A.
2019323764	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Australia
PI2021000802	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Malaysia
772889	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	New Zealand
BR112021003107-3	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Brazil

Application No.	Title	Country / Region
3109258	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Canada
201980062283.3	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	China
19802247.7	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	European Patent Office
62021045278.0	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Hong Kong
62022046260.5	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Hong Kong
202117011223	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	India
P00202101716	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Indonesia
280921	Cyclobenzaprine or Amitriptyline Containing Compositions for Use in Treating Stress Disorders	Israel
2021-509201	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Japan
MX/a/2021/002012	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Mexico
11202101443W	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Singapore
2021/01121	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	South Africa

CBP – Fibromyalgia

Application No.	Title	Country / Region
PCT/US2021/062244	Cyclobenzaprine Treatment for Fibromyalgia	PCT

CBP – Alcohol Use Disorder

Application No.	Title	Country / Region
PCT/US2021/060011	Cyclobenzaprine Treatment for Alcohol Use Disorder	PCT

CBP – Sexual dysfunction

Application No.	Title	Country / Region
PCT/US2022/045791	Cyclobenzaprine Treatment for Sexual Dysfunction	PCT
17/226,058	Cyclobenzaprine Treatment for Sexual Dysfunction	U.S.A
2021253592	Cyclobenzaprine Treatment for Sexual Dysfunction	Australia
3179754	Cyclobenzaprine Treatment for Sexual Dysfunction	Canada
202180040673.8	Cyclobenzaprine Treatment for Sexual Dysfunction	China
21721779.3	Cyclobenzaprine Treatment for Sexual Dysfunction	European Patent Office
2022-562023	Cyclobenzaprine Treatment for Sexual Dysfunction	Japan

CBP – Post-Acute Sequelae of SARS-CoV-2 (PASC)

Application No.	Title	Country / Region
63/354,215	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	U.S.A.

Oxytocin therapeutics

Application No.	Title	Country / Region
2020286221	Magnesium-Containing Oxytocin Formulations and Methods of Use	Australia
BR1120170145456	Magnesium-Containing Oxytocin Formulations and Methods of Use	Brazil
2972975	Magnesium-Containing Oxytocin Formulations and Methods of Use	Canada
16735422.4	Magnesium-Containing Oxytocin Formulations and Methods of Use	European Patent Office
18112297.5	Magnesium-Containing Oxytocin Formulations and Methods of Use	Hong Kong
2021-179295	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan
1020177021998	Magnesium-Containing Oxytocin Formulations and Methods of Use	Republic of Korea
734097	Magnesium-Containing Oxytocin Formulations and Methods of Use	New Zealand
771693	Magnesium-Containing Oxytocin Formulations and Methods of Use	New Zealand
201705176	Magnesium-Containing Oxytocin Formulations and Methods of Use (Allowed)	South Africa
16/976,912	Labeled Oxytocin and Method of Manufacture and Use	U.S.A.
19710979.6	Labeled Oxytocin and Method of Manufacture and Use	European Patent Office
2020-545532	Labeled Oxytocin and Method of Manufacture and Use	Japan
16/093,104	Magnesium-Containing Oxytocin Formulations and Methods of Use	U.S.A.
2017250505	Magnesium-Containing Oxytocin Formulations and Methods of Use	Australia
3,020,179	Magnesium-Containing Oxytocin Formulations and Methods of Use	Canada
2017800361853	Magnesium-Containing Oxytocin Formulations and Methods of Use (Allowed)	China
2023100344997	Magnesium-Containing Oxytocin Formulations and Methods of Use	China
17783080.9	Magnesium-Containing Oxytocin Formulations and Methods of Use	European Patent Office
19128645.9	Magnesium-Containing Oxytocin Formulations and Methods of Use	Hong Kong
2022-60727	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan
MX/a/2018/012351	Magnesium-Containing Oxytocin Formulations and Methods of Use	Mexico
747221	Magnesium-Containing Oxytocin Formulations and Methods of Use	New Zealand
787097	Magnesium-Containing Oxytocin Formulations and Methods of Use	New Zealand

Nociceptin/Orphanin FQ therapeutics

Application No.	Title	Country / Region
BR122021007932-3	Methods for Treatment of Pain	Brazil

Tianeptine Hemioxalate – Salts and Crystalline Forms

Application No.	Title	Country / Region
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
62020006380.3	Tianeptine Oxalate Salts and Polymorphs	Hong Kong
62020006381.1	Tianeptine Oxalate Salts and Polymorphs	Hong Kong
267708	Tianeptine Oxalate Salts and Polymorphs, Compositions Comprising Same and Uses Thereof	Israel
201917029300	Tianeptine Oxalate Salts and Polymorphs	India
2019-535330	Tianeptine Oxalate Salts and Polymorphs	Japan
2022-180549	Tianeptine Oxalate Salts and Polymorphs	Japan
MX/a/2019/007891	Tianeptine Oxalate Salts and Polymorphs	Mexico
PI2019003711	Tianeptine Oxalate Salts and Polymorphs	Malaysia
519402021	Tianeptine Oxalate Salts and Polymorphs	Saudi Arabia
11201905974W	Tianeptine Oxalate Salts and Polymorphs	Singapore

Tianeptine and Naloxone – Major Depressive Disorder

Application No.	Title	Country / Region
PCT/US2022/020406	Tianeptine Oxalate and Naloxone Treatment for Major Depressive Disorder	PCT

Synthetic Chimeric Poxviruses

Application No.	Title	Country / Region
17/827,320	Synthetic Chimeric Poxviruses	U.S.A.
P 20170103043	Synthetic Chimeric Poxviruses	Argentina
2017/34209	Synthetic Chimeric Poxviruses	Gulf Cooperation Council
2017/41626	Synthetic Chimeric Poxviruses	Gulf Cooperation Council
106137976	Synthetic Chimeric Poxviruses	Taiwan R.O.C.
2017353868	Synthetic Chimeric Poxviruses	Australia
BR112019008781-8	Synthetic Chimeric Poxviruses	Brazil
BR122023000373-0	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
2022-140113	Synthetic Chimeric Poxviruses	Japan
PI2019002462	Synthetic Chimeric Poxviruses	Malaysia
752893	Synthetic Chimeric Poxviruses	New Zealand
11201903893P	Synthetic Chimeric Poxviruses	Singapore
2022/04981	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
2019/37492	Synthetic Chimeric Vaccinia Virus	Gulf Cooperation Council
2019/41458	Synthetic Chimeric Vaccinia Virus	Gulf Cooperation Council
20190101165	Synthetic Chimeric Vaccinia Virus	Argentina
108115290	Synthetic Chimeric Vaccinia Virus	Taiwan R.O.C.
17/050,946	Synthetic Chimeric Vaccinia Virus	U.S.A.
2019262149	Synthetic Chimeric Vaccinia Virus	Australia
BR112020022181-3	Synthetic Chimeric Vaccinia Virus	Brazil
3099330	Synthetic Chimeric Vaccinia Virus	Canada
201980029677.9	Synthetic Chimeric Vaccinia Virus	China
19796145.1	Synthetic Chimeric Vaccinia Virus	European Patent Office
202017052398	Synthetic Chimeric Vaccinia Virus	India
P00202008694	Synthetic Chimeric Vaccinia Virus	Indonesia
278419	Synthetic Chimeric Vaccinia Virus	Israel
2020-560920	Synthetic Chimeric Vaccinia Virus	Japan

Application No.	Title	Country / Region
PI 2020005696	Synthetic Chimeric Vaccinia Virus	Malaysia
MX/a/2020/011586	Synthetic Chimeric Vaccinia Virus	Mexico
768999	Synthetic Chimeric Vaccinia Virus	New Zealand
11202010272P	Synthetic Chimeric Vaccinia Virus	Singapore
2020/06350	Synthetic Chimeric Vaccinia Virus	South Africa
62021036744.2	Synthetic Chimeric Vaccinia Virus	Hong Kong
62021038254.0	Synthetic Chimeric Vaccinia Virus	Hong Kong

Stem cells-scPV treatment

Application No.	Title	Country / Region
2019/37505	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Gulf Cooperation Council
2019/41460	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 R.O.C.
17/049,741	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	U.S.A.
2019262150	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Australia
3098145	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Canada
201980029672.6	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	China
19797026.2	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	European Patent Office
278420	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Israel
2020-561064	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Japan
62021038255.7	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Hong Kong
62021031667.0	Stem Cells Comprising Synthetic Chimeric Vaccinia Virus and Methods of Using Them	Hong Kong

Poxvirus vaccine against COVID-19

Application No.	Title	Country / Region
17/187,678	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	U.S.A.
110107179	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Taiwan
20210100512	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Argentina
63/315,520	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	U.S.A.
1202200348	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	African Intellectual Property Organization
AP/P/2022/014318	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	African Regional Intellectual Property Organization
2021226592	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Australia
BR112022016992-2	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Brazil
3173996	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Canada
202180027983.6	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	China
202292431	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Eurasian Patent Office
21715007.7	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	European Patent Office
202217053476	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	India
P00202210244	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Indonesia
295925	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Israel
2022-551297	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Japan
PI 2022004613	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Malaysia
MX/a/2022/010588	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Mexico
791924	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	New Zealand
10-2022-7033014	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Republic of Korea
522440323	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Saudi Arabia
2022/09895	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	South Africa

Salts of glutathione

Application No.	Title	Country / Region
17/442,258	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	U.S.A.
2020249868	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	Australia
3,134,875	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	Canada
202080034626.8	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	China
20727359.0	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	European Patent Office
286730	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	Israel
2021-557223	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	Japan
62022054457.6	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	Hong Kong
62022057646.1	Salt forms of S-(N, N-diethylcarbamolyl) glutathione	Hong Kong

TFF2 therapeutics

Application No.	Title	Country / Region
17/638,761	Modified TFF2 polypeptides	U.S.A.
2020338947	Modified TFF2 polypeptides	Australia
3152665	Modified TFF2 polypeptides	Canada
202080071768.1	Modified TFF2 polypeptides	China
20781063.1	Modified TFF2 polypeptides	European Patent Office
202217016249	Modified TFF2 polypeptides	India
290910	Modified TFF2 polypeptides	Israel
2022-513154	Modified TFF2 polypeptides	Japan
MX/a/2022/002337	Modified TFF2 polypeptides	Mexico
786004	Modified TFF2 polypeptides	New Zealand
2022/03355	Modified TFF2 polypeptides	South Africa
62023066535.3	Modified TFF2 polypeptides	Hong Kong
62023066928.0	Modified TFF2 polypeptides	Hong Kong

Radioprotection therapeutics

Application No.	Title	Country / Region
17/991,292	Radio-Protective and Chemo-Protective Substituted Thiols	U.S.A.
17/923,831	Radio-and Chemo-Protective Compounds	U.S.A.
2021269125	Radio-and Chemo-Protective Compounds	Australia
3182014	Radio-and Chemo-Protective Compounds	Canada
Not Yet Assigned	Radio-and Chemo-Protective Compounds	China
21728771.3	Radio-and Chemo-Protective Compounds	European Patent Office
202217070148	Radio-and Chemo-Protective Compounds	India
298025	Radio-and Chemo-Protective Compounds	Israel
2022-567802	Radio-and Chemo-Protective Compounds	Japan
793900	Radio-and Chemo-Protective Compounds	New Zealand
522441204	Radio-and Chemo-Protective Compounds	Saudi Arabia
11202254727V	Radio-and Chemo-Protective Compounds	Singapore

Clinical data statistical analysis

Application No.	Title	Country / Region
PCT/US2021/056213	Randomization Honoring Methods to Assess the Significance of Interventions on Outcomes in Disorders	PCT
17/508,182	Randomization Honoring Methods to Assess the Significance of Interventions on Outcomes in Disorders	U.S.A.

Monoclonal Antibodies – anti-SARS-CoV-2 Spike

Application No.	Title	Country / Region
63/421,137	Anti-SARS-CoV-2-Spike Monoclonal Antibodies and Antigen-Binding Fragments Thereof and Use in Treating SARS-CoV-2 Infection	U.S.A.
63/421,138	Anti-SARS-CoV-2-Spike Monoclonal Antibodies and Antigen-Binding Fragments Thereof and Use in Treating SARS-CoV-2 Infection	U.S.A.
63/421,141	Anti-SARS-CoV-2-Spike Monoclonal Antibodies and Antigen-Binding Fragments Thereof and Use in Treating SARS-CoV-2 Infection	U.S.A.

Nanoparticles – T cell Immune Response

Application No.	Title	Country / Region
63/338,217	Nanoparticles for Inducing a TH1 T Cell Immune Response	U.S.A.

Nanoparticles – mRNA vaccine

Application No.	Title	Country / Region
PCT/US2022/070739	RNA Stabilizing Nanoparticles	PCT
PCT/US2022/075944	mRNA Vaccine Formulations and Methods of Using the Same	PCT

Virus Vaccine – Bovine Parainfluenza Virus Vaccine

Application No.	Title	Country / Region
17/755,359	Broadly Protective Bovine Parainfluenza 3 Virus and Bovine Viral Diarrhea Virus Vaccine	U.S.A.
PCT/US2022/072433	SARS-Coronavirus 2 (SARS-CoV-2) Spike Protein Subunit Vaccines	PCT

Antiviral Drugs – Cathepsin Inhibitors

Application No.	Title	Country / Region
63/327,431	Therapeutic Agents and Combinations for Treating Viral Diseases	U.S.A.
18/055,596	Compositions and Methods for Increasing Efficacy of a Drug	U.S.A.

Application No.	Title	Country / Region
2021271806	Compositions and Methods for Increasing Efficacy of a Drug	Australia
21803283.7	Compositions and Methods for Increasing Efficacy of a Drug	European Patent Office
2022-569505	Compositions and Methods for Increasing Efficacy of a Drug	Japan
202217072271	Compositions and Methods for Increasing Efficacy of a Drug	India
PCT/US2021/052664	Methods and Compositions for the Treatment of Viral Diseases	PCT

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).

We are the owner of the following marks for which applications for U.S. federal registration are currently pending: FYMRALIN (Serial No. 97/458017, filed June 14, 2022), MODALTIN (Serial No. 97/424052, filed May 23, 2022), RAPONTIS (Serial No. 97/424058, filed May 23, 2022), PROTECTIC (Serial No. 97/424071, filed May 23, 2022), TONIX PHARMACEUTICALS (Serial No. 88/896150, filed April 30, 2020), and ANGSTRO-TECHNOLOGY (Serial No. 88/690384, filed November 13, 2019) and TONMYA (Serial No. 97/185424, filed December 22, 2021).

Research and Development

We have approximately 94 employees dedicated to research and development. Our research and development operations are located in Chatham, NJ, Dartmouth, MA, Frederick, Maryland, 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. We acquired the RDC in Frederick, Maryland consisting of two buildings totaling approximately 48,000 square feet. The acquisition closed in October 2021 and is operational.

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- and mpox-preventing vaccine candidate is a biologic and employs a 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.

On September 28, 2020, we completed the purchase of our 45,000 square foot facility in Massachusetts, to house our new Advanced Development Center for accelerated development and manufacturing of vaccines and biologics. As of October 1, 2022, the facility was ready for its intended use and is operational.

On December 23, 2020, we completed the purchase of our approximately 44-acre site in Hamilton, Montana, for the construction of a vaccine development and commercial scale manufacturing facility. As of December 31, 2022, the facility was not ready for its intended use.

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, Long COVID and PTSD, for TNX-1900 for chronic migraine and TNX-2900 for Prader Willi Syndrome 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, Long COVID and PTSD; TNX-1900 for chronic migraine, and TNX-2900 for Prader Willi Syndrome. The FDA may not agree that these product candidates are approvable 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, the time and financial resources required to obtain FDA approval could substantially and materially increase and be less likely to be approved. If the FDA requires a full NDA 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 reference listed 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 505(b)(2) NDAs, 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

The Food and Drug Administration Safety and Innovation Act, or FDASIA, Section 902 provides for Breakthrough Therapy designation. 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.

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.

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.

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 implementation of 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.

Human Capital Resources

As of March 13, 2023, we had 117 full-time employees, of whom 19 hold M.D. or Ph.D. degrees. We have 94 employees dedicated to research and development. None of our employees are represented by a collective bargaining agreement. We believe that the skills, experience and industry knowledge of our key employees significantly benefit our operations and performance. Our research and development operations are located in Chatham, NJ, San Diego, CA, Dartmouth, MA, Frederick, Maryland, 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.

Employee health and safety in the workplace is one of our core values. The COVID-19 pandemic has underscored for us the importance of keeping our employees safe and healthy. In response to the pandemic, we have taken actions aligned with the World Health Organization and the Centers for Disease Control and Prevention in an effort to protect our workforce so they can more safely and effectively perform their work.

Employee levels are managed to align with the pace of business and management believes it has sufficient human capital to operate its business successfully.

Corporate Information

We lease the space for our principal executive offices, which are located at 26 Main Street, Suite 101, Chatham, New Jersey 07928, and our telephone number is (862) 799 8599. Our website address is www.tonixpharma.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

Summary of Risk Factors

- We have a history of operating losses and may never generate revenues or achieve profitability.
- We expect our operating results to fluctuate, which may make it difficult to predict our future performance.
- Our product candidates are novel and still in development.
- We do not expect to generate any revenues from product sales in the foreseeable future, if at all.
- We are largely dependent on the success of our product candidates and cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized.
- Clinical studies required for our product candidates are expensive and time-consuming, and their outcome is uncertain.
- We are subject to extensive and costly government regulation.
- We have never submitted an NDA before, and may be unable to do so for our product candidates we are developing.
- Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- We may be unable to meet our anticipated development and commercialization timelines for approval of any of our product candidates.
- Any breakthrough, fast track or orphan drug 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 assure FDA approval of our product candidates.
- Even if approved, our products may not be accepted by the market.
- 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.

