

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, 2023

☐ 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
(State or other jurisdiction of incorporation or organization)

26-1434750
(IRS Employer Identification No.)

26 Main Street, Suite 101
Chatham, New Jersey
(Address of principal executive office)

07928
(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 ☐
Non-accelerated filer ☒

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, 2023, based on the closing sales price of the common stock as quoted on The NASDAQ Global Market was \$16,996,283. 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 April 1, 2024, there were 84,490,862 shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

	PAGE
 <u>PART I</u>	
<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	47
<u>Item 1B. Unresolved Staff Comments</u>	72
<u>Item 1C. Cybersecurity Disclosures</u>	72
<u>Item 2. Properties</u>	73
<u>Item 3. Legal Proceedings</u>	73
<u>Item 4. Mine Safety Disclosures</u>	74
 <u>PART II</u>	
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	74
<u>Item 6. Reserved</u>	74
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	74
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	86
<u>Item 8. Financial Statements and Supplementary Data</u>	F-1 – F-30
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	87
<u>Item 9A. Controls and Procedures</u>	87
<u>Item 9B. Other Information</u>	87
<u>Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</u>	88
 <u>PART III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	88
<u>Item 11. Executive Compensation</u>	93
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	100
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	101
<u>Item 14. Principal Accounting Fees and Services</u>	101
 <u>PART IV</u>	
<u>Item 15. Exhibits, Financial Statement Schedules</u>	102
<u>Signatures</u>	106

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.

Forward-looking statements include, but are not necessarily limited to, those relating to:

- Our prospects are dependent on the success of TonmyaTM and progressing our pipeline through development stages. To the extent regulatory approval of Tonmya is delayed or not granted or, if approved, Tonmya is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.
- The commercial success and market acceptance of our products, including the coverage of our products by payors and pharmacy benefit managers; our ability to successfully develop and execute our sales, marketing and non-personal and digital promotion strategies, including developing and maintaining relationships with customers, physicians, payors and other constituencies, the entry of other products competitive with our commercial products;
- Our ability to successfully execute business development, strategic partnerships, and investment opportunities to build and grow for the future;
- Our ability to achieve the expected financial performance from our marketed products Tosymra® and Zembrace® Symtouch® which we recently acquired from Upsher Smith Laboratories, as well as delays, challenges and expenses, and unexpected costs associated with integrating and operating this new commercial business;
- The ability of our third-party manufacturers to manufacture adequate quantities of commercially saleable inventory and active pharmaceutical ingredients for each of our products, and our ability to maintain our supply chain, which relies on single-source suppliers;
- Our ability to raise additional capital or refinance or pay-off our debt, if necessary;
- The timing and results of any future research and development efforts including potential clinical studies relating to any future product candidates;
- Our common stock maintaining compliance with Nasdaq's minimum closing bid requirement of at least \$1.00 per share.

Business Overview

We are a fully-integrated biopharmaceutical company focused on developing and commercializing therapeutics to treat and prevent human disease and alleviate suffering.

Our near-term priority is to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for TonmyaTM* (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablet) for the management of fibromyalgia ("FM"). FM is a chronic pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. Tonmya is a non-opioid analgesic designed for long-term bedtime use and has completed two positive Phase 3 studies. Tonix announced the positive results of the second Phase 3 study in December of 2023. Tonmya treatment resulted in highly statistically significant improvement in the primary endpoint of pain reduction (p=0.00005) and statistical significance in all six of the key secondary endpoints. Tonmya was well tolerated. Systemic adverse events were similar between Tonmya and placebo. No serious adverse events were reported. The FDA conditionally accepted Tonmya as the trade name for TNX-102 SL for the management of fibromyalgia in January 2024. We have scheduled a type B pre-NDA meeting with the FDA in the first half of 2024, plan to submit an NDA for the approval of Tonmya in the second half of 2024 and expect an FDA decision on the NDA in the second half of 2025. We are preparing for a commercial launch of Tonmya conditional on FDA approval.

Tonmya is a proprietary sublingual tablet formulation of cyclobenzaprine (“CBP”) designed for bedtime administration. In December 2020, we reported positive results from the Phase 3 RELIEF study of Tonmya 5.6 mg for the management of FM. In July 2021, we had disappointing results from a second Phase 3 study, RALLY. In December 2023, we reported positive results from the third Phase 3 RESILIENT study, which met its pre-specified endpoint by significantly reducing daily pain compared to placebo in patients with fibromyalgia.

In preparation for the launch of Tonmya, we have built a team of professionals to market and distribute our products. Our commercial portfolio consists of two FDA-approved prescription products for the treatment of migraine which were acquired from Upsher-Smith Laboratories (“Upsher Smith”) in June 2023: Zembrace SymTouch (sumatriptan injection) 3 mg and Tosymra (sumatriptan nasal spray) 10 mg. Zembrace SymTouch and Tosymra are both indicated for the treatment of acute migraine with or without aura in adults. Zembrace SymTouch is the only branded sumatriptan autoinjector professionally promoted in the United States and is designed for ease of use and favorable tolerability with a low 3 mg dose. Tosymra is a novel intranasal sumatriptan product formulated with a permeation enhancer that provides rapid and efficient absorption of sumatriptan. Tosymra was approved on the basis of bioequivalence to subcutaneous (*s.c.*) sumatriptan. Our commercial team is engaged in marketing and distributing our products, and also engaged in planning the launch of Tonmya.

In addition to Tonmya and our marketed products, we have a pipeline of products in development that include therapeutics and vaccines which are based on small molecules and biologics. Our pipeline has been generated from internal discovery, as well as licenses, acquisitions and collaborations with academic institutions and non-profit organizations.

Our portfolio is focused on central nervous system (“CNS”), disorders, but also consists of 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 immunology portfolio includes TNX-1500*, a biologic to address organ transplant rejection and autoimmune diseases. Finally, our infectious disease portfolio includes a vaccine in development to prevent smallpox and mpox (formerly known as monkeypox), TNX-801*. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine (“RPV”) platform for vaccines to protect against other infectious diseases, including TNX-1800* and TNX-1850* for COVID-19.

In addition to fibromyalgia, TNX-102 SL* is being developed as a potential treatment for a type of Long COVID, the symptoms of which overlap with fibromyalgia, that we term fibromyalgia-type Long COVID. TNX-102 SL has completed a Phase 2 proof-of-concept study. Long COVID is also known as PASC, (“post-acute sequelae of SARS-CoV-2 infection”) is a chronic post-acute COVID-19 condition. We initiated enrollment in the Phase 2 PREVAIL study, in August 2022, and topline results were reported in September 2023. The study did not meet the primary endpoint of change in mean pain from baseline but did show activity in improving fatigue, a hallmark symptom of Long COVID.

TNX-102 SL also is being developed also as a treatment for acute stress reaction (“ASR”) and to prevent acute stress disorder (“ASD”) and posttraumatic stress disorder (“PTSD”) under a physician-initiated Investigational New Drug Application (“IND”) in partnership with the University of North Carolina (“UNC”) Institute for Trauma Recovery. The Phase 2 OASIS study at UNC is supported by the U.S. Department of Defense (“DoD”). We expect enrollment in the OASIS study to begin in the second quarter of 2024. The UNC-led OASIS study will build upon the existing AURORA initiative, a major national research initiative to improve the understanding, prevention, and recovery of individuals who have experienced a traumatic event.

In addition, TNX-102 SL has active INDs for PTSD, agitation in Alzheimer’s disease (“AAD”), and alcohol use disorder (“AUD”). TNX-102 SL for AAD has been granted Fast Track designation by the FDA. We are currently not actively studying TNX-102 SL in PTSD, AAD or AUD.

Another CNS candidate in development is TNX-1300* (double-mutant cocaine esterase) which is in Phase 2 for the treatment of cocaine intoxication. TNX-1300 has been granted Breakthrough Therapy designation by the FDA. TNX-1300 was licensed from Columbia University in 2019 after a Phase 2 study showed that it rapidly and efficiently disintegrates cocaine in the blood of volunteers who received intravenous (*i.v.*) cocaine. In August of 2022, we received a Federal Grant from the U.S. National Institute on Drug Abuse (“NIDA”) a part of the U.S. National Institutes of Health (“NIH”) to advance the development of TNX-1300 as a treatment for cocaine intoxication. We expect to initiate enrollment in a potentially pivotal Phase 2 study of TNX-1300 in emergency rooms in the second quarter of 2024.

Our rare disease portfolio includes TNX-2900* (intranasal potentiated oxytocin) for Prader-Willi syndrome (“PWS”), a genetic disorder characterized by complex symptoms. The formulation technology for TNX-2900 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. The therapeutic technology was licensed from Inserm, the French National Institute of Health and Medical Research. TNX-2900 was granted Orphan-Drug Designation by the FDA in the second half of 2023 and the IND was cleared by the FDA in the fourth quarter of 2023 and received Rare Pediatric Disease Designation on March 21, 2024. 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 PWS genes.

We are developing a different intranasal oxytocin product, TNX-1900* (intranasal potentiated oxytocin with magnesium) for several CNS disorders through investigator-initiated studies. TNX-1900 is in development through investigator-initiated studies for the treatment of binge eating disorder (“BED”), adolescent obesity, social anxiety disorder (“SAD”), and bone health in pediatric autism. We received IND clearance from the FDA in the fourth quarter of 2021 to study TNX-1900 in chronic migraine and we initiated the Phase 2 PREVENTION study for the prevention of migraine headaches in chronic migraineurs in the first quarter of 2023. Topline results from the study, reported in December 2023, showed that TNX-1900 did not meet the primary endpoint as measured by a reduction from 28-day run-in baseline in the mean number of migraine headache days during the last 28 days of the treatment phase. PREVENTION was a small proof-of-concept study with 88 patients enrolled across three arms (TNX-1900 30 IU QD, TNX-1900 30 IU BID, and placebo), and was not powered to result in a statistically significant outcome. In the trial, TNX-1900 was generally well-tolerated with no treatment-emergent serious or severe adverse events. We have discontinued development of TNX-1900 in chronic migraine.

Our lead candidate in the immunology pipeline is TNX-1500, an Fc-modified humanized mAb, directed against CD40-ligand (CD40L, also known as CD154). TNX-1500 was engineered to modulate binding to Fc receptors. TNX-1500 is being developed as a prophylaxis against organ transplant rejection as well as to treat autoimmune conditions. The IND was cleared and a Phase 1 study of TNX-1500 in healthy volunteers was initiated in the second quarter of 2023 and completed the clinical phase in the first quarter of 2024. TNX-1500 is being studied in combination with other immunosuppressive agents in allogeneic and xenogeneic organ transplants in non-human primates at Massachusetts General Hospital, a teaching hospital of Harvard Medical School (“MGH”). In experiments at MGH, 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. Results from 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. Some results from this collaboration were published in the peer-reviewed journal, *American Journal of Transplantation* in 2023.

TNX-1500 also is being studied in combination with other immunosuppressive agents in xenogeneic organ transplants in non-human primates at MGH. In some of these studies, genetically engineered (“GE”) pigs in baboon transplants were treated with cold perfused ischemia minimization and a novel costimulation-based immunosuppressive regimen including TNX-1500. The results of these preclinical studies were encouraging and demonstrated the potential of genetically engineered pig hearts in the context of a clinically applicable regimen. The multi-GE pigs were provided by eGenesis and Revivicor. Revivicor is a subsidiary of United Therapeutics. Some results from the collaboration with MGH and eGenesis were published in the peer-reviewed journal, *Nature* in 2023. In March of 2024, MGH announced the first GE pig kidney transplant into a living recipient supported in part by the pre-clinical work with TNX-1500. TNX-1500 therapy was not used in the human transplant recipient.

Our immunology pipeline also includes TNX-1700*, a recombinant Trefoil Factor Family 2 (“rTFF2”) fusion protein that was licensed from Columbia University in 2019. TNX-1700 consists of TFF2 fused to human serum albumin (HAS) 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 presented data that show a murine version of TNX-1700 consisting of a fusion protein with murine serum albumin 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 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. Mpox has become endemic in the U.S. since it spread in the U.S. and other countries outside of Africa, mostly in populations of men who have sex with men. Non-human primates vaccinated with TNX-801 were protected from mpox in studies reported in the first quarter of 2020. These data were published in the peer-reviewed journal *Vaccines* in 2023. In October 2023, at the World Vaccine Congress - Europe, we reported that the TNX-801 vaccine was shown to be greater than 10 to 1,000-fold more attenuated than older vaccinia-based smallpox vaccines in both human primary cell lines and immunocompromised mice. That work has been posted on BioRxiv, which is not peer-reviewed. 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-1800 is a live virus vaccine on the RPV platform that expresses the SARS-CoV-2 spike protein from the ancestral Wuhan strain, which has shown encouraging results in non-human primates. In the third quarter of 2023, TNX-1800 was selected by the U.S. National Institute of Allergy and Infectious Diseases (“NIAID”), a part of the NIH, to be included in their Project NextGen initiative, an initiative to advance a pipeline of new, innovative vaccines and therapeutics for COVID-19. The COVID-19 vaccines approved for use 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. These data were published in the peer-reviewed journal *Vaccines* in 2023. 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.

Tonix has three pre-clinical research and development programs developing broad spectrum antivirals. The DoD announced in December 2022 a plan to move beyond a ‘one bug, one drug’ approach and are seeking broad-spectrum drugs since it may be hard to predict which or how many viruses may be deployed on the battlefield. TNX-3900* are broad-spectrum small molecule oral antivirals which inhibit essential cathepsins required by viruses such as coronaviruses and filoviruses to infect cells. TNX-4200* are orally available CD45 antagonists in preclinical development. We believe that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations and a lower dose, and therefore will have a higher safety window. Tonix plans to leverage previous research on phosphatase inhibitors, specifically compounds that target CD45, to optimize lead compounds for therapeutic intervention of biothreat agents. TNX-4000* are viral glycan-targeted engineered biologics. These antivirals are currently in preclinical development.

Relating to our development programs, we own and operate the Research and Development Center (“RDC”) in Frederick, Maryland consisting of one building totaling approximately 48,000 square feet. The RDC conducts research on central nervous system, immunology, and infectious disease candidates. The RDC facility is mostly biosafety level 2 (BSL-2), with some components designated BSL-3. We also own and operate an Advanced Development Center (“ADC”) located in the New Bedford business park in Dartmouth, Massachusetts. 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 have engaged CBRE, an international real estate brokerage firm, to find a strategic partner for, or buyer of, ADC.

*Tonix’s product development 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.

Our Strategy

Our strategy is to use our integrated development engine to advance innovative programs across multiple therapeutic areas through the drug development process, with the ultimate objectives of FDA approval and commercialization. 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.*** We are pursuing multiple indications that are underserved with limited, effective treatment options. One of our latest stage product candidates is Tonmya for the management of FM, a condition which affects between 6-12 million adults in the U.S. 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 ASR, ASD, AAD and AUD, all of which are underserved by currently approved medications or have no approved treatment. Within CNS, Tonix is also developing TNX-1300 to treat cocaine intoxication and TNX-1900 to treat binge eating disorder, adolescent obesity, social anxiety disorder and bone loss associated with autism. 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 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-1800 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 the acquisition of our two FDA-approved, marketed products for the treatment of acute migraine (Zembrace SymTouch and Tosymra) positions Tonix to build out commercial capability to market the migraine products and to launch Tonmya for fibromyalgia. 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-1800, 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 have filed patent applications for TNX-1500. 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, and insulin resistance. 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 of development is set forth below.

Central Nervous System

Fibromyalgia (FM)

FM is a chronic syndrome characterized by widespread pain accompanied by fatigue, non-restorative sleep, cognitive dysfunction or “brain fog” and mood issues. The peak incidence of FM occurs between 20-50 years of age, and the majority 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.

Fibromyalgia-type 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 the development of TNX-102 SL specifically on fibromyalgia-type Long COVID, the symptoms of which 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*, 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 19% 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.

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.

Acute Stress Disorder (ASD)

ASD is a mental health condition that can occur within the first month of experiencing a traumatic event. The symptoms are similar to those of PTSD and can affect both civilian and military populations. According to the National Center for PTSD, in the U.S. about 60% of men and 50% of women experience at least one trauma in their lives. In the U.S. alone, one-third of emergency department visits (40-50 million patients per year) involve evaluation after trauma exposures, and in a 2014 study involving U.S. veterans, 87% reported exposure to at least one potentially traumatic event during their service. No medications are currently available at or near the point of care to treat patients suffering from acute traumatic events and to support long-term health.

Rare Disease

Prader-Willi Syndrome (PWS)

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 Clade 2 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. An outbreak of Clade 1 mpox in the Democratic Republic of the Congo is raising concerns by the U.S. Bipartisan Commission on Biodefense.

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. The U.S. National Academy of Sciences has recently issued a consensus report raising concerns about the state of new mpox vaccines in development.

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.

Tonix's Marketed Migraine Products

Zembrace SymTouch and Tosymra – Acute Migraine in Adults

In June 2023, we acquired two FDA-approved, marketed products from Upsher-Smith : Zembrace SymTouch (sumatriptan injection) 3 mg and Tosymra (sumatriptan nasal spray) 10 mg. Zembrace SymTouch and Tosymra are both indicated for the treatment of acute migraine with or without aura in adults. These products collectively generated combined gross retail product sales of approximately \$28.5 million for the twelve months ended December 31, 2023.

Zembrace SymTouch is the only actively promoted brand of sumatriptan autoinjector in the United States. It has a unique low dose and has demonstrated onset of migraine pain relief in as few as 10 minutes (17% of patients vs. 5% for placebo). Zembrace SymTouch also demonstrated migraine pain freedom for 46% of patients (vs 27% for placebo) at 2 hours in a single-attack, double-blind study (N=230). Zembrace SymTouch currently has patent protection to 2036. Tosymra employs Intravail® permeation enhancer technology and is pharmacokinetically equivalent to 4 mg subcutaneous sumatriptan. Tosymra delivers migraine pain relief in as little as 10 minutes with just one spray for some patients (13% vs. 5% for placebo). Tosymra® currently has patent protection to 2031.

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
Tonmya (TNX-102 SL)	Fibromyalgia	Two Positive Phase 3 studies completed, preparing NDA submission
TNX-102 SL	Fibromyalgia-type Long COVID	Phase 2 study completed
TNX-102 SL	Acute Stress Reaction	Phase 2 ready* – investigator-initiated IND
TNX-1300	Cocaine Intoxication	Mid-Phase 2, targeted 2Q 2024 start
TNX-2900	Prader-Willi Syndrome	Phase 2 ready, IND cleared
TNX-1900	Adolescent Obesity, Binge Eating Disorder, Bone Health in Pediatric Autism, Social Anxiety Disorder, *	Phase 2 completed for chronic migraine and currently enrolling for other indications*
TNX-1500	Kidney Transplant Rejection	Phase 1 study ongoing
TNX-801	Smallpox and Mpox vaccine	Preclinical, pre-IND
TNX-1800	COVID-19 vaccine	Preclinical, pre-IND

*Investigator Initiated Studies

TNX-102 SL

Overview

TNX-102 SL is a proprietary sublingual tablet formulation of CBP that efficiently delivers CBP across the oral mucosal membrane into the systemic circulation. We have active IND's for TNX-102 SL as a bedtime treatment for fibromyalgia, PTSD, fibromyalgia-type Long COVID, AAD and AUD. The University of North Carolina has an investigator-initiated IND for ASD that references our INDs. We own all rights to TNX-102 SL in all geographies, and we bear no obligations to third parties for any future development or commercialization. Excipients used in TNX-102 SL are approved for pharmaceutical use. Some of the excipients were specially selected to promote a local oral environment that facilitates mucosal absorption of CBP.

The current TNX-102 SL sublingual tablets each contain 2.8 mg of CBP. TNX-102 SL 5.6 mg (two 2.8 mg tablets) at bedtime has completed two positive Phase 3 studies for the management of fibromyalgia. 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 multi-functional drug that blocks the serotonin-2A, alpha-1 adrenergic, 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 pharmacokinetic 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 (FDCA) with Amrix as the reference listed drug (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 fibromyalgia, fibromyalgia-type 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.

We have also successfully completed a bridging pharmacokinetic study in ethnic Japanese and Chinese volunteers that shows similar characteristics to our historical data in Caucasian volunteers. We believe this will satisfy one of the criteria for approval in Japan and China and will allow us to reference the U.S. efficacy data to support marketing applications in those countries.

Tonmya (TNX-102 SL) – FM program

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

Clinical Development Plan

Completed Positive Phase 3 RESILIENT Study (F307)

The first patient was enrolled in the pivotal Phase 3 RESILIENT study in April 2022. The RESILIENT study was a double-blind, randomized, placebo-controlled adaptive design trial designed to evaluate the efficacy and safety of Tonmya in FM. The two-arm trial enrolled 457 participants in the U.S. The first two weeks of treatment consist of a run-in period in which participants start on Tonmya 2.8 mg (1 tablet) or placebo. Thereafter, all participants increase their dose to Tonmya 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks. The RESILIENT study achieved statistical significance on the pre-specified primary efficacy endpoint: change from baseline in the weekly average of daily diary pain severity numerical rating scale (NRS) scores for Tonmya 5.6 mg (LS mean [SE]: -1.8 [0.12] units) versus placebo (-1.2 [0.12] units), analyzed by mixed model repeated measures with multiple imputation (LS mean [SE] difference: -0.7 [0.16] units, p=0.00005). In addition, all pre-specified sensitivity analyses of the primary endpoint were statistically significant (p≤0.001). We observed reduction in pain across all weeks of the 14-week study, with nominal p<0.01 for every week. The rapid onset of action with separation from placebo at Week 1 was sustained throughout all weeks of dosing. Tonmya was well tolerated and consistent with prior trials, with no new safety signals observed. Among participants randomized to the Tonmya and placebo arms, 81.0% and 79.2%, respectively, completed the 14-week dosing period. As expected based on prior Tonmya studies, administration site reactions were the most commonly reported adverse events and were higher in the Tonmya treatment group. Hypoaesthesia oral and paraesthesia oral, or tongue and mouth numbness or tingling, product taste abnormal (typically a bitter aftertaste upon dosing), and tongue discomfort were local effects nearly always temporally related to dose administration and transiently expressed (<60 minutes) in most occurrences. The only treatment-emergent adverse events that occurred at a rate of 3.0% or greater in either arm were these four oral adverse events, along with COVID-19, somnolence, and headache. Adverse events resulted in premature study discontinuation in 6.1% of those who received Tonmya compared with 3.5% of placebo recipients. There were a total of seven serious adverse events in five patients, five of which were experienced by three patients in the placebo arm, and two of which were in the Tonmya arm. Of the two in the Tonmya arm, one was renal cancer, deemed unrelated to study drug, and the other was acute pancreatitis with onset 14 days after dosing was completed, reported as possibly related to study drug, and was resolved before the final study visit.