- 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.
- 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.
- Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.
- Competition and technological change may make our product candidates and technologies less attractive or obsolete.
- If we fail to protect our intellectual property rights, our ability to pursue the development of our technologies and products would be negatively affected.
- We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.
- If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.
- 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 will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.
- Our executive officers and other key personnel are critical to our business, and our future success depends on our ability to retain them.
- If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.
- 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.
- 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.
- Adverse global conditions, including economic uncertainty, may negatively impact our financial results.
- Our internal computer systems, or those of our CRO's or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.
- Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products.
- 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.
- Our product candidates may face competition sooner than expected.
- 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 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.
- 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.
- Healthcare legislative reform measures may have a negative impact on our business and results of operations.
- 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.
- We face the risk of product liability claims and may not be able to obtain insurance.
- 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.
- If we retain collaborative partners and our partners do not satisfy their obligations, we will be unable to develop our partnered product candidates.
- We may be unsuccessful in obtaining a priority review voucher for material threat medical countermeasures.
- Government entities may take actions that directly or indirectly have the effect of limiting opportunities for our vaccines for COVID-19.
- 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.
- We face risks in connection with existing and future collaborations with respect to the development, manufacture, and commercialization of our product candidates.

- We face risks in connection with the testing, production and storage of our vaccine product candidates.
- An active trading market for our common stock may not be sustained.
- The market price of our common stock has been extremely volatile and may continue to be volatile due to numerous circumstances beyond our control.
- We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.
- 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 expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline.
- 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 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.
- 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.
- 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.
- 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.

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, and if and when we acquire rights to additional product candidates. 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 latest stage product candidate, TNX-102 SL for FM, Long COVID and potentially other CNS conditions. 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, Long COVID and potentially other CNS indications;
- 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 Long COVID, TNX-1900 for chronic migraine, TNX-601 ER for depression or any of our other product candidates in the United States and foreign jurisdictions;
- potential nonclinical toxicity and/or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of REMS, or cause an approved drug to be taken off the market;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; and
- potential product liability claims;

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

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

Our product candidates are novel and still in development.

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

Further, we and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical studies, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have one product candidate, TNX-102 SL, in Phase 3 development for the treatment of FM and Phase 2 development for the treatment of Long COVID, and we have three other products in Phase 2 development for the treatment of chronic migraine, depression and cocaine intoxication. The success of our business currently depends on the successful development, approval and commercialization of our product candidates and TNX-102 SL. Any projected sales or future revenue predictions are predicated upon FDA approval and market acceptance. 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 lead product candidates, and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

We have not yet submitted an NDA or foreign equivalent or received marketing approval for our lead product candidates anywhere in the world. The clinical development programs 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 our lead product candidates 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 COVID-related products 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 our COVID-related products 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 IRB 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 our product candidates we are developing.

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, 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 our 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, Long COVID 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 other CNS indications is our most advanced development product candidate which is in mid-Phase 3 for FM. The timeline for filing and review of our NDA for TNX-102 SL for FM is based on our plan to submit this NDA under Section

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

We may not be able to realize a shortened development timeline for TNX-102 SL for FM, Long COVID (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 breakthrough, fast track or orphan drug 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.

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 development of our lead product candidates. 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, 2022 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 anticipate that our existing cash and cash equivalents will enable us to maintain our current operations into the fourth quarter of 2023, but not beyond. 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 and the buildout of our research and development and manufacturing facilities. We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations into the fourth quarter of 2023, but not beyond. 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. The outbreak of such communicable diseases, such as COVID-19, has and may result in future widespread health crisis that 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.

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. For example, at least three vaccines for the prevention of COVID-19 have been approved to date, and we expect that other vaccines will be approved prior to the approval of our COVID-19 vaccine candidate, if it is approved at all. 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.

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.

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.

Except for the oppositions to European Patents 2501234, 2968992, and 2683245 (the Opposition Division in each of those oppositions maintained our claims in unamended form; Opponent has appealed that decision in the ‘234 Opposition and we expect the opponents to appeal the decisions in the ‘992 and ‘245 oppositions), 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 RESILIENT 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 and buildout of our research and development and manufacturing facilities, 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, the Phase 3 RECOVERY study, Phase 3 RELIEF study, the Phase 3 RALLY study and the Phase 3 RESILIENCE 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 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. 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.

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, or inflation could adversely impact our business. In addition, the global macroeconomic environment has been and may continue to be negatively affected by, among other things, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the Russian invasion of the Ukraine, the withdrawal of the United Kingdom from the European Union, and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which may adversely affect our business.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures.

While we have not, to our knowledge, experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, our information security systems and those of our CROs are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information gathered and used in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In the European Union the General Data Protection Regulation, or GDPR, is even more restrictive with respect to all personal information, including information masked by a coding system. In addition to HIPAA and GDPR, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed, our competitive position could be compromised, or our business reputation could be harmed.

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 BPCIA could be repealed or amended 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 or regulatory reform measures, including government restrictions on pricing and reimbursement, may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product 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. For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way healthcare is financed by both the government and private insurers, and significantly affects the pharmaceutical industry. Many provisions of the ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS.

Additionally, the Inflation Reduction Act of 2022, which took in 2023, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs covered by Medicare or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs.

Legislative, administrative, and private payor efforts to control drug costs span a range of proposals, including drug price negotiation, Medicare Part D redesign, drug price inflation rebates, international mechanisms, generic drug promotion and anticompetitive behavior, manufacturer reporting, and reforms that could impact therapies utilizing the accelerated approval pathway. We cannot predict the ultimate content, timing or effect of any changes to the ACA, the Inflation Reduction Act, or other federal and state healthcare policy reform efforts including those aimed at drug pricing. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare policy will affect our business.

At the federal level, the now-departed Trump administration proposed numerous prescription drug cost control measures. Similarly, the new Biden administration has made lowering prescription drug prices one of its priorities. The Biden administration has not yet proposed any specific plans, but we expect that these will be forthcoming in the near term. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Other examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. 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.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

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 $2,000,000 per annum. We cannot provide any assurances that we will be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

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

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

In 2016, the 21st Century Cures Act, or the Act, was signed into law to support ongoing biomedical innovation. One part of the Act, Section 3086, is aimed at "Encouraging Treatments for Agents that Present a National Security Threat." The Act created a new priority review voucher program for 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.

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. During 2020, $735 million was appropriated to SRF. As such, even if TNX-801 were to receive FDA licensure, the commercial success of TNX-801 remains uncertain.

Government entities may take actions that directly or indirectly have the effect of limiting opportunities for our vaccine candidates for COVID-19.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against COVID-19, which may have the effect of increasing the number of competitors and/or providing advantages to competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share if we ultimately receive regulatory approval for our vaccines as a vaccine for COVID-19. COVID-19 vaccines may also be subject to government pricing controls, which could adversely affect the profitability of any COVID-19 vaccine we are able to develop and commercialize.

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. 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-1850 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-1850 and TNX-801 may carry risk of infection and harm to individuals.

In addition, our TNX-1850 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-1850 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 Capital 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 of our common stock has been extremely volatile and may continue to be volatile due to numerous circumstances beyond our control.

The market price of our common stock has fluctuated, and may continue to fluctuate, widely, due to many factors, some of which may be beyond our control. These factors include, without limitation:

- "short squeezes";
- comments by securities analysts or other third parties, including blogs, articles, message boards and social and other media;
- large stockholders exiting their position in our common stock or an increase or decrease in the short interest in our common stock;
- actual or anticipated fluctuations in our financial and operating results;
- risks and uncertainties associated with the ongoing COVID-19 pandemic;
- the timing and allocations of new product candidates;
- public perception of our product candidates and competitive products;
- changes in financial estimates or recommendations by securities analysts;
- changes in the reimbursement policies of third party insurance companies or government agencies; and
- overall general market fluctuations.

Stock markets in general and our stock price in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies and our company. Broad market fluctuations may adversely affect the trading price of our common stock. In particular, a proportion of our common stock has been and may continue to be traded by short sellers which may put pressure on the supply and demand for our common stock, further influencing volatility in its market price. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

A "short squeeze" due to a sudden increase in demand for shares of our common stock that largely could lead to extreme price volatility in shares of our common stock.

Investors may purchase shares of our common stock to hedge existing exposure or to speculate on the price of our common stock. Speculation on the price of our common stock may involve long and short exposures. To the extent aggregate short exposure exceeds the number of shares of our common stock available for purchase on the open market, investors with short exposure may have to pay a premium to repurchase shares of our common stock for delivery to lenders of our common stock. Those repurchases may in turn, dramatically increase the price of our common stock until additional shares of our common stock are available for trading or borrowing. This is often referred to as a "short squeeze." A proportion of our common stock has been and may continue to be traded by short sellers which may increase the likelihood that our common stock will be the target of a short squeeze. A short squeeze could lead to volatile price movements in shares of our common stock that are unrelated or disproportionate to our operating performance or prospectus and, once investors purchase the shares of our common stock necessary to cover their short positions, the price of our common stock may rapidly decline. Investors that purchase shares of our common stock during a short squeeze may lose a significant portion of their investment.

We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.

We have had in the past, and may in the future, have difficulty satisfying Nasdaq listing requirements for our common stock. If we are unable to satisfy Nasdaq listing requirements, we will cease to be eligible to trade on Nasdaq. In such event:

- 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.

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, 2022.

ITEM 2 – PROPERTIES

We maintain our principal office at 26 Main Street, Suite 101, Chatham, New Jersey 07928. Our telephone number at that office is (862) 799-8599 and our fax number is (212) 923-5700. On August 28, 2020, we entered into a lease, whereby we agreed to lease new office space, commencing September 2020 and expiring December 2025. In connection therewith, we maintain a letter of credit, which has a remaining balance of $140,201 as of December 31, 2022, and such amount is deposited into the restricted cash account maintained at the bank that issued the letter of credit.

On December 6, 2018, we entered into a lease amendment, whereby we agreed to lease new office space in New York, New York, commencing January 15, 2019, and expiring on November 30, 2020. In August 2020, we signed a one-year extension, expiring in November 2021. In September 2021, we signed a one-year extension, expiring in November 2022. In May 2022, we signed a one-year extension, expiring in November 2023. In connection therewith, we maintain a letter of credit, which has a remaining balance of $100,653 as of December 31, 2022, and such amount is deposited into the restricted cash account maintained at the bank that issued the letter of credit.

On October 1, 2021, we completed the purchase of a research and development facility in Maryland totaling $17.5 million, to process development activities. As of December 31, 2022, the asset was operational and the asset was ready for its intended use.

On December 23, 2020, we completed the purchase of our approximately 44-acre site in Hamilton, Montana for $4.5 million, for the construction of a vaccine development and commercial scale manufacturing facility. As of December 31, 2022, the facility was not ready for its intended use.

On September 28, 2020, we completed the purchase of our 45,000 square foot facility in Massachusetts for $4.0 million, to house our new Advanced Development Center for accelerated development and manufacturing of vaccines. As of December 31, 2022, the facility was operational and ready for its intended use.

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

Year Ending December 31,		
2023	$	441
2024		164
2025		159
2026		9
2027		2
		775
Included interest		(15)
	$	760

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

Market Information

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

Holders

On March 10, 2023, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was $0.62 per share. On March 10, 2023, there were 231 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 – RESERVED

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 developing therapeutics and vaccines to treat and prevent human disease and alleviate suffering. We have a rich pipeline of products in development that has been curated from internal discovery, as well as licenses, acquisitions and collaborations with academic institutions and contract research organizations. We continue to build capabilities in synthetic biology, precision medicine, protein engineering, medicinal chemistry, molecular biology, pharmacogenomics and clinical-scale manufacturing. Our therapeutics under development include both small molecules and biologics.

Our portfolio consists of central nervous system, or CNS, rare disease, immunology, and infectious disease product candidates. The CNS portfolio includes small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Our rare disease portfolio focuses on developing novel therapies for patients with rare diseases, including those caused by genetic disorders which are characterized by complex symptoms and for which no drug is approved. Our immunology portfolio includes biologics to address organ transplant rejection, autoimmune diseases and cancer. Our infectious disease portfolio includes a vaccine in development to prevent smallpox and mpox (formerly known as monkeypox), next-generation vaccines to prevent COVID-19, a platform to make fully human mAbs to treat COVID-19 and humanized anti-SARS-CoV-2 mAbs. Our vaccine in development to prevent smallpox and mpox also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases.

Our latest stage CNS product candidate is TNX-102 SL*, a proprietary sublingual tablet formulation of cyclobenzaprine (CBP) designed for bedtime administration. TNX-102 SL has active INDs for fibromyalgia, or FM, FM-type Long COVID or PASC (post-acute sequelae of SARS-CoV-2 infection), posttraumatic stress disorder, or PTSD, agitation in Alzheimer's disease, or AAD, and alcohol use disorder, or AUD.

TNX-102 SL is in mid-Phase 3 development for the management of FM, a pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. In December 2020, we reported positive results from the Phase 3 RELIEF study of TNX-102 SL 5.6 mg for the management of FM. In July 2021, we reported pre-planned interim analysis results from a second Phase 3 study, RALLY. Based on the recommendation from the independent data monitoring committee that the RALLY trial was unlikely to demonstrate a statistically significant improvement in the primary endpoint, we stopped enrollment of new participants but allowed those participants who were already enrolled to complete the study. We reported topline data from the completed study in March of 2022. As expected, based on interim analysis results, TNX-102 SL did not achieve statistical significance over placebo on the primary endpoint of reduction in daily pain, and relative to the previous positive Phase 3 Study (RELIEF), RALLY had an unexpected increase in study participant adverse event-related discontinuations in both drug and placebo groups. In April 2022, we started a new potentially confirmatory Phase 3 study of TNX-102 SL in FM, RESILIENT. Interim analysis results are expected in the second quarter of 2023 and topline results are expected in the fourth quarter of 2023. Following a positive outcome of the RESILIENT study, we believe we would be positioned to file a New Drug Application (NDA) for TNX-102 SL for the management of FM.

TNX-102 SL is also being developed as a potential treatment for a type of Long COVID, the symptoms of which overlap with FM, that we term FM-type Long COVID. We initiated enrollment in the Phase 2 study PREVAIL, in August 2022. The primary endpoint is a change in daily pain scores from baseline.

For TNX-102 SL in PTSD, we completed the Phase 3 RECOVERY trial and reported topline results in the fourth quarter of 2020 in which TNX-102 SL did not meet the primary efficacy endpoint. PTSD is a serious psychiatric condition that develops in response to experiencing a traumatic event. We subsequently completed a meeting with the FDA to discuss potential new endpoints for the indication of treatment of PTSD. Future studies will employ the one month look-back CAPS-5 as the primary endpoint rather than the one week look-back used in prior studies.

The AAD program is Phase 2 ready with an active IND and FDA Fast Track designation. AAD, which includes emotional lability, restlessness, irritability, and aggression, is one of the most distressing and debilitating of the behavioral complications of Alzheimer's disease. We do not have any near-term plans to start a Phase 2 study in AAD.

The AUD program is also Phase 2 ready with an active IND. 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 alcohol. We do not have any near-term plans to start a Phase 2 study in AUD.

TNX-1900* (intranasal potentiated oxytocin) is in development for the treatment of chronic migraine and obesity-associated binge eating disorder, or BED. TNX-1900 was acquired from Trigemina, Inc. and licensed from Stanford University in 2020. The potentiated formulation includes magnesium, which has been shown in animal studies to potentiate binding of oxytocin to the oxytocin receptor. We received IND clearance from the FDA in the fourth quarter of 2021 to study TNX-1900 in chronic migraine and we initiated a Phase 2 study in migraine in the first quarter of 2023. We expect interim analysis results from the first 50 percent of patients enrolled in the fourth quarter of 2023. In March 2022, we announced an agreement with Massachusetts General Hospital, a teaching hospital of Harvard Medical School, to conduct an investigator-initiated Phase 2 clinical trial to study TNX-1900 in BED. The Phase 2 clinical trial is expected to start in the second quarter of 2023. We do not own an IND for BED. We also licensed technology to use TNX-1900 for the treatment of insulin resistance from the University of Geneva and also have rights to develop it as a treatment for craniofacial pain, but we are not imminently pursuing clinical trials in either of these indications at this time.

TNX-601 ER* (tianeptine hemioxalate extended-release tablets) is a CNS product candidate in development as a treatment for major depressive disorder, or depression, and with possible additional indications of PTSD, and neurocognitive dysfunction associated with corticosteroid use. TNX-601 ER represents a novel approach to treating depression in the U.S., since the active ingredient tianeptine induces a neuroprotective and resilient phenotype in both neurons and microglia under conditions of stress in animals. The dramatic and unique effects of tianeptine are illustrated in animal models by the restoration of dendritic arborization of pyramidal neurons of CA3 region of hippocampus and the dentate gyrus region new neuron formation and integration into hippocampal networks. In contrast, antidepressants that are marketed in the U.S. act by modulating the levels or receptor binding of neurotransmitters in the synapse. We have completed a Phase 1 trial for formulation development outside of the U.S. We expect to initiate a potentially pivotal Phase 2 study in the first quarter of 2023 for the treatment of major depressive disorder and we expect interim analysis results from the first 50 percent of patients enrolled in the fourth quarter of 2023.

Another CNS candidate in development is TNX-1300* (double-mutant cocaine esterase) which is in Phase 2 for the treatment of life-threatening cocaine intoxication. TNX-1300 has been granted Breakthrough Therapy designation, or BTD, by the U.S. Food and Drug Administration, or FDA. TNX-1300 was licensed from Columbia University in 2019 after a Phase 2 study showed that it rapidly and efficiently disintegrates cocaine in the blood of volunteers who received intravenous, or i.v., cocaine. In August of 2022, we received

a Federal Grant from the National Institute on Drug Abuse (NIDA) to advance the development of TNX-1300 as a treatment for cocaine intoxication. We expect to initiate a potentially pivotal Phase 2 study of TNX-1300 in emergency rooms in the second quarter of 2023.

Finally, our CNS pipeline includes TNX-1600*, an inhibitor of the reuptake of neurotransmitters serotonin, norepinephrine and dopamine, or a triple reuptake inhibitor. TNX-1600 was licensed from Wayne State University in 2019 and is expected to be developed as a treatment for PTSD, depression and attention-deficit/hyperactivity disorder, or ADHD. TNX-1600 is in the preclinical stage of development.

Our rare disease portfolio consists of TNX-2900*, another magnesium-potentiated, intranasal oxytocin-based therapeutic in development for the treatment of Prader-Willi syndrome, or PWS. The technology for TNX-2900 was licensed from Inserm, the French National Institute of Health and Medical Research. PWS, an orphan condition, is a rare genetic disorder of failure to thrive in infancy, associated with uncontrolled appetite beginning in childhood with complications of obesity and diabetes. We have sponsored a research program at Inserm to study oxytocin on suckling behavior in mice that have been engineered to express one of the Prader-Willi genes. TNX-2900 has been granted Orphan-Drug Designation for the treatment of PWS, and is in the pre-IND stage of development.

Our lead candidate in the immunology pipeline is TNX-1500*, a humanized mAb, directed against CD40-ligand, or CD40L (also known as CD154), engineered to modulate binding to Fc receptors, that is being developed as a prophylaxis against organ transplant rejection as well as to treat autoimmune conditions. In experiments at the Massachusetts General Hospital or MGH, a teaching hospital of Harvard Medical School, TNX-1500 is being studied as monotherapy or in combination with other immunosuppressive agents in heart and kidney allogeneic organ transplants in non-human primates. Preliminary results from ongoing experiments in kidney and heart transplants indicate that TNX-1500 appears to have comparable efficacy to historical experiments using the chimeric mouse/human IgG1 version (5c8H1) of the anti-CD40L mAb 5c8. First generation anti-CD40L mAb therapies were associated with an increased risk of blood clots or thrombosis. In the non-human primate studies with TNX-1500 for allogeneic kidney or heart transplantation, no evidence of thrombosis has been observed so far. We expect to start a Phase 1 study of TNX-1500 in the second quarter of 2023. TNX-1500 also is being studied in combination with other immunosuppressive agents in xenogeneic organ transplants in non-human primates at MGH and at the University of Maryland at Baltimore or UMB. In experiments at UMB, TNX-1500 is being studied to prevent rejection of xenogeneic hearts from genetically engineered pigs developed by the Revivicor division of United Therapeutics Corporation.

Our immunology pipeline also includes TNX-1700*, a recombinant Trefoil Factor Family 2, or rTFF2, fusion protein that was licensed from Columbia University in 2019. TNX-1700 consists of TFF2 fused to human serum albumin or I and is a biologic being developed to treat gastric and colorectal cancers by an immune-oncology mechanism, in combination with PD1 blockers, and is in the preclinical stage of development. We recently presented data that show a murine version of TNX-1700 consisting of a fusion protein with murine serum albumin or MSA was able to evoke anti-tumor immunity in the MC38 mouse model of colorectal cancer as monotherapy and that TNX-1700 augmented the efficacy of anti-PD1 therapy in both the MC38 mouse model and the CT26.wt models of colorectal cancer.

Our infectious disease portfolio includes vaccines based on our live virus vaccine or recombinant pox vaccine, "RPV" platform. Live virus vaccines are believed to protect against poor clinical outcomes of infectious diseases by eliciting T cell responses in addition to antibody responses. TNX-801*, a live attenuated vaccine based on synthesized horsepox is in the pre-IND stage of development to protect against smallpox and mpox. Non-human primates vaccinated with TNX-801 were protected from monkeypox in studies reported in the first quarter of 2020. A Phase 1 study of TNX-801 in humans is expected to start in the second half of 2023. TNX-801 also serves as the live virus vaccine platform for other infectious diseases for which subsequent products will be designed by expressing other viral antigens in the horsepox vector.

TNX-1850* is a live virus vaccine that expresses the SARS-CoV-2 spike protein from the BA.2 strain that has not yet been tested in animals. TNX-1800* is a live virus vaccine that expresses the SARS-CoV-2 spike protein from the ancestral Wuhan strain, which has shown encouraging results in non-human primates. Because the subsequent omicron variant out-competed the ancestral Wuhan strain, we began work on new vaccine versions, TNX-1840* and TNX-1850*, that are designed to express spike protein from the omicron variant and from the BA.2 variant, respectively. Of those, based on the trajectory of COVID-19, the focus is now on TNX-1850. The COVID-19 vaccines that are approved for use, or have emergency use authorization, or EUA, in the U.S. have provided significant health benefits to the vaccinated population; however, they have shown limitations in the durability of protection conferred and in their ability to block forward transmission. Live virus vaccines that protect against other viral diseases by eliciting T cell responses have shown durability of protection that lasts years to decades and some live virus vaccines have significantly inhibited forward transmission. With respect to TNX-1800 vaccination, we reported positive efficacy data from animal challenge studies using live SARS-CoV-2 in the first quarter of 2021. In this study, TNX-1800 vaccinated, SARS-CoV-2 challenged animals had undetectable SARS-CoV-2 in the upper airways, which we believe relates to potential inhibition of forward transmission of this respiratory pathogen.

TNX-2300* is a live virus vaccine based on bovine parainfluenza virus in development to protect against COVID-19. In April 2022, we extended a sponsored research agreement with Kansas State University to develop a vaccine candidate, TNX-2300, for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform based on bovine parainfluenza virus. The efficacy of co-expression of the CD40-ligand, also known as CD154, to stimulate T cell immunity will also be tested. Attenuated bovine parainfluenza virus has previously been shown to be an effective antigen delivery vector in humans. Previous work by others has shown

that attenuated BPI3V is tolerated and immunogenic in non-human primates and human infants and children. We believe the vector is well suited for mucosal immunization using a nasal atomizer, and can also be delivered parenterally. TNX-2300 is in the preclinical stage of development.

TNX-3600* and TNX-3800* are mAbs directed against SARS-CoV-2 which are in development as potential therapeutic or preventative agents for COVID-19. Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants, we seek to contribute a broad set of anti-SARS-CoV-2 mAbs, that can be scaled up quickly and potentially combined with other mAbs. We envision the future of mAb therapy for COVID-19 to be cocktails of mAbs with specificity to variants of concern. TNX-3600 refers to a series of fully human mAbs generated by human-human hybridomas from COVID-19 convalescent volunteers. We are collaborating with Columbia University to produce these fully human mAbs to SARS-CoV-2 spike proteins from variants such as delta, omicron and XBB1.5 and to other viral targets. TNX-3800 refers to three humanized murine mAbs which we licensed exclusively in December 2022 from Curia Global, Inc. for the treatment or prophylaxis of SARS-CoV-2 infection. The initial focus is to develop COVID-19 therapeutic mAbs. We plan to seek indications similar to previously EUA-approved therapeutic mAbs for treating individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease or for prophylaxis in individuals with compromised immune systems who are at high risk for severe COVID-19 disease. None of the previously EUA-approved therapeutic or preventative mAbs are still available, because each has become obsolete since the SARS-CoV-2 virus has mutated to evade their binding. TNX-3600 and TNX-3800 mAbs may also be used in combination therapy with other COVID-19 therapeutic mAbs. Combination therapies with other anti-SARS-CoV-2 mAbs may reduce the emergence of resistant viral strains. TNX-3600 and TNX-3800 are in the preclinical stage of development.

TNX-3700* is a COVID-19 mRNA vaccine candidate employing a zinc nanoparticle (ZNP) formulation. In collaboration with Kansas State University, we are developing this ZNP technology as a potential replacement for the lipid nanoparticle (LNP) technology used in current mRNA vaccines. ZNP technology potentially allows for improved stability which facilitates shipping and storage and addresses the limitations in current mRNA vaccines which require ultra-cold storage and shipping. This current requirement limits the use of mRNA vaccines in less developed countries. We plan to seek initial indications as a booster, similar to the current FDA approved mRNA vaccines for COVID-19. We intend to conduct research with Kansas State University on ZNP SARS-CoV-2 spike based vaccines in tissue culture and animals in the first half of 2023. TNX-3700 is in the preclinical stage of development.

Relating to our COVID-19 and other infectious disease development programs, we are developing the resources necessary to enable internal research, development and manufacturing capabilities necessary to meet the goal of producing new vaccine candidates within 100 days of recognition within weeks of obtaining sequence information of a novel pathogen. We seek to be a leader in the movement to re-build domestic U.S. research, development and manufacturing capabilities. Because this movement follows a protracted period when domestic research, development and manufacturing were moved out of the U.S., or "off-shore" by other companies to save on labor and other costs, the movement to reverse that trend has been described as "on-shoring" or "re-domestication". The COVID-19 pandemic taught that national borders may close during a health emergency. Therefore, domestic capabilities are essential for the health security of the U.S., which has also been described as pandemic preparedness and biodefense. As articulated in the American Pandemic Preparedness Plan, or AP3, released by the U.S. Office of Science and Technology Policy, this 100-day goal for vaccines is a key component of preparedness for future pandemics. We believe we have established the infrastructure necessary to support the pandemic preparedness goals established in the AP3, specifically with respect to our RPV vaccine and potentially to other vaccine and therapeutic platforms. This infrastructure consists of (i) our R&D Center, or "RDC", (ii) our Advanced Development Center, or ADC, and (iii) our Commercial Manufacturing Center, or CMC. We acquired the RDC in Frederick, Maryland consisting of one building totaling approximately 48,000 square feet. The acquisition closed in October 2021 and the facility is operational. The RDC facility focuses on our development of vaccines and antiviral drugs against SARS-CoV-2, its variants, and other infectious diseases. The RDC also conducts research on central nervous system and immunology drugs. The RDC facility is mostly biosafety level 2 (BSL-2), with some components designated BSL-3. We completed the substantial renovation of the ADC located in the New Bedford business park in Dartmouth, Massachusetts, which became operational as of the fourth quarter 2022. This approximately 45,000 square foot BSL-2 facility is intended to accelerate development and clinical scale manufacturing of live-virus vaccines and biologics to support clinical trials. We also plan to build the CMC in Hamilton, Montana, where we purchased approximately 44 acres of land and have built a field office to manage construction of the facility. The CMC will focus on developing and manufacturing commercial scale live-virus vaccines and biologics and is also intended to be BSL-2. Site enabling work is expected to be initiated for the CMC in 2023. Together, we expect these facilities may qualify the RPV vaccine platform for programs that are designed to carry out the goals of AP3.

*All of our product candidates are investigational new drugs or biologics and have not been approved for any indication.

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.

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, 2022 Compared to Fiscal year Ended December 31, 2021

The following table sets forth our operating expenses for the fiscal years ended December 31, 2022 and 2021 (in thousands):

	Year ended December 31,	
	2022	2021
COSTS AND EXPENSES:		
Research and development	$ 81,876	$ 68,838
General and administrative	30,215	23,474
Total operating expenses	112,091	92,312
Operating loss	(112,091)	(92,312)
Interest income, net	1,873	25
Net loss	$ (110,218)	$ (92,287)

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2022, were $81.9 million, an increase of $13.1 million, or 19%, from $68.8 million for the fiscal year ended December 31, 2021. This increase is predominately due to increased employee-related expenses of $9.0 million, predominately related to new hires at the RDC and ADC, lab supplies of $3.3 million, and office-related expenses of $1.4 million related to our new facilities offset by a decrease in regulatory expenses of $0.4 million and a decrease in market research expenses of $0.3 million. We expect research and development expenses to increase during 2023 as we move our clinical development programs forward and continue to invest in our development pipeline.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the years ended December 31, 2022, and 2021.

	December 31, (in thousands)		
	2022	2021	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	$ 13,530	$ 13,974	$ (444)
Direct expenses – TNX - 1800	3,819	8,049	(4,230)
Direct expenses – TNX - 601 ER	1,308	4,602	(3,294)
Direct expenses – TNX - 801	2,111	81	2,030
Direct expenses – TNX - 1300	3,233	5,882	(2,649)
Direct expenses – TNX - 1500	11,510	5,334	6,176
Direct expenses – TNX - 1900	4,155	2,429	1,726
Direct expenses – TNX - 2100	1,434	3,410	(1,976)
Direct expenses – TNX - 3500	1,162	5,368	(4,206)
Direct expenses – Other programs	7,912	4,861	3,051
Internal staffing, overhead and other	31,702	14,848	16,854
Total research & development	$ 81,876	$ 68,838	$ 13,038

Our direct research and development expenses consist principally of external costs for clinical, nonclinical and manufacturing, such as fees paid to contractors, consultants and CROs in connection with our development work. Included in "Internal Staffing, Overhead and Other" is overhead, supplies, research and development employee costs (including stock option expenses), travel, regulatory and legal.

General and Administrative Expenses. General and administrative expenses for the fiscal year ended December 31, 2022 were $30.2 million, an increase of $6.7 million, or 29%, from $23.5 million incurred in the fiscal year ended December 31, 2021. The increase is primarily due to employee-related expenses of $4.3 million, of which $2.4 million relates to stock-based compensation, an increase in legal fees of $0.1 million due to increased patent prosecution costs, an increase in software/technology expenses of $0.5 million, an increase in financial reporting expenses of $1.1 million, and an increase in travel-related of $0.4 million.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2022 was $110.2 million, compared to a net loss of $92.3 million for the year ended December 31, 2021.

License Agreements

On February 13, 2023, we exercised an option to obtain an exclusive license from Columbia for the development of a portfolio of both fully human and murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection, including our TNX-3600 and TNX-4100 product candidates, respectively. The licensed mAbs were developed as part of a research collaboration and option agreement between us and Columbia.

On December 12, 2022, we entered into an exclusive license agreement with Curia for the development of three humanized murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection. We believe that the licensing of these mAbs strengthens our pipeline of next-generation therapeutics to treat COVID-19, which is caused by SARS-CoV-2. As consideration for entering into the License Agreement, we paid a license fee of approximately $0.4 million to Curia. The License Agreement also provides for single-digit royalties and contingent milestone payments. As of December 31, 2022, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

On May 18, 2022, we entered into an exclusive License Agreement with the University of Alberta focused on identifying and testing broad-spectrum antiviral drugs against future variants of SARS-CoV-2 and other emerging viruses. As consideration for entering into the License Agreement, we paid a low-five digit license fee to University of Alberta. The License Agreement also provides for single-digit royalties and contingent milestone payments. As of December 31, 2022, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

On April 14, 2021, we and OyaGen, Inc. ("OyaGen") entered into an exclusive License Agreement (the "OyaGen License Agreement") pursuant to which OyaGen granted us an exclusive license to certain patents and technical information related to an antiviral inhibitor of SARS-CoV-2, sangivamycin, and to develop and commercialize products thereunder, and to acquire rights to any technology based thereon for the prevention or treatment of Covid-19 developed by OyaGen during the term of the License Agreement.

As consideration for entering into the License Agreement, we agreed to pay a low-seven digit license fee to OyaGen, and agreed to issue to OyaGen and an affiliated entity an aggregate of 86,010 shares of our common stock, valued at $3.0 million, which are unregistered and subject to a six-month lock-up and a voting agreement, pursuant to which OyaGen and the affiliated entity have agreed to vote the common stock on any matter put to a vote of the shareholders of the Company in accordance with management's recommendations. The OyaGen License also provides for single-digit royalties and contingent milestone payments. No milestone payments were accrued or paid in relation to this agreement. In July 2022, we notified OyaGen of our intent to terminate the License Agreement, and the agreement was terminated effective September 20, 2022.

On February 11, 2021, we entered into a license agreement (the "Inserm License Agreement") pursuant to which we licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from Inserm (the French National Institute of Health and Medical Research), Aix-Marseille Université and Centre Hospitalier Universitaire of Toulouse. The Inserm License Agreement provides for the payment of annual fees and milestone payments upon the occurrence of specified sales milestones, totaling approximately $0.4 million, as well royalties on net sales of products based on the licensed technology, and assignment/transfer and sublicense royalties. As of December 31, 2022, no milestone payments have been accrued or paid in relation to this agreement.

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"), as subsequently amended, pursuant to which Columbia granted to us an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the "TFF2 Technology") related to a recombinant Trefoil Family Factor 2 (TFF2), and to develop and commercialize products thereunder (each, a "TFF2 Product"). Pursuant to the terms of the 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 research and development expenses in the statement of operations for the year ended December 31, 2019. We are 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 are obligated to pay Columbia single-digit royalties on net sales of (i) TFF2 Products sold by us or a sublicensee and (ii) any other products that involve material or technical information related to the TFF2 Product and transferred to us pursuant to the License Agreement ("Other Products") sold by us or a sublicensee. Royalties on each particular TFF2 Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the 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 us to any third party

for intellectual property rights which are necessary for the practice of the rights licensed to us 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, 2022, 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 paid 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.

We are obligated to pay Columbia single-digit royalties on net sales of (i) Products sold by us or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to us pursuant to the License Agreement ("Other Products") sold by us or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the 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, 2022, no milestone payments have been accrued or paid in relation to this agreement.

Asset Purchase Agreements

On February 2, 2023, we entered into an asset purchase agreement (the "Asset Purchase Agreement") with Healion Bio Inc., pursuant to which we acquired all the pre-clinical infectious disease assets of Healion, including its portfolio of next-generation antiviral technology assets. Healion's drug portfolio includes a class of broad-spectrum small molecule oral antiviral drug candidates with a novel host-directed mechanism of action, including TNX-3900, formerly known as HB-121. As consideration for entering into the Asset Purchase Agreement, we paid $1.2 million to Healion. Because the Healion intellectual property was acquired prior to FDA approval, the cash consideration totaling $1.2 million, is expected to be expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

On December 22, 2020, we entered into an asset purchase agreement (the "Asset Purchase Agreement") with Katana Pharmaceuticals, Inc. ("Katana") pursuant to which we acquired Katana assets related to insulin resistance and related syndromes, including obesity (the "Katana Assets"). In connection with the acquisition of the Assets, we assumed Katana's rights and obligations under that certain Exclusive License Agreement by and between Katana and The University of Geneva ("Geneva") (the "Geneva License "Agreement") pursuant to an Assignment and Assumption Agreement with Geneva ("Geneva Assignment and Assumption Agreement"), dated December 22, 2020. As consideration for entering into the Asset Purchase Agreement, we paid $0.7 million to Katana. Because the Katana intellectual property was acquired prior to FDA approval, the cash consideration totaling $0.7 million, was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

Pursuant to the terms of the Geneva Assignment and Assumption Agreement, Geneva granted us an exclusive license, with the right to sublicense, certain patents related to the Katana Assets. We are obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Geneva 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 Geneva. As of December 31, 2022, no milestone payments have been accrued or paid in relation to this agreement.