Completed Phase 3 RALLY Study (F306)

The RALLY study was a double-blind, randomized, placebo-controlled adaptive design trial intended to evaluate the efficacy and safety of Tonmya in FM. The trial was designed 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 Tonmya 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients had the dose increased to Tonmya 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. 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, Tonmya 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.

Completed Positive 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 Tonmya 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 Tonmya 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 Tonmya 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 Tonmya acts in fibromyalgia through improving sleep quality, Tonmya 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, Tonmya 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, Tonmya was similarly well tolerated as in the Phase 2 BESTFIT and Phase 3 AFFIRM studies, which both studied Tonmya 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 Tonmya and placebo arms, 82.3% and 83.5%, respectively, completed the 14-week dosing period. As expected, based on prior studies, administration site reactions are the most commonly reported adverse events and were higher in the Tonmya treatment group, including rates of hypoaesthesia oral (17.3% vs. 0.8%), oral pain/discomfort (11.7% v. 2.0%), product taste abnormal (6.5% vs. 0.4%), and paraesthesia oral (5.6% v. 0.4%). Hypoaesthesia or paraesthesia oral and product taste abnormal 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 Tonmya 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 Tonmya 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 Tonmya arm. Of the two in the Tonmya arm, one was a motor vehicle accident with multiple bone fractures, and the other was a case of 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 Tonmya 2.8 mg 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 Tonmya 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 mixed model for repeated measure ("MMRM"⁰ ($p<0.001$) or by MMRM with multiple imputation for missing data ($p=0.005$), a generally accepted approach to pain data. Tonmya 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 Tonmya on measures of sleep quality, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, Sleep Disturbance instrument ($p<0.001$).

Tonmya 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 hypoesthesia oral occurring in 40% of participants on Tonmya 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 Tonmya. Systemic adverse events were similar between Tonmya and placebo. No serious adverse events were reported.

Other NDA Requirements

An Agreed Initial Pediatric Study Plan ("Agreed iPSP") is required for the initial NDA submission. The Agreed iPSP was accepted by the FDA in September 2015. We submitted an amended iPSP in the third quarter of 2021 and received comments from the FDA in the fourth quarter of 2021. We submitted a second amended iPSP in first quarter 2024 and plan to come to an Agreed PSP by the time of NDA submission. 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, such as geriatric and renal/hepatic impaired patients, drug-drug interaction or cardiovascular safety studies to support the Tonmya NDA filing since the pivotal systemic exposure bridging study using Amrix as the reference listed drug (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 Tonmya 5.6 mg, the FDA has not requested a risk management plan or medication guide for this product.

Other NDA Requirements

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 new chemical entity NCE. 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. Since the similarity in PK profile between people of Japanese and Chinese descent was confirmed, the PK data from the two ethnic groups were pooled as for Asian data ($n=20$) and compared retrospectively with the Caucasian study data from Study TNX-CY-F110 ($n=16$). The Asian/Caucasian geometric mean ratios of cyclobenzaprine C_{max} , AUC_{0-T} and $AUC_{0-\infty}$ were between 0.9 and 1.11 after both the 5.6 mg dose and the 2.8 mg dose. The 90% CI of Asian/Caucasian geometric mean ratios for C_{max} , AUC_{0-T} and $AUC_{0-\infty}$, were all within the formal narrow equivalence limit of 0.8 to 1.25 after both the 5.6mg dose and 2.8mg dose, respectively. These results support similarity in cyclobenzaprine PK between Asian (pooled Japanese and Chinese) and Caucasian samples.

We have initiated nonclinical safety, pharmacology and embryo-fetal development toxicology studies as part of the agreed IND-enabling nonclinical data package to support clinical studies of Tonmya in Japan.

TNX-102 SL – Fibromyalgia-type Long COVID Program

We are developing TNX-102 SL as a bedtime treatment for fibromyalgia-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.

Completed Phase 2 PREVAIL Study (TNX-CY-PA201)

We initiated a Phase 2 study of TNX-102 SL as a treatment for fibromyalgia-type Long COVID, 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 fibromyalgia-type Long COVID. In the study, 63 subjects were enrolled and randomized 1:1 across approximately 30 U.S. sites to receive either TNX-102 SL or placebo daily at bedtime for 14 weeks. Subjects started with one TNX-102 SL 2.8 mg tablet or one placebo tablet for the first 2 weeks and then increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks of the treatment period. Given the lack of Long COVID treatments and the size of the current proof-of-concept study, an effect size (“ES”) ≥ 0.2 was the pre-specified threshold for declaring the primary endpoint positive. The study trended towards a benefit but did not achieve statistical significance on the primary efficacy endpoint of change from baseline in the diary numerical rating scale (NRS) weekly average of daily self-reported worst Long COVID pain intensity scores for TNX-102 SL at the Week 14 endpoint versus placebo ES = 0.08)

The change from baseline to the Week 14 endpoint for the daily sleep quality diary, PROMIS Sleep Disturbance, PROMIS Fatigue, PROMIS Cognitive function, the Insomnia Severity Index (ISI) and Sheehan Disability Scale showed numerical improvements in (MMRM, ES ≥ 0.2): sleep diary (MMRM, ES =0.23), PROMIS sleep Disturbance (MMRM, ES=0.32), PROMIS fatigue (MMRM, ES=0.50), PROMIS Cognitive Function – Abilities, (MMRM, ES=0.21), the ISI (ANCOVA, ES=0.24) and the Sheehan Disability Scale (ANCOVA, ES=0.26). Moreover, robust activity was observed in the PGIC responder (very much improved or much improved) rate for TNX-102 SL compared to placebo: week 6 (31.3% vs. 9.7%, difference=21.6%), week 10 (28.1% vs. 12.9%, difference=15.2%), week 14 (34.4% vs. 16.1%, difference=18.2%). TNX-102 SL was generally well tolerated with an adverse event (“AE”) profile comparable to prior studies with TNX-102 SL. AE-related discontinuations were similar in drug and placebo arms. No new safety signals were observed.

We intend to request an End-of-Phase 2 meeting with the FDA to discuss a potential Phase 3 program based on a proposed primary outcome measure using the PROMIS Fatigue scale. Fatigue is the symptom of Long COVID that principally overlaps with chronic fatigue syndrome/myalgic encephalomyelitis and fibromyalgia. In the NIH funded RECOVER study analysis, fatigue was the top featured symptom and is common in each of the four clusters.

TNX-102 SL – Acute Stress Disorder Program

TNX-102 SL is being developed as a bedtime treatment for ASR in collaboration with the University of North Carolina under an investigator-initiated IND.

Phase 2 OASIS Study

This investigator-initiated study will be conducted by the University of North Carolina Institute for Trauma Recovery. The University of North Carolina has been awarded a \$3 million grant from the DoD to investigate the potential of Tonix’s TNX-102 SL to reduce the frequency and severity of adverse effects of acute trauma. The proposed Optimizing Acute Stress reaction Interventions with TNX-102 SL (OASIS) trial will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients presenting to the emergency department after a motor vehicle collision. The trial will enroll approximately 180 individuals who acutely experienced trauma at study sites across the U.S. and participants will be randomized in the emergency department to receive a two-week course of either TNX-102 SL or placebo.

The OASIS trial will build upon a foundation of knowledge and infrastructure developed through the University of North Carolina-led, \$40 million AURORA initiative. The AURORA study is a major national research initiative to improve the understanding, prevention, and recovery of individuals who have experienced a traumatic event. AURORA is supported by funding from the NIH, leading brain health nonprofit One Mind, private foundations, and partnerships with leading tech companies such as Mindstrong Health and Verily Life Sciences, the health care arm of Google’s parent company Alphabet.

Initiation of patient enrollment in the proposed investigator sponsored OASIS trial is anticipated in the second quarter of 2024. The FDA granted IND clearance in the first quarter of 2024.

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 fibromyalgia.

Manufacturing

Tonix 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 fibromyalgia market.

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 sequelae 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 NIDA, part of NIH, to support development of TNX-1300. 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.

We expect to initiate a Phase 2 clinical trial of TNX-1300 in the second quarter of 2024. 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.

TNX-2900 – Prader-Willi Syndrome (PWS)

TNX-2900 is based on our patented intranasal potentiated oxytocin formulation, or TNX-1900, but being developed for PWS. Tonix licensed technology using oxytocin-based therapeutics for the treatment of PWS 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. 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. There is currently no approved treatment for either the suckling deficit in infants or the obesity and hyperphagia in older children associated with PWS. Since PWS is an orphan disease that occurs in approximately one in 15,000 births, TNX-2900 for PWS has been granted Orphan Drug Designation and Rare Pediatric Disease Designation 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, and Tonix has received IND clearance.

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 PWS 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. A Phase 1 study of TNX-1500 in healthy volunteers was initiated in the second quarter of 2023 and has completed the clinical phase. Topline results are expected in the third quarter of 2024.

In pre-clinical experiments at MGH, TNX-1500 is being studied as monotherapy or in combination with immunosuppressive drugs in heart and kidney organ transplants in non-human primates. The data demonstrates that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate models of cardiac and kidney allograft model without clinical thrombosis. Furthermore, pre-clinical research supports TNX-1500's activity in preventing pig xenograft organ rejection.

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 TNF α include: infliximab (Remicade®), adalimumab (Humira®), certolizumab pegol (Cimzia®), and golimumab (Simponi®) for the treatment of certain autoimmune conditions. Also, etanercept (Enbrel®) is a TNF α 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 Fc γ R2. 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. The IND was cleared and a Phase 1 study of TNX-1500 in healthy volunteers was initiated in the second quarter of 2023 and completed the clinical phase in the first quarter of 2024.

Remicade® and Simponi® are trademarks of Janssen; Humira® is a trademark of AbbVie Inc.; Cimzia® is a trademark of UCB S. A.; Enbrel®, Prolia® and Xgeva® are trademarks of Amgen Inc.

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. Jynneos® requires two-doses, with an efficacy of approximately 35% after one dose. During the most recent mpox outbreak in the United States, dropout between doses was 24%. 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. We also believe that TNX-801 would require only one dose.

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. The Bipartisan Commission on Biodefense (2024) noted that “Smallpox and other orthopoxviruses pose significant threats to the United States and the world due to their potential for weaponization, accidental release, and vulnerability of populations who stopped routinely vaccinating against smallpox in the 1970s” (Bipartisan Commission on Biodefense).

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 remains a growing epidemic threat in certain regions of Africa and beyond. 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 93,000 cases have been reported as of Feb. 2024 with 32,000 reported in the U.S. 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. These results were published in the peer-reviewed journal *Viruses* in 2023. In October 2023, at the World Vaccine Congress - Europe, we reported that the TNX-801 vaccine was shown to be greater than 10-1,000 fold more attenuated than older vaccinia-based smallpox vaccines in both human primary cell lines and immunocompromised mice and that work has been posted on BioRxiv, which is not peer-reviewed.

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.

In August 2023 we received pre-IND meeting written responses from the FDA. Tonix believes the FDA feedback provides a path to agreement on the design of a Phase 1/2 study and the overall clinical development plan. The Phase 1/2 clinical trial will assess the safety, tolerability, and immunogenicity of TNX-801, following the submission and clearance of an IND. We are actively working to develop a vaccine that meeting cGMP quality to support a clinical study.

TNX-1800 – Potential COVID-19 Vaccine

TNX-1800 is an attenuated, live virus vaccine based on our RPV platform that expresses the SARS-CoV-2 spike protein from the ancestral Wuhan strain. TNX-1800 is being further developed to rapidly address new variants as they emerge. The vaccine platform itself can carry a payload of genes. The vaccine protects against COVID-19 by eliciting a durable T cell, humoral and mucosal immune response. It is delivered in only one dose and is being configured for simplified delivery by using a microneedle patch to increase accessibility and acceptability. In November 2023, Tonix announced that the NIAID, a part of the NIH, will conduct a Phase 1 clinical trial with TNX-1800 as part of the Project NextGen Covid-19 Vaccine initiative. This NIAID/NIH program is funded to take selected NextGen vaccine candidates into Phase 1 and Phase 2 trials.

The COVID-19 vaccines that are approved for use 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 limited ability to block the spread of infection (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 (e.g. smallpox). The TNX-1800 vaccine development plan is wholly consistent with priority vaccine attributes advanced by the White House Office of Science and Technology Policy’s Pandemic Preparedness Plan (“AP3”) from September 2021, the National Biodefense Science Board report from August 2023, and the BARDA Strategic Plan 2022-2026. Tonix believes its RPV platform can address a wide variety of disease targets of public health interest.

The results of a non-human primate study data showing the protective effect of TNX-1800 vaccine was published in the peer-reviewed journal *Vaccines* in 2023 and show that TNX-1800 induces complete protection against SARS-CoV-2 infection as well as evidence that indicates an impact on spread of infection. These data also 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 has also begun undertaking studies to show attenuation of the RPV platform itself, in order to evaluate the potential use of the live vaccine platform in the immunocompromised host by the use of mouse model system. These data (detailed below) demonstrate that the RPV vaccine platform that is used for TNX-1800 is >10- to 1,000-fold more attenuated than older VACV-based smallpox vaccines in human primary cell lines and immunocompromised mice (Trefry, SV et al. Recombinant chimeric Horsepox Virus (TNX-801) is attenuated relative to Vaccinia Virus Strains in Human Primary Cell Lines and in Immunocompromised Mice).

We received pre-IND meeting written responses from the FDA in 2021 regarding our investigational plan to establish the safety and effectiveness evidence in support of the licensure of TNX-1800. We believe that the FDA feedback provides a clear pathway forward towards utilizing its underlying RPV platform for a COVID-19 vaccine.

We announced the issuance of U.S. Patent for TNX-801 smallpox and mpox vaccine and 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.

Scientific Results

At the World Vaccine Congress in October 2023, Tonix presented its positive, published non-human primate data for the TNX-1800 (spike from Wuhan strain) from animal challenge studies using live SARS-CoV- 2. 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. 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 1×10^6 PFU is an appropriate dose for a one-dose vaccine in humans. These data were published in the peer-reviewed journal *Vaccines* in 2023.

Additional studies have been undertaken to show attenuation of the RPV platform alone (TNX-801), in order to evaluate the potential use of this live vaccine in the immunocompromised host. These data demonstrate that the RPV platform used with TNX-1800 is >10- to 1,000-fold more attenuated than older VACV-based smallpox vaccines in human primary cell lines and immunocompromised mice.

TNX-1900 –Adolescent Obesity, Binge Eating Disorder and Social Anxiety

TNX-1900 (intranasal potentiated oxytocin) is a proprietary formulation of oxytocin primarily in development under investigator-initiated INDs for the treatment of adolescent obesity, binge eating disorder, bone health in pediatric autism, and social anxiety disorder. 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.

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.

We initiated a Phase 2 study of TNX-1900 for the prevention of migraine headaches in chronic migraineurs in the first quarter of 2023. Topline results from the study, reported in December 2023, showed that TNX-1900 did not meet the primary endpoint of reducing migraine days. We discontinued the program. TNX-1900 was generally well-tolerated with no treatment-emergent serious or severe adverse events.

There are three ongoing Phase 2 investigator-led studies enrolling at MGH: the POWER study for the treatment of adolescent obesity, the STROBE study for the treatment of BED, and the BOX study for the treatment of bone health in pediatric autism. In addition to the studies at MGH, Tonix is conducting an investigator-initiated study of TNX-1900 for the treatment of SAD at the University of Washington.

Tonix's Facilities Overview

Relating to our COVID-19 and other infectious disease development programs, 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 demonstrated 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. Our goal is to establish 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 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 which can employ up to 70 researchers, scientists, manufacturing, and technical support staff. We have engaged CBRE, an international real estate brokerage firm, to find a strategic partner for, or buyer of, ADC.

Marketing, Sales and Distribution

Marketing activity for Zembrace Symtouch and Tosymra in the United States will be conducted by our wholly-owned subsidiary, Tonix Medicines, Inc. We focus our sales and marketing efforts on physicians in private practice and in public treatment systems. We employ standard pharmaceutical marketing practices to promote our products, encompassing advertisements, professional symposia, sales initiatives, and educational outreach aimed at physicians, nurses, social workers, counselors, and other stakeholders involved in treating acute migraine in adults. We have established contracts with third-party vendors to handle logistics, offer customer services, and manage other related aspects for our products. These services include managing product-specific websites, conducting insurance research, processing orders, and handling delivery and fulfillment services. Zembrace Symtouch and Tosymra are primarily sold to pharmaceutical wholesalers, pharmacies, and specialty distributors.

We intend to implement patient access programs and expand distribution channels in our marketing efforts for our migraine drugs.

Competition

Our sector faces intense competition and experiences rapid, substantial technological advancements both domestically and internationally. Our potential competitors encompass major pharmaceutical and biotechnology firms, specialty pharmaceutical and generic drug manufacturers, academic institutions, government agencies, and research organizations. We consider efficacy, safety, tolerability, reliability, pricing, and reimbursement levels as crucial competitive factors influencing the development and commercial success of our product candidates. Numerous potential competitors, including some of the organizations listed below, possess considerably larger financial, technical, and human resources, as well as extensive experience in discovering and developing product candidates, securing FDA and other regulatory approvals, and commercializing those products, far surpassing our own capabilities. Hence, our competitors might achieve greater success in securing FDA approval for drugs and gaining widespread market acceptance compared to us. The drugs offered by our competitors may prove to be more effective or better marketed and sold than any product we bring to market, potentially rendering our product candidates obsolete or non-competitive before we can recoup the expenses incurred in their development and commercialization. We expect to encounter heightened competition as the market sees the introduction of new drugs and the emergence of advanced technologies. Additionally, the evolution of novel treatment approaches for the conditions we are focusing on may potentially diminish the competitiveness or relevance of our drugs. Below, we provide an overview of the competitive landscape for the indications where Tonix has product candidates either in or nearing the clinical stages of development.

Migraine

Zembrace Symtouch and Tosymra are indicated for the treatment of acute migraine and compete with generic versions of sumatriptan. Zembrace is an autoinjector formulation of sumatriptan and competes with generic subcutaneous products. Tosymra is an intranasal formulation of sumatriptan and competes with generic intranasal products. Zembrace and Tosymra also compete with the new molecular entities including oral migraine therapies such as Nurtec® (Rimegepant) from Pfizer Inc. and Ubrelvy® (Ubrogepant) and QULIPTA® (atogepant) from AbbVie Inc. and intranasal migraine therapies such as Zavzpret™ (vazegepant) by Pfizer, Inc.

Fibromyalgia

Tonix is developing TNX-102 SL for the treatment of fibromyalgia. Products approved for the treatment of fibromyalgia include Lyrica® (pregabalin), developed by Pfizer, Inc., Cymbalta® (duloxetine), developed by Eli Lilly and Company, and Savella® (milnacipran) marketed by AbbVie. Pregabalin and duloxetine are available as generics, while Savella still enjoys exclusivity. Tonix is aware of several other companies developing treatments for fibromyalgia. Axsome Therapeutics expects to submit an NDA for AXS-14 (esreboxetine) for the management of fibromyalgia in the first half of 2024. UCB S.A. is developing Rystiggo® (rozanolixizumab), a monoclonal antibody targeting the neonatal Fc receptor (FcRn) blocker in a Phase 2 trial to treat adults with severe fibromyalgia syndrome. Scilex Pharmaceuticals, Inc. have a Phase 1, open label, randomized, single-dose, 3-period, 3-treatment crossover study to evaluate the pharmacokinetics of SP-104 under fasting and fed conditions and to compare to Naltrexone Hydrochloride Tablets USP in healthy adult subjects in New Zealand. Virios Therapeutics, Inc. is investigating IMC-1 for the treatment of fibromyalgia. In September 2023, Tryp Therapeutics, Inc. initiated a Phase IIa, open-label, pilot study to assess the safety and efficacy of Psilocybin (TRP-8802) administration in concert with psychotherapy among adult patients with fibromyalgia. In the first quarter of 2024, Silo Pharma announced preclinical data on SP-26, its novel time-released, dose-controlled formulation of ketamine initially targeted for fibromyalgia.

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 companies developing therapeutics for long COVID including, but not limited to, Direct Biologics, LLC (DB-001 in Phase III), American CryoStem Corporation, Ampio Pharmaceuticals, Inc. (AMPE), Pieris Pharmaceuticals, Inc., Resolve Therapeutics, LLC, GeNeuro, Organicell Regenerative Medicine, Inc., Berlin Cures Holding AG (Phase II currently enrolling in Europe) and Statera BioPharma, Inc.

PaxMedica, Inc. is developing PAX-101 for the treatment of long COVID-19. Virios Therapeutics, Inc. announced that it is targeting the initiation of a phase II program for IMC-2 (combination of valacyclovir and celecoxib) as a treatment for the fatigue, orthostatic intolerance and other symptoms associated with Long COVID in second half of 2024.