On June 11, 2020, we entered into an asset purchase agreement (the "Trigemina Asset Purchase Agreement") with Trigemina, Inc. ("Trigemina") and certain shareholders named therein (the "Executive Shareholders") pursuant to which we acquired Trigemina assets related to migraine and pain treatment technologies (the "Trigemina Assets"). In connection with the acquisition of the Trigemina Assets, we assumed Trigemina's rights and obligations under that certain Amended and Restated Exclusive License Agreement, dated November 30, 2007, as amended, by and between Trigemina and The Board of Trustees of the Leland Stanford Junior University ("Stanford") (the "Stanford License "Agreement") pursuant to an Assignment and Assumption Agreement with Stanford ("Assignment and Assumption Agreement"), dated June 11, 2020.

As consideration for entering into the Trigemina Asset Purchase Agreement, we paid $824,759 to Trigemina and issued to Trigemina 62,500 shares of our common stock and paid Stanford $250,241 pursuant to the terms of the Assignment and Assumption Agreement. The common stock is unregistered and subject to a 12 month lock-up and a Shareholder Voting Agreement, dated June 11, 2020, pursuant to which Trigemina and the Executive Shareholders have agreed to vote the common stock on any matter put to a vote of our shareholders in accordance with management's recommendations. Both the costs associated with the cash payments and share issuance, totaling $2.4 million, were recorded to research and development in the statement of operations for the year ended December 31, 2020. Because the Trigemina intellectual property was acquired prior to FDA approval, the cash and stock consideration was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

Pursuant to the terms of the Assignment and Assumption Agreement, Stanford has granted us an exclusive license, with the right to sublicense, certain patents related to the Trigemina Assets. Stanford has reserved for itself the right to practice under the patents for academic research and educational purposes. We are obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Stanford 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 Stanford. As of December 31, 2022, other than the annual maintenance fee, 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 "TRImaran 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 "TRImaran Assets"). In connection with the acquisition of the TRImaran 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 subsequently amended. As consideration for entering into the TRImaran Asset Purchase Agreement, we paid $100,000 to TRImaran and have assumed certain liabilities of TRImaran totaling $68,500. The $168,500 was recorded to research and development expenses in the statement of operations in 2019. 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. Pursuant to the terms of the TRImaran Asset Purchase Agreement, TRImaran and the Selling Shareholders are prohibited from disclosing confidential information related to the TRImaran 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. As of December 31, 2022, no milestone payments have been accrued or paid in relation to this agreement.

Pursuant to the terms of the WSU License Agreement, WSU granted us an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the "Technology") related to the TRImaran 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. We are 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 paid $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, 2022, no milestone payments have been accrued or paid in relation to this agreement.

Liquidity and Capital Resources

As of December 31, 2022, we had working capital of $112.6 million, comprised primarily of cash and cash equivalents of $120.2 million and prepaid expenses and other of $10.5 million, offset by $8.1 million of accounts payable, $9.7 million of accrued expenses and other current liabilities and $0.4 million of lease liabilities, short term. 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 our vaccine program.

The following table provides a summary of operating, investing and financing cash flows for the years ended December 31, 2022, and 2021, respectively (in thousands):

	December 31,	
	2022	2021
Net cash used in operating activities	$ (98,053)	$ (75,557)
Net cash used in investing activities	(48,147)	(35,307)
Net cash provided by financing activities	87,844	212,487

For the years ended December 31, 2022 and 2021, we used approximately $98.1 million and $75.6 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 research and development and general and administrative activities.

Cash used by investing activities for the years ended December 31, 2022 and 2021 was approximately $48.1 million and $35.3 million, respectively, related to the purchase of property and equipment. A significant portion of capital expenditure relates to the build-out of the RDC and ADC.

For the years ended December 31, 2022 and 2021, net proceeds from financing activities were $87.8 million and $212.5 million, respectively, predominately from the sale of our common stock.

We believe that our cash resources at December 31, 2022 and the proceeds that we raised from equity offerings in the first quarter of 2023, net of amounts paid to repurchase shares in the first quarter of 2023, will meet our operating and capital expenditure requirements into the fourth quarter of 2023, but not beyond.

We 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 believe 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 and the buildout of our research and development operations and manufacturing. 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.

Share Repurchase Program

Since January 1, 2023, the Company has repurchased 15,700,269 of its shares of common stock outstanding under a $12.5 million share purchase program at prices ranging from $0.44 to $1.38 per share for a gross aggregate cost of approximately $12.5 million.

In January 2023, the Board of Directors approved a new share repurchase program pursuant to which the Company may repurchase up to an additional $12.5 million in value of its outstanding common stock from time to time on the open market and in privately negotiated transactions subject to market conditions, share price and other factors. Since January 1, 2023, the Company has repurchased 1,000,000 of its shares of common stock outstanding under the new share repurchase program at $1.14 per share for a gross aggregate cost of $1.1 million.

Convertible Redeemable Preferred stock

On October 26, 2022, we issued 1,400,000 shares of Series A Preferred Stock and 100,000 shares of Series B Preferred Stock to certain institutional investors in a private placement. The Preferred Stock had an aggregate stated value of $15,000,000. Each share of the Preferred Stock had a purchase price of $9.50, representing an original issue discount ("OID") of 5% of the stated value. The shares of the preferred stock were convertible into shares of our common stock, upon the occurrence of certain events, at a conversion price of $1.00 per share, at the option of the holder, and at our option upon the fulfillment of certain conditions and subject to certain limitations. The Company and the holders of the preferred stock also entered into a registration rights agreement to register the resale of the shares of common stock issuable in the event of the conversion of the preferred stock. The $14.3 million in gross proceeds of the offering were held in an escrow account, along with an additional $1.5 million deposited by the Company to cover the aggregate OID as well as the additional amount that would have been necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock.

All outstanding shares of the Series A Convertible Redeemable Preferred Stock and Series B Convertible Redeemable Preferred Stock were redeemed in December 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $15.8 million in the aggregate.

On June 24, 2022, we issued 2,500,000 shares of Series A Preferred Stock and 500,000 shares of Series B Preferred Stock to certain institutional investors in a private placement. The Preferred Stock had an aggregate stated value of $30,000,000. Each share of the Preferred Stock had a purchase price of $9.50, representing an OID of 5% of the stated value. The shares of the preferred stock were convertible into shares of our common stock, upon the occurrence of certain events, at a conversion price of $4.00 per share, at the option of the holder, and at our option upon the fulfillment of certain conditions and subject to certain limitations. The Company and the holders of the preferred stock also entered into a registration rights agreement to register the resale of the shares of common stock issuable in the event of the conversion of the preferred stock. The $28.5 million in gross proceeds of the offering were held in an escrow account, along with an additional $3.0 million deposited by the Company to cover the aggregate OID as well as the additional amount that would have been necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock.

All outstanding shares of the Series A Convertible Redeemable Preferred Stock and Series B Convertible Redeemable Preferred Stock were redeemed in August 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $31.5 million in the aggregate.

2022 Lincoln Park Transaction

On August 16, 2022, we entered into a purchase agreement (the "2022 Purchase Agreement") and a registration rights agreement (the "2022 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2022 Purchase Agreement, Lincoln Park has agreed to purchase from us up to $50,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2022 Purchase Agreement. Pursuant to the terms of the 2022 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 2022 Purchase Agreement.

Pursuant to the terms of the 2022 Purchase Agreement, at the time we signed the 2022 Purchase Agreement and the 2022 Registration Rights Agreement, we issued 625,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2022 Purchase Agreement. The commitment shares were valued at $1,000,000 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 2022 Purchase Agreement.

During the year ended December 31, 2022, we sold 1.0 million shares of common stock under the 2022 Purchase Agreement, for net proceeds of approximately $0.5 million. Subsequent to December 31, 2022, the Company sold 0.6 million shares of common stock under the Purchase Agreement with Lincoln Park for net proceeds of approximately $0.4 million.

Purchase Agreement with Lincoln Park

On December 3, 2021, we entered into a purchase agreement (the "Purchase Agreement with Lincoln Park") and a registration rights agreement (the "Lincoln Park Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the Purchase Agreement with Lincoln Park, Lincoln Park agreed to purchase from us up to $80,000,000 of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement with Lincoln Park. Pursuant to the terms of the Lincoln Park 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 Purchase Agreement with Lincoln Park.

Pursuant to the terms of the Purchase Agreement with Lincoln Park, at the time we signed the Purchase Agreement with Lincoln Park and the Lincoln Park Registration Rights Agreement, we issued 90,910 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement with Lincoln Park. The commitment shares were valued at $1.6 million 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 Purchase Agreement with Lincoln Park.

During the year ended December 31, 2022, we sold 2.9 million shares of common stock under the Purchase Agreement with Lincoln Park, for net proceeds of approximately $8.7 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 Purchase Agreement (approximately 2.9 million shares) with Lincoln Park under the Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the Purchase Agreement equals or exceeds a threshold amount. As we have issued approximately 2.9 million shares to Lincoln Park under the Purchase Agreement at less than the threshold amount, we will not sell any additional shares under the Purchase Agreement without shareholder approval.

2021 Lincoln Park Transaction

On May 14, 2021, we entered into a purchase agreement (the "2021 Purchase Agreement") and a registration rights agreement (the "2021 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2021 Purchase Agreement, Lincoln Park agreed to purchase from us up to $80,000,000 of our common stock (subject to certain limitations) from time to time during the term of the 2021 Purchase Agreement. Pursuant to the terms of the 2021 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 2021 Purchase Agreement.

Pursuant to the terms of the 2021 Purchase Agreement, at the time we signed the 2021 Purchase Agreement and the 2021 Registration Rights Agreement, we issued 40,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2021 Purchase Agreement. The commitment shares were valued at $1.6 million 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 2021 Purchase Agreement.

During the year ended December 31, 2021, we sold an aggregate of approximately 2.0 million shares of common stock under the 2021 Purchase Agreement, for gross proceeds of approximately $41.3 million. During the year ended December 31, 2022, no shares of common stock were sold under the 2021 Purchase Agreement.

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 2021 Purchase Agreement (approximately 2.0 million shares) to Lincoln Park under the 2021 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of our common stock to Lincoln Park under the 2021 Purchase Agreement equals or exceeds a threshold amount.

As we have issued approximately 2.0 million shares to Lincoln Park under the 2021 Purchase Agreement, at less than the threshold amount, we will not sell any additional shares under the 2021 Purchase Agreement without shareholder approval.

February 2021 Financing

On February 8, 2021, we entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.8 million shares of our common stock, in a registered direct public offering ("the February 2021 Financing"), with A.G.P/Alliance Global Partners ("AGP"), acting as placement agent. The public offering price for each share of common stock was $38.40. The February 2021 Financing closed on February 9, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate

amount of $4.9 million. We incurred other offering expenses of approximately $0.1 million. We received net proceeds of approximately $65.0 million, after deducting the fees and other offering expenses.

January 2021 Financing

On January 11, 2021, we entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.6 million shares of its common stock in a registered direct public offering ("the January 2021 Financing"), with AGP as placement agent. The public offering price for each share of common stock was $25.60. The January 2021 Financing closed on January 13, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate of $2.8 million. We incurred other offering expenses of approximately $0.3 million. The Company received net proceeds of approximately $36.9 million, after deducting the fees and other offering expenses.

At-the-Market Offerings

On April 8, 2020, we entered into a sales agreement (the "Sales Agreement") with AGP 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 $320.0 million in at-the-market offerings ("ATM") sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. Our common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the year ended December 31, 2022, we sold approximately 56.4 million shares of common stock under the Sales Agreement, for net proceeds of approximately $85.3 million. During the year ended December 31, 2021, we sold approximately 3.5 million shares of common stock under the Sales Agreement, for net proceeds of approximately $69.3 million. Subsequent to December 31, 2022, we sold 2.1 million shares of common stock under the Sales Agreement, for net proceeds of approximately $1.4 million.

Stock Compensation

Stock Options

On May 3, 2019, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the "2019 Plan"). The 2019 Plan provided for the issuance of up to 4,375 shares of our common stock. With the adoption of the 2020 Plan (as defined below), no further grants may be made under the 2019 Plan. On January 16, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan (the "2020 Plan"). The 2020 Plan provided for the issuance of up to 18,750 shares of our common stock. With the adoption of the Amended and Restated 2020 Plan (as defined below), no further grants may be made under the 2020 Plan.

On May 1, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan ("Amended and Restated 2020 Plan"), and together with the 2020 Plan and the 2019 Plan, the "Plans").

Under the terms of the Amended and Restated 2020 Plan, we may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights ("SARs"), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 312,500 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the Amended and Restated 2020 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 Amended and Restated 2020 Plan may not be more than ten years. As of December 31, 2022, 627,735 shares were available for future grants under the Amended and Restated 2020 Plan.

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. The fair value of the award is measured on the grant date. One-third of most stock options granted pursuant to the Plans vest 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. The Company also issues premium options to executive officers which have an exercise price greater than the grant date fair value and has issued performance-based options which vest when target parameters are met or

probable of being met, 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 service period using the straight-line method.

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.

The weighted average grant date fair value of options granted during the years ended December 31, 2022 and 2021, was $5.25 and $33.78 per share, respectively.

Stock-based compensation expense relating to options granted of $10.9 million, of which $7.9 million and $3.0 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2022. Stock-based compensation expense relating to options granted of $7.9 million, of which $5.5 million and $2.4 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2021.

As of December 31, 2022, we have approximately $11.6 million of unrecognized compensation cost related to non-vested awards granted under the Plans, which we expect to recognize over a weighted average period of 1.73 years.

Employee Stock Purchase Plan

On May 3, 2019, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2019 Employee Stock Purchase Plan (the "2019 ESPP"). As a result of adoption of the 2020 ESPP, as defined below, by the stockholders, no further grants may be made under the 2019 ESPP Plan. On May 1, 2020, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2020 Employee Stock Purchase Plan (the "2020 ESPP"). No further grants may be made under the 2020 ESPP Plan. On May 6, 2022, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan (the "2022 ESPP", and together with the 2019 ESPP and the 2020 ESPP, the "ESPP Plans")).

The 2022 ESPP allows eligible employees to purchase up to an aggregate of 93,750 shares of our common stock. Under the 2022 ESPP, on the first day of each offering period, each eligible employee for that offering period has the option to enroll for that offering period, which allows the eligible employees to purchase shares of our common stock at the end of the offering period. Each offering period under the 2022 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 2022 ESPP, subject to the statutory limit under the Code. As of December 31, 2022, 9 shares were available for future sales under the 2022 ESPP.

The 2022 and 2020 ESPP are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the year ended December 31, 2022 and 2021, $46,000 and $89,000, respectively were expensed. In January 2021, 1,703 shares that were purchased as of December 31, 2020, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2021, approximately $28,000 of employee payroll deductions accumulated at December 31, 2020, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $4,000 was returned to the employees. In January 2022, 4,033 shares that were purchased as of December 31, 2021, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2022, approximately $40,000 of employee payroll deductions accumulated at December 31, 2021, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $30,000 was returned to the employees. As of December 31, 2022, approximately $43,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses. In January 2023, 93,741 shares that were purchased as of December 31, 2022, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2023, approximately $29,000 of employee payroll deductions accumulated at December 31, 2022, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $14,000 was returned to the employees.

Commitments

Research and Development Contracts

We have entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $58.6 million at December 31, 2022 for future work to be performed.

We have entered into a construction contract with outstanding commitments aggregating approximately $2.0 million at December 31, 2022 for future work to be performed.

Operating Leases

At December 31, 2022, 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,	
2023	$ 441
2024	164
2025	159
2026	9
2027	2
	775
Included interest	(15)
	$ 760

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our condensed 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 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.

Redeemable Convertible Preferred Stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

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.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. We adopted ASU 2020-06

on January 1, 2023, under the modified retrospective method of transition. We do not anticipate the adoption of ASU 2020-06 to impact the Company's financial position, results of operations or cash flows.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.

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, 2022 and 2021, 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 the Company as of December 31, 2022 and 2021, 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.

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.

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrual and prepaid balance for clinical trial expenses

As described in Note 2 to the consolidated financial statements, at each balance sheet date the Company estimates its expenses resulting from its obligations under contracts with vendors, clinical research organizations and under clinical site agreements in connection with conducting clinical trials. The Company accounts for trial expenses according to the timing of various aspects of the trial. The Company's accrual for clinical trial expenses of approximately $3.3 million is included in accrued expenses and other current liabilities in the December 31, 2022 consolidated balance sheet. The Company also recorded prepaid clinical trial expenses of approximately $8.0 million within prepaid expenses and other in the December 31, 2022 consolidated balance sheet. The amounts recorded for clinical trial expenses represent the Company's estimates of the unpaid and prepaid clinical trial expenses based on facts and circumstances known to the Company at that time, and are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. The estimation of clinical trial expenses was also identified as a critical accounting estimate by management.

We identified the accrual for clinical trial expenses as a critical audit matter due to the significant judgment and estimation required by management in determining progress or state of completion of clinical trials or services completed. This in turn led to a high degree of auditor subjectivity, and significant audit effort was required in performing our procedures and evaluating audit evidence relating to estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence, in connection with forming our overall opinion on the consolidated financial statements. We obtained an understanding of Management's process and evaluated the design of controls over developing its estimate of accrued and prepaid clinical trial expenses, including the process of estimating the expenses incurred to date based on the status of the clinical trials. Our procedures also included, among others, reading agreements and contract amendments with vendors, consultants and clinical research organizations and clinical site agreements in connection with conducting clinical trials, and evaluating the significant assumptions described above and the methods used in developing the clinical trial estimates and re-calculating the amounts that were unpaid and prepaid at the balance sheet date. We confirmed contractual commitments and amounts completed, paid and unpaid directly with the third parties involved in performing the clinical trial services on behalf of the Company. We also made direct inquiries of financial and clinical Company personnel regarding the contract amount including change orders, status and progress to completion of clinical trials, amounts paid to date under each contract, and description of future commitments. We also assessed the historical accuracy of management's estimates by comparing current expenses to prior-period expenses to identify unusual fluctuations, if any.

We have served as the Company's auditor since 2010

EISNERAMPER LLP
Iselin, New Jersey
March 13, 2023

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2022 AND 2021
(In Thousands, Except Par Value and Share Amounts)

	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 120,229	$ 178,660
Prepaid expenses and other	10,548	10,389
Total current assets	130,777	189,049
Property and equipment, net	93,814	50,558
Operating lease right-to-use assets	715	914
Other non-current assets	384	379
Total assets	$ 225,690	$ 240,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,068	$ 13,282
Accrued expenses and other current liabilities	9,680	7,945
Lease liability, short term	432	489
Total current liabilities	18,180	21,716
Lease liability, long term	328	467
Total liabilities	18,508	22,183
Commitments (See Note 20)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized		
Series B Convertible Preferred stock, 0 shares designated as of both December 31, 2022 and 2021; issued and outstanding - None	—	—
Series A Convertible Preferred stock, 0 shares designated as of both December 31, 2022 and 2021; issued and outstanding - None	—	—
Common stock, $0.001 par value; 1,000,000,000 and 25,000,000 shares authorized as of December 31, 2022 and 2021, respectively; 76,478,656 and 15,638,274 shares issued and outstanding as of December 31, 2022 and 2021, respectively and 93,741 and 4,033 shares to be issued as of December 31, 2022 and December 31, 2021, respectively	76	16
Additional paid in capital	677,311	578,613
Accumulated deficit	(470,038)	(359,820)
Accumulated other comprehensive loss	(167)	(92)
Total stockholders' equity	207,182	218,717
Total liabilities and stockholders' equity	$ 225,690	$ 240,900

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, 2022	2021
COSTS AND EXPENSES:		
Research and development	$ 81,876	$ 68,838
General and administrative	30,215	23,474
	112,091	92,312
Operating loss	(112,091)	(92,312)
Interest income	1,873	25
Net loss	(110,218)	(92,287)
Preferred stock deemed dividend	6,659	—
Net loss available to common stockholders	$ (116,877)	$ (92,287)
Net loss per common share, basic and diluted	$ (3.27)	$ (8.10)
Weighted average common shares outstanding, basic and diluted	35,739,057	11,387,308

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2022	**2021**
Net loss	$ (110,218)	$ (92,287)
Other comprehensive loss:		
Foreign currency translation loss	(75)	(30)
Comprehensive loss	$ (110,293)	$ (92,317)

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)

	Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Income (loss)	Deficit	Total
Balance, December 31, 2021	15,638,274	$ 16	$ 578,613	$ (92)	$ (359,820)	$ 218,717
Issuance of common stock under At-the-market offering, net of transactional expenses of $3,078	56,357,869	56	85,237	—	—	85,293
Issuance of common stock under 2022 Purchase Agreement	1,000,000	1	487	—	—	488
Issuance of common stock under 2021 Purchase Agreement	2,853,480	3	8,679	—	—	8,682
Issuance of commitment shares under 2022 Purchase agreement	625,000	—	—	—	—	—
Preferred stock deemed dividend	—	—	(6,659)	—	—	(6,659)
Employee stock purchase plan	4,033	—	40	—	—	40
Stock-based compensation	—	—	10,914	—	—	10,914
Foreign currency transaction loss	—	—	—	(75)	—	(75)
Net loss	—	—	—	—	(110,218)	(110,218)
Balance, December 31, 2022	76,478,656	$ 76	$ 677,311	$ (167)	$ (470,038)	$ 207,182

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)

	Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Income (loss)	Deficit	Total
Balance, December 31, 2020	6,568,335	$ 6	$ 355,237	$ (62)	$ (267,533)	$ 87,648
Issuance of common stock in January 2021 ($25.60 per share), net of transactional expenses of $3,096	1,562,500	2	36,902	—	—	36,904
Issuance of common stock in exchange for exercise of warrants in March 2021 ($18.24 per share)	107	—	2	—	—	2
Issuance of common stock in February 2021 ($38.40 per share), net of transactional expenses of $5,002	1,822,917	2	64,995	—	—	64,997
Issuance of common stock under At-the-market offering, net of transactional expenses of $2,332	3,445,297	4	69,288	—	—	69,292
Issuance of common stock under 2021 Purchase Agreement, net of transactional expenses of $75	2,016,855	2	41,194	—	—	41,196
Issuance of commitment shares under 2021 Purchase agreement	40,000	—	—	—	—	—
Issuance of common stock in the acquisition of the OyaGen license	86,010	—	3,000	—	—	3,000
Issuance of commitment shares under Lincoln park Purchase agreement	90,909	—	—	—	—	—
Employee stock purchase plan	5,344	—	96	—	—	96
Stock-based compensation	—	—	7,899	—	—	7,899
Foreign currency transaction loss	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(92,287)	(92,287)
Balance, December 31, 2021	15,638,274	$ 16	$ 578,613	$ (92)	$ (359,820)	$ 218,717

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31, 2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (110,218)	$ (92,287)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,253	50
Common stock issued to acquire in-process research and development	—	3,000
Stock-based compensation	10,914	7,899
Changes in operating assets and liabilities:		
Prepaid expenses	(164)	518
Accounts payable	(1,045)	3,526
Lease liabilities and ROU asset, net	2	(11)
Accrued expenses and other current liabilities	1,205	1,748
Net cash used in operating activities	(98,053)	(75,557)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(48,147)	(35,307)
Net cash used in investing activities	(48,147)	(35,307)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	—	2
Proceeds from ESPP	40	96
Proceeds, net of $6,659 expenses, from sale of convertible redeemable preferred stock	40,591	—
Redemption of convertible redeemable preferred stock	(47,250)	—
Proceeds, net of $3,078 and $10,505 expenses, from sale of common stock and warrants	94,463	212,389
Net cash provided by financing activities	87,844	212,487
Effect of currency rate change on cash	(74)	(31)
Net (decrease) increase in cash, cash equivalents and restricted cash	(58,430)	101,592
Cash, cash equivalents and restricted cash beginning of the period	178,900	77,308
Cash, cash equivalents and restricted cash end of period	$ 120,470	$ 178,900
Supplemental disclosures of cash flow information:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 3,092	$ 6,730
Preferred stock deemed dividend	$ 6,659	$ —

See the accompanying notes to consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp., through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. ("Tonix Sub"), is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and vaccines to treat and prevent human disease and alleviate suffering. The therapeutics include both small molecules and biologics. All drug product and vaccine candidates are still in development and none are approved or marketed.

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., Jenner LLC, Tonix R&D Center LLC, Tonix Pharma Holdings Limited and Tonix Pharma Limited (collectively hereafter referred to as the "Company" or "Tonix"). All intercompany balances and transactions have been eliminated in consolidation.

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, 2022, the Company had working capital of approximately $112.6 million. At December 31, 2022, the Company had an accumulated deficit of approximately $470.0 million. The Company held cash and cash equivalents of approximately $120.2 million as of December 31, 2022.

The Company believes that its cash resources at December 31, 2022 and the proceeds that it raised from equity offerings in the first quarter of 2023, net of amounts paid to repurchase shares in the first quarter of 2023 (See Note 22), will meet its operating and capital expenditure requirements into the fourth quarter of 2023, but not beyond.

These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company faces significant challenges and uncertainties and, as a result, its available capital resources may be consumed more rapidly than currently expected due to changes it may make in its research and development spending plans. The Company believes that it has the ability to obtain additional funding through public and private financing and collaborative arrangements with strategic partners to increase the funds available to fund operations. However, the Company may not be able to raise capital on terms acceptable to the Company. Without additional funds, it 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 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

Reverse Stock Split

On May 16, 2022, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 17, 2022. Pursuant to the Certificate of Change, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock. The Company accounted for the reverse stock split on a retrospective basis pursuant to ASC 260, Earnings Per Share. All authorized, issued and outstanding common stock, common stock warrants, stock option awards, exercise prices and per share data have been adjusted in these consolidated financial statements, on a retroactive basis, to reflect the reverse stock split for all periods presented. Authorized preferred stock was not adjusted because of the reverse stock split.

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. Moreover, the extent to which COVID-19 impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time.

Use of estimates

The preparation of financial statements in accordance with Generally Accepted Accounting Principles ("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 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, 2022 and December 31, 2021, cash equivalents, which consisted of money market funds, amounted to $116.3 million and $120.4 million, respectively. Restricted cash, which is included in Other non-current assets on the consolidated balance sheet at December 31, 2022 and December 31, 2021 of approximately $241,000 and $240,000, respectively, collateralizes a letter of credit issued in connection with the lease of office space in Chatham, New Jersey and New York City (see Note 19).

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 flows:

	December 31, 2022	December 31, 2021
	(in thousands)	
Cash and cash equivalents	$ 120,229	$ 178,660
Restricted cash	241	240
Total	$ 120,470	$ 178,900

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 ranges from 20 to 30 years for buildings, 15 years for land improvements, and laboratory equipment, three years for computer assets, five years for furniture and all other equipment and term of lease for leasehold improvements. Depreciation on assets begin when the asset is available for its intended use. Depreciation and amortization expense for the years ended December 31, 2022, and 2021 was $1,253,000 and $50,000, respectively. The Company's property and equipment is located in the United States.

Intangible assets 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, which are included in Other non-current assets on the consolidated balance sheet, are not amortized but are tested for impairment annually or whenever events or changes in circumstances indicate that their carrying amount may be less than fair value. As of December 31, 2022, and 2021, the Company believed that no impairment existed.

Leases

The Company determines if an arrangement is, or contains, a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, lease liability, short term and lease liability, long term in the Company's 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 subsequent lease commencement dates 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 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 made under operating leases is recognized on a straight-line basis over the lease term.

Convertible Preferred Stock

Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

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 is 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.

Government Grants

From time to time, the Company may enter into arrangements with governmental entities for the purpose of obtaining funding for research and development activities. The Company is reimbursed for costs incurred that are associated with specified research and development activities included in the grant application approved by the government authority. The Company classifies government grants received under these arrangements as a reduction to the related research and development expense in the same period as the relevant expenses are incurred. In August 2022, the Company announced that it received a Cooperative Agreement grant from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health, to support the development of its TNX-1300 product candidate for the treatment of cocaine intoxication. No funding was received during 2022.

Stock-based compensation

All stock-based payments to employees and to nonemployees for their services, including grants of restricted stock units ("RSUs"), and stock options, are measured at fair value on the grant date and recognized in the consolidated statements of operations as compensation or other expense over the requisite service period. The Company accounts for share-based awards in accordance with the provisions of the Accounting Standards Codification ("ASC") 718, Compensation – Stock Compensation.

Foreign Currency Translation

Operations of the Company's Canadian subsidiary, Tonix Pharmaceuticals (Canada), Inc., 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 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.

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, 2022, 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.

Per Share Data

The computation of basic and diluted loss per share for the years ended December 31, 2022 and 2021 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.

All warrants issued participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing EPS, these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the years ended December 31, 2022 and 2021, as results of operations were a loss for the period.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share, as of December 31, 2022 and 2021, are as follows:

	2022	2021
Warrants to purchase common stock	19,970	19,970
Options to purchase common stock	2,453,031	805,762
Totals	2,473,001	825,732

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. The Company will adopt ASU 2020-06 on January 1, 2023, under the modified retrospective method of transition. The Company does not anticipate the adoption of ASU 2020-06 to impact the Company's financial position, results of operations or cash flows.

NOTE 3 – PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following (in thousands):

	December 31 2022	December 31 2021
	(in thousands)	
Property and equipment, net:		
Land	$ 8,011	$ 7,911
Land improvements	79	—
Buildings	65,644	—
Office furniture and equipment	1,893	756
Laboratory equipment	18,440	347
Leasehold improvements	34	23
Construction in progress	1,366	41,921
	95,467	50,958
Less: Accumulated depreciation and amortization	(1,653)	(400)
	$ 93,814	$ 50,558

On October 1, 2021, the Company completed the acquisition of its approximately 45,000 square foot research and development facility in Frederick, Maryland totaling $17.5 million, to process development activities. Of the total purchase price, $2.1 million was allocated to the value of land acquired, and $13.9 million was allocated to buildings, and approximately $1.5 million was allocated to Office furniture and equipment and Laboratory equipment. During the year ended December 31, 2022, the assets became ready for the intended use and were placed in service.

On September 28, 2020, the Company completed the purchase of its approximately 45,000 square foot facility in Dartmouth, Massachusetts for $4.0 million, to house its new Advanced Development Center for the development and manufacturing of vaccines. Of the total purchase price, $1.2 million was allocated to the value of land acquired, and $2.8 million was allocated to buildings. Additionally, the Company incurred approximately $38.8 million of costs during the year ended December 31, 2022, bringing total costs incurred-to-date to $61.6 million, of which the majority relates to the build-out of the facility. During the year ended December 31, 2022, the assets became ready for the intended use and were placed in service.

On December 23, 2020, the Company completed the purchase of its approximately 44-acre site in Hamilton, Montana for $4.5 million, for the construction of a vaccine development and commercial scale manufacturing facility. As of December 31, 2022, the asset was not ready for its intended use.

NOTE 4 – OTHER BALANCE SHEET INFORMATION

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

	December 31, 2022	December 31, 2021
	(in thousands)	
Prepaid expenses and other:		
Contract-related	$ 8,043	$ 7,726
Insurance	1,275	1,482
Other	1,230	1,181
	$ 10,548	$ 10,389
Accrued expenses and other current liabilities:		
Contract-related	$ 3,273	$ 2,832
Compensation and compensation-related	3,645	2,868
Construction in progress	2,103	1,572
Professional fees and other	659	673
	$ 9,680	$ 7,945

NOTE 5 – 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, 2022, and December 31, 2021, the Company used Level 1 quoted prices in active markets to value cash equivalents of $116.3 million and $120.4 million, respectively. The Company did not have any Level 2 or Level 3 assets or liabilities as of both December 31, 2022 and 2021.

NOTE 6 – STOCKHOLDERS' EQUITY

On May 16, 2022, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 17, 2022. Pursuant to the Certificate of Change, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common

stock, whereby 599,679,596 outstanding shares of the Company's common stock were exchanged for 18,740,141 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 130,462 shares of the Company's common stock due to fractional shares. Furthermore, pursuant to the Certificate of Change, the number of authorized shares of common stock was reduced from 800 million to 50 million. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

On August 5, 2022, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 50,000,000 to 150,000,000.

On December 13, 2022, the Company filed an amendment to its articles of incorporation, as amended, to increase the number of shares of common stock authorized from 150,000,000 to 1,000,000,000.

NOTE 7 – TEMPORARY EQUITY

On October 26, 2022, the Company closed on an offering ("the October offering") with certain institutional investors (the "Investors"), pursuant to which the Company issued and sold, in a private placement, 1,400,000 shares of the Company's Series A Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 100,000 shares of the Company's Series B Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock," and together with the Series A Preferred Stock, the "Preferred Stock"), at an offering price of $9.50 per share, representing a 5% original issue discount ("OID) to the stated value of $10.00 per share, for gross proceeds of $14.3 million in the aggregate for the October offering, before the deduction of fees and offering expenses. The shares of Preferred Stock were convertible, at a conversion price of $1.00 per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, at the option of the holders and, in certain circumstances, by the Company.

On December 13, 2022, an amendment (the "December Amendment") to the Company's Articles of Incorporation, as amended, to increase the Company's authorized shares of common stock from 150,000,000 to 1,000,000,000, was approved at a special meeting of shareholders. The Series A Preferred Stock had the right to vote on such December Amendment on an as-converted to common stock basis. The shares of the Series B Preferred Stock were automatically voted in a manner that "mirrored" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that were not voted) and Series A Preferred Stock were voted to increase the Authorized Shares. The December Amendment required the approval of the majority of the votes associated with the Company's outstanding stock entitled to vote on the proposal. Because the Series B Preferred Stock were automatically and without further action of the purchaser voted in a manner that "mirrored" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that were not voted) and Series A Preferred Stock were voted on the December Amendment, abstentions by common stockholders did not have any effect on the votes cast by the holders of the Series B Preferred Stock. The Certificates of Designation for the Preferred Stock provides that the Preferred Stock have no voting rights other than the right to vote on the December Amendment and as a class on certain other specified matters, and, with respect to the Series B Certificate of Designation, the right to cast 2,500 votes per share of Series B Preferred Stock on the December Amendment.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of Common Stock at a conversion price of $1.00 per share. The holders of the Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares through January 23, 2023. The Company had the option to redeem the Preferred Stock for cash at 105% of the stated value, subject to the holders' rights to convert the shares prior to such redemption.

The $14.3 million in gross proceeds of the October offering was held in an escrow account, along with an additional $1.5 million deposited by the Company to cover the aggregate OID as well as the additional amount that would be necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock, as applicable, subject to the earlier payment to redeeming holders. Upon expiration of the redemption period, any proceeds remaining in the escrow account would be disbursed to the Company.

Since the Preferred Stock had a redemption feature at the option of the holder, it was classified as temporary equity. The Series A Preferred Stock and Series B Preferred Stock was recorded at redemption value of approximately $14.7 million and $1.1 million, respectively, as calculated in the following table (in thousands):

	Series A Preferred Stock	Series B Preferred Stock
Gross Proceeds	$ 13,300	$ 950
Less:		
Preferred stock issuance costs	(844)	(60)
Plus:		
Accretion of carrying value to redemption value	2,244	160
Preferred stock subject to possible redemption	$ 14,700	$ 1,050

During December 2022, the Company received redemption notices for all outstanding shares of Preferred Stock. The Preferred Stock was redeemed during December 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $15.8 million in the aggregate.

On June 24, 2022, the Company closed on an offering ("the Offering") with certain institutional investors (the "Investors"), pursuant to which the Company issued and sold, in a private placement, 2,500,000 shares of the Company's Series A Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock"), and 500,000 shares of the Company's Series B Convertible Redeemable Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock," and together with the Series A Preferred Stock, the "Preferred Stock"), at an offering price of $9.50 per share, representing a 5% original issue discount ("OID) to the stated value of $10.00 per share, for gross proceeds of $28.5 million in the aggregate for the Offering, before the deduction of fees and offering expenses. The shares of Preferred Stock were convertible, at a conversion price of $4.00 per share (subject in certain circumstances to adjustments), into shares of the Company's common stock, at the option of the holders and, in certain circumstances, by the Company.