Acute Stress Reaction/Acute Stress Disorder (ASR/ASD)

There are no approved drugs for treating ASR or for the prevention of ASD or PTSD.

Cocaine Intoxication

There are no approved antidotes for the treatment of cocaine intoxication. Patients generally receive supportive care. We are not aware of any drugs in development for the treatment of cocaine intoxication. We are aware of companies that are targeting cocaine use disorder and we monitor their progress.

Anti-CD40-ligand Monoclonal Antibodies

We are aware of several companies developing biologics that target the CD40L molecule and block its interaction with CD40 including Sanofi, UCB, Eledon Pharmaceuticals, and Amgen (which acquired Horizon Therapeutics plc). In February 2024, Sanofi published their Phase II clinical trial of frexalimab in people with relapsing multiple sclerosis in *The New England Journal of Medicine*. The phase II trial involving participants with multiple sclerosis, inhibition of CD40L with frexalimab had an effect that generally favored a greater reduction in the number of new gadolinium-enhancing T1-weighted lesions at week 12 as compared with placebo. In August 2023, H.Lundbeck A/S (in partnership with AprilBio) completed their phase I, 2-part, single ascending dose, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of Lu AG22515 (APB-A1) in healthy adult subjects. There are multiple companies in the process of developing antagonistic anti-CD40 mAbs, including Novartis, Boehringer Ingelheim GmbH, Kiniska Pharmaceuticals, Boston Immune Therapies, and NapaJen Pharma Inc.

Prader-Willi Syndrome (PWS)

Somatropin, which targets the Growth Hormone Receptor is approved in the U.S. and marketed by Pfizer Inc. and Novo Nordisk. Novartis AG markets Omnitrope® in Europe. There are no approved products for the treatment of hyperphagia or over-eating in PWS. Patients generally receive care to best manage individual symptom presentation. ACADIA Pharmaceuticals Inc. currently have ACP-101 (intranasal carbetocin) (acquired Levo Therapeutics in June 2022) in a Phase 3, randomized, double-blind, placebo-controlled, 8-week clinical study to assess the efficacy, safety, and tolerability, of ACP-101 in PWS with long term follow-up. Soleno is developing diazoxide chloride controlled release (DCCR) which had positive results in a randomized withdrawal study of PWS and based on which Soleno expects to file an NDA. Tonix is aware of several companies that are focused on developing a therapeutic for the treatment of PWS including, but not limited to, Aadvark Therapeutics, ConSynance Therapeutics, Lipidio Pharma, Helsinn, Inversago Pharma, Saniona, 9 Meters Biopharma, Neuren Pharmaceuticals, Neuracle Science, Harmony Biosciences Holding Inc., and Notitia Biotechnologies.

Carmot Therapeutics Inc. announced that they plan to release Phase I single ascending dose (SAD)/MAD data for CT-PYY in 2025 for the treatment of PWS. Harmony Biosciences Holdings, Inc. just received Orphan Drug Designation for their asset Wakix (pitolisant hydrochloride) for the treatment of PWS. Harmony Biosciences announced initial topline results from its Phase II proof-of-concept study in patients with PWS, which showed a signal on improvement in the primary outcome related to excessive daytime sleepiness in November 2022. Neuren Pharmaceuticals Limited initiated their Phase II in August 2023.

Gastric and Colorectal Cancer

The effectiveness of KEYTRUDA® has sparked a surge of activity in the field of oncology and immunotherapy, driving a multitude of research endeavors focused on enhancing cancer treatment results and prolonging patient survival. GRANITE for colorectal cancer is in Phase III for Gritstone bio, Inc. Last year, Amgen Inc. announced topline results for the global Phase III CodeBreaK 300 study evaluating LUMAKRAS combined with Vectibix vs current standard of care in chemorefractory metastatic KRAS G12C-mutated colorectal cancer. Again in 2023, Bexion Pharmaceuticals announced that the first adult patient has been dosed in the Phase Ib/II placebo controlled, double blinded study on the efficacy and safety of BXQ-350 in combination with mFOLFOX7 and Bevacizumab in newly diagnosed metastatic colorectal carcinoma. Several other companies developing biologics for the treatment of gastric and colorectal cancer include Medivir AB (Birinapant), PDS Biotechnology Corporation, GSK plc (Jemperli) in partnership with AnaptysBio, Inc.

COVID-19 Vaccine

Vaccines for COVID-19 granted full FDA regulatory approval include Comirnaty® (BNT162b2), marketed by Pfizer-BioNTech, Spikevax® (mRNA-1273), marketed by Moderna, Inc. and Covovax® (NVX-CoV2373) marketed by Novavax. Other vaccines have received emergency use authorization (“EUA”) in international markets. Other companies developing COVID-19 vaccines include Ocugen Inc., Invivyd, Inc. and Vaxxinity, Inc.. Ocugen’s OCU500 was selected by NIH/NIAID Project NextGen for clinical trials.

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 Moderna, EpiVax, Inc., Emergex Vaccines Holding Ltd., BioFactura, Blue Water Vaccines, NightHawk Biosciences, Ascleitis Pharma, Inc., and Hyundai Bioscience Co., Ltd.

Intellectual Property

We believe that we have an extensive patent portfolio and substantial know-how relating to Tonmya/TNX-102 SL, Zembrace, Tosymra, TNX-1300, TNX-1500, TNX-2900, TNX-1900, TNX-801, TNX-1800 and TNX-1700, 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, 2024, the patents we are either the owner of record or own the contractual right to include 42 issued U.S. patents and 337 issued non-U.S. patents. We are actively pursuing an additional 23 U.S. non-provisional patent applications, 4 international patent applications, and 237 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, 2024 are summarized below.

TNX-102 SL — Central Nervous System Conditions

Our patent portfolio for TNX-102 SL includes patents and 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 pain, fatigue and 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.

Certain eutectic compositions were discovered by development partners and are termed the “Eutectic Technology.” The patent portfolio for CBP compositions (e.g., TNX-102 SL) relating to the Eutectic Technology includes patents and 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, U.S. Patent No. 11,026,898, and U.S. Patent No. 11,839,594. These U.S. patents and counterpart non-U.S. patents, and any U.S. and non-U.S. patents that issue in the future from this portfolio 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. On January 11, 2024, the European Patent Office Technical Board of Appeal reversed the October 2019 decision of the Opposition Division of the European Patent Office maintaining the patent in unamended form and held the patent to be invalid. No appeal may be taken from that decision.

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 a eutectic of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics.

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. Hexal AG did not appeal that decision.

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. Hexal AG did not appeal that decision.

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 December 12, 2023, U.S. Patent No. 11,839,594 entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, issued. The claims recite a method of manufacturing a eutectic comprising cyclobenzaprine hydrochloride and beta-mannitol comprising mixing or milling.

On February 14, 2024, European Patent No. 3,650,081, entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, issued. The claims recite a eutectic of mannitol and cyclobenzaprine hydrochloride and methods of manufacturing a eutectic.

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, Japan, and Hong Kong. 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, International Patent Application No. PCT/IB2018/001509, entitled “Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions,” was 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 November 28, 2023, U.S. Patent No. 11,826,321, entitled “Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions,” issued. The claims are directed to a method for treating or preventing one or more agitation associated symptoms comprising administering a eutectic of cyclobenzaprine HCl and mannitol.

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 PCT application is now nationalized in 13 countries. 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 PCT is now nationalized in 15 countries. 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 of cyclobenzaprine hydrochloride and mannitol in dosage units with a basifying agent.

On June 21, 2023, U.S. non-provisional Patent Application No. 18/212,500 and International Patent Application No. PCT/US2023/025895, entitled “Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC),” were filed. The claims are directed to methods of treating PASC or one or more associated symptoms comprising administering cyclobenzaprine or a pharmaceutically acceptable salts of cyclobenzaprine.

TNX-1900 — Oxytocin-Based Treatments for Obesity, Eating Disorders, Pain, Insulin Resistance, and Diabetes

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. On October 4, 2023, European Patent No. 3242676, entitled “Magnesium-Containing Oxytocin Formulations and Methods of Use,” issued.

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 (PWS)

We have licensed technology using oxytocin-based therapeutics for the treatment of PWS 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-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 (nationalized in 14 countries).

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-1800 and TNX-1850 — Live Modified Horsepox Vaccine for Prevention of COVID-19

We are developing TNX-1800 and TNX-1850, live attenuated modified HPXVs, as a COVID-19 preventing vaccine against different strains of SARS-CoV-2. 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 19 countries. These applications are directed to synthetic poxviruses comprising a SARS-CoV-2 virus protein, poxvirus delivery vectors for SARS-CoV-2 virus proteins and methods of using these modified poxviruses to protect individuals against COVID-19.

On March 1, 2023, we filed International Patent Application No. PCT/US2023/063503, entitled “Recombinant Poxvirus Based Vaccine Against the Omicron Strain of SARS-CoV-2 Virus and Variants Thereof.” This application is directed to synthetic poxviruses comprising a SARS-CoV-2 virus protein of an omicron strain, poxvirus delivery vectors for SARS-CoV-2 virus proteins of an omicron strain and methods of using these modified poxviruses to protect individuals against the SARS-CoV-2 virus of an omicron strain.

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 rTFF2 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-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 6 countries) and U.S. Patent Application No. 18/055,596, both entitled “Compositions and Methods for Increasing Efficacy of a Drug.”

Zembrace and Tosymra — Sumatriptan

We have acquired the intellectual property rights of Zembrace SymTouch and Tosymra and their uses in treating migraine from Upsher-Smith Laboratories, LLC. These rights include U.S. Patent No. 9,211, 282, U.S. Patent No. 9,610,280, U.S. Patent No. 9,974,770, U.S. Patent No. 10,603,305, U.S. Patent No. 11,337,962, U.S. Patent No. 10,537,554, and U.S. Patent No. 11,364, 224. These rights also include International Patent Application No. PCT/US2016/015961, entitled “Pharmaceutical Composition Comprising Sumatriptan for Treating Migraine,” (nationalized in 7 countries, excluding rights in Brazil and China) and International Patent Application No. PCT/IB2010/001708, entitled “Formulations Comprising Triptan Compounds,” (nationalized in 11 countries, excluding rights in Brazil, Russia, India, and China).

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	European Patent Office – 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	Mutants of Cocaine Esterase (CocE) Polypeptide, Nucleic Acids Encoding Them, Pharmaceutical Compositions Comprising Them and Uses Thereof	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
1590820	Compositions and Methods for Transmucosal Absorption	Taiwan R.O.C.	June 14, 2033
2013274003	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
1642429	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
1683660	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

(AL/P/2020/15 in Albania; MK/P/2020/68 in North Macedonia; 602012066717.6 in Germany; 3103147 in Greece; 502020000014740 in Italy; SM-T-202000083 in San Marino; 60240 in Serbia; 202000139T4 in Turkey)

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

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 – Agitation in Neurodegenerative Condition

Patent No.	Title	Country / Region	Expiration Date
11,826,321	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	U.S.A.	December 11, 2038
275289	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Israel	December 11, 2038

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
11,737,991	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
11,839,594	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.	March 14, 2034
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
ZL201580050140.2	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	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
(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)			
3650081	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,	March 14, 2034

		Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	
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
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
441374	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	India	March 14, 2034
MY-196014-A	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Malaysia	March 14, 2034
ZL201910263541.6	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	China	March 14, 2034
2020289838	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Australia	September 18, 2035
HK40047283	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Hong Kong	September 18, 2035
ZL202011576351.9	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China	September 18, 2035
730379	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand	September 18, 2035
768064	Eutectic Formulations of Cyclobenzaprine Hydrochloride	New Zealand	September 18, 2035

Analog of CBP

Patent No.	Title	Country / Region	Expiration Date
11,517,557	Analog of Cyclobenzaprine and Amitryptilene	U.S.A.	July 13, 2037

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
3242676	Magnesium-Containing Oxytocin Formulations and Methods of Use	Europe – (Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom)	January 7, 2036
2017/05176	Magnesium-Containing Oxytocin Formulations and Methods of Use	South Africa	January 7, 2036
1252942	Magnesium-Containing Oxytocin Formulations and Methods of Use	Hong Kong	January 7, 2036
7093559	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan	April 12, 2037
2017250505	Magnesium-Containing Oxytocin Formulations and Methods of Use	Australia	April 12, 2037
ZL201780036185.3	Magnesium-Containing Oxytocin Formulations and Methods of Use	China	April 12, 2037
40005263	Magnesium-Containing Oxytocin Formulations and Methods of Use	Hong Kong	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 – 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, and 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, and 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
MY-200354-A	Synthetic Chimeric Poxviruses	Malaysia	November 2, 2037

Triptan Compound – Formulations

Patent No.	Title	Country / Region	Expiration Date
9,211,282	Formulations Comprising Triptan Compounds	U.S.A	July 19, 2031
9,610,280	Formulations Comprising Triptan Compounds	U.S.A	June 16, 2030
9,974,770	Formulations Comprising Triptan Compounds	U.S.A	June 16, 2030
10,603,305	Formulations Comprising Triptan Compounds	U.S.A	June 16, 2030
11,337,962	Formulations Comprising Triptan Compounds	U.S.A.	June 16, 2030
2010299607	Formulations Comprising Triptan Compounds	Australia	June 17, 2030
2775404	Formulations Comprising Triptan Compounds	Canada	June 17, 2030
2480197	Formulations Comprising Triptan Compounds	European Patent Office - Austria, Belgium, Czechia, Denmark, France, Germany, Italy, Spain, Switzerland, and United Kingdom	June 17, 2030
(502016000000073 in Italy			
5845183	Formulations Comprising Triptan Compounds	Japan	June 17, 2030
101646079	Formulations Comprising Triptan Compounds	Republic of Korea	June 17, 2030
338110	Formulations Comprising Triptan Compounds	Mexico	June 17, 2030
599344	Formulations Comprising Triptan Compounds	New Zealand	June 17, 2030
2012/02168	Formulations Comprising Triptan Compounds	South Africa	June 17, 2030

Triptan Compound – Migraine

Patent No.	Title	Country / Region	Expiration Date
10,537,554	Pharmaceutical Composition for Treating Migraine	U.S.A	January 29, 2036
11,364,224	Pharmaceutical Composition for Treating Migraine	U.S.A	January 29, 2036
385725	Pharmaceutical Composition Comprising Sumatriptan for Treating Migraine	Mexico	February 1, 2036
2994748	Pharmaceutical Composition Comprising Sumatriptan for Treating Migraine	Canada	February 1, 2036

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 (Allowed)	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
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
18/271,098	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	U.S.A.
2022205313	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Australia
BR112023013285-1	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Brazil
3207098	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Canada
202280019221.6	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	China
22701768.8	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	European Patent Office
P00202307159	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Indonesia
304253	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Israel
2023-541043	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Japan
PI 2023003993	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Malaysia
MX/a/2023/008055	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Mexico
801414	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	New Zealand
11202305000R	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Singapore
2023/06791	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	South Africa
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
18/385,468	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	U.S.A.
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 (Allowed)	Canada
15841528.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride	European Patent Office
18101200.4	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Hong Kong
42020003105.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride (Allowed)	Hong Kong
42020019748.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong
2023-188486	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Japan
2023-116057	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Japan

Application No.	Title	Country / Region
PI 20233000078	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Malaysia
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
20230100254	Compositions and Methods for Transmucosal Absorption	Argentina
3,118,913	Compositions and Methods for Transmucosal Absorption (Allowed)	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 – Agitation in Neurodegenerative Condition

Application No.	Title	Country / Region
18/382,262	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 (Allowed)	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
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 (Allowed)	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
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
523442519	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Saudi Arabia
10202303446R	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Singapore
2023-186441	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Japan

CBP – Depression

Application No.	Title	Country / Region
13/412,571	Methods and Compositions for Treating Depression Using Cyclobenzaprine (Allowed)	U.S.A.

Analogs of CBP

Application No.	Title	Country / Region
18/075,386	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	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
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
11202101443W
2021/01121

Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder
Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder
Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder

Mexico
Singapore
South Africa

CBP – Fibromyalgia

Application No.	Title	Country / Region
18/265,525	Cyclobenzaprine Treatment for Fibromyalgia	U.S.A.
2021396509	Cyclobenzaprine Treatment for Fibromyalgia	Australia
3204202	Cyclobenzaprine Treatment for Fibromyalgia	Canada
202180089897.8	Cyclobenzaprine Treatment for Fibromyalgia	China
21844438.8	Cyclobenzaprine Treatment for Fibromyalgia	European Patent Office
202317044026	Cyclobenzaprine Treatment for Fibromyalgia	India
P00202306147	Cyclobenzaprine Treatment for Fibromyalgia	Indonesia
303497	Cyclobenzaprine Treatment for Fibromyalgia	Israel
2023-542924	Cyclobenzaprine Treatment for Fibromyalgia	Japan
PI 2023003286	Cyclobenzaprine Treatment for Fibromyalgia	Malaysia
MX/a/2023/006720	Cyclobenzaprine Treatment for Fibromyalgia	Mexico
800700	Cyclobenzaprine Treatment for Fibromyalgia	New Zealand
523441103	Cyclobenzaprine Treatment for Fibromyalgia	Saudi Arabia
11202304340U	Cyclobenzaprine Treatment for Fibromyalgia	Singapore
2023/06139	Cyclobenzaprine Treatment for Fibromyalgia	South Africa

CBP – Alcohol Use Disorder

Application No.	Title	Country / Region
18/037,815	Cyclobenzaprine Treatment for Alcohol Use Disorder	U.S.A.
2021382668	Cyclobenzaprine Treatment for Alcohol Use Disorder	Australia
112023009731-2	Cyclobenzaprine Treatment for Alcohol Use Disorder	Brazil
3202722	Cyclobenzaprine Treatment for Alcohol Use Disorder	Canada
202180088339.X	Cyclobenzaprine Treatment for Alcohol Use Disorder	China
21827298.7	Cyclobenzaprine Treatment for Alcohol Use Disorder	European Patent Office
202317038485	Cyclobenzaprine Treatment for Alcohol Use Disorder	India
303050	Cyclobenzaprine Treatment for Alcohol Use Disorder	Israel
2023-530204	Cyclobenzaprine Treatment for Alcohol Use Disorder	Japan
MX/a/2023/005899	Cyclobenzaprine Treatment for Alcohol Use Disorder	Mexico
800112	Cyclobenzaprine Treatment for Alcohol Use Disorder	New Zealand
11202303835Y	Cyclobenzaprine Treatment for Alcohol Use Disorder	Singapore
2023/05747	Cyclobenzaprine Treatment for Alcohol Use Disorder	South Africa

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
62023077251.4	Cyclobenzaprine Treatment for Sexual Dysfunction	Hong Kong
62023078964.1	Cyclobenzaprine Treatment for Sexual Dysfunction	Hong Kong

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

Application No.	Title	Country / Region
PCT/US2023/025895	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	PCT
18/212,500	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
23201255.9	Magnesium-Containing Oxytocin Formulations and Methods of Use	European Patent Office
2021-179295	Magnesium-Containing Oxytocin Formulations and Methods of Use (Allowed)	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
16/976,912	Labeled Oxytocin and Method of Manufacture and Use (Allowed)	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.
3,020,179	Magnesium-Containing Oxytocin Formulations and Methods of Use	Canada
2023100344997	Magnesium-Containing Oxytocin Formulations and Methods of Use	China
17783080.9	Magnesium-Containing Oxytocin Formulations and Methods of Use	European Patent Office
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
2023203831	Magnesium-Containing Oxytocin Formulations and Methods of Use	Australia
42023079422.4	Magnesium-Containing Oxytocin Formulations and Methods of Use	Hong Kong
MX/a/2023/008840	Magnesium-Containing Oxytocin Formulations and Methods of Use	Mexico

Nociceptin/Orphanin FQ therapeutics

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

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 (Allowed)	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
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
792678	Synthetic Chimeric Poxviruses	New Zealand

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
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

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
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
523451920	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Saudi Arabia
62023075022.1	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Hong Kong
62023083678.0	Recombinant Poxvirus Based Vaccine against SARS-CoV-2 virus	Hong Kong
PCT/US2023/063503	Recombinant Poxvirus Based Vaccine Against the Omicron Strain of SARS-CoV-2 Virus and Variants Thereof	PCT

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

Antiviral Drugs – Cathepsin Inhibitors

Application No.	Title	Country / Region
18/055,596	Compositions and Methods for Increasing Efficacy of a Drug	U.S.A.
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
202180060848.1	Compositions and Methods for Increasing Efficacy of a Drug	China
62023079383.3	Compositions and Methods for Increasing Efficacy of a Drug	Hong Kong
62023082611.2	Compositions and Methods for Increasing Efficacy of a Drug	Hong Kong

Triptan Compound – Formulations

Application No.	Title	Country / Region
17/750,354	Formulations Comprising Triptan Compounds	U.S.A.

Triptan Compound – Migraine

Application No.	Title	Country / Region
17/273,811	Methods of Treating Migraine	U.S.A.
17/833,105	Pharmaceutical Composition for Treating Migraine	U.S.A.

Trademarks and Service Marks

Tonix Pharmaceuticals, Inc.

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 mark: 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. 98/327953, filed December 22, 2023), 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), ANGSTRO-TECHNOLOGY (Serial No. 98/006538, filed May 22, 2023) and TONMYA (Serial No. 97/185424, filed December 22, 2021).

Tonix Medicines, Inc.