On August 5, 2022, an amendment (the "Amendment") to the Company's Articles of Incorporation, as amended, to increase the Company's authorized shares of common stock from 50,000,000 to 150,000,000, was approved at a special meeting of shareholders. The Series A Preferred Stock had the right to vote on such Amendment on an as-converted to common stock basis. The shares of the Series B Preferred Stock were automatically voted in a manner that "mirrored" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that were not voted) and Series A Preferred Stock were voted to increase the Authorized Shares. The Amendment required the approval of the majority of the votes associated with the Company's outstanding stock entitled to vote on the proposal. Because the Series B Preferred Stock were automatically and without further action of the purchaser voted in a manner that "mirrored" the proportions on which the shares of Common Stock (excluding any shares of Common Stock that were not voted) and Series A Preferred Stock were voted on the Amendment, abstentions by common stockholders did not have any effect on the votes cast by the holders of the Series B Preferred Stock. The Certificates of Designation for the Preferred Stock provides that the Preferred Stock have no voting rights other than the right to vote on the Amendment and as a class on certain other specified matters, and, with respect to the Series B Certificate of Designation, the right to cast 2,500 votes per share of Series B Preferred Stock on the Amendment.

The holders of Preferred Stock were entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of Common Stock. The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of Common Stock at a conversion price of $4.00 per share. The holders of the Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares through September 22, 2022. The Company had the option to redeem the Preferred Stock for cash at 105% of the stated value, subject to the holders' rights to convert the shares prior to such redemption.

The $28.5 million in gross proceeds of the Offering was held in an escrow account, along with an additional $3.0 million deposited by the Company to cover the aggregate OID as well as the additional amount that would be necessary to fund the 105% redemption price until the expiration of the redemption period for the Preferred Stock, as applicable, subject to the earlier payment to redeeming holders. Upon expiration of the redemption period, any proceeds remaining in the escrow account would be disbursed to the Company.

Since the Preferred Stock had a redemption feature at the option of the holder, it was classified as temporary equity. The Series A Preferred Stock and Series B Preferred Stock was recorded at redemption value of approximately $26.3 million and $5.2 million, respectively, as calculated in the following table (in thousands):

	Series A Preferred Stock	Series B Preferred Stock
Gross Proceeds	$ 23,750	$ 4,750
Less:		
Preferred stock issuance costs	(1,046)	(209)
Plus:		
Accretion of carrying value to redemption value	3,546	709
Preferred stock subject to possible redemption	$ 26,250	$ 5,250

During August 2022, the Company received redemption notices for all outstanding shares of Preferred Stock. The Preferred Stock was redeemed during August 2022 at 105% of the $10.00 stated value of the Preferred Stock, or $31.5 million in the aggregate.

NOTE 8 – ASSET PURCHASE AGREEMENT WITH KATANA

On December 22, 2020, the Company entered into an asset purchase agreement (the "Katana Asset Purchase Agreement") with Katana Pharmaceuticals, Inc. ("Katana") pursuant to which Tonix acquired Katana assets related to insulin resistance and related syndromes, including obesity (the "Katana Assets"). In connection with the acquisition of the Katana Assets, Tonix assumed Katana's rights and obligations under that certain Exclusive License Agreement by and between Katana and The University of Geneva ("Geneva") (the "Geneva License "Agreement") pursuant to an Assignment and Assumption Agreement with Geneva ("Geneva Assignment and Assumption Agreement"), dated December 22, 2020. As consideration for entering into the Katana Asset Purchase Agreement, Tonix paid $0.7 million to Katana. The costs associated with the cash payments were recorded to research and development expenses in the statement of operations for the year ended December 31, 2020. Because the Katana intellectual property was acquired prior to U.S. Food and Drug Administration (FDA) approval, the cash consideration totaling $0.7 million, was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

Pursuant to the terms of the Geneva Assignment and Assumption Agreement, Geneva has granted to Tonix an exclusive license, with the right to sublicense, certain patents related to the Katana Assets. Tonix is obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products. The Geneva 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 Geneva. As of December 31, 2022, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 9 – ASSET PURCHASE AGREEMENT WITH TRIGEMINA

On June 11, 2020, the Company entered into an asset purchase agreement (the "Trigemina Asset Purchase Agreement") with Trigemina, Inc. ("Trigemina") and certain shareholders named therein (the "Executive Shareholders") pursuant to which Tonix acquired Trigemina assets related to migraine and pain treatment technologies (the "Trigemina Assets"). In connection with the acquisition of the Trigemina Assets, Tonix assumed Trigemina's rights and obligations under that certain Amended and Restated Exclusive License Agreement, dated November 30, 2007, as amended, by and between Trigemina and The Board of Trustees of the Leland Stanford Junior University ("Stanford") (the "Stanford License "Agreement") pursuant to an Assignment and Assumption Agreement with Stanford ("Assignment and Assumption Agreement"), dated June 11, 2020. As consideration for entering into the Asset Purchase Agreement, Tonix paid $824,759 to Trigemina and issued to Trigemina 62,500 shares of the Company's common stock, valued at $21.76 per share, based on the closing stock price on June 11, 2020, and paid Stanford $250,241 pursuant to the terms of the Assignment and Assumption Agreement. The common stock is unregistered and subject to a 12-month lock-up and a Shareholder Voting Agreement, dated June 11, 2020, pursuant to which Trigemina and the Executive Shareholders have agreed to vote the common stock on any matter put to a vote of the shareholders of the Company in accordance with management's recommendations. Both the costs associated with the cash payments and share issuance, totaling $2.4 million, were recorded to research and development expenses in the statement of operations for the year ended December 31, 2020. Because the Trigemina intellectual property was acquired prior to FDA approval, the cash and stock consideration, was expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

Pursuant to the terms of the Assignment and Assumption Agreement, Stanford has granted to Tonix an exclusive license, with the right to sublicense, certain patents related to the Trigemina Assets. Stanford has reserved for itself the right to practice under the patents for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop

markets for such products. The Trigemina 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 Stanford. As of December 31, 2022, other than the annual maintenance fee, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 10 – 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 subsequently amended. 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. The $168,500 was previously recorded to research and development expenses in the statement of operations. 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 Our option, a total of approximately $3.4 million. Pursuant to the terms of the Asset Purchase Agreement, TRImaran and the Selling Shareholders are prohibited from disclosing confidential information related to the Assets and are restricted from engaging, for a period of three years, in the development or commercialization of any therapeutic containing any pyran-based drug compound for the treatment of post-traumatic stress disorder, attention deficit hyperactivity disorder or major depressive disorder. Also for a period of three years, if TRImaran or any Selling Shareholder engage in the research or development of any potential therapeutic compound for the treatment of any central nervous system disorder, TRImaran or such Selling Shareholder is obliged to provide notice and opportunity to Tonix to make an offer to acquire or license rights with respect to such product candidate.

Pursuant to the terms of the WSU License Agreement, WSU has granted to Tonix an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the "Technology") related to the Assets. WSU has reserved for itself the right to practice the Technology for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to obtain regulatory approval for one or more products utilizing the Technology ("WSU Products") and to use commercially reasonable marketing efforts throughout the term of the WSU License Agreement. The WSU License Agreement specifies developmental milestones and the period of time during which such milestones must be completed and provides for an annual maintenance fee payable to WSU. Tonix is obligated to substantially manufacture WSU Products in the United States if WSU Products will be sold in the United States.

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 has also agreed to pay WSU single-digit royalties on net sales of WSU Products sold by Tonix or a sublicensee on a tiered basis based on net sales, and additional sublicense fees on certain consideration received from sublicensees. Royalties on each particular WSU Product are payable on a country-by-country and Product-by-Product basis until the date of expiration of the last valid claim in the last to expire of the issued patents covered by the WSU License Agreement. Royalties payable on net sales of WSU Products may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the WSU License Agreement, provided that the royalty payable on a WSU Product may not be reduced by more than 50%. Each party also has the right to terminate the agreement for customary reasons such as material breach and bankruptcy. The WSU License Agreement contains provisions relating to termination, indemnification, confidentiality and other customary matters for an agreement of this kind. As of December 31, 2022, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 11 – LICENSE AGREEMENT WITH CURIA

On December 12, 2022, the Company entered into an exclusive license agreement with Curia for the development of three humanized murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection. We believe that the licensing of these mAbs strengthens our pipeline of next-generation therapeutics to treat COVID-19, which is caused by SARS-CoV-2. As consideration for entering into the License Agreement, we paid a license fee of approximately $0.4 million to Curia. The License Agreement also provides for single-digit royalties and contingent milestone payments. As of December 31, 2022, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

NOTE 12 – LICENSE AGREEMENT WITH UNIVERSITY OF ALBERTA

On May 18, 2022, the Company entered into an exclusive License Agreement with the University of Alberta focused on identifying and testing broad-spectrum antiviral drugs against future variants of SARS-CoV-2 and other emerging viruses. As consideration for entering into the License Agreement, Tonix paid a low-five digit license fee to University of Alberta. The License Agreement also provides for single-digit royalties and contingent milestone payments. As of December 31, 2022, other than the upfront fee, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 13 – LICENSE AGREEMENT WITH OYAGEN

On April 14, 2021, the Company and OyaGen, Inc. ("OyaGen") entered into an exclusive License Agreement (the "OyaGen License Agreement") pursuant to which OyaGen granted to Tonix an exclusive license to certain patents and technical information related to an antiviral inhibitor of SARS-CoV-2, sangivamycin, and to develop and commercialize products thereunder, and to acquire rights to any technology based thereon for the prevention or treatment of COVID-19 developed by OyaGen during the term of the License Agreement.

As consideration for entering into the License Agreement, Tonix paid a low-seven digit license fee to OyaGen, and issued to OyaGen and an affiliated entity an aggregate of 86,010 shares of the Company's common stock. The shares were valued at $3.0 million, which was recorded as research and development expense. The OyaGen License also provided for single-digit royalties and contingent milestone payments. In July 2022, the Company notified OyaGen of its intent to terminate the OyaGen License Agreement, and the agreement was terminated effective September 20, 2022.

NOTE 14 – LICENSE AGREEMENT WITH INSERM

On February 11, 2021, the Company entered into a license agreement (the "Inserm License Agreement") pursuant to which it licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from Inserm (the French National Institute of Health and Medical Research), Aix-Marseille Université and Centre Hospitalier Universitaire of Toulouse. The Inserm License Agreement provides for the payment of annual fees and milestone payments upon the occurrence of specified sales milestones totaling approximately $0.4 million, as well royalties on net sales of products based on the licensed technology, and assignment/transfer and sublicense royalties. As of December 31, 2022, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 15 – 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"), as subsequently amended, 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 reserved for itself the right to practice the TFF2 Technology for academic research and educational purposes.

The Company paid a five-digit license fee to Columbia as consideration for entering into the Columbia License Agreement, which was recorded to research and development 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 is obligated 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, 2022, 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.

The Company paid a six-digit license fee to Columbia as consideration for entering into the License Agreement. The Company is obligated to use Commercially Reasonable Efforts, as defined in the License Agreement, to develop and commercialize the Product, and to achieve specified developmental milestones.

The 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, 2022, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 16 – SALE OF COMMON STOCK

2022 Lincoln Park Transaction

On August 16, 2022, the Company entered into a purchase agreement (the "2022 Purchase Agreement") and a registration rights agreement (the "2022 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2022 Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to $50,000,000 of the Company's common stock (subject to certain limitations) from time to time during the term of the 2022 Purchase Agreement. Pursuant to the terms of the 2022 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 2022 Purchase Agreement.

Pursuant to the terms of the 2022 Purchase Agreement, at the time the Company signed the 2022 Purchase Agreement and the 2022 Registration Rights Agreement, the Company issued 625,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company's common stock under the 2022 Purchase Agreement. The commitment shares were valued at $1,000,000 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 2022 Purchase Agreement.

During the year ended December 31, 2022, the Company sold 1.0 million shares of common stock under the 2022 Purchase Agreement, for net proceeds of approximately $0.5 million.

Subsequent to December 31, 2022, the Company sold 0.6 million shares of common stock under the 2022 Purchase Agreement with Lincoln Park for net proceeds of approximately $0.4 million.

Purchase Agreement with Lincoln Park

On December 3, 2021, the Company entered into a purchase agreement (the "Purchase Agreement with Lincoln Park") and a registration rights agreement (the "Lincoln Park Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the Purchase Agreement with Lincoln Park, Lincoln Park agreed to purchase from the Company up to $80,000,000 of the Company's common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement with Lincoln Park. Pursuant to the terms of the Lincoln Park 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 Purchase Agreement with Lincoln Park.

Pursuant to the terms of the Purchase Agreement with Lincoln Park, at the time the Company signed the Purchase Agreement with Lincoln Park and the Lincoln Park Registration Rights Agreement, the Company issued 90,910 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement with Lincoln Park.

The commitment shares were valued at $1.6 million 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 Purchase Agreement with Lincoln Park.

During the year ended December 31, 2022, the Company sold 2.9 million shares of common stock under the Purchase Agreement with Lincoln Park, for net proceeds of approximately $8.7 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 Purchase Agreement with Lincoln Park (approximately 2.9 million shares) to Lincoln Park under the Purchase Agreement with Lincoln Park without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the Purchase Agreement with Lincoln Park equals or exceeds a threshold amount. As the Company has issued approximately 2.9 million shares to Lincoln Park, by December 31, 2022, under the Purchase Agreement with Lincoln Park at less than the threshold amount, the Company will not sell any additional shares under the Purchase Agreement with Lincoln Park without shareholder approval.

2021 Lincoln Park Transaction

On May 14, 2021, the Company entered into a purchase agreement (the "2021 Purchase Agreement") and a registration rights agreement (the "2021 Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2021 Purchase Agreement, Lincoln Park agreed to purchase from the Company up to $80,000,000 of the Company's common stock (subject to certain limitations) from time to time during the term of the 2021 Purchase Agreement. Pursuant to the terms of the 2021 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 2021 Purchase Agreement.

Pursuant to the terms of the 2021 Purchase Agreement, at the time the Company signed the 2021 Purchase Agreement and the 2021 Registration Rights Agreement, the Company issued 40,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2021 Purchase Agreement. The commitment shares were valued at $1.6 million 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 2021 Purchase Agreement.

During the year ended December 31, 2021, the Company sold an aggregate of approximately 2.0 million shares of common stock under the 2021 Purchase Agreement, for gross proceeds of approximately $41.3 million. During the year ended December 31, 2022, no shares of common stock were sold under the 2021 Purchase Agreement.

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 2021 Purchase Agreement (approximately 2.0 million shares) to Lincoln Park under the 2021 Purchase Agreement without stockholder approval, unless the average price of all applicable sales of its common stock to Lincoln Park under the 20121 Purchase Agreement equals or exceeds a threshold amount. As the Company has issued approximately 2.0 million shares to Lincoln Park under the 2021 Purchase Agreement, at less than the threshold amount, the Company will not sell any additional shares under the 2021 Purchase Agreement without shareholder approval.

February 2021 Financing

On February 8, 2021, the Company entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.8 million shares of its common stock, in a registered direct public offering (the "February 2021 Financing"), with A.G.P/Alliance Global Partners ("AGP"), acting as placement agent. The public offering price for each share of common stock was $38.40. The February 2021 Financing closed on February 9, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate amount of $4.9 million. The Company incurred other offering expenses of approximately $0.1 million. The Company received net proceeds of approximately $65.0 million, after deducting the fees and other offering expenses.

January 2021 Financing

On January 11, 2021, the Company entered into a securities purchase agreement with certain institutional investors relating to the issuance and sale of 1.6 million shares of its common stock in a registered direct public offering (the "January 2021 Financing"), with AGP as placement agent. The public offering price for each share of common stock was $25.60. The January 2021 Financing closed on January 13, 2021. AGP received a cash fee of 7% of the gross proceeds, for an aggregate of $2.8 million. The Company incurred other offering expenses of approximately $0.3 million. The Company received net proceeds of approximately $36.9 million, after deducting the fees and other offering expenses.

At-the-Market Offerings

On April 8, 2020, the Company entered into a sales agreement (the "Sales Agreement") with AGP pursuant to which the Company may issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to

$320.0 million in at-the-market offerings ("ATM") sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the Sales Agreement. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the year ended December 31, 2022, the Company sold approximately 56.4 million shares of common stock under the Sales Agreement, for net proceeds of approximately $85.3 million. During the year ended December 31, 2021, the Company sold approximately 3.5 million shares of common stock under the Sales Agreement, for net proceeds of approximately $69.3 million. Subsequent to December 31, 2022, the Company has sold 2.1 million shares of common stock under the Sales Agreement, for net proceeds of approximately $1.4 million.

NOTE 17 – STOCK-BASED COMPENSATION

Stock Incentive Plans

On May 3, 2019, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan (the "2019 Plan"). The 2019 Plan provided for the issuance of up to 4,375 shares of common stock. With the adoption of the 2020 Plan (as defined below), no further grants may be made under the 2019 Plan. On January 16, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan (the "2020 Plan"). The 2020 Plan provided for the issuance of up to 18,750 shares of common stock. With the adoption of the Amended and Restated 2020 Plan (as defined below), no further grants may be made under the 2020 Plan.

On May 1, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan ("Amended and Restated 2020 Plan"), and together with the 2020 Plan and the 2019 Plan, the "Plans").

Under the terms of the Amended and Restated 2020 Plan, the Company may issue (1) stock options (incentive and nonstatutory), (2) restricted stock, (3) stock appreciation rights ("SARs"), (4) RSUs, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 312,500 shares of common stock, which amount will be increased to the extent that awards granted under the Plans are forfeited, expire or are settled for cash (except as otherwise provided in the Amended and Restated 2020 Plan). In addition, the Amended and Restated 2020 Plan contains an "evergreen provision" providing for an annual increase in the number of shares of our common stock available for issuance under the Amended and Restated 2020 Plan on January 1 of each year for a period of ten years, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the difference between (x) twenty percent (20%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the Amended and Restated 2020 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards). The Board of Directors determines the exercise price, vesting and expiration period of the grants under the Amended and Restated 2020 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 Amended and Restated 2020 Plan may not be more than ten years. As of December 31, 2022, 627,744 options were available for future grants under the Amended and Restated 2020 Plan.

A summary of the stock option activity and related information for the Plans for the years ended December 31, 2022, and 2021 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	319,179	$ 2.93	9.26	$ 131,558
Grants	486,639	$ 40.85	—	—
Exercised	—	—		
Forfeitures or expirations	(56)	149,713.14		
Outstanding at December 31, 2021	805,762	$ 78.02	8.83	$ —
Grants	1,695,608	$ 12.06	—	$ —
Exercised	—	—		
Forfeitures or expirations	(48,339)	$ 255.40		
Outstanding at December 31, 2022	2,453,031	$ 28.93	8.70	$ —
Exercisable at December 31, 2022	590,582	$ 70.82	7.64	$ —

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 grant date fair value of options granted during the years ended December 31, 2022 and 2021, was $5.25 and $33.78 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. The fair value of the award is measured on the grant date. One-third of most stock options granted pursuant to the Plans vest 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. The Company also issues premium options to executive officers which have an exercise price greater than the grant date fair value and has issued performance-based options which vest when target parameters are met or probable of being met, 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 service period using the straight-line method.

The assumptions used in the valuation of stock options granted during the year ended December 31, 2022 and 2021 were as follows:

	2022	2021
Risk-free interest rate	1.67% to 3.05%	0.79% to 1.63%
Expected term of option	5.5 to 10 years	5.5 to 6 years
Expected stock price volatility	120.32% - 133.22	124.37% to 137.73%
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 $10.9 million, of which $7.9 million and $3.0 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2022. Stock-based compensation expense relating to options granted of $7.9 million, of which $5.5 million and $2.4 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2021.

As of December 31, 2022, the Company had approximately $11.6 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 1.73 years.

Employee Stock Purchase Plans

On May 3, 2019, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2019 Employee Stock Purchase Plan (the "2019 ESPP"). As a result of adoption of the 2020 ESPP, as defined below, by the stockholders, no further grants may be made under the 2019 ESPP Plan. On May 1, 2020, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2020 Employee Stock Purchase Plan (the "2020 ESPP"). No further grants may be made under the 2020 ESPP Plan. On May 6, 2022, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan (the "2022 ESPP", and together with the 2019 ESPP and the 2020 ESPP, the "ESPP Plans")).

The 2022 ESPP allows eligible employees to purchase up to an aggregate of 93,750 shares of the Company's common stock. Under the 2022 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 2022 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 2022 ESPP, subject to the statutory limit under the Code. As of December 31, 2022, 9 shares were available for future sales under the 2022 ESPP.

The 2022 and 2020 ESPP are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the year ended December 31, 2022 and 2021, $46,000 and $89,000, respectively were expensed. In January 2021, 1,703 shares that were purchased as of December 31, 2020, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2021, approximately $28,000 of employee payroll deductions accumulated at December 31, 2020, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $4,000 was returned to the employees. In January 2022, 4,033 shares that were purchased as of December 31, 2021, under the 2020 ESPP, were issued. Accordingly, during the first quarter of 2022, approximately $40,000 of employee payroll deductions accumulated at December 31, 2021, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $30,000 was returned to the employees. As of December

31, 2022, approximately $43,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses. In January 2023, 93,741 shares that were purchased as of December 31, 2022, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2023, approximately $29,000 of employee payroll deductions accumulated at December 31, 2023, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $14,000 was returned to the employees.

NOTE 18 – WARRANTS TO PURCHASE COMMON STOCK

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2022:

Exercise Price	Number Outstanding	Expiration Date
$ 16.00	779	November 2024
$ 18.24	3,860	February 2025
$ 1,120.00	15,331	December 2023
	19,970	

No warrants were exercised during the year ended December 31, 2022.

During the year ended December 31, 2021, 107 warrants from the February 2020 Financing, with an exercise price of $18.24, were exercised for proceeds of approximately $2,000.

During the year ended December 31, 2021, 5,441 and 474 warrants with a per share exercise price of $630.00 and $687.50, respectively, expired.

NOTE 19 – 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, 2022, the Company has right-of-use assets of $0.7 million and a total lease liability for operating leases of $0.7 million of which $0.3 million is included in long-term lease liabilities and $0.4 million is included in current lease liabilities.

At December 31, 2022, 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,	
2023	$ 441
2024	164
2025	159
2026	9
2027	2
	775
Included interest	(15)
	$ 760

During the year ended December 31, 2022, the Company entered into new operating leases and lease amendments, resulting in the Company recognizing an additional operating lease liability of approximately $386,000 based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately $386,000, which represents a non-cash investing and financing activity.

During the year ended December 31, 2021, the Company entered into lease amendments, resulting in the Company recognizing an operating lease liability of approximately $467,000 based on the present value of the future minimum rental payments. The Company also recognized corresponding ROU assets of approximately $467,000.

Operating lease expense was $0.6 million for both years ended December 31, 2022 and 2021.

Other information related to leases was as follows:

Cash paid for amounts included in the measurement of lease liabilities:	December 31, 2022	December 31, 2021
Operating cash flow from operating leases (in thousands)	$ 598	$ 632
Weighted Average Remaining Lease Term		
Operating leases	2.20 years	2.71 years
Weighted Average Discount Rate		
Operating leases	2.19%	1.34%

NOTE 20 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $58.6 million at December 31, 2022 for future work to be performed.

The Company entered into a construction contract with outstanding commitments aggregating approximately $2.0 million at December 31, 2022 for future work to be performed.

Defined contribution plan

The Company has a qualified defined contribution plan (the "401(k) Plan") pursuant to Section 401(k) of the Code, whereby all eligible employees may participate. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) Plan, subject to defined limitations. The Company is required to make contributions to the 401(k) Plan equal to 100 percent of each participant's pretax contributions of up to six percent of his or her eligible compensation, and the Company is also required to make a contribution equal to three percent of each participant's salary, on an annual basis, subject to limitations under the Code. The Company charged operations $0.9 million and $0.4 million for the year ended December 31, 2022, and 2021, respectively, for contributions under the 401(k) Plan.

NOTE 21 – INCOME TAXES

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

	Year ended December 31, 2022	2021
Foreign	$ (88,478)	$ (73,689)
Domestic	(21,740)	(18,598)
Total	$ (110,218)	$ (92,287)

In 2022, the foreign losses are primarily comprised of $86.7 million related to the Irish operations and $1.5 million related to the Bermudan operations of Tonix International Holding. In 2021, the foreign losses were primarily comprised of $71.9 million related to the Bermudan operations of Tonix International Holding.

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, 2022	2021
Statutory federal income tax	(21.0)%	(21.0)%
Change in valuation allowance	9.6%	15.0%
Foreign loss not subject to income tax	7.0%	7.0%
Attribute reduction from control change	4.0%	(1.2)%
Other	0.4%	0.2%
Income Tax Provision	0.0%	0.0%

Deferred tax assets (liabilities) and related valuation allowance as of December 31, 2022 and 2021 were as follows (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets/(liabilities):		
Net operating loss carryforward	$ 21,642	$ 13,297
Stock-based compensation	7,353	5,832
Other	1,997	2,285
Total deferred assets	30,992	21,414
Valuation allowance	(30,992)	(21,414)
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, 2022 have been reduced to $0.0 million to reflect IRC section 383 ownership changes through December 31, 2022 and the resulting inability to utilize a portion of the R&D credit prior to its expiration.

At December 31, 2022, the Company has $165.5 million of Ireland net operating loss ("NOL") carryforwards that do not expire. As of December 31, 2022, the Company's Federal NOL carryforwards of $3.6 million, which do not expire, but their utilization is limited to 80% of taxable income. Additionally, the Company has New Jersey NOL carryforwards of $2.3 million and Massachusetts NOL carryforwards of $0.3 million, which both expire in 20 years. The NOL carryforwards at December 31, 2022 have been reduced to reflect IRC section 382 ownership changes through December 31, 2022 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, 2022. 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 in the valuation allowance for the years ended December 31, 2022 and 2021 were $9.5 million, and $15.3 million respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2022 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, 2022, the Company's tax returns remain open and subject to examination by the tax authorities for the tax years 2019 and after.

NOTE 22 – SUBSEQUENT EVENTS

Since January 1, 2023, the Company has repurchased 15,700,269 of its shares of common stock outstanding under its $12.5 million share repurchase program at prices ranging from $0.44 to $1.38 per share for a gross aggregate cost of approximately $12.5 million.

In January 2023, the Board of Directors approved a new share repurchase program pursuant to which the Company may repurchase up to $12.5 million in value of its outstanding common stock from time to time on the open market and in privately negotiated transactions subject to market conditions, share price and other factors. Since January 1, 2023, the Company has repurchased 1,000,000 of its shares of common stock outstanding under the new share repurchase program at $1.14 per share for a gross aggregate cost of $1.1 million.

The timing and amount of any shares repurchased will be determined based on the Company's evaluation of market conditions and other factors and the New Share Repurchase Program may be discontinued or suspended at any time. Repurchases will be made in accordance with the rules and regulations promulgated by the Securities and Exchange Commission and certain other legal requirements to which the Company may be subject. Repurchases may be made, in part, under a Rule 10b5-1 plan, which allows stock repurchases when the Company might otherwise be precluded from doing so.

Subsequent to December 31, 2022, the Company regained compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market because the Company's shares had a closing bid price at or above $1.00 per share for a minimum of 10 consecutive business days, as set forth in Nasdaq Listing Rule 5550(a)(2).

On February 2, 2023, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") with Healion Bio Inc., pursuant to which the Company acquired all the pre-clinical infectious disease assets of Healion, including its portfolio of next-generation antiviral technology assets. Healion's drug portfolio includes a class of broad-spectrum small molecule oral antiviral drug candidates with a novel host-directed mechanism of action, including TNX-3900, formerly known as HB-121. As consideration for entering into the Asset Purchase Agreement, the Company paid $1.2 million to Healion. Because the Healion intellectual property was acquired prior to FDA approval, the cash consideration totaling $1.2 million, is expected to be expensed as research and development costs since there is no alternative future use and the acquired intellectual property does not constitute a business.

On February 13, 2023, the Company announced that it exercised an option to obtain an exclusive license from Columbia for the development of a portfolio of both fully human and murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection, including the Company's TNX-3600 and TNX-4100 product candidates, respectively. The licensed mAbs were developed as part of a research collaboration and option agreement between the Company and Columbia.

On February 23, 2023, the Company granted options to purchase an aggregate of 4,394,303 shares of the Company's common stock to employees with an exercise price of $0.73, 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 1,327,500 shares of the Company's common stock to certain employees with an exercise price of $0.91, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months.

Subsequent to December 31, 2022, the Company sold 2.1 million shares of common stock under the Sales Agreement with AGP for net proceeds of approximately $1.4 million.

Subsequent to December 31, 2022, the Company sold 0.6 million shares of common stock under the 2022 Purchase Agreement with Lincoln Park for net proceeds of approximately $0.4 million.

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, 2022 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, 2022, 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

None.

ITEM 9C – DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable

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	65	President, CEO and Chairman of the Board of Directors
Richard Bagger	62	Director
Margaret Smith Bell	63	Director
David Grange	75	Director
Adeoye Olukotun	78	Director
Carolyn Taylor	63	Director
James Treco	67	Lead Director
Jessica Morris	45	Chief Operating Officer
Bradley Saenger	49	Chief Financial Officer and Treasurer
Gregory Sullivan	57	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; and TNX-102 SL's pharmacokinetic profile and related therapeutic properties. 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 mAb 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.

Richard Bagger became a Director in June 2020. Mr. Bagger has been a Partner and Executive Director of Christie 55 Solutions, LLC, a New Jersey based consulting firm, since January 2020. Mr. Bagger has also been an Adjunct Faculty member at the Rutgers University Eagleton Institute since 2018. From 2012 through 2019, Mr. Bagger was Executive Vice President of Corporate Affairs and Market Access for Celgene Corporation (NASDAQ: CELG), a global biopharmaceutical company, as well as a member of its Executive Committee. From 1993 to 2010, Mr. Bagger held roles of increasing responsibility with Pfizer Inc. (NYSE: PFE), a global pharmaceutical company, and served as Senior Vice President, Worldwide Public Affairs and Policy, from 2006 to 2009. Prior to joining Pfizer, Mr. Bagger was Assistant General Counsel of Blue Cross and Blue Shield of New Jersey, a health insurer, and practiced law with the law firm of McCarter & English. Mr. Bagger served as Board Chair of the National Pharmaceutical Council for 2019 and is a member of the Board of Directors of the U.S. Chamber of Commerce. He is also on the advisory board for the Lerner Center for the Study of Pharmaceutical Management Issues at Rutgers University Business School. Mr. Bagger received an A.B. degree from Princeton

University's School of Public and International Affairs and a J.D. degree from Rutgers University Law School. Mr. Bagger's extensive healthcare and public policy experience 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.

Major General David Grange (U.S. Army retired) became a director in February 2018. MG Grange has been President and founder of Osprey Global Solutions, LLC ("OGS"), a Service Disabled Veterans Organization, since 2011. MG 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, MG Grange was a member of the Board of Pharmaceutical Product Development, Inc. (Nasdaq: 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. MG 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. MG Grange commanded the Ranger Regiment and the First Infantry Division (the Big Red One). MG Grange holds a master's degree in Public Service from Western Kentucky University. MG 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 is a board member of Arrowhead Pharmaceuticals. Dr Olukotun is a member of management of Genesis Unicorn Corporation, a special acquisition company recently listed on Nasdaq (GENQU). 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.

Carolyn Taylor became a Director in July 2021. Ms. Taylor was general counsel of Strike Protocols Inc., a financial technology company, from 2019 to 2020, and held positions of varying responsibility, including partner, and most recently, of counsel, at the law firm of Covington & Burling LLP from 1989 to 2000 and 2004 to 2015. From 2000 to 2003, Ms. Taylor served as Executive Vice President and General Counsel of Longitude, Inc., a financial services company. Ms. Taylor graduated from Columbia Law School and earned a B.A. from Brown University. Ms. Taylor's broad transactional experience was instrumental in her selection as a member of the 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 Operating 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) Richard Bagger, Margaret Smith Bell, David Grange, Adeoye Olukotun, Carolyn Taylor and James Treco are each an independent director as defined in the Marketplace Rules of The NASDAQ Stock Market.

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. Treco. 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, 26 Main Street, Suite 101, Chatham, New Jersey 07928. 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, 2022, the Board held 10 meetings, the Audit Committee held eight meetings, the Compensation Committee held seven meetings and the Nominating and Corporate Governance Committee held four 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
Richard Bagger	*		**
Margaret Smith Bell	*	**	
David Grange		*	*
Adeoye Olukotun		*	
Carolyn Taylor		*	
James Treco	**		*

* Member of Committee
** Chairman of Committee

Audit Committee

Our Audit Committee consists of James Treco, Chair of the Committee, Richard Bagger and Margaret Smith Bell. Our Board has determined each of the members 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, 2022.

Compensation Committee

Our Compensation Committee consists of Margaret Smith Bell, Chair of the Committee, David Grange, Adeoye Olukotun and Carolyn Taylor. 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 and the related executive compensation information for inclusion in the Company's Annual Report on Form 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 Richard Bagger, Chair of the Committee, David Grange and James Treco. 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 identifies and evaluates the qualifications of all candidates for nomination for election as directors, and seeks director nominees that complement and enhance the effectiveness of the existing Board to ensure that its members have varied and relevant backgrounds, skills, knowledge, perspectives and experiences. Our Board currently includes two female directors and one director who contributes racial/ethnic diversity, and one who identifies as LGBTQ+. 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.

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 2022 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, including pre-specified corporate, strategic or developmental goals, 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 believes 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. Accordingly, a significant portion of our executives' compensation are stock based, including stock options that are exercisable at a percentage above market value at the time of grant; 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 2022, 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, or accelerate the vesting of unvested equity grants issued to, our executives upon a change in control, absent an actual termination of employment.

At our annual meeting in May 2022, we conducted our tri-annual advisory vote on executive compensation, commonly referred to as a "say-on-pay" vote. At that time, a majority 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 2025 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 2022 and 2021.

Name & Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) [1]	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Seth Lederman	2022	675,000	355,000	—	3,550,167	—	—	—	4,580,167
Chief Executive Officer	2021	675,000	506,250	—	6,527,139	—	—	—	7,708,389
Jessica Morris	2022	455,175	155,000	—	781,037	—	—	—	1,391,212
Chief Operations Officer	2021	425,000	170,000	—	1,174,885	—	—	—	1,769,885
Bradley Saenger	2022	445,400	152,000	—	639,030	—	—	—	1,236,430
Chief Financial Officer	2021	425,000	170,000	—	1,174,885	—	—	—	1,769,885
Gregory Sullivan	2022	461,120	130,000	—	887,541	—	—	—	1,478,661
Chief Medical Officer	2021	440,000	176,000	—	1,631,785	—	—	—	2,247,785

(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 14 to our audited financial statements.

Grants of Plan-Based Awards in Fiscal 2022

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, 2022.

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	2/15/2022	156,250	6.62	931,630
	2/15/2022	156,250	13.24[2]	898,172
	2/15/2022	156,250	19.85[3]	870,904
	2/15/2022	156,250	26.47[4]	849,461
Bradley Saenger	2/15/2022	28,125	6.62	167,693
	2/15/2022	28,125	13.24[2]	161,671
	2/15/2022	28,125	19.85[3]	156,763
	2/15/2022	28,125	26.47[4]	152,903
Jessica Morris	2/15/2022	34,375	6.62	204,959
	2/15/2022	34,375	13.24[2]	197,598
	2/15/2022	34,375	19.85[3]	191,599
	2/15/2022	34,375	26.47[4]	186,882
Gregory Sullivan	2/15/2022	39,063	6.62	232,907
	2/15/2022	39,063	13.24[2]	224,543
	2/15/2022	39,063	19.85[3]	217,726
	2/15/2022	39,063	26.47[4]	212,365

(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 200% premium of the closing price of the Company's common stock on the grant date.
(3) Represents an exercise price at a 300% premium of the closing price of the Company's common stock on the grant date.
(4) Represents an exercise price at a 400% premium of the closing price of the Company's common stock on the grant date.

Outstanding Equity Awards at December 31, 2022

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2022.