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: NOTIME4MIGRAINES (Reg. No. 5392512, issued January 30, 2018); SYMTOUCH (Reg. No. 5186988, issued April 18, 2017); TOSYMRA (Reg. No. 5981221, issued February 11, 2020); TOSYMRA & DROPLET Design (Reg. No. 6142333, issued August 11, 2020); ZEMBRACE (Reg. No. 5186989, issued April 18, 2017); ZEMBRACE SYMTOUCH (Reg. No. 5478282, issued May 29, 2018); DROPLET Design (Reg. No. 6117797, issued August 4, 2020). We are the owner of the following International Registrations under the Madrid Protocol: TOSYMRA (Reg. No. 1501060, issued October 16, 2019 – Extensions of Protection to: Canada, European Union, Japan, Republic of Korea, United Kingdom); ZEMBRACE (Reg. No. 1683288, issued August 17, 2022 – Extensions of Protection to: Canada (still pending), China, European Union, Israel, Mexico, United Kingdom); DROPLET Design (Reg. No. 1545038, issued June 29, 2020 – Extensions of Protection to: Canada, European Union, Israel, Japan, Norway, Republic of Korea, Switzerland, Turkey, United Kingdom).

Research and Development

We have approximately 71 employees dedicated to research and development. Our research and development operations are located in Chatham, NJ, 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. 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.

Marketing

We have two employees supporting sales administration and marketing initiatives. We also have three sales employees who are focused on customer service requests and top-tier headache specialists. We utilize third party vendors to support trade, managed markets, marketing initiatives, and promotional compliance programs.

Manufacturing

We have contracted with third-party cGMP-compliant contract manufacturer organizations (“CMOs”), for the manufacture of TNX-102 SL drug substance and drug products for clinical and commercial supply. Our manufacturing operations are managed and controlled out of our Dublin, Ireland offices.

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.

We own a 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. This facility, in addition to contract CMOs, is currently used for the manufacture of nonclinical and clinical investigational products for our Immunology and Infectious Disease portfolio. The current focus of which is TNX-1500 for Organ Transplant Rejection/Autoimmune Disorders, TNX-01 a Smallpox and Monkeypox Preventing Vaccine and TNX-1800 a COVID vaccine selected by NIH/NIAID Project NextGen for Inclusion in Clinical Trials.

We own an approximately 44-acre site in Hamilton, Montana, for the construction of a vaccine development and commercial scale manufacturing facility. As of December 31, 2023, the facility was not ready for its intended use.

Our two marketed products, Zembrace and Tosymra, are manufactured at cGMP compliant, FDA audited, U.S. based CMOs with expertise in pre-filled syringe and inhalation expertise.

Government Regulations

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

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

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

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

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

Clinical Trials

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

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

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

- Phase 2 clinical trials are generally conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks. Phase 2 clinical trials, in particular Phase 2b trials, can be undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites.
- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

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

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

New Drug Applications

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

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA or BLA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA or BLA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market.

Section 505(b) NDAs

There are two types of NDAs: the Section 505(b)(1) NDA, or full NDA, and the Section 505(b)(2) NDA. We intend to file Section 505(b)(2) NDAs for TNX-102 SL for FM, and FM-type Long COVID, 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, FM-type Long COVID, 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 exclusivities 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 FDA 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 April 1, 2024, we had 103 full-time employees, of whom 16 hold M.D. or Ph.D. degrees. We have 71 employees dedicated to research and development. We have two employees supporting sales administration and marketing initiatives and three sales employees who are focused on customer service requests and top-tier headache specialists. 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, 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.

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

- Our prospects are dependent on the continued successful commercialization of Tosymra and Zembrace.
- Our prospects are dependent on the success of Tonmya.
- We are exposed to cybersecurity and data privacy risks that, if realized, could expose us to legal liability, damage our reputation and harm our business.
- We have a history of operating losses and may never 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 revenues from product sales to offset our expenses 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

Our prospects are dependent on the continued successful commercialization of Zembrace and Tosymra. To the extent we cannot maintain or increase sales of Zembrace and Tosymra, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Zembrace and Tosymra are our only drugs that have been approved for sale. Continued successful commercialization of Zembrace and Tosymra is subject to many risks, and there is no guarantee that we will be able to maintain or increase sales of Zembrace and Tosymra. While we have established our commercial team and have hired our U.S. sales force, we may need to further expand and develop the team in order to continue to successfully grow the business. Even if we are successful in developing our commercial team, there are many factors that could negatively impact sales of Zembrace and Tosymra or cause the continued commercialization of Zembrace and Tosymra to be unsuccessful, including several factors that are outside our control. If the continued commercialization of Zembrace and Tosymra or future sales are less successful than expected or perceived as disappointing, our stock price could decline significantly, and the long-term success of the product and our company could be harmed.

Additionally, our strategy in the U.S. includes distributing Zembrace and Tosymra solely through a limited network of third-party specialty distributors and specialty pharmacies. While we have entered into agreements with each of these distributors and pharmacies to distribute Zembrace and Tosymra in the U.S., they may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors or pharmacies, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. In the event we are unable to maintain, or expand, if needed, our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our network of third-party specialty distributors and specialty pharmacies, our ability to continue commercializing Zembrace and Tosymra would be limited, and Zembrace and Tosymra may not be profitable.

Our prospects are dependent on the success of Tonmya. To the extent regulatory approval of Tonmya is delayed or not granted or, if approved, Tonmya is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA. We have focused a significant portion of our activities and resources on the development of Tonmya, and we believe our prospects are also dependent on our ability to obtain regulatory approval for and successfully commercialize Tonmya in the U.S. The regulatory approval and successful commercialization of Tonmya is subject to many risks, including those discussed in other risk factors, and Tonmya may not receive approval from the FDA. If the results or timing of regulatory filings, the regulatory process, regulatory developments, commercialization, or other activities, actions or decisions related to Tonmya do not meet our or others' expectations, the market price of our common stock could decline significantly.

In December 2023, we announced positive results from our pivotal Phase 3 RESILIENT study. The study demonstrated a statistically significant improvement over placebo for both primary endpoints as well as key secondary endpoints.

The FDA retains complete discretion in deciding whether to approve the NDA for Tonmya and there are many components to an NDA filing beyond the efficacy and safety data provided to the FDA. No assurances can be given that the FDA will approve Tonmya for the treatment of FM, or that if approved, we will successfully commercialize Tonmya.

We have a history of operating losses and expect to incur losses for the foreseeable future. We may never achieve profitability.

We are focused on product development, and we started generating revenues from product sales in the third quarter of 2023. 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 two products that have generated commercial revenue starting in the third quarter of 2023, but we do not expect revenues from the commercial sale of products to exceed expenses in the near future. 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, FM-type 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 FM-type Long COVID, 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.

We are exposed to cybersecurity and data privacy risks that, if realized, could expose us to legal liability, damage our reputation and harm our business.

We face risks of cyber-attacks, computer hacks, theft, viruses, malicious software, phishing, employee error, denial-of-service attacks and other security breaches that could jeopardize the performance of our software and expose us to financial and reputational harm. Any of these occurrences could create liability for us, put our reputation in jeopardy and harm our business. Such harm could be in the form of theft of our or our customers' confidential information, the inability to access our systems. In some cases, we rely on the safeguards put in place by third parties to protect against security threats. These third parties, including vendors that provide products and services for our operations, could also be a source of security risk to us in the event of a failure or a security incident affecting their own security systems and infrastructure. Our network of partners could also be a source of vulnerability to the extent their applications interface with ours, whether unintentionally or through a malicious backdoor. We do not review the software code included in third-party integrations in all instances. Because the techniques used to obtain unauthorized access or to sabotage systems change frequently and generally are not recognized until launched against a target, we or these third parties may be unable to anticipate these techniques or to implement adequate preventative measures. We have internal controls designed to prevent cyber-related frauds related to authorizing the transfer of funds, but such internal controls may not be adequate. With the increasing frequency of cyber-related frauds to obtain inappropriate payments and other threats related to cyber-attacks, we may find it necessary to expend resources to remediate cyber-related incidents or to enhance and strengthen our cybersecurity. Our remediation efforts may not be successful and could result in interruptions, delays or cessation of service. Although we have insurance coverage for losses associated with cyber-attacks, as with all insurance policies, there are coverage exclusions and limitations, and our coverage may not be sufficient to cover all possible claims, and we may still suffer losses that could have a material adverse effect on our reputation and business.

The increase in remote working arrangements by our employees, vendors, and other third parties also increase the risk of a data security compromise and the possible attack surfaces. Although we conduct training as part of our information security, cybersecurity, and data privacy efforts, that training cannot be completely effective in preventing those attacks from being successful. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

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

Our product candidates are novel and still in development.

We are a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. 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, Tonmya, for the management of fibromyalgia and have completed two successful Phase 3 trials and for which we are preparing an NDA. We also have TNX-102 SL in Phase 2 development for the treatment of FM-type Long COVID, and we have two other products in Phase 2 development: TNX-1300 for the treatment of cocaine intoxication, and TNX-1900 for the treatment of binge eating disorder, adolescent obesity, social anxiety disorder and bone loss associated with autism. TNX-2900 is in development for Prader Willi Syndrome and has a cleared IND, orphan drug designation and Pediatric Rare Disease Designation. 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 two approved products on the market, we do not expect revenues from product sales to exceed expenses in the foreseeable future, if at all.

To date, we have two approved products on the market and have started generating product revenues in the second half of 2023. However, we have primarily funded our operations from sales of our securities. We expect to rely on investment capital for the foreseeable future.

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.

Tonmya or TNX-102 SL for FM is our most advanced development product candidate which has completed two successful Phase 3 trials in FM and for which we are submitting the 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 product candidates 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, 2023 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 second quarter of 2024, 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 second quarter of 2024, 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:

- increased sales of our two commercialized products;
- 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. Accordingly, if our CROs fail to comply with these regulations, 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.

In addition, we currently rely on foreign CROs and CMOs, including WuXi Biologics, and will likely continue to rely on foreign CROs and CMOs in the future. Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the U.K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs.

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, buildout of our research and development and manufacturing facilities, and develop our commercialization organization, 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;
- maintain a marketing, distribution and sales infrastructure in addition to a post-marketing surveillance program; 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 our marketed products and the compounds used in our studies, and we intend to rely on them in the future. If these third parties do not manufacture our products and product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our products and 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 rely on CMOs to manufacture all of our product candidates in clinical studies and our commercial products. Completion of our clinical studies and commercialization of our products requires the manufacture of a sufficient supply of our products. We have contracted with outside sources to manufacture our development compounds and commercial products. If, for any reason, we become unable to rely on our current manufacturing sources, either for clinical studies or for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers. 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 our 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 and final product. 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, and our efforts to commercialize our marketed products will be materially impaired. This may result in delays in filing for and receiving FDA approval for one or more of our products and impair our revenues from sales. Any such delays could cause our prospects and financial condition to suffer significantly.

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

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 PPACA. 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 for our marketed products and 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.

We are in the process of establishing sales, marketing or distribution capabilities. In order to successfully generate and increase sales of our marketed products or any of our 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, which we have commenced, requires 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 is subject, 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 our products. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors 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, 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 products, which could make it difficult for us to sell profitably.

Market acceptance and sales of any of our products depends 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 is 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 or continue to 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 we commercialize. 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 products.

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 of our commercialized products.

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 PPACA 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 effect 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 sale and 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 expanded our insurance coverage to include the sale of our commercial products Tosymra and Zembrace Symtouch. We intend to further expand our insurance coverage to include the sale of Tonmya upon receiving FDA approval 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 mpox 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;
- 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.

On October 17, 2023, we received a written notice from the Nasdaq staff indicating that, based upon the closing bid price of our common stock, we no longer met the requirement to maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). In accordance with Nasdaq listing rules, we have a period of 180 calendar days, or until April 15, 2024, in which to regain compliance. In order to regain compliance with the Minimum Bid Price Requirement, the closing bid price of our common stock must be at least \$1 per share for a minimum of ten consecutive business days during this 180-day period. In the event we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, our common stock will be subject to delisting. If we are unable to maintain compliance with the Minimum Bid Price or other listing requirements, we could lose eligibility for continued listing on the Nasdaq Capital Market or any comparable trading market. 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 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, 2023.

ITEM 1C. Cybersecurity Disclosures

Cybersecurity Risk Management

We, like other companies in our industry, face several cybersecurity risks in connection with our business. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we use, store and process data including data of our employees, partners, collaborators, and vendors. To effectively prevent, detect, and respond to cybersecurity threats, we maintain a cyber risk management program, which is comprised of a wide array of policies, standards, architecture, and processes. The cyber risk management program falls under the responsibility of our Director of Information Technology (“IT”), who has cross-functional expertise in IT, computer science, cyber security, and more than 20 years of experience. The IT Director leads a team of IT specialists with similar IT and cybersecurity backgrounds. Under the guidance of our IT Head, we develop, maintain, and evidence the policies, standards, and processes in a manner consistent with applicable legal requirements. We also utilize a variety of cybersecurity software from reputable vendors in cybersecurity.

We have implemented a cybersecurity risk management program that is designed to identify, assess, and mitigate risks from cybersecurity threats to this data and our systems and ensure the effectiveness of our security controls. Our cybersecurity risk management program is intended to address applicable NIST 800-171 & CMMC requirements for our business. Our cybersecurity risk management program incorporates several components, including information security program assessments, continuous monitoring of critical risks from cybersecurity threats using automated tools, backup testing, periodic threat testing, and documented standards, policies, and procedures. We deploy a wide range of security tools across the environment, and implement access control policies to further limit access to data within the systems.

We periodically engage third parties to conduct risk assessments, including penetration testing, tabletops and other system vulnerability analyses. As a result of these assessments and testing, we have not identified any material cybersecurity risks and are constantly hardening our environment. Additionally, our program includes annual cybersecurity training for all employees.

Cybersecurity Governance

Our Board of Directors (“Board”) is responsible for the oversight of cybersecurity risk management. The Board delegates oversight of the cybersecurity risk management program to the Information Security Oversight Committee (“ISOC”). The Chief Financial Officer (“CFO”), who serves on ISOC, provides updates to the Audit Committee on our cybersecurity risk management program, including any critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards on a quarterly basis. The CFO also notifies the Board and Audit Committee of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities as appropriate.

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 \$142,407 as of December 31, 2023, and such amount is deposited into the restricted cash account maintained at the bank that issued the letter of credit.

We own a research and development facility in Maryland used for process development activities. As of August, 1 2022, the asset was operational and the asset was ready for its intended use.

We own an approximately 44-acre site in Hamilton, Montana, for the construction of a vaccine development and commercial scale manufacturing facility. As of December 31, 2023, the facility was not ready for its intended use.

We own a 45,000 square foot facility in Massachusetts that houses our Advanced Development Center for accelerated development and manufacturing of vaccines. As of October 1, 2022, the facility was operational and ready for its intended use.

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

<u>Year Ending December 31,</u>	
2024	\$ 305
2025	299
2026	142
2027	139
2028 and beyond	107
	992
Included interest	(90)
	<u>\$ 902</u>

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 28, 2024, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was \$0.19 per share. On March 28, 2024, there were 228 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

None.

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.”

We are a fully-integrated biopharmaceutical company focused on developing and commercializing therapeutics to treat and prevent human disease and alleviate suffering.

Our near-term priority is to submit a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for TonmyaTM* (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablet) for the management of fibromyalgia (“FM”). FM is a chronic pain disorder characterized by chronic widespread pain, non-restorative sleep, fatigue and impaired cognition. Tonmya is a non-opioid analgesic designed for long-term bedtime use and has completed two positive Phase 3 studies. Tonix announced the positive results of the second Phase 3 study in December of 2023. Tonmya treatment resulted in highly statistically significant improvement in the primary endpoint of pain reduction (p=0.00005) and statistical significance in all six of the key secondary endpoints. Tonmya was well tolerated. Systemic adverse events were similar between Tonmya and placebo. No serious adverse events were reported. The FDA conditionally accepted Tonmya as the trade name for TNX-102 SL for the management of fibromyalgia in January 2024. We have scheduled a type B pre-NDA meeting with the FDA in the first half of 2024, plan to submit an NDA for the approval of Tonmya in the second half of 2024 and expect an FDA decision on the NDA in the second half of 2025. We are preparing for a commercial launch of Tonmya conditional on FDA approval.

Tonmya is a proprietary sublingual tablet formulation of cyclobenzaprine (“CBP”) designed for bedtime administration. In December 2020, we reported positive results from the Phase 3 RELIEF study of Tonmya 5.6 mg for the management of FM. In July 2021, we had disappointing results from a second Phase 3 study, RALLY. In December 2023, we reported positive results from the third Phase 3 RESILIENT study, which met its pre-specified endpoint by significantly reducing daily pain compared to placebo in patients with fibromyalgia.

In preparation for the launch of Tonmya, we have built a team of professionals to market and distribute our products. Our commercial portfolio consists of two FDA-approved prescription products for the treatment of migraine which were acquired from Upsher-Smith Laboratories (“Upsher Smith”) in June 2023: Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg. Zembrace SymTouch and Tosymra are both indicated for the treatment of acute migraine with or without aura in adults. Zembrace SymTouch is the only branded sumatriptan autoinjector professionally promoted in the United States and is designed for ease of use and favorable tolerability with a low 3 mg dose. Tosymra is a novel intranasal sumatriptan product formulated with a permeation enhancer that provides rapid and efficient absorption of sumatriptan. Tosymra was approved on the basis of bioequivalence to subcutaneous (*s.c.*) sumatriptan. Our commercial team is engaged in marketing and distributing our products, and also engaged in planning the launch of Tonmya.

In addition to Tonmya and our marketed products, we have a pipeline of products in development that include therapeutics and vaccines which are based on small molecules and biologics. Our pipeline has been generated from internal discovery, as well as licenses, acquisitions and collaborations with academic institutions and non-profit organizations.

Our portfolio is focused on central nervous system, or CNS, disorders, but also consists of 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 immunology portfolio includes TNX-1500*, a biologic to address organ transplant rejection and autoimmune diseases. Finally, our infectious disease portfolio includes a vaccine in development to prevent smallpox and mpox (formerly known as monkeypox), TNX-801*. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine (“RPV”) platform for vaccines to protect against other infectious diseases, including TNX-1800* and TNX-1850* for COVID-19.

In addition to fibromyalgia, TNX-102 SL* is being developed as a potential treatment for a type of Long COVID, the symptoms of which overlap with fibromyalgia, that we term fibromyalgia-type Long COVID. TNX-102 SL has completed a Phase 2 proof-of-concept study. Long COVID also known as PASC, (post-acute sequelae of SARS-CoV-2 infection) is a chronic post-acute COVID-19 condition. We initiated enrollment in the Phase 2 PREVAIL study, in August 2022, and topline results were reported in September 2023. The study did not meet the primary endpoint of change in mean pain from baseline but did show activity in improving fatigue, a hallmark symptom of Long COVID.

TNX-102 SL also is being developed also as a treatment for acute stress reaction (“ASR”) and to prevent acute stress disorder (“ASD”) and posttraumatic stress disorder (“PTSD”) under an investigator-initiated Investigational New Drug Application (“IND”) in partnership with the University of North Carolina (“UNC”) Institute for Trauma Recovery. The Phase 2 OASIS study at UNC is supported by the U.S. Department of Defense (“DoD”). We expect enrollment in the OASIS study to begin in the second quarter of 2024. The UNC-led OASIS study will build upon the existing AURORA initiative, a major national research initiative to improve the understanding, prevention, and recovery of individuals who have experienced a traumatic event.

In addition, TNX-102 SL has active INDs for PTSD, agitation in Alzheimer’s disease (“AAD”), and alcohol use disorder (“AUD”). TNX-102 SL for AAD has been granted Fast Track designation by the FDA. We are not currently actively studying TNX-102 SL in PTSD, AAD or AUD.

Another CNS candidate in development is TNX-1300* (double-mutant cocaine esterase) which is in Phase 2 for the treatment of cocaine intoxication. TNX-1300 has been granted Breakthrough Therapy designation by the FDA. TNX-1300 was licensed from Columbia University in 2019 after a Phase 2 study showed that it rapidly and efficiently disintegrates cocaine in the blood of volunteers who received intravenous 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 enrollment in a potentially pivotal Phase 2 study of TNX-1300 in emergency rooms in the second quarter of 2024.

Our rare disease portfolio includes TNX-2900* (intranasal potentiated oxytocin) for Prader-Willi syndrome (“PWS”), a genetic disorder characterized by complex symptoms. The formulation technology for TNX-2900 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. The therapeutic technology was licensed from Inserm, the French National Institute of Health and Medical Research. TNX-2900 was granted Orphan-Drug Designation by the FDA in the second half of 2023 and the IND was cleared by the FDA in the fourth quarter of 2023 and Rare Pediatric Disease Designation was granted in March 2024. 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 PWS genes.

We are developing a different intranasal oxytocin product, TNX-1900* (intranasal potentiated oxytocin with magnesium) for several CNS disorders through investigator-initiated studies. TNX-1900 is in development through investigator-initiated studies for the treatment of BED, adolescent obesity, social anxiety disorder (“SAD”), and bone health in pediatric autism. We received IND clearance from the FDA in the fourth quarter of 2021 to study TNX-1900 in chronic migraine and we initiated the Phase 2 PREVENTION study for the prevention of migraine headaches in chronic migraineurs in the first quarter of 2023. Topline results from the study, reported in December 2023, showed that TNX-1900 did not meet the primary endpoint as measured by a reduction from 28-day run-in baseline in the mean number of migraine headache days during the last 28 days of the treatment phase. PREVENTION was a small proof-of-concept study with 88 patients enrolled across three arms (TNX-1900 30 IU QD, TNX-1900 30 IU BID, and placebo), and was not powered to result in a statistically significant outcome. In the trial, TNX-1900 was generally well-tolerated with no treatment-emergent serious or severe adverse events. We have discontinued development of TNX-1900 in chronic migraine.

Our lead candidate in the immunology pipeline is TNX-1500, an Fc-modified humanized mAb, directed against CD40-ligand (CD40L, also known as CD154). TNX-1500 was engineered to modulate binding to Fc receptors. TNX-1500 is being developed as a prophylaxis against organ transplant rejection as well as to treat autoimmune conditions. The IND was cleared and a Phase 1 study of TNX-1500 in healthy volunteers was initiated in the second quarter of 2023 and completed the clinical phase in the first quarter of 2024. TNX-1500 is being studied in combination with other immunosuppressive agents in allogeneic and xenogeneic organ transplants in non-human primates at Massachusetts General Hospital, a teaching hospital of Harvard Medical School (“MGH”). In experiments at MGH, 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. Results from 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. Some results from this collaboration were published in the peer-reviewed journal, *American Journal of Transplantation* in 2023.

TNX-1500 also is being studied in combination with other immunosuppressive agents in xenogeneic organ transplants in non-human primates at MGH. In some of these studies, genetically engineered (GE) pigs in baboon transplants were treated with cold perfused ischemia minimization and a novel costimulation-based immunosuppressive regimen including TNX-1500. The results of these preclinical studies were encouraging and demonstrated the potential of genetically engineered pig hearts in the context of a clinically applicable regimen. The multi-GE pigs were provided by eGenesis and Revivicor. Revivicor is a subsidiary of United Therapeutics. Some results from the collaboration with MGH and eGenesis were published in the peer-reviewed journal, *Nature* in 2023. In March of 2024, MGH announced the first GE pig kidney transplant into a living recipient supported in part by the pre-clinical work with TNX-1500. TNX-1500 therapy was not used in the human transplant recipient.

Our immunology pipeline also includes TNX-1700*, a recombinant Trefoil Factor Family 2 (“rTFF2”) fusion protein that was licensed from Columbia University in 2019. TNX-1700 consists of TFF2 fused to human serum albumin (HAS) 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 presented data that show a murine version of TNX-1700 consisting of a fusion protein with murine serum albumin 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 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. Mpox has become endemic in the U.S. since it spread in the U.S. and other countries outside of Africa, mostly in populations of men who have sex with men. Non-human primates vaccinated with TNX-801 were protected from mpox in studies reported in the first quarter of 2020. These data were published in the peer-reviewed journal *Vaccines* in 2023. In October 2023, at the World Vaccine Congress - Europe, we reported that the TNX-801 vaccine was shown to be greater than 10 to 1,000 fold more attenuated than older vaccinia-based smallpox vaccines in both human primary cell lines and immunocompromised mice. That work has been posted on BioRxiv, which is not peer-reviewed. 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-1800 is a live virus vaccine on the RPV platform that expresses the SARS-CoV-2 spike protein from the ancestral Wuhan strain, which has shown encouraging results in non-human primates. In the third quarter of 2023, TNX-1800 was selected by the National Institute of Allergy and Infectious Diseases, a part of the National Institutes of Health, to be included in their Project NextGen initiative, an initiative to advance a pipeline of new, innovative vaccines and therapeutics for COVID-19. The COVID-19 vaccines approved for use 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. These data were published in the peer-reviewed journal *Vaccines* in 2023. 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.

Tonix has three pre-clinical research and development programs developing broad spectrum antivirals. The DoD announced in December 2022 a plan to move beyond a ‘one bug, one drug’ approach and are seeking broad-spectrum drugs since it may be hard to predict which or how many viruses may be deployed on the battlefield. TNX-3900* are broad-spectrum small molecule oral antivirals which inhibit essential cathepsins required by viruses such as coronaviruses and filoviruses to infect cells. TNX-4200* are orally available CD45 antagonists in preclinical development. We believe that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations and a lower dose, and therefore will have a higher safety window. Tonix plans to leverage previous research on phosphatase inhibitors, specifically compounds that target CD45, to optimize lead compounds for therapeutic intervention of biothreat agents. TNX-4000* are viral glycan-targeted engineered biologics. These antivirals are currently in preclinical development.

Relating to our development programs, we own and operate the Research and Development Center (“RDC”) in Frederick, Maryland consisting of one building totaling approximately 48,000 square feet. The RDC conducts research on CNS, immunology, and infectious disease candidates. The RDC facility is mostly biosafety level 2 (BSL-2), with some components designated BSL-3. We also own and operate an Advanced Development Center (ADC) located in the New Bedford business park in Dartmouth, Massachusetts. 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 have engaged CBRE, an international real estate brokerage firm, to find a strategic partner for, or buyer of, ADC.

*Tonix’s product development 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 sale of our commercialized assets, 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. Since the acquisition of Zembrace and Tosymra on June 30, 2023, we are now reporting product revenue and related costs.

Fiscal year Ended December 31, 2023 Compared to Fiscal year Ended December 31, 2022

The following table sets forth our operating expenses for the fiscal years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,	
	2023	2022
REVENUE		
Product revenue, net	\$ 7,768	\$ —
COSTS AND EXPENSES:		
Cost of sales	\$ 4,741	\$ —
Research and development	86,655	81,876
General and administrative	34,752	30,215
Total operating expenses	126,148	112,091
Operating loss	(118,380)	(112,091)
Other income, net	1,722	1,873
Net loss	\$ (116,658)	\$ (110,218)

Revenues. The Company recognized revenue beginning in the year ended December 31, 2023, as a result of the acquisition of two marketed products. See discussion at Note 12 to our financial statements appearing in this Annual Report on Form 10-K. Revenue recognized for the year ended December 31, 2023 was \$7.8 million.

The Company’s net product revenues are summarized below:

	Year Ended December 31,	
	2023	2022
Zembrace Symtouch	\$ 6,304	\$ —
Tosymra	1,464	—
Total product revenues	\$ 7,768	\$ —

Cost of Sales. The Company recognized cost of sales beginning in the year ended December 31, 2023 as a result of the acquisition of Zembrace and Tosymra from Upsher Smith. See discussion at Note 12 to our financial statements appearing in this Annual Report on Form 10-K. Cost of sales recognized for the year ended December 31, 2023, was \$4.7 million.

Research and Development Expenses. Research and development expenses for the fiscal year ended December 31, 2023, were \$86.7 million, an increase of \$4.8 million, or 6%, from \$81.9 million for the fiscal year ended December 31, 2022. This increase is predominately due to increased employee-related expenses of \$4.3 million, predominately related to new hires at the RDC and ADC, lab supplies of \$1.6 million, and office-related expenses of \$3.5 million related to our new facilities offset by a decrease in regulatory expenses of \$1.0 million and a decrease in non-clinical expenses of \$4.7 million. In August 2022, we 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. During the year ended December 31, 2023, we recorded \$2.9 million in funding as a reduction of related research and development expenses.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the years ended December 31, 2023, and 2022.

	December 31, (in thousands)		
	2023	2022	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	\$ 12,250	\$ 13,530	\$ (1,280)
Direct expenses – TNX - 1800	1,608	3,819	(2,211)
Direct expenses – TNX - 601 ER	8,531	1,308	7,223
Direct expenses – TNX - 801	2,931	2,111	820
Direct expenses – TNX - 1500	7,044	11,510	(4,466)
Direct expenses – TNX - 1900	5,254	4,155	1,099
Direct expenses – Other programs	6,826	13,741	(6,915)
Internal staffing, overhead and other	42,211	31,702	10,509
Total research & development	<u>\$ 86,655</u>	<u>\$ 81,876</u>	<u>\$ 4,779</u>

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, 2023, were \$34.8 million, an increase of \$4.6 million, or 15%, from \$30.2 million incurred in the fiscal year ended December 31, 2022. The increase is primarily due to an increase in sales and marketing of \$1.8 million, and transition services agreement fees payable to Upsher Smith of \$1.5 million, and office-related expenses of \$1.0 million.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2023, was \$116.7 million, compared to a net loss of \$110.2 million for the year ended December 31, 2022.

License Agreements

On February 13, 2023, we exercised an option to obtain an exclusive license from Columbia University (“Columbia”) for the development of a portfolio of 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. As of December 31, 2023, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

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. 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, 2023, 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, 2023, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

Asset Purchase Agreements

On June 23, 2023, we entered into an asset purchase agreement with Upsher Smith for the acquisition of certain assets related to Zembrace SymTouch (sumatriptan injection) 3 mg (“Zembrace”) and Tosymra (sumatriptan nasal spray) 10 mg (“Tosymra”) products (such businesses collectively, the “Business”) and certain inventory related to the Business for an aggregate purchase price of approximately \$26.5 million, including certain deferred payments (such transaction, the “USL Acquisition”). The transaction closed on June 30, 2023.

Additionally, in connection with the acquisition from Upsher Smith, we and Upsher Smith entered into a transition services agreement pursuant to which Upsher Smith agreed to provide certain transition services to us for base fees equal to \$100,000 per month for the first six months, and \$150,000 per month for the seventh through ninth months, plus additional monthly fees for each service category totaling up to \$150,000 per month. We have signed an amendment to the transitional services agreement with Upsher Smith so that Upsher Smith will continue to provide administrative services.

As the assets acquired from Upsher Smith met the definition of a business under the current accounting guidance, the total purchase price was allocated to the acquired inventory and other tangible assets, and the developed technology intangible assets related to Zembrace and Tosymra based on their estimated fair values on the acquisition date. The excess of the purchase price over the fair value of the acquired assets was recorded as goodwill.

We have assumed certain obligations of Upsher Smith, including the payment of quarterly earn-out payments on annual net sales from the Business in the U.S. as follows: for Tosymra, 4% for net sales of \$0 to \$30 million, 7% of net sales of \$30 to \$75 million; 9% for net sales of \$75 to \$100 million; 12% for net sales of \$100 to \$150 million; and 15% for net sales greater than \$150 million. Earn-out payments with respect to Tosymra are payable until the expiration or termination of the product’s Orange Book listed patent(s) with respect to the United States or, outside the United States, the expiration of the last valid claim covering the product in the relevant country of the territory. For Zembrace, earn-out payments on annual net sales in the U.S. are 3% for net sales of \$0 to \$30 million, 6% of net sales of \$30 to \$75 million; 12% for net sales of \$75 to \$100 million; 16% for net sales of greater than \$100 million. Such earn-out payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable earn-out rates will be reduced by 90% percent for Zembrace, and by 66.7% percent for Tosymra.

In addition, we have assumed the obligation to pay an additional 3% royalty on net sales of Tosymra, plus an additional 3% if a patent containing certain claims related to Tosymra issues in the U.S., for 15 years from the first commercial sale of Tosymra in the applicable country or for as long as the manufacture, use or sale of Tosymra in such country is covered by a valid claim of a licensed patent, and up to \$15 million per Tosymra product on the achievement of sales milestones.

On February 2, 2023, we entered into an asset purchase agreement (the “Healion Purchase Agreement”) with Healion Bio Inc., pursuant to which we acquired all the pre-clinical infectious disease assets of Healion for \$1.2 million. Because the Healion intellectual property was acquired prior to FDA approval, the \$1.2 million cash 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.

Liquidity and Capital Resources

As of December 31, 2023, we had working capital of \$28.9 million, comprised primarily of cash and cash equivalents of \$24.9 million inventory of \$13.6 million, and prepaid expenses and other of \$9.2 million, offset by \$3.8 million of accounts payable, \$12.5 million of accrued expenses and other current liabilities, \$2.4 million of term loan payable, short term and \$0.3 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 clinical programs, and the acquisition of Zembrace and Tosymra.

The following table provides a summary of operating, investing, and financing cash flows for the years ended December 31, 2023, and 2022, respectively (in thousands):

	December 31,	
	2023	2022
Net cash used in operating activities	\$ (102,003)	\$ (98,053)
Net cash used in investing activities	(29,070)	(48,147)
Net cash provided by financing activities	36,517	87,844

For the years ended December 31, 2023, and 2022, we used approximately \$102.0 million and \$98.1 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 year ended December 31, 2023, was approximately \$29.1 million related to the purchase of Zembrace and Tosymra assets and property and equipment. Cash used in investing activities for the year ended December 31, 2022, was \$48.1 million, related to the purchase of property and equipment. A significant portion of capital expenditure in 2022 is related to the build-out of the RDC and ADC.

For the year ended December 31, 2023, net proceeds from financing activities were \$36.5 million, primarily related to the sale of common stock and warrants; and debt raised which was offset by repurchase of common stock. For the year ended December 31, 2022, net proceeds from financing activities were \$87.8 million, predominately from the sale of our common stock.

We believe that our cash resources at December 31, 2023 and the proceeds that we raised from equity offerings in the first quarter of 2024, will meet our operating and capital expenditure requirements into the second quarter of 2024, but not beyond.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to changes we may make in our research and development spending plans. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period from the date of filing of this Form 10-K. We must 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 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 and we may be forced to cease operations.

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 build out 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 2,512,044 of its shares of common stock outstanding under a \$12.5 million share purchase program at prices ranging from \$2.75 to \$8.61 per share for a gross aggregate cost of approximately \$12.5 million. In addition, we incurred expenses of \$0.3 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 160,000 of its shares of common stock outstanding under the new share repurchase program at \$7.12 per share for a gross aggregate cost of \$1.1 million.

Debt Financing

On December 8, 2023, we executed a Loan and Guaranty Agreement (the “Loan Agreement”) to issue a 36-month term loan (the “Term Loan”) in the principal amount of \$11.0 million with a maturity date of December 8, 2026 (the “Maturity Date”). The Term Loan was funded with an original issue discount of 9% of the principal amount of the Term Loan, or \$1.0 million, which is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

Borrowings under the Term Loan bear interest at a fluctuating rate equal to the greater of (i) the prime rate as defined in the Loan Agreement plus 3.5% and (ii) 12%. Interest is payable monthly in arrears commencing in December 2023. In connection with the Term Loan, we deposited into a reserve account \$1.8 million to be used exclusively to fund interest payments related to the Term Loan. The deposit is reflected as prepaid and other current assets on the consolidated balance sheet.

Commencing on March 8, 2024 and continuing monthly through the Maturity Date, the outstanding principal will be due and payable in monthly installments of \$0.2 million, with the final remaining balance of unpaid principal and interest due and payable on the Maturity Date. In addition, we must pay a monthly collateral monitoring charge equal to 0.23% of the outstanding principal amount of the term loan as of the date of payment. We incurred \$1.1 million in issuance costs, which is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

The Loan Agreement provides for voluntary prepayments of the Term Loan, in whole or in part, subject to a prepayment premium. The Loan Agreement contains customary affirmative and negative covenants by us, which among other things, will require us to provide certain financial reports to the lenders, to maintain a deposit account to fund interest payments, and limit the ability of us to incur or guarantee additional indebtedness, pay dividends or make other equity distributions, sell assets, engage in certain transactions, and effect a consolidation or merger. Our obligations under the Loan Agreement may be accelerated upon customary events of default, including non-payment of principal, interest, fees and other amounts, covenant default, insolvency, material judgements, inaccuracy of representations and warranties, invalidity of guarantees. The Term Loan is secured by first priority security interests in our R&D Center in Frederick, Maryland, the Advanced Development Center in North Dartmouth, Massachusetts, and substantially all of the relevant deposit accounts.

As of December 31, 2023, the carrying amount of the Term Loan approximated its fair value as the contractual interest rate for the Term Loan was representative of the then market interest rate.

April 2024 Financing

On March 28, 2024, we sold 10,766,666 shares of common stock, pre-funded warrants to purchase up to 3,900,000 shares of common stock, and accompanying Series E warrants to purchase up to 14,666,666 shares of common stock with an exercise price of \$0.33 per share and expiring five and a half years from date of issuance in a public offering, which closed on April 1, 2024. The offering price per share of common stock was \$0.30, accompanying warrants was \$0.33, and the offering price per share of pre-funded warrants was \$0.2999.

We incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. We received net proceeds of approximately \$3.9 million, after deducting the underwriting discount and other offering expenses.

Additionally, we entered into warrant amendments with certain holders of its Common Warrants. The exercise price of each Existing Warrant will be amended to \$0.33 upon approval by the Company's stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635, or as otherwise provided in the Amendment if stockholder approval is not obtained by October 1, 2024. Upon stockholder approval, the termination date for Common Warrants to purchase up to an aggregate of 6,950,000 shares will be amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 8,900,000 shares will be April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 8,900,000 shares will be April 1, 2029; the termination date for Series C Warrants to purchase up to an aggregate of approximately 34,823,928 shares will be the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by the Company to the Series C Warrant holder of the Company's public announcement of the FDA's acknowledgement and acceptance of our NDA relating to TNX-102 SL in patients with Fibromyalgia; the termination date for Series D Warrants to purchase up to an aggregate of approximately 34,823,928 shares will be April 1, 2029. The other terms of the Existing Warrants will remain unchanged. If stockholder approval is not obtained on or by October 1, 2024, then the Company has agreed to automatically amend the exercise price of the Existing Warrants to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of the Common Stock on October 1, 2024 if and only if the Minimum Price is below the then current exercise price.

December 2023 Financing

On December 20, 2023, we issued (i) 25,343,242 shares of our common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 28,710,812 shares of common stock and (iii) Series C warrants to purchase up to 81,081,081 shares of common stock (the "Series C Warrants"), and (iv) Series D warrants to purchase up to 81,081,081 shares of common stock (the "Series D Warrants" and, together with the Series C Warrants, the "Common Warrants") in a registered direct offering. The securities were sold in fixed combinations as units. The offering price per share of common stock and accompanying Common Warrants was \$0.555, and the offering price per Pre-Funded Warrant and accompanying Common Warrants was \$0.5549. The offering closed on December 22, 2023, generating gross proceeds of approximately \$30.0 million, before deducting offering expenses of \$2.3 million payable by us.

The Pre-Funded Warrants have an exercise price of \$0.0001 per share, are immediately exercisable subject to certain ownership limitations, and can be exercised at any time until exercised in full. The Series C Warrants have an exercise price of \$0.555 per share, and are exercisable on the later of approval by the Company's stockholders of (i) a proposal to approve the filing of an amendment to the Company's Articles of Incorporation, increasing the number of authorized shares of common stock from 160,000,000 to 1,000,000,000 and (ii) a proposal to allow the Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 (the later of such events, the "Approval Date") and will expire on the later of (a) 10 trading days following the Approval Date and (b) the earlier of (x) the two year anniversary of the Approval Date and (y) 10 trading days following the public announcement of the FDA's acknowledgement and acceptance of the NDA relating to TNX-102 SL in patients with fibromyalgia. The Series D Warrants have an exercise price of \$0.85 per share and are exercisable beginning on the Approval Date through the five-year anniversary of the Approval Date.

September 2023 Financing

On September 28, 2023, we sold 4,050,000 shares of common stock; pre-funded warrants to purchase up to 4,950,000 shares of common stock, and accompanying common warrants to purchase up to 9,000,000 shares of common stock with an exercise price of \$0.50 per share and expiring one year from date of issuance, and common warrants to purchase up to 9,000,000 shares of common stock with an exercise price of \$0.50 per share and expiring five years from date of issuance in a public offering which closed on October 3, 2023. The offering price per share of common stock and accompanying common warrant was \$0.50, and the offering price per share of pre-funded warrant and accompanying common warrant was \$0.4999.

We incurred other offering expenses of approximately \$0.5 million, including a placement agent discount. We received net proceeds of approximately \$4.0 million, after deducting the underwriting discount and other offering expenses.

July 2023 Financing

On July 27, 2023, we sold securities consisting of 2,530,000 shares of common stock; pre-funded warrants to purchase up to 4,470,000 shares of common stock and common warrants to purchase up to 7,000,000 shares of common stock in a public offering that closed on August 1, 2023. The offering price per share of common stock and accompanying common warrant was \$1.00, and the offering price per pre-funded warrant and accompanying common warrant was \$0.9999.

We incurred offering expenses of approximately \$0.7 million, including placement agent fees of approximately \$0.5 million. We received net proceeds of approximately \$6.3 million, after deducting the underwriting discount and other offering expenses.

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 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 \$6.25 per share.

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 \$25.00 per share.

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 with Lincoln Park, pursuant to which Lincoln Park agreed to purchase from us up to \$50,000,000 of our common stock (subject to certain limitations) from time to time. We filed a registration statement to register for resale the shares that have been or may be issued to Lincoln Park under the 2022 Purchase Agreement.

We issued 100,000 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, 2023, we sold 0.1 million shares of common stock under the 2022 Purchase Agreement, for net proceeds of approximately \$0.4 million. During the year ended December 31, 2022, we sold 0.2 million shares of common stock under the 2022 Purchase Agreement for net proceeds of approximately \$0.5 million.

2021 Lincoln Park Transaction

On December 3, 2021, we entered into a purchase agreement (the “2021 Purchase Agreement”) and a registration rights agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to \$80,000,000 of our common stock (subject to certain limitations) from time to time. We filed a registration statement to register for resale the shares that have been or may be issued to Lincoln Park under the 2021 Purchase Agreement.

We issued 14,546 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the 2021 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 0.5 million shares of common stock under the 2021 Purchase Agreement for net proceeds of approximately \$8.7 million. No sales occurred in 2023, and we may not sell any additional shares under the 2021 Purchase Agreement.

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, 2023, we sold approximately 1.0 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$3.0 million. During the year ended December 31, 2022, we sold approximately 9.1 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$85.3 million.

Stock Compensation

On May 1, 2020, our stockholders approved the Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan (“Amended and Restated 2020 Plan”).

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) restricted stock units, (5) other stock-based awards, and (6) cash-based awards. The Amended and Restated 2020 Plan initially provided for the issuance of up to 50,000 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, 2023, 1,071,599 options 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's historical stock price volatility.

The weighted average fair value of options granted during the year ended December 31, 2023, was \$3.99 per share. The weighted average fair value of options granted during the year ended December 31, 2022, was \$32.81 per share.

Stock-based compensation expense relating to options granted of \$9.3 million, of which \$6.4 million and \$2.9 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2023. 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.