Name	Number of Securities underlying Unexercised Options(#) Exercisable	Number of Securities underlying Unexercised Options(#) Unexercisable	Option Exercise Price ($/Sh)	Option Expiration Date
Seth Lederman	3	—	$ 326,400.00	2/12/2023
	3	—	$ 508,160.00	2/11/2024
	4	—	$ 315,840.00	6/17/2024
	4	—	$ 213,760.00	10/29/2024
	6	—	$ 190,400.00	2/25/2025
	1	—	$ 190,400.00	2/25/2025
	4	—	$ 160,960.00	2/9/2026
	—	4(1)	$ 160,960.00	2/9/2026
	5	—	$ 17,600.00	3/1/2027
	49	—	$ 10,880.00	2/13/2028
	49	—	$ 13,600.00	2/13/2028
	73	—	$ 604.80	2/26/2029
	73	—	$ 755.20	2/26/2029
	406	—	$ 656.00	5/6/2029
	406	—	$ 819.20	5/6/2029
	3,549	201(2)	$ 12.80	2/25/2030
	3,549	201(2)	$ 16.00	2/25/2030
	53,827	8,673(3)	$ 24.64	5/4/2030
	53,827	8,673(3)	$ 30.72	5/4/2030
	57,295	36,455(4)	$ 39.04	2/23/2031
	57,295	36,455(4)	$ 48.96	2/23/2031
	—	156,250(5)	$ 6.62	2/15/2032
	—	156,250(5)	$ 13.24	2/15/2032
	—	156,250(5)	$ 19.85	2/15/2032
	—	156,250(5)	$ 26.47	2/15/2032
Jessica Morris	1	—	$ 508,160.00	2/11/2024
	1	—	$ 315,840.00	6/17/2024
	1	—	$ 213,760.00	10/29/2024
	1	—	$ 190,400.00	2/25/2025
	1	—	$ 160,960.00	2/9/2026
	—	1(1)	$ 160,960.00	2/9/2026
	3	—	$ 17,600.00	3/1/2027
	13	—	$ 10,880.00	2/13/2028
	13	—	$ 13,600.00	2/13/2028
	17	—	$ 604.80	2/26/2029
	17	—	$ 755.20	2/26/2029
	91	—	$ 656.00	5/6/2029
	91	—	$ 819.20	5/6/2029
	712	38(2)	$ 12.80	2/25/2030
	712	38(2)	$ 16.00	2/25/2030
	9,688	1,562(3)	$ 24.64	5/4/2030
	9,687	1,563(3)	$ 30.72	5/4/2030
	10,315	6,560(4)	$ 39.04	2/23/2031
	10,315	6,560(4)	$ 48.96	2/23/2031
	—	34,375(5)	$ 6.62	2/15/2032
	—	34,375(5)	$ 13.24	2/15/2032
	—	34,375(5)	$ 19.85	2/15/2032
	—	34,375(5)	$ 26.47	2/15/2032

Name	Number of Securities underlying Unexercised Options(#) Exercisable	Number of Securities underlying Unexercised Options(#) Unexercisable	Option Exercise Price ($/Sh)	Option Expiration Date
Bradley Saenger	1	—	$ 315,840.00	6/17/2024
	1	—	$ 213,760.00	10/29/2024
	1	—	$ 190,400.00	2/25/2025
	1	—	$ 160,960.00	2/9/2026
	—	2[1]	$ 77,440.00	5/27/2026
	1	—	$ 77,440.00	5/27/2026
	2	—	$ 17,600.00	3/1/2027
	13	—	$ 10,880.00	2/13/2028
	13	—	$ 13,600.00	2/13/2028
	17	—	$ 604.80	2/26/2029
	17	—	$ 755.20	2/26/2029
	91	—	$ 656.00	5/6/2029
	91	—	$ 819.20	5/6/2029
	712	38[2]	$ 12.80	2/25/2030
	712	38[2]	$ 16.00	2/25/2030
	9,688	1,562[3]	$ 24.64	5/4/2030
	9,687	1,563[3]	$ 30.72	5/4/2030
	10,315	6,560[4]	$ 39.04	2/23/2031
	10,315	6,560[4]	$ 48.96	2/23/2031
	—	28,125[5]	$ 6.62	2/15/2032
	—	28,125[5]	$ 13.24	2/15/2032
	—	28,125[5]	$ 19.85	2/15/2032
	—	28,125[5]	$ 26.47	2/15/2032
Gregory Sullivan.	1	—	$ 315,840.00	6/17/2024
	1	—	$ 213,760.00	10/29/2024
	1	—	$ 190,400.00	2/25/2025
	1	—	$ 160,960.00	2/9/2026
	—	1[1]	$ 160,960.00	2/9/2026
	3	—	$ 17,600.00	3/1/2027
	19	—	$ 10,880.00	2/13/2028
	19	—	$ 13,600.00	2/13/2028
	25	—	$ 604.80	2/26/2029
	25	—	$ 755.20	2/26/2029
	136	—	$ 656.00	5/6/2029
	136	—	$ 819.20	5/6/2029
	1,155	64[2]	$ 12.80	2/25/2030
	1,154	65[2]	$ 16.00	2/25/2030
	13,464	2,161[3]	$ 24.64	5/4/2030
	13,464	2,161[3]	$ 30.72	5/4/2030
	14,328	9,110[4]	$ 39.04	2/23/2031
	14,328	9,110[4]	$ 48.96	2/23/2031
	—	39,063[5]	$ 6.62	2/15/2032
	—	39,063[5]	$ 13.24	2/15/2032
	—	39,063[5]	$ 19.85	2/15/2032
	—	39,063[5]	$ 26.47	2/15/2032

(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 $192,000.00, $224,000.00 and $256,000.00 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 February 25, 2021, 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 May 4, 2021, 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 23, 2022, 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 10% of the shares on February 15, 2023, 10% of the shares on February 15, 2024, 40% of the shares on February 15, 2025 and 40% of the shares on February 15, 2026.

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, 2022.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2022.

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]	2,453,031	$ 28.93	627,753
Equity compensation plans not approved by security holders	—	—	—
Total	2,453,031	$ 28.93	627,753

(1) Consists of the Company's 2012 Amended and Restated Incentive Stock Option Plan, the 2014 Stock Incentive Plan, the 2016 Stock Incentive Plan, the 2017 Stock Incentive Plan, the 2018 Equity Incentive Plan, the 2019 Stock Incentive Plan, the 2020 Stock Incentive Plan, the Amended and Restated 2020 Stock Incentive Plan and the 2019 Employee Stock Purchase Plan, the 2020 Employee Stock Purchase Plan, and the 2022 Employee Stock Purchase Plan (the "ESPP").

(2) Consists of shares available for future issuance under the Amended and Restated 2020 Plan and our ESPP. As of December 31, 2022, 627,744 shares of common stock were available for issuance under the Amended and Restated 2020 Plan and 9 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 to continue to serve as our President, Chief Executive Officer and Chairman of the Board.

The base salary for Dr. Lederman under the Lederman Agreement was $425,000 per annum and as of January 1, 2023, the base salary is $675,000. The Lederman Agreement has an initial term of one year and automatically renew for successive one year terms unless either party delivers written notice not to renew at least 60 days prior to the end of the current term.

Pursuant to the Lederman Agreement, if the Company terminates Dr. Lederman's employment without Cause (as defined in the Lederman Agreement) or Dr. Lederman resigns for Good Reason (as defined in the Lederman Agreement), Dr. 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 Dr. 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 Dr. 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 Dr, Lederman remained continuously employed by the Company during such period.

Pursuant to the Lederman Agreement, if Dr. Lederman's employment is terminated as a result of death or permanent disability, Dr. 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 Dr. 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, Dr. 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 Dr. Dr. Lederman is still entitled to the Sale Bonus (as defined below), it will only be 18 months; (2) continuation of health benefits for Dr. Lederman and his eligible dependents for a period of 24 months following the date of termination, except that, if and while Dr. 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 Dr. 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, Dr. 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 Dr. Lederman long-term incentive compensation mutually agreed to by the Board and Dr. 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 Dr. 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 Dr. 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 Dr. Lederman's title, authority, duties or responsibilities, (2) a material diminution in Dr. 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 Dr. 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 Dr. 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 in directly, 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 to serve as our Chief Medical Officer. The base salary for Dr. Sullivan under the Sullivan Agreement was $225,000 per annum and as of January 1, 2023, the base salary is $480,000. 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 Dr. Sullivan's employment without Cause (as defined below) or Executive resigns for Good Reason (as defined below), Dr. 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 Dr. 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 Dr. 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 Dr. Sullivan remained continuously employed by the Company during such period.

Pursuant to the Sullivan Agreement, if Dr. 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 Dr. 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 Dr. 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 Dr. Sullivan'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 Dr. Sullivan under the Agreement, or (5) the Company elects not to renew the Agreement for another term.

Employment Agreement with Bradley Saenger

On February 23, 2021, the Company entered into an employment agreement (the "Saenger Agreement") with Mr. Bradley Saenger to serve as our Chief Financial Officer. The base salary for Saenger under the Saenger Agreement was $465,000 per annum as of January 1, 2023. The Saenger Agreement has 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 Saenger Agreement, if the Company terminates Mr. Saenger's employment without Cause (as defined below) or Executive resigns for Good Reason (as defined below), Saenger 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 Mr. Saenger 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 Mr. Saenger 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 Saenger remained continuously employed by the Company during such period.

Pursuant to the Saenger Agreement, if Mr. Saenger's employment is terminated as a result of death or permanent disability, Saenger 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 Saenger 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 Mr. Saenger, (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 Mr. Saenger'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 Saenger Agreement.

For purposes of the Saenger Agreement, "Good Reason" generally means (1) a material diminution in Mr. Saenger'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 Mr. Saenger under the Agreement, or (5) the Company elects not to renew the Agreement for another term.

Employment Agreement with Jessica Morris

On February 23, 2021, the Company entered into an employment agreement (the "Morris Agreement") with Ms. Jessica Morris to serve as our Chief Operations Officer. The base salary for Morris under the Morris Agreement was $475,000 per annum as of January 1, 2023. The Morris Agreement has 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 Morris Agreement, if the Company terminates Ms. Morris's employment without Cause (as defined below) or Executive resigns for Good Reason (as defined below), Morris is entitled to the following payments and benefits: (1) her 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 Ms. Morris 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 her base salary as in effect immediately prior to the date of termination; (3) continuation of health benefits for Ms. Morris and her 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 Morris remained continuously employed by the Company during such period.

Pursuant to the Morris Agreement, if Ms. Morris's employment is terminated as a result of death or permanent disability, Morris or her estate, as applicable, is entitled to her 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 Morris 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 Ms. Morris, (5) ongoing and repeated failure or refusal to perform or neglect of her duties as required by her employment agreement, which failure, refusal or neglect continues for 30 days following Ms. Morris'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 Morris Agreement.

For purposes of the Morris Agreement, "Good Reason" generally means (1) a material diminution in Ms. Morris'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 her 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 Ms. Morris under the Agreement, or (5) the Company elects not to renew the Agreement for another term.

Directors Compensation Table

As of February 2023, each of our non-employee directors, other than the lead director, receives an annual cash retainer of $55,000; the retainer for the lead director is $70,000. In addition, during 2022, each of our non-employee directors received stock options to purchase shares of our common stock valued at $250,000 as determined by the Black Scholes method on the date of grant, which vest on the next annual meeting of stockholders. The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2022 for services to our Company.

Name	Cash Compensation ($)	Option Awards ($)[1]	Total ($)
Richard Bagger	$ 50,000	$ 250,000	$ 300,000
Margaret Smith Bell	$ 50,000	$ 250,000	$ 300,000
David Grange	$ 50,000	$ 250,000	$ 300,000
Adeoye Olukotun	$ 50,000	$ 250,000	$ 300,000
Carolyn Taylor	$ 50,000	$ 250,000	$ 300,000
James Treco [2]	$ 70,000	$ 250,000	$ 320,000
Total:	$ 320,000	$ 1,500,000	$ 1,820,000

(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 14 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. Treco received additional cash compensation for serving as lead director.

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 13, 2023:

- 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., 26 Main Street, Suite 101, Chatham, New Jersey 07928.

NAME OF OWNER	TITLE OF CLASS	NUMBER OF SHARES OWNED[1]	PERCENTAGE OF COMMON STOCK[2]
5% Stockholders			
Tang Capital Partners, LP	Common Stock	4,280,916[3]	6.85%
Directors and Executive Officers			
Seth Lederman	Common Stock	404,404[4]	*
Jessica Morris	Common Stock	72,315[5]	*
Bradley Saenger	Common Stock	68,622[6]	*
Gregory Sullivan	Common Stock	97,937[7]	*
Richard Bagger	Common Stock	77,538[8]	*
Margaret Smith Bell	Common Stock	77,697[9]	*
David Grange	Common Stock	77,524[10]	*
Adeoye Olukotun	Common Stock	77,682[11]	*
Carolyn Taylor	Common Stock	74,030[12]	*
James Treco	Common Stock	79,187[13]	*
Officers and Directors as a Group (10 persons)	Common Stock	1,106,936[14]	1.74 %

* 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 13, 2023 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 62,539,497 shares of common stock issued and outstanding as of March 13, 2023.

(3) Based solely on information contained in a Schedule 13G filed with the SEC on December 16, 2022. The mailing address of this beneficial owner is 4747 Executive Drive, Suite 210, San Diego, CA.

(4) Includes 376,650 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 7 shares of common stock owned by Lederman & Co, 2 shares of common stock owned by L&L, 2 shares of common stock owned by Targent, 1 share of common stock owned by Leder Laboratories, Inc. (Leder Labs), 1 share of common stock owned by Starling, 24,235 shares owned through an IRA account and 1 share 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.

(5) Includes 72,314 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(6) Includes 68,008 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(7) Includes 94,836 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(8) Includes 77,225 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(9) Includes 77,528 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(10) Includes 77,524 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(11) Includes 77,514 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(12) Includes 74,030 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days

(13) Includes 78,874 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days

(14) Includes 1,074,503 shares of common stock underlying options which are currently exercisable or vested or become exercisable within 60 days, 7 shares of common stock owned by Lederman & Co, 2 shares of common stock owned by L&L, 2 shares of common stock owned by Targent, 1 share of common stock owned by Leder Labs, 1 share of common stock owned by Starling, 24,235 shares owned through an IRA account of Dr. Lederman, and 1 share owned by Dr. Lederman's spouse.

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 the lesser of $120,000 of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years.

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.

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

Our independent registered public accounting firm is EisnerAmper LLP, Iselin, New Jersey, PCAOB ID: 274.

(1) 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, 2022 and 2021, including review of our interim financial statements as well as registration statement filings with the SEC and comfort letters issued to underwriters were $383,880 and $312,291, respectively.

(2) 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, 2022 and 2021.

(3) Tax Fees

We did not incur fees to our independent registered public accounting firm for tax services during the fiscal years ended December 31, 2022 and 2021.

(4) All Other Fees

None.

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
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	Form of 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 October 25, 2022 and incorporated herein by reference.
3.09	Form of Certificate of Designation of Series B Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
3.10	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.'s Articles of Incorporation, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 16, 2022 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 as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 24, 2020 and incorporated herein by reference.
10.19	License Agreement, dated May 5, 2020, between Tonix Pharmaceuticals (Canada) Inc. and The Governors of the University of Alberta, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference. †
10.20	Asset Purchase Agreement, dated June 11, 2020, between Tonix Pharmaceuticals, Inc. and Trigemina, Inc., filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on May 12, 2020 and incorporated herein by reference. †
10.21	Amended and Restated Exclusive License Agreement, dated June 11, 2020, between Tonix Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference.
10.22	Assignment and Agreement, dated June 11, 2020, between Tonix Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference.
10.23	Purchase and Sale Agreement, dated July 1, 2020, between Tonix Pharmaceuticals Holding Corp. and Seller named therein, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference. †
10.24	Real Property Purchase and Sale Agreement, dated October 14, 2020, between Tonix Pharmaceuticals Holding Corp. and the Seller named therein, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on November 9, 2020 and incorporated herein by reference. †
10.25	Tonix Pharmaceuticals Holding Corp. Amended and Restated 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 March 30, 2020.*
10.26	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Jessica Morris, dated February 23, 2021, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 26, 2021 and incorporated herein by reference.*
10.27	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Bradley Saenger, dated February 23, 2021, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 26, 2021 and incorporated herein by reference.*
10.28	Purchase and Sale Agreement, dated March 5, 2021, between Tonix Pharmaceuticals Holding Corp. and the Seller named therein, filed as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 15, 2021 and incorporated herein by reference. †
10.29	License Agreement, dated April 14, 2021, between the Company and OyaGen, Inc., filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on May 10, 2021 and incorporated herein by reference †
10.30	Purchase Agreement, dated May 14, 2021, by and 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 May 14, 2021 and incorporated herein by reference.
10.31	Purchase and Sale Agreement, dated July 26, 2021, between the Company and Southern Research, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on August 9, 2021 and incorporated herein by reference.

10.32	Purchase Agreement, dated August 16, 2022, by and 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 17, 2022 and incorporated herein by reference.
10.33	Tonix Pharmaceuticals Holding Corp. 2022 Employee Stock Purchase Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A, filed with the Commission on March 18, 2022.*
10.34	Form of Securities Purchase Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
10.35	Form of Side Letter between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
10.36	Form of Registration Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
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, 2022, 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.
104	The cover page from this Annual Report on Form 10-K, formatted as Inline XBRL.

† Certain portions of this exhibit, that are not material and would likely cause competitive harm to the registrant if publicly disclosed, have been redacted pursuant to Item 601(b)(10) of Regulation S-K.
* Denotes a management compensatory agreement or arrangement.

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 13, 2023

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

Date: March 13, 2023

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 13, 2023
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 13, 2023
/s/ RICHARD BAGGER Richard Bagger	Director	March 13, 2023
/s/ MARGARET SMITH BELL Margaret Smith Bell	Director	March 13, 2023
/s/ DAVID GRANGE David Grange	Director	March 13, 2023
/s/ ADEOYE OLUKOTUN Adeoye Olukotun	Director	March 13, 2023
/s/ CAROLYN TAYLOR Carolyn Taylor	Director	March 13, 2023
/s/ JAMES TRECO James Treco	Director	March 13, 2023