As of December 31, 2023, the Company had approximately \$6.1 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.70 years.

Employee Stock Purchase Plan

On May 6, 2022, our stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan (the "2022 ESPP"), which was replaced by the Tonix Pharmaceuticals Holdings Corp. 2023 Employee Stock Purchase Plan (the "2023 ESPP", and together with the 2022 ESPP, the "ESPP Plans"), which was approved by the Company's stockholders on May 5, 2023.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 800,000 shares of the Company's common stock. Under the 2023 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 2023 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 2023 ESPP, subject to the statutory limit under the Code. As of December 31, 2023, 800,000 shares were available for future sales under the 2023 ESPP.

The ESPP Plans are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the year ended December 31, 2023 and 2022, \$34,000 and \$46,000, respectively, was expensed. In January 2022, 646 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. In January 2023, 14,999 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. As of December 31, 2023, approximately \$44,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses. In January 2024, 66,359 shares that were purchased as of December 31, 2023, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2024, approximately \$24,000 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 \$20,000 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 \$23.2 million at December 31, 2023 for future work to be performed.

Operating leases

As of December 31, 2023, future minimum lease payments are as follows (in thousands):

Year Ending December 31,		
2024	\$	305
2025		299
2026		142
2027		139
2028 and beyond		107
Included interest		(90)
	\$	<u>902</u>

Critical Accounting Policies and Estimates

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

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

Business Combinations. We apply the acquisition method of accounting for business combinations. Under the acquisition method, the acquiring entity recognizes all of the identifiable assets acquired and liabilities assumed at their acquisition date fair values. We use our best estimates and assumptions to estimate the fair values of these tangible and intangible assets. Any excess of the purchase price over amounts allocated to the assets acquired is recorded as goodwill. The acquired intangible assets are amortized using the straight-line method over the estimated useful lives of the respective assets. Goodwill is reviewed for impairment on an annual basis, or more frequently if events or changes in circumstances indicate that the carrying amount of goodwill may be impaired.

Revenue Recognition. Our gross product revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration represents chargebacks, rebates, prompt pay and other sales discounts, and product returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on gross sales for a reporting period. We began recognizing revenue following the completion of the USL Acquisition, beginning July 1, 2023, and required variable consideration estimates are currently primarily based on the acquired products historical results. Adjustments to these estimates to reflect actual results or updated expectations will be assessed each period. If any of our ratios, factors, assessments, experiences, or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. The potential of our estimates to vary differs by program, product, type of customer and geographic location. In addition, estimates associated with U.S. Medicare and Medicaid governmental rebate programs are at risk for material adjustment because of the extensive time delay.

Research and Development. We outsource certain of 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.

Deferred financing costs. Deferred financing costs represent the cost of obtaining financing arrangements and are amortized over the term of the related debt agreement using the effective interest method. Deferred financing costs related to term debt arrangements are reflected as a direct reduction of the related debt liability on the consolidated balance sheet. Amortization of deferred financing costs is included in interest expense on the consolidated statements of operations.

Original issue discount. Certain term debt issued by the Company provides the debt holder with an original issue discount. Original issue discounts are reflected as a direct reduction of the related debt liability on the consolidated balance sheets and are amortized over the term of the related debt agreement using the effective interest method. Amortization of original issue discounts are included in interest expense on the consolidated statements of operations.

Derivative Instruments and Warrant Liabilities. The Company evaluates all of its financial instruments, including issued warrants to purchase common stock under ASC 815 – Derivatives and Hedging, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The Company uses the Black-Scholes option pricing model to value the derivative instruments at inception and subsequent valuation dates, which is adjusted for instrument-specific terms as applicable.

From time to time, certain equity-linked instruments may be classified as derivative liabilities due to the Company having insufficient authorized shares to fully settle the equity-linked financial instruments in shares. In such a case, the Company has adopted a sequencing approach under ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity to determine the classification of its contracts at issuance and at each subsequent reporting date. If reclassification of contracts between equity and assets or liabilities is necessary, the Company first allocates remaining authorized shares to equity on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest issuance date receiving the first allocation of shares. In the event of identical issuance dates, shares are then allocated to equity beginning with instruments with the latest maturity date first.

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 Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB" issued Accounting Standards Update ("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. The adoption of ASU 2020-06 did not impact the Company's financial position, results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. ASU 2016-13 will be effective for us for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption is permitted. We adopted ASU 2016-13 and related updates as of January 1, 2023. The adoption of ASU 2016-13 did not 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.

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated balance sheets as of December 31, 2023 and 2022</u>	F-3
<u>Consolidated statements of operations for the years ended December 31, 2023 and 2022</u>	F-4
<u>Consolidated statements of comprehensive loss for the years ended December 31, 2023 and 2022</u>	F-5
<u>Consolidated statements of stockholders’ equity for the years ended December 31, 2023 and 2022</u>	F-6 – F-7
<u>Consolidated statements of cash flows for the years ended December 31, 2023 and 2022</u>	F-8
<u>Notes to consolidated financial statements</u>	F-9 – F-30

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, 2023 and 2022, and the related consolidated statements of operations, comprehensive loss, stockholders’ equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023 and 2022, 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were 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 matters 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 matters or on the accounts or disclosures to which they relate.

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 \$3.0 million is included in accrued expenses and other current liabilities in the December 31, 2023 consolidated balance sheet. The Company also recorded prepaid clinical trial expenses of approximately \$4.6 million within prepaid expenses and other in the December 31, 2023 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.

Valuation of intangible assets acquired in a business combination

As described in Note 12 to the consolidated financial statements, the Company acquired certain assets from Upsher-Smith Laboratories LLC, which was accounted for as a business combination using the acquisition method of accounting. The acquired intangible assets consisted of developed technology related to Zembrace and Tosymra, including the value associated with the acquired patents, customer relationships, and trademarks and tradenames associated with the technology. The developed technology intangible assets were valued as composite assets under the premise that each asset is reliant on one another to generate cash flow, and is not considered separable from the technology. The intangible assets had an estimated acquisition date fair value of \$10.1 million. The accounting for business combinations, including valuation of intangible assets, was also identified as a critical accounting estimate by management.

We identified valuation of intangible assets acquired in a business combination as a critical audit matter due to the significant judgment and estimation required by management in the use of fair valuation methodologies, including sensitive significant assumptions such as revenue growth rates and risk premium. 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 the purchase price allocation. Our procedures also included, among others, assessing the appropriateness of the valuation methodology utilized, testing of significant assumptions, and ensuring completeness and accuracy of the underlying data used by the Company. We involved our valuation specialist to assist in evaluating the valuation methodologies and risk premium used in the purchase price allocation valuation.

We have served as the Company's auditor since 2010.

EISNERAMPER LLP
Iselin, New Jersey
April 1, 2024

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2023 AND 2022
(In Thousands, Except Par Value and Share Amounts)

	<u>2023</u>	<u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 24,948	\$ 120,229
Inventory, net	13,639	—
Prepaid expenses and other current assets	9,181	10,548
Total current assets	47,768	130,777
Property and equipment, net	94,028	93,814
Intangible assets, net	9,743	120
Goodwill	965	—
Operating lease right-to-use assets	824	715
Other non-current assets	1,129	264
Total assets	<u>\$ 154,457</u>	<u>\$ 225,690</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,782	\$ 8,068
Accrued expenses and other current liabilities	12,482	9,680
Term loan payable, short term	2,350	—
Lease liability, short term	270	432
Total current liabilities	18,884	18,180
Term loan payable, long term	6,561	—
Series C Warrant liabilities	14,595	—
Series D Warrant liabilities	8,260	—
Lease liability, long term	632	328
Total liabilities	48,932	18,508
Commitments (See Note 21)		
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, 2023 and 2022; issued and outstanding - None	—	—
Series A Convertible Preferred stock, 0 shares designated as of both December 31, 2023 and December 31, 2022; issued and outstanding - none	—	—
Common stock, \$0.001 par value; 160,000,000 shares authorized; 58,614,593 and 12,368,620 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively and 66,329 and 14,999 shares to be issued as of December 31, 2023 and December 31, 2022, respectively	59	12
Additional paid in capital	706,356	677,375
Accumulated deficit	(600,658)	(470,038)
Accumulated other comprehensive loss	(232)	(167)
Total stockholders' equity	105,525	207,182
Total liabilities and stockholders' equity	<u>\$ 154,457</u>	<u>\$ 225,690</u>

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,	
	2023	2022
REVENUES:		
Product revenue, net	\$ 7,768	\$ —
COSTS AND EXPENSES:		
Cost of sales	4,741	—
Research and development	86,655	81,876
General and administrative	34,752	30,215
Total Operating Expenses	<u>126,148</u>	<u>112,091</u>
Operating loss	(118,380)	(112,091)
Other income, net	<u>1,722</u>	<u>1,873</u>
Net loss	(116,658)	(110,218)
Preferred stock deemed dividend	<u>—</u>	<u>6,659</u>
Net loss available to common stockholders	<u>\$ (116,658)</u>	<u>\$ (116,877)</u>
Net loss to common stockholders per common share, basic and diluted	<u>\$ (6.85)</u>	<u>\$ (20.01)</u>
Weighted average common shares outstanding, basic and diluted	<u>17,039,309</u>	<u>5,841,447</u>

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2023	2022
Net loss	\$ (116,658)	\$ (110,218)
Other comprehensive loss:		
Foreign currency translation loss	(65)	(75)
Comprehensive loss	<u>\$ (116,723)</u>	<u>\$ (110,293)</u>

See the accompanying notes to the consolidated financial statements

TONIX PHARMACEUTICALS HOLDING CORP.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In Thousands, Except Share and Per Share Amounts)

	Common stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2022	12,368,620	\$ 12	\$ 677,375	\$ (167)	\$ (470,038)	\$ 207,182
Repurchase of common stock under Share Repurchase Program, including transactional expenses of \$334	(2,672,044)	(3)	—	—	(13,962)	(13,965)
Issuance of common stock under 2022 Purchase agreement	96,000	—	441	—	—	441
Issuance of common stock under At-the- market offering, net of transactional expenses of \$137	954,766	1	3,023	—	—	3,024
Issuance of common stock and warrants under AGP Financing, net of transactional expenses of \$2,663	31,923,242	32	16,230	—	—	16,262
Issuance of common stock upon exercise of prefunded common warrants	15,929,010	17	(17)	—	—	—
Employee stock purchase plan	14,999	—	29	—	—	29
Stock-based compensation	—	—	9,275	—	—	9,275
Foreign currency transaction gain	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	(116,658)	(116,658)
Balance, December 31, 2023	58,614,593	\$ 59	\$ 706,356	\$ (232)	\$ (600,658)	\$ 105,525

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 Capital	Accumulated Other Comprehensive Gain (loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance, December 31, 2021	2,634,110	\$ 3	\$ 578,626	\$ (92)	\$ (359,820)	\$ 218,717
Issuance of common stock under At-the-market offering, net of transactional expenses of \$3,078	9,017,307	9	85,284	—	—	85,293
Issuance of commitment shares under 2022 Purchase agreement	100,000	—	—	—	—	—
Issuance of common stock under 2022 Purchase agreement	160,000	—	488	—	—	488
Issuance of common stock under 2021 Purchase agreement	456,557	—	8,682	—	—	8,682
Preferred stock deemed dividend	—	—	(6,659)	—	—	(6,659)
Employee stock purchase plan	646	—	40	—	—	40
Stock-based compensation	—	—	10,914	—	—	10,914
Foreign currency transaction gain	—	—	—	(75)	—	(75)
Net loss	—	—	—	—	(110,218)	(110,218)
Balance, December 31, 2022	12,368,620	\$ 12	\$ 677,375	\$ (167)	\$ (470,038)	\$ 207,182

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (116,658)	\$ (110,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,291	1,253
Stock-based compensation	9,275	10,914
Change in fair value of warrant liabilities	283	—
Offering costs allocated to warrant liabilities	903	—
Gain on sale of property and equipment	(62)	—
Changes in operating assets and liabilities:		
Inventory	61	—
Prepaid expenses and other	1,573	(164)
Accounts payable	(3,490)	(1,045)
Operating lease liabilities and ROU asset, net	35	2
Accrued expenses and other current liabilities	1,786	1,205
Net cash used in operating activities	(102,003)	(98,053)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(7,895)	(48,147)
Disposal of property and equipment	999	—
Purchase of a business	(22,174)	—
Net cash used in investing activities	(29,070)	(48,147)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from ESPP	29	40
Proceeds, net of \$6,659 expenses, from sale of convertible redeemable preferred stock	—	40,591
Redemption of convertible preferred stock	—	(47,250)
Proceeds from debt financing	8,942	—
Proceeds, net of \$2,800 and \$3,078 expenses, from sale of common stock and warrants	18,939	94,463
Proceeds from allocated warrant liabilities	22,572	—
Repurchase of common stock	(13,965)	—
Net cash provided by financing activities	36,517	87,844
Effect of currency rate change on cash	(65)	(74)
Net decrease in cash, cash equivalents and restricted cash	(94,621)	(58,430)
Cash, cash equivalents and restricted cash beginning of the period	120,470	178,900
Cash, cash equivalents and restricted cash end of period	<u>\$ 25,849</u>	<u>\$ 120,470</u>
Supplemental disclosures of cash flow information:		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 106	\$ 3,092
Debt financing costs included in accrued liabilities and other current liabilities	\$ 85	\$ -
Issuance costs included in accrued liabilities and other current liabilities	\$ 117	\$ -
Preferred stock deemed dividend	\$ —	\$ 6,659
New operating leases and lease amendments	\$ 898	\$ 386

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 fully-integrated biopharmaceutical company focused on developing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. The therapeutics under development include both small molecules and biologics. Tonix, through its recent acquisition, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg (“Zembrace”) and Tosymra® (sumatriptan nasal spray) 10 mg (“Tosymra”). Zembrace and Tosymra, which were acquired as of June 30, 2023 (See Note 12), are each indicated for the treatment of acute migraine with or without aura in adults. All other drug product and vaccine candidates are still in development and are not 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 Institute 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, 2023, the Company had working capital of approximately \$28.9 million. At December 31, 2023, the Company had an accumulated deficit of approximately \$600.7 million. The Company held cash and cash equivalents of approximately \$24.9 million as of December 31, 2023.

The Company believes that its cash resources at December 31, 2023 and the proceeds that it raised from equity offerings in the first quarter of 2024 (See Note 23), will not meet its operating and capital expenditure requirements through the second quarter of 2024.

These factors raise substantial doubt about the Company’s ability to continue as a going concern. The Company continues to face significant challenges and uncertainties and must 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, or at all. 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, its ability to achieve our development and commercialization goals would be adversely affected and the Company may be forced to cease operations. 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 9, 2023, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 10, 2023. Pursuant to the Certificate of Change, the Company effected a 1-for-6.25 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 retrospective 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 now has commercial products available for sale, and generates revenue from the sale of its Zembrace® SymTouch® and Tosymra® products, with no assurance that the Company will be able to generate sufficient cash flow to fund operations from its commercial products or products in development if and when approved. 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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, but are not limited to, provisions for product returns, coupons, rebates, chargebacks, discounts, allowances, inventory realization, the assumptions used in the fair value of stock-based compensation and other equity instruments, the percent of completion of research and development contracts, fair value estimates for assets acquired in business combinations, and assessment of useful lives of acquired intangible assets.

Business Combinations

The Company accounts for business combinations in accordance with the provisions of ASC 805, Business Combinations and ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. Business combinations are accounted for using the acquisition method, whereby the consideration transferred is allocated to the net assets acquired based on their respective fair values measured on the acquisition date. The difference between the fair value of these assets and the purchase price is recorded as goodwill. Transaction costs other than those associated with the issue of debt or equity securities, and other direct costs of a business combination are not considered part of the business acquisition transaction and are expensed as incurred.

Segment Information and Concentrations

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

The Company has two products that each accounted for more than 10% of total revenues during the year ended December 31, 2023. These products collectively accounted for 100% of revenues during the year ended December 31, 2023.

As of December 31, 2023, accounts receivable from five customers accounted for 26%, 21%, 16%, 14% and 13% of total accounts receivable. For the year ended December 31, 2023, revenues from five customers accounted for 23%, 21%, 19%, 17% and 10% of net product revenues, respectively. As of December 31, 2022, and for the year ended December 31, 2022, the Company had no commercialized products and therefore had no accounts receivable or revenues.

Cash, Cash Equivalents and Restricted Cash

The Company considers cash equivalents to be those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased. At December 31, 2023, and December 31, 2022, cash equivalents, which consisted of money market funds, amounted to approximately \$23,000 and \$116.3 million, respectively. Restricted cash, which is included in Other non-current assets on the consolidated balance sheet, at December 31, 2023, of approximately \$0.9 million, collateralizes a letter of credit issued in connection with the lease of office space in Chatham, New Jersey (see Note 20) and restricted cash held by vendors in escrow accounts for patient support services. Restricted cash at December 31, 2022, of approximately \$241,000, collateralizes a letter of credit issued in connection with the lease of office space in Chatham, New Jersey and New York, New York.

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, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	\$ 24,948	\$ 120,229
Restricted cash	901	241
Total	<u>\$ 25,849</u>	<u>\$ 120,470</u>

Accounts Receivable, net

Accounts receivable consists of amounts due from our wholesale and other third-party distributors and pharmacies and have standard payment terms that generally require payment within 30 to 90 days. For certain customers, the accounts receivable for the customer is net of prompt payment or specialty pharmacy discounts. We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale. We provide reserves against accounts receivable for estimated losses that may result from a customer’s inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve. However, during the period covered by the Transition Services Agreement, the Seller has agreed to collect the accounts receivable on behalf of the Company and net settle within 45 days from each month-end. See Note 12 for further details. The Company had no accounts receivable as of December 31, 2022.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of December 31, 2023, the Company did not have an allowance for doubtful accounts. An allowance for doubtful accounts is determined based on the financial condition and creditworthiness of customers and the Company considers economic factors and events or trends expected to affect future collections experience. Any allowance would reduce the net receivables to the amount that is expected to be collected. The payment history of the Company's customers will be considered in future assessments of collectability as these patterns are established over a longer period.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk include cash and cash equivalents, and accounts receivable. We attempt to minimize the risks related to cash and cash equivalents by investing in a broad and diverse range of financial instruments, and we have established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Concentrations of credit risk with respect to receivables, which are typically unsecured, are somewhat mitigated due to the wide variety of customers using our products, as well as their dispersion across different geographic areas.

We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions and assess their possible impact on our business.

Inventories

Inventories are recorded at the lower of cost or net realizable value, with cost determined by the weighted average cost method. The Company periodically reviews the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise non-saleable items taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand. If non-saleable items are observed and there are no alternate uses for the inventory, the Company records a write-down to net realizable value in the period that the decline in value is first recognized. Although the Company makes every effort to ensure the accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of inventories and reported operating results. The Company's reserves were approximately \$21,000 as of December 31, 2023. The Company did not have inventory on hand prior to the acquisition of Zembrace and Tosymra on June 30, 2023.

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 the shorter of the useful life or term of lease for leasehold improvements. Depreciation on assets begins when the asset is placed in service. Depreciation and amortization expense for the years ended December 31, 2023, and 2022, were \$3.8 million and \$1.3 million, respectively. All property and equipment are located in the United States.

Intangible assets, net

Intangible assets deemed to have finite lives are carried at acquisition-date fair value less accumulated amortization and impairment, if any. Finite-lived intangible assets consist of developed technology intangible assets acquired in connection with the acquisition of certain products from Upsher Smith Laboratories, LLS ("Upsher Smith") consummated on June 30, 2023 (See Note 5). The acquired intangible assets are amortized using the straight-line method over the estimated useful lives of the respective assets. Amortization expense for the year ended December 31, 2023, was \$477,000. The annual impairment assessment date will be June 30. No triggering events were identified during the period of July 1, 2023 through December 31, 2023.

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 Intangible assets, net 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, 2023, the Company believed that no impairment existed.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Goodwill

Goodwill represents the excess of the aggregate purchase price over the fair value of the net tangible and intangible assets acquired in a business combination. Goodwill is reviewed for impairment on an annual basis, or more frequently if events or changes in circumstances indicate that the carrying amount of goodwill may be impaired. As of December 31, 2023, the Company has recognized goodwill in connection with the USL Acquisition consummated on June 30, 2023 (See Note 5). The annual impairment assessment date will be June 30. No triggering events were identified during the period of July 1, 2023 through December 31, 2023.

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, operating lease liabilities, current and operating lease liabilities, noncurrent 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.

Deferred financing costs

Deferred financing costs represent the cost of obtaining financing arrangements and are amortized over the term of the related debt agreement using the effective interest method. Deferred financing costs related to term debt arrangements are reflected as a direct reduction of the related debt liability on the consolidated balance sheet. Amortization of deferred financing costs are included in interest expense on the consolidated statements of operations.

Original issue discount

Certain term debt issued by the Company provides the debt holder with an original issue discount. Original issue discounts are reflected as a direct reduction of the related debt liability on the consolidated balance sheets and are amortized over the term of the related debt agreement using the effective interest method. Amortization of original issue discounts are included in interest expense on the consolidated statements of operations.

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.

Revenue Recognition

The Company records and recognizes revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company’s revenues primarily result from contracts with customers, which are generally short-term and have a single performance obligation - the delivery of product. The Company’s performance obligation to deliver products is satisfied at the point in time that the goods are received by the customer, which is when the customer obtains title to and has the risks and rewards of ownership of the products, which is generally upon shipment or delivery to the customer as stipulated by the terms of the sale agreements. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Our contractual payment terms are typically 30 to 90 days.

Revenues from product sales, net of gross-to-net deductions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring and when the uncertainty associated with gross-to-net deductions is subsequently resolved. Taxes assessed by governmental authorities and collected from customers are excluded from product sales. Shipping and handling activities are considered to be fulfillment activities and not a separate performance obligation.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Many of the Company's products sold are subject to a variety of deductions. Revenues are recognized net of estimated rebates and chargebacks, cash discounts, distributor fees, sales return provisions and other related deductions. Deductions to product sales are referred to as gross-to-net deductions and are estimated and recorded in the period in which the related product sales occur. Accruals for these provisions are presented in the consolidated financial statements as reductions to gross sales in determining net sales, and as a contra asset within accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). Amounts recorded for revenue deductions can result from a complex series of judgements about future events and uncertainties and can rely heavily on estimates and assumptions. The following section briefly describes the nature of the Company's provisions for variable consideration and how such provisions are estimated:

Chargebacks - The Company sells a portion of its products indirectly through wholesaler distributors, and enters into specific agreements with these indirect customers to establish pricing for the Company's products, and in-turn, the indirect customers and entities independently purchase these products. Because the price paid by the indirect customers and/or entities is lower than the price paid by the wholesaler, the Company provides a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and the wholesale customer's purchase price. The Company's provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to the indirect customers and estimated wholesaler inventory levels as well as historical chargeback rates. The Company continually monitors its reserve for chargebacks and adjusts the reserve accordingly when expected chargebacks differ from actual experience.

Rebates - The Company participates in certain government and specific sales rebate programs which provides discounted prescription drugs to qualified recipients, and primarily relate to Medicaid and managed care rebates in the U.S., pharmacy rebates, Tri-Care rebates and discounts, specialty pharmacy program fees and other governmental rebates or applicable allowances.

- Managed Care Rebates are processed in the quarter following the quarter in which they are earned. The managed care reporting entity submits utilization data after the end of the quarter and the Company processes the payment in accordance with contract terms. All rebates earned but not paid are estimated by the Company according to historical payments trended for market growth assumptions.
- Medicaid and State Agency rebates are based upon historical experience of claims submitted by various states. The Company monitors Medicaid legislative changes to determine what impact such legislation may have on the provision for Medicaid rebates. The accrual of State Agency reserves is based on historical payment rates. There is an approximate three-month lag from the time of product sale until the rebate is paid.
- Tri-Care represents a regionally managed health care program for active duty and retired members, dependents and survivors of the US military. The Tri-Care program supplements health care resources of the US military with civilian health care professionals for greater access and quality healthcare coverage. Through the Tri-Care program, the Company provides pharmaceuticals on a direct customer basis. Prices of pharmaceuticals sold under the Tri-Care program are pre-negotiated and a reserve amount is established to represent the proportionate rebate amount associated with product sales.
- Coverage Gap refers to the Medicare prescription drug program and represents specifically the period between the initial Medicare Part D prescription drug program coverage limit and the catastrophic coverage threshold. Applicable pharmaceutical products sold during this coverage gap timeframe are discounted by the Company. Since the nature of the program is that coverage limits are reset at the beginning of the calendar year; the payments escalate each quarter as the participants reach the coverage limit before reaching the catastrophic coverage threshold. The Company has determined that the cost of this reserve will be viewed as an annual cost. Therefore, the accrual will be incurred evenly during the year with quarterly review of the liability based on payment trends and any revision to the projected annual cost.

Prompt-Pay and other Sales Discounts - The Company provides for prompt pay discounts, which early payments are recorded as a reduction of revenue and as a reduction in the accounts receivable at the time of sale based on the customer's contracted discount rate. Consumer sales discounts represent programs the Company has in place to reduce costs to the patient. This includes copay buy down and eVoucher programs.

Product Returns - Consistent with industry practice, the Company offers customers a right to return any unused product. The customer's right of return commences typically six months prior to product expiration date and ends one year after product expiration date. Products returned for expiration are reimbursed at current wholesale acquisition cost or indirect contract price. The Company estimates the amount of its product sales that may be returned by the Company's customers and accrues this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company estimates products returns as a percentage of sales to its customers. The rate is estimated by using historical sales information, including its visibility and estimates into the inventory remaining in the distribution channel. Adjustments are made to the current provision for returns when data suggests product returns may differ from original estimates.

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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. During the year ended December 31, 2023, we received \$2.7 million in funding as a reduction of related research and development expense. Included in Prepaid expenses and other is an additional \$0.2 million which was not received until January 2024. 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 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, 2023, 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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Derivative Instruments and Warrant Liabilities

The Company evaluates all of its financial instruments, including issued warrants to purchase common stock under ASC 815 – Derivatives and Hedging, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives (See Note 17). For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The Company uses the Black-Scholes option pricing model to value the derivative instruments at inception and subsequent valuation dates, which is adjusted for instrument-specific terms as applicable.

From time to time, certain equity-linked instruments may be classified as derivative liabilities due to the Company having insufficient authorized shares to fully settle the equity-linked financial instruments in shares. In such case, the Company has adopted a sequencing approach under ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity to determine the classification of its contracts at issuance and at each subsequent reporting date. In the event that reclassification of contracts between equity and assets or liabilities is necessary, the Company first allocates remaining authorized shares to equity on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest issuance date receiving the first allocation of shares. In the event of identical issuance dates, shares are then allocated to equity beginning with instruments with the latest maturity date first.

Per Share Data

The computation of basic and diluted loss per share for the year ended December 31, 2023, and 2022 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 and preferred stock 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 the purposes of computing EPS, these warrants and preferred stock 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. The weighted average number of outstanding shares of common stock used in the denominator for the calculation of basic loss per share for the year ended December 31, 2023, include pre-funded warrants that are accounted for as equity instruments, beginning with their respective issuance dates, as their stated exercise price of \$0.0001 is non-substantive and there are no further vesting conditions or limitations on exercise. No income was allocated to the warrants and preferred stock for the year ended December 31, 2023, and 2022, as results of operations were a loss for the periods.

Potentially dilutive securities excluded from the computation of basic and diluted net loss per share, as of December 31, 2023, and 2022, are as follows:

	2023	2022
Warrants to purchase common stock	209,364,707	3,196
Options to purchase common stock	1,375,539	392,643
Totals	<u>210,740,246</u>	<u>395,839</u>

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 adopted ASU 2020-06 on January 1, 2023, under the modified retrospective method of transition. The adoption of ASU 2020-06 did not impact the Company's financial position, results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*. The main objective of ASU 2016-13 is to provide financial statement users with more decision-useful information about an entity's expected credit losses on financial instruments and other commitments to extend credit at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology currently used today with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to develop credit loss estimates. ASU 2016-13 will be effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, using a modified retrospective approach. Early adoption is permitted. The Company adopted ASU 2016-13 and related updates as of January 1, 2023. The adoption of ASU 2016-13 did not impact the Company's financial position, results of operations or cash flows.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, *Segment Reporting--Improvements to Reportable Segment Disclosures*, which requires incremental disclosures about a public entity’s reportable segments but does not change the definition of a segment or the guidance for determining reportable segments. The new guidance requires disclosure of significant segment expenses that are (1) regularly provided to (or easily computed from information regularly provided to) the chief operating decision maker and (2) included in the reported measure of segment profit or loss. The new standard also allows companies to disclose multiple measures of segment profit or loss if those measures are used to assess performance and allocate resources. The guidance will first be effective in our annual disclosures for the year ending December 31, 2024, and will be adopted retrospectively unless impracticable. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2023-07 on our disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which requires disaggregated information about our effective tax rate reconciliation as well as information on income taxes paid. The guidance will first be effective in our annual disclosures for the year ending December 31, 2025, and should be applied on a prospective basis with the option to apply retrospectively. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2023-09 on our disclosures.

In March 2024, the SEC adopted new rules relating to the disclosure of a range of climate-change-related physical and transition risks, data, and opportunities. The adopted rule contains several new disclosure obligations, including, (i) disclosure on how the board of directors and management oversee climate-related risks and certain climate-related governance items, (ii) disclosure of information related to a registrant’s climate-related targets, goals, and/or transition plans, and (iii) disclosure on whether and how climate-related events and transition activities impact line items above a threshold amount on a registrant’s consolidate financial statements, including the impact of the financial estimates and the assumptions used. This new rule will first be effective in the Company’s disclosures for the year ending December 31, 2027. The Company is in the process of assessing the impact on our consolidated financial statements and disclosures.

NOTE 3 – INVENTORY

The components of inventory consisted of the following as of December 31, 2023:

	December 31, 2023	December 31, 2022
	(in thousands)	
Raw Materials	\$ 3,611	\$ —
Work-in-process	2,539	—
Finished Goods	7,510	—
	13,660	\$ —
Less: Inventory reserves	(21)	—
Total Inventory	\$ 13,639	\$ —

NOTE 4 – PROPERTY AND EQUIPMENT, NET

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Property and equipment, net:		
Land	\$ 8,011	\$ 8,011
Land improvements	326	79
Buildings	66,749	65,644
Office furniture and equipment	2,366	1,893
Laboratory equipment	21,904	18,440
Leasehold improvements	34	34
Construction in progress	—	1,366
	99,390	95,467
Less: Accumulated depreciation and amortization	(5,362)	(1,653)
	\$ 94,028	\$ 93,814

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. As of August 1, 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 related to the build-out of the facility. As of October 1, 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, 2023, the asset was not ready for its intended use.

During the year ended December 31, 2023, property and equipment with a net book value of approximately \$0.9 million were sold for net proceeds of approximately \$1.0 million.

NOTE 5 – GOODWILL AND INTANGIBLE ASSETS

The following table provides the gross carrying value of goodwill as follows:

	Amounts
	(in thousands)
Balance at December 31, 2022	\$ —
Acquired during the period (see Note 12)	965
Balance at December 31, 2023	<u>\$ 965</u>

The following table provides the gross carrying amount and accumulated amortization for each major class of intangible asset:

	December 31,	December 31,
	2023	2022
	(in thousands)	
Intangible assets subject to amortization		
Developed technology	\$ 10,100	\$ —
Less: Accumulated amortization	477	—
Total	<u>\$ 9,623</u>	<u>\$ —</u>
Intangible assets not subject to amortization		
Internet domain rights	\$ 120	\$ 120
Total intangible assets, net	<u>\$ 9,743</u>	<u>\$ 120</u>

During the year ended December 31, 2023, the Company recorded amortization of \$477,000.

At December 31, 2023, the related amortization for each of the next five years ended December 31 is as follows (in thousands):

<u>Year Ending December 31,</u>	
2024	\$ 953
2025	953
2026	953
2027	953
2028 and beyond	5,811
	<u>\$ 9,623</u>

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 6 – 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, 2023, and December 31, 2022, the Company used Level 1 quoted prices in active markets to value cash equivalents of \$0.1 million and \$116.3 million, respectively. The Company did not have any Level 2 or Level 3 assets or liabilities as of December 31, 2022. As of December 31, 2023, Level 3 liabilities include a portion of the Series D Warrants and all Series C Warrants issued on December 22, 2023, which did not meet the criteria for equity classification due to insufficient authorized shares to settle the instruments and are therefore accounted for as liabilities at fair value.

The Company estimates the fair value of the Series D Warrants and the Series C Warrants using significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The Company estimated the fair value of these instruments using the Black-Scholes option pricing model, which was then adjusted by applying a discount for lack of marketability (“DLOM”) based on the expected timing of receipt of stockholder approval to increase the number of authorized shares and to allow the Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635.

The significant unobservable inputs used in the valuation models at issuance and as of December 31, 2023, to measure the fair value of the Series D Warrants and the Series C Warrants are as follows:

Valuation Date:	Series C Warrants		Series D Warrants	
	December 22, 2023	December 31, 2023	December 22, 2023	December 31, 2023
Common stock price	\$ 0.398	\$ 0.403	\$ 0.398	\$ 0.403
Risk-free rate	4.31%	4.23%	3.87%	3.84%
Expected term (in years)	1.80	1.78	5.18	5.15
Expected volatility	108.0%	108.0%	108.0%	108.0%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Discount for lack of marketability	5.0%	5.0%	5.0%	5.0%

The liability-classified Series D Warrants and the Series C Warrants were recognized at their aggregate issuance date fair values totaling \$22.5 million. From the date of issuance to December 31, 2023, the Company recognized a change in fair value resulting in a loss of \$0.3 million related to the liability-classified warrants. Changes in the fair value of the liability-classified warrants are recognized as a component of other income, net in the consolidated statement of operations.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 7 – OTHER BALANCE SHEET INFORMATION

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

	December 31,	
	2023	2022
	(in thousands)	
Prepaid expenses and other:		
Contract-related	\$ 4,590	\$ 8,043
Debt interest and fees	1,513	—
Inventory	508	—
Insurance	143	1,275
Other	2,427	1,230
	<u>\$ 9,181</u>	<u>\$ 10,548</u>
Accrued expenses and other current liabilities:		
Contract-related	\$ 2,980	\$ 3,273
Upsher Smith obligation	3,000	—
Compensation and compensation-related	4,361	3,645
Product returns	743	—
Construction in progress	—	2,103
Professional fees and other	1,398	659
	<u>\$ 12,482</u>	<u>\$ 9,680</u>

NOTE 8 – DEBT FINANCING

Long-term debt consists of the following:

	December 31,
	2023
	(in thousands)
Term Loan	\$ 11,000
Less: current portion	(2,350)
Total long-term debt	8,650
Less: unamortized debt discount and deferred financing costs	(2,089)
Total long-term debt, net	<u>\$ 6,561</u>

On December 8, 2023, the Company entered into a Loan and Guaranty Agreement (the “Loan Agreement”) by and among the Company, Krele LLC, Tonix Pharmaceuticals, Inc., Jenner and Tonix R&D Center (“Loan Parties”), with JGB Capital, LP, JGB Partners, LP, JGB (Cayman) Port Ellen Ltd., and any other lender from time to time party hereto (collectively, the “Lenders”), and JGB Collateral LLC, as administrative agent and collateral agent for the Lenders (in such capacity, “JGB Agent”) for a 36-month term loan (the “Term Loan”) in the aggregate principal amount of \$11.0 million, with a maturity date of December 8, 2026 (the “Maturity Date”). The Term Loan was funded with an original issue discount of 9% of the principal amount of the Term Loan, or \$1.0 million, which is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

Borrowings under the Term Loan bear interest at a fluctuating rate equal to the greater of (i) the prime rate as defined in the Loan Agreement plus 3.5% and (ii) 12%. Interest is payable monthly in arrears commencing in December 2023. In connection with the Term Loan, the Company deposited into a reserve account \$1.8 million to be used exclusively to fund interest payments related to the Term Loan. The deposit is reflected in Prepaid expenses and other current assets on the consolidated balance sheet.

Commencing on March 8, 2024 and continuing monthly through the Maturity Date, the outstanding principal will be due and payable in monthly installments of \$0.2 million, with the final remaining balance of unpaid principal and interest due and payable on the Maturity Date. In addition, the Company must pay a monthly collateral monitoring charge equal to 0.23% of the outstanding principal amount of the term loan as of the date of payment. The Company incurred \$1.1 million in issuance costs, which is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

The Loan Agreement provides for voluntary prepayments of the Term Loan, in whole or in part, subject to a prepayment premium. The Loan Agreement contains customary affirmative and negative covenants by the Company, which among other things, will require the Borrowers to provide certain financial reports to the lenders, to maintain a deposit account to fund interest payments, and limit the ability of the Company to incur or guarantee additional indebtedness, pay dividends or make other equity distributions, sell assets, engage in certain transactions, and effect a consolidation or merger. The obligations of the Company under the Loan Agreement may be accelerated upon customary events of default, including non-payment of principal, interest, fees and other amounts, covenant default, insolvency, material judgements, inaccuracy of representations and warranties, invalidity of guarantees. The Term Loan is secured by first priority security interests in the Company’s R&D Center in Frederick, Maryland, the Advanced Development Center in North Dartmouth, Massachusetts, and substantially all of the relevant deposit accounts.

As of December 31, 2023, the carrying amount of the Term Loan approximated its fair value as the contractual interest rate for the Term Loan was representative of the then market interest rate.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Annual future principal payments due on the Term Loan as of December 31, 2023 are as follows (in thousands):

Fiscal years ending	
2024	\$ 2,350
2025	2,820
2026	5,830
	<u>\$ 11,000</u>

NOTE 9 – STOCKHOLDERS’ EQUITY

On May 9, 2023, the Company filed a Certificate of Change with the Nevada Secretary of State, effective May 10, 2023. Pursuant to the Certificate of Change, the Company effected a 1-for-6.25 reverse stock split of its issued and outstanding shares of common stock, whereby 64,627,246 outstanding shares of the Company’s common stock were exchanged for 10,340,506 shares of the Company’s common stock. In connection with the reverse stock split, the Company issued an additional 131,902 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 1,000,000,000 to 160,000,000. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

On October 17, 2023, the Company received a letter from the Listing Qualifications staff of The Nasdaq Stock Market LLC (“Nasdaq”) indicating that, based upon the closing bid price of the Company’s common stock for the last 30 consecutive business days, the Company no longer meets the requirement to maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 55450(a)(1) (the “Minimum Bid Price Requirement”).

The Company was initially provided with a 180 calendar day period, or until April 15, 2024, in which to regain compliance. In the event that the Company does not regain compliance within this 180-day period, the Company may be eligible to seek an additional 180 day compliance period if it meets the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and provides written notice to Nasdaq of its intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary.

On January 25, 2024, the Company filed a Certificate of Amendment to its Articles of Incorporation, as amended, with the Secretary of State of the State of Nevada to increase the number of authorized shares of the Company’s common stock from 160,000,000 to 1,000,000,000 shares (the “Charter Amendment”). The Charter Amendment was approved by the Company’s shareholders at a special meeting of shareholders held on January 25, 2024.

NOTE 10 – 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 \$6.25 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 24,000,000 to 160,000,000, as adjusted for the reverse split, 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 \$6.25 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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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	<u>\$ 14,700</u>	<u>\$ 1,050</u>

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% 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 \$25.00 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 8,000,000 to 24,000,000, as adjusted for the reverse split, 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 \$25.00 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	<u>\$ 26,250</u>	<u>\$ 5,250</u>

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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 11 – REVENUES

Disaggregation of Net Revenues

The Company's net product revenues are summarized below:

	Year Ended December 31,	
	2023	2022
Zembrace Symtouch	\$ 6,304	\$ —
Tosymra	1,464	—
Total product revenues	<u>\$ 7,768</u>	<u>\$ —</u>

All sales are generated in the United States.

Gross-to-Net Sales Accruals

We record gross-to-net sales accruals for chargebacks, rebates, sales and other discounts, and product returns, which are all customary to the pharmaceutical industry.

Our provision for gross-to-net allowances was \$2.9 million at December 31, 2023, \$0.6 million of which was recorded as a reduction to accounts receivable and \$2.3 million recorded as a component of accrued expenses.

NOTE 12 – ASSET PURCHASE AGREEMENT WITH UPSHER-SMITH

On June 30, 2023, the Company completed the acquisition of certain assets from Upsher Smith related to Zembrace SymTouch (sumatriptan injection) 3 mg ("Zembrace") and Tosymra (sumatriptan nasal spray) 10 mg ("Tosymra") products (such businesses collectively, the "Business") and certain inventory related to the Business for an aggregate purchase price of approximately \$26.5 million, including certain deferred payments and subject to customary adjustments (such transaction, the "USL Acquisition").

On June 30, 2023, in connection with the USL Acquisition, the Company and Upsher Smith entered into a Transition Services Agreement (the "Transition Services Agreement"), pursuant to which Upsher Smith will provide certain transition services to the Company for base fees equal to \$100,000 per month for the first six months, and \$150,000 per months for the seventh through ninth months, plus additional monthly fees for each service category totaling up to \$150,000 per month. The Company has amended the transitional services agreement with Upsher Smith so that Upsher Smith can continue to provide administrative services.

The Company has assumed certain obligations of Seller, including the payment of quarterly earn-out payments on annual net sales from the Business in the U.S. as follows: for Tosymra, 4% for net sales of \$0 to \$30 million, 7% of net sales of \$30 to \$75 million; 9% for net sales of \$75 to \$100 million; 12% for net sales of \$100 to \$150 million; and 15% for net sales greater than \$150 million. Earn-out payments with respect to Tosymra are payable until the expiration or termination of the product's Orange Book listed patent(s) with respect to the United States or, outside the United States, the expiration of the last valid claim covering the product in the relevant country of the territory. For Zembrace, earn-out payments on annual net sales in the U.S. are 3% for net sales of \$0 to \$30 million, 6% of net sales of \$30 to \$75 million; 12% for net sales of \$75 to \$100 million; 16% for net sales of greater than \$100 million. Such earn-out payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable earn-out rates shall be reduced by 90% percent with respect to Zembrace, and by 66.7% percent for Tosymra. Prior to Purchaser or a licensee filing an application for marketing authorization for either of the products in a permitted country outside the U.S., the parties will negotiate in good faith the earn-out payment rates annual net sales tiers that will apply for such country, based on the market opportunity for the product in such country. If the parties fail to agree, then the earn-out payment rates and annual net sales tiers described above will apply.

In addition, the Company has assumed the obligation to pay an additional 3% royalty on net sales of Tosymra, plus an additional 3% if a patent containing certain claims related to Tosymra issues in the U.S., for 15 years from the first commercial sale of Tosymra in the applicable country or for as long as the manufacture, use or sale of Tosymra in such country is covered by a valid claim of a licensed patent, and up to \$15 million per Tosymra product on the achievement of sales milestones.

As consideration for acquisition of the Business and certain product-related inventories, the Company paid approximately \$23.5 million in cash upfront. On the earlier of March 2024 and the completion of the transition services to be provided by Upsher Smith, as described above, the Company agreed to pay an additional deferred payment of \$3.0 million in cash, which is included in Accrued expenses and other current liabilities on the accompanying balance sheet. The following table summarizes the components of the purchase consideration (in thousands):

Purchase consideration	Amount
Closing cash consideration	\$ 22,174
Inventory adjustment payment liability	1,348
Deferred payment liability	3,000
Purchase price to be allocated	<u>\$ 26,522</u>

The USL Acquisition was accounted for as a business combination using the acquisition method, in accordance with the provisions of ASC 805, *Business Combinations* and ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The tangible and intangible assets acquired were recorded at their estimated fair values on the acquisition date, and the difference between the fair value of these assets and the purchase price has been recorded as goodwill. The purchase price allocation is based upon preliminary valuations and estimates and assumptions which are subject to change. As the Company receives additional information about facts and circumstances that existed at the acquisition date, the fair values of the acquired inventory and intangible assets may be adjusted, with the offset recorded to goodwill.

The following table represents the allocation of the purchase price to the assets acquired by the Company in the USL Acquisition recognized in the Company's consolidated balance sheets (in thousands):

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Preliminary purchase price allocation	Amount
Inventory	\$ 13,700
Prepaid expenses and other	1,757
Intangible assets, net	10,100
Goodwill	965
Fair value of assets acquired	<u>\$ 26,522</u>

The acquired inventory consists of Upsher Smith's raw materials, semi-finished goods, and finished goods inventory as of the Closing date. The fair value was determined based on the estimated selling price of the inventory, less the estimated total costs to complete, disposal effort and holding costs.

The \$1.0 million of goodwill arising from the USL Acquisition represents expected synergies from combining operations, intangible assets that do not qualify for separate recognition, and other factors, of which all is expected to be deductible for tax purposes, subject to any limitations.

Intangible assets eligible for recognition separate from goodwill were those that satisfied either the contractual or legal criterion or the separability criterion in the accounting guidance. The identifiable intangible assets acquired and their estimated useful lives for amortization are as follows (in thousands):

	Fair Value	Useful Life (years)
Developed technology - Tosymra	\$ 3,400	9
Developed technology - Zembrace	6,700	14
Total	<u>\$ 10,100</u>	

The developed technology intangible assets related to Zembrace and Tosymra includes the value associated with the acquired patents, customer relationships, and trademarks and trade names associated with the technology. The developed technology intangible assets were valued as composite assets under the premise that each asset is reliant on one another to generate cash flow, is not considered separable from the technology, and are assumed to have similar useful lives. The composite intangible assets were valued using a multi-period excess earnings method and are being amortized over their estimated useful lives using the straight-line method of amortization. The key assumptions used in estimating the fair values of intangible assets include forecasted financial information, the weighted average cost of capital, customer retention rates, and certain other assumptions.

The fair values assigned to the assets acquired are based on reasonable assumptions and estimates that market participants would use. Actual results may differ from these estimates and assumptions.

Supplemental Pro Forma Information

The following unaudited pro forma consolidated financial information reflects the results of operations of the Company for the year ended December 31, 2023 and 2022 as if the USL Acquisition had occurred as of January 1, 2022 and gives effect to transactions that are directly attributable to the acquisition. These amounts are based on financial information of the acquired business and are not necessarily indicative of what the Company's operating results would have been had the acquisition taken place on the date presented, nor is it indicative of the Company's future operating results. The net loss of USL acquisition is included in the Company's consolidated results since the date of acquisition. The revenue and net loss of the USL Acquisition business reflected in the consolidated statements the year ended December 31, 2023 would have been \$7.6 million and \$2.4 million, respectively.

	December 31 2023	December 31 2022
Net Product Sales	\$ 15,389	\$ 11,591
Net Loss	<u>\$ (119,905)</u>	<u>\$ (130,342)</u>

The pro forma information for all periods presented include additional amortization expense related to the fair value of the acquired intangible assets as if such assets were acquired on January 1, 2022. The pro forma financial information for the year ended December 31, 2022 also reflects an increase in Cost of Sales related to the preliminary acquisition-date fair value adjustment to inventory.

As described above, in connection with the USL Acquisition, the Company and Upsher Smith entered into a Transition Services Agreement with the Seller related to providing ongoing services associated with the assets acquired, such as procuring and selling migraine therapy products, providing accounting and billing services and collecting accounts receivable and paying trade payables. The Seller collected and will continue to collect cash on behalf of Tonix for revenue generated by sales of the assets acquired from June 30, 2023 through the transition period and the Seller is obligated to transfer cash generated by such sales to the Buyer.

The amount due to Upsher Smith for reimbursement of services performed under the transition services agreement was \$0.5 million as of December 31, 2023. The transition service fees were netted against the receivables collected of \$5.1 million and liabilities paid of \$4.4 million, including gross-to-net on behalf of the Company with the net amount due to the Company of \$0.2 million recorded within prepaid expenses and other on the consolidated balance sheet as of December 31, 2023.

NOTE 13 – ASSET PURCHASE AGREEMENT WITH HEALION

On February 2, 2023, the Company entered into an asset purchase agreement (the "Healion Asset Purchase Agreement") with Healion Bio Inc., ("Healion") 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 Healion Asset Purchase Agreement, the Company paid \$1.2 million to Healion. Because the Healion intellectual property was acquired prior to U.S. Food and Drug Administration (FDA) approval, the cash consideration totaling \$1.2 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.

**TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 14 – 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, 2023, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

NOTE 15 – 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, 2023, other than the upfront fee, no milestone payments have been accrued or paid in relation to this agreement.

NOTE 16 – LICENSE AGREEMENTS WITH COLUMBIA UNIVERSITY

On February 13, 2023, Tonix exercised an option to obtain an exclusive license from Columbia University (“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 Tonix and Columbia. As of December 31, 2023, other than the upfront fee, no payments have been accrued or paid in relation to this agreement.

NOTE 17 – SALE OF COMMON STOCK

December 2023 Financing

On December 20, 2023, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with certain institutional investors, pursuant to which the Company sold and issued (i) 25,343,242 shares of the Company’s common stock, (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 28,710,812 shares of common stock and (iii) Series C warrants to purchase up to 81,081,081 shares of common stock (the “Series C Warrants”), and (iv) Series D warrants to purchase up to 81,081,081 shares of common stock (the “Series D Warrants” and, together with the Series C Warrants, the “Common Warrants”). The securities sold in the offering were sold in fixed combinations as units. The offering price per share of common stock and accompanying Common Warrants was \$0.555, and the offering price per Pre-Funded Warrant and accompanying Common Warrants was \$0.5549. The offering closed on December 22, 2023, generating gross proceeds of approximately \$30.0 million, before deducting offering expenses of \$2.3 million payable by the Company. At the closing of the offering, 6,509,010 Pre-Funded Warrants were immediately exercised into shares of common stock for nominal proceeds.

The Pre-Funded Warrants have an exercise price of \$0.0001 per share, are immediately exercisable subject to certain ownership limitations, and can be exercised at any time until exercised in full. The Series C Warrants have an exercise price of \$0.555 per share, and are exercisable on the later of approval by the Company’s stockholders of (i) a proposal to approve the filing of an amendment to the Company’s Articles of Incorporation, increasing the number of authorized shares of common stock from 160,000,000 to 1,000,000,000 and (ii) a proposal to allow the Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 (the later of such events, the “Approval Date”) and will expire on the later of (a) 10 trading days following the Approval Date and (b) the earlier of (x) the two year anniversary of the Approval Date and (y) 10 trading days following the public announcement of the U.S. Food and Drug Administration’s (“FDA”) acknowledgement and acceptance of the New Drug Application (“NDA”) relating to the Company’s TNX-102 SL product candidate in patients with fibromyalgia. The Series D Warrants have an exercise price of \$0.85 per share and are exercisable beginning on the Approval Date through the five-year anniversary of the Approval Date.

Upon the closing of the offering, the Company determined that certain of the Common Warrants did not meet the criteria for equity classification due to the lack of sufficient authorized and unissued shares to settle the instruments. The Company has adopted a sequencing approach under ASC 815-40, Derivatives and Hedging - Contracts in Entity’s Own Equity to determine the classification of its contracts at issuance and at each subsequent reporting date, whereby shares are allocated based on the earliest issuance date of potentially dilutive instruments, with the earliest issuance date receiving the first allocation of shares. In the event of identical issuance dates, shares are then allocated beginning with instruments with the latest maturity date first. Pursuant to this sequencing approach, the Company’s authorized and unissued shares were applied to the Pre-Funded Warrants and the Common Warrants in the following order: (i) the Pre-Funded Warrants, (ii) the Series D Warrants, and (iii) the Series C Warrants. Based on this analysis, the Company determined that the authorized shares are sufficient to settle the remaining Pre-Funded Warrants and 50,933,271 Series D Warrants and were therefore classified in equity. The remaining 30,147,810 Series D Warrants and the Series C Warrants associated with the deficit shares were classified as liabilities and are accounted for at fair value.

The \$30.0 million in gross proceeds received by the Company were first allocated to the Series C Warrants and the liability-classified Series D Warrants at their respective fair values of approximately \$14.4 million and \$8.1 million, respectively. The residual proceeds of approximately \$7.5 million were allocated to the shares of common stock, the Pre-Funded Warrants, and the equity-classified Series D Warrants on a relative fair value basis. The issuance costs totaling \$2.3 million were allocated between the equity and liability-classified instruments on a relative fair value basis. Issuance costs of \$1.4 million allocated to the shares, the Pre-Funded Warrants, and the equity-classified Series D Warrants were recognized as a discount to the proceeds allocated to the equity-classified instruments. Issuance costs of \$0.9 million were allocated to the liability-classified Series D Warrants and the Series C Warrants and expensed within Selling, general and administrative expense on the consolidated statements of operations.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The liability-classified Series D Warrants and all of the Series C Warrants are presented within non-current liabilities on the consolidated balance sheets as of December 31, 2023, and will be adjusted to fair value at each subsequent balance sheet date until the warrants are reclassified to equity or settled. Changes in the fair value of the liability-classified warrants are recognized as a component of other income, net in the consolidated statement of operations.

On January 25, 2024, the Company's stockholders approved the proposal to file an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 160,000,000 to 1,000,000,000.

September 2023 Financing

On September 28, 2023, the Company sold 4,050,000 shares of common stock; pre-funded warrants to purchase up to 4,950,000 shares of common stock, and accompanying Series A warrants to purchase up to 9,000,000 shares of common stock with an exercise price of \$0.50 per share and expiring five years from date of issuance, and Series B warrants to purchase up to 9,000,000 shares of common stock with an exercise price of \$0.50 per share and expiring one year from date of issuance in a public offering, which closed on October 3, 2023. The offering price per share of common stock and accompanying warrants was \$0.50, and the offering price per share of pre-funded warrant and accompanying warrants was \$0.4999.

The Company incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. The Company received net proceeds of approximately \$4.0 million, after deducting the underwriting discount and other offering expenses.

July 2023 Financing

On July 27, 2023, the Company sold 2,530,000 shares of common stock; pre-funded warrants to purchase up to 4,470,000 shares of common stock and accompanying common warrants to purchase up to 7,000,000 shares of common stock with an exercise price of \$1.00 per share in a public offering that closed on August 1, 2023. The offering price per share of common stock and accompanying common warrant was \$1.00, and the offering price per share of pre-funded warrant and accompanying common warrant was \$0.9999.

The Company incurred offering expenses of approximately \$0.7 million, including placement agent fees of approximately \$0.5 million. The Company received net proceeds of approximately \$6.3 million, after deducting the underwriting discount and other offering expenses.

2022 Lincoln Park Transaction

On August 16, 2022, the Company entered into an equity line of credit with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park agreed to purchase up to \$50,000,000 of the Company's common stock (subject to certain limitations) from time to time. 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. The Company issued 100,000 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of the Company's common stock. 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 equity line of credit.

During the year ended December 31, 2023, the Company sold 0.1 million shares of common stock under the equity line of credit with Lincoln Park, for net proceeds of approximately \$0.4 million. During the year ended December 31, 2022, the Company sold 0.2 million shares of common stock under the equity line of credit with Lincoln Park, for net proceeds of approximately \$0.5 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 14,546 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 0.5 million shares of common stock under the Purchase Agreement with Lincoln Park, for net proceeds of approximately \$8.7 million. No sales occurred in 2023.

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 0.5 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 0.5 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.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

At-the-Market Offerings

On April 8, 2020, the Company entered into a sales agreement with AGP pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$320.0 million in at-the-market offerings (“ATM”) sales at prevailing market prices at the time of the sale, and, as a result, prices will vary. AGP receives a 3% commission on each ATM sale under the Sales Agreement.

During the year ended December 31, 2023, the Company sold approximately 1.0 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$3.0 million. During the year ended December 31, 2022, the Company sold approximately 9.1 million shares of common stock under the Sales Agreement, for net proceeds of approximately \$85.3 million.

Stock Repurchases

During the first quarter of 2023, the Company has repurchased 2,512,044 of its shares of common stock outstanding under the 2022 share repurchase program for up to \$12.5 million at prices ranging from \$2.75 to \$8.61 per share for a gross aggregate cost of approximately \$12.5 million. In addition, the Company incurred expenses of \$0.3 million.

In January 2023, the Board of Directors approved a new 2023 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. During the first quarter of 2023, the Company has repurchased 160,000 of our shares of common stock outstanding under the new 2023 share repurchase program at \$7.12 per share for a gross aggregate cost of \$1.1 million. No additional repurchases have occurred since the first quarter of 2023.

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.

NOTE 18 – STOCK-BASED COMPENSATION

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”).

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 50,000 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, 2023, 1,071,599 options were available for future grants under the Amended and Restated 2020 Plan.

General

A summary of the stock option activity and related information for the Plans for the year ended December 31, 2023 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2021	101,754	\$ 487.63	8.83	\$ —
Grants	298,657	\$ 67.46	—	—
Exercised	—	—	—	—
Forfeitures or expirations	(7,768)	8,238.07	—	—
Outstanding at December 31, 2022	392,643	\$ 334.08	8.70	\$ —
Grants	1,019,130	\$ 4.64	—	\$ —
Exercised	—	—	—	—
Forfeitures or expirations	(36,234)	\$ 345.92	—	—
Outstanding at December 31, 2023	1,375,539	\$ 89.62	8.75	\$ —
Exercisable at December 31, 2023	259,991	\$ 381.80	7.51	\$ —

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The weighted average fair value of options granted during the year ended December 31, 2023, and December 31, 2022 was \$3.99 per share and \$32.81, 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, 2023 and 2022 were as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Risk-free interest rate	3.42% to 4.35%	1.67% to 3.05%
Expected term of option	5.0 to 10 years	5.5 to 10 years
Expected stock price volatility	122.19% - 142.72%	120.32% - 133.22%
Expected dividend yield	0.0	0.0

The risk-free interest rate is based on the yield of Daily U.S. Treasury Yield Curve Rates with terms equal to the expected term of the options as of the grant date. The expected term of options is determined using the simplified method, as provided in an SEC Staff Accounting Bulletin, and the expected stock price volatility is based on the Company's historical stock price volatility.

Stock-based compensation expense relating to options granted of \$9.3 million, of which \$6.4 million and \$2.9 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2023. 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.

As of December 31, 2023, the Company had approximately \$6.1 million of total unrecognized compensation cost related to non-vested awards granted under the Plans, which the Company expects to recognize over a weighted average period of 1.70 years.

Employee Stock Purchase Plans

On May 6, 2022, the Company's stockholders approved the Tonix Pharmaceuticals Holdings Corp. 2022 Employee Stock Purchase Plan. (the "2022 ESPP"), which was replaced by the Tonix Pharmaceuticals Holdings Corp. 2023 Employee Stock Purchase Plan (the "2023 ESPP", and together with the 2022 ESPP, the "ESPP Plans"), which was approved by the Company's stockholders on May 5, 2023.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 800,000 shares of the Company's common stock. Under the 2023 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 2023 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 2023 ESPP, subject to the statutory limit under the Code. As of December 31, 2023, 800,000 shares were available for future sales under the 2023 ESPP.

The ESPP Plans are considered compensatory plans with the related compensation cost expensed over the six-month offering period. For the year ended December 31, 2023 and 2022, \$34,000 and \$46,000, respectively, was expensed. In January 2022, 646 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. In January 2023, 14,999 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. As of December 31, 2023, approximately \$44,000 of employee payroll deductions have accumulated and have been recorded in accrued expenses. In January 2024, 66,359 shares that were purchased as of December 31, 2023, under the 2022 ESPP, were issued. Accordingly, during the first quarter of 2024, approximately \$24,000 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 \$20,000 was returned to the employees.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 19 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2023:

Exercise Price	Number Outstanding	Expiration Date
\$ 0.0001	22,201,802	N/A
\$ 0.555	81,081,081	December 2025
\$ 0.85	81,081,081	December 2028
\$ 0.50	18,000,000	August 2028
\$ 1.00	7,000,000	August 2028
\$ 100.00	125	November 2024
\$ 114.00	618	February 2025
	<u>209,364,707</u>	

In connection with the July 2023 Financing, the Company issued 4,470,000 prefunded common warrants with an exercise price of \$0.0001. All prefunded common warrants were exercised during the year ended December 31, 2023. Additionally, the Company issued common warrants to purchase up to an aggregate of 7,000,000 shares of the Company's common stock. The common warrants are exercisable at \$1.00 per share, expire five years from the date of issuance.

In connection with the September 2023 Financing, the Company issued 4,950,000 prefunded common warrants with an exercise price of \$0.0001. All prefunded common warrants were exercised during the year ended December 31, 2023. Additionally, the Company issued common warrants to purchase up to an aggregate of 18,000,000 shares of the Company's common stock. The common warrants are exercisable at \$0.50 per share, expire five years from the date of issuance.

In connection with the December 2023 Financing, the Company issued 28,710,812 prefunded common warrants with an exercise price of \$0.0001. Only 6,509,010 prefunded common warrants were exercised during the year ended December 31, 2023. Subsequent to December 31, 2023, 15,043,244 prefunded common warrants were exercised. Additionally, the Company issued Series C common warrants to purchase up to an aggregate of 81,081,081 shares of the Company's common stock. The common warrants are exercisable at \$0.555 per share, expire two years from the date of issuance. Additionally, the Company issued Series D common warrants to purchase up to an aggregate of 81,081,081 shares of the Company's common stock. The common warrants are exercisable at \$0.85 per share, expire five years from the date of issuance.

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

For the year ended December 31, 2023, 2,453 warrants with an exercise price of \$7,000.00 expired.

On April 1, 2024, the Company issued 3,900,000 pre-funded common warrants with an exercise price of \$0.0001. Additionally, the Company issued Series E warrants to purchase up to 14,666,666 shares of common stock with an exercise price of \$0.33 per share and expiring five and a half years from date of issuance.

Additionally, the Company entered into warrant amendments with certain holders of its Common Warrants. The exercise price of each Existing Warrant will be amended to \$0.33 upon approval by the Company's stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635, or as otherwise provided in the Amendment if stockholder approval is not obtained by October 1, 2024. Upon stockholder approval, the termination date for Common Warrants to purchase up to an aggregate of 6,950,000 shares will be amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 8,900,000 shares will be April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 8,900,000 shares will be April 1, 2029; the termination date for Series C Warrants to purchase up to an aggregate of approximately 34,823,928 shares will be the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by the Company to the Series C Warrant holder of the Company's public announcement of the FDA's acknowledgement and acceptance of the Company's NDA relating to TNX-102 SL in patients with Fibromyalgia; the termination date for Series D Warrants to purchase up to an aggregate of approximately 34,823,928 shares will be April 1, 2029. The other terms of the Existing Warrants will remain unchanged. If stockholder approval is not obtained on or by October 1, 2024, then the Company has agreed to automatically amend the exercise price of the Existing Warrants to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of the Common Stock on October 1, 2024 if and only if the Minimum Price is below the then current exercise price.

NOTE 20 – 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, 2023, the Company has right-of-use assets of \$0.8 million and a total lease liability for operating leases of \$0.9 million of which \$0.6 million is included in long-term lease liabilities and \$0.3 million is included in current lease liabilities. During the year ended December 31, 2023, the Company exited a lease which had a right-of-use assets, net of \$0.2 million and a total lease liability for operating leases of \$0.2 million.

At December 31, 2023, 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,	
2024	\$ 305
2025	299
2026	142
2027	139
2028 and beyond	<u>107</u>
	992
Included interest	<u>(90)</u>
	<u>\$ 902</u>

During the year ended December 31, 2023, the Company entered into new operating leases and lease amendments, resulting in the Company recognizing an additional operating lease liability of approximately \$898,000 based on the present value of the minimum rental payments. The Company also recognized a corresponding increase to ROU assets of approximately \$898,000, which represents a non-cash operating activity.

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 operating activity.

Other information related to leases is as follows:

Operating lease expense was \$0.6 million for both the years ended December 31, 2023 and 2022.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Other information related to leases is as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow from operating leases (in thousands)	\$ 556	\$ 598
Weighted Average Remaining Lease Term		
Operating leases	3.78 years	2.20 years
Weighted Average Discount Rate		
Operating leases	4.53%	2.19%

NOTE 21 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately \$23.2 million at December 31, 2023 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 \$1.3 million and \$0.9 million for the year ended December 31, 2023 and 2022, respectively, for contributions under the 401(k) Plan.

NOTE 22 – INCOME TAXES

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

	Year ended December 31, 2023	2022
Foreign	\$ (98,204)	\$ (88,478)
Domestic	(18,454)	(21,740)
Total	<u>\$ (116,658)</u>	<u>\$ (110,218)</u>

In 2023, the foreign losses are primarily comprised of \$98.4 million related to the Irish operations netted against \$0.2 million related to Canada operations of Tonix International Holding. In 2022, the foreign losses are primarily comprised of the \$86.7 million related to the Irish operations and \$1.5 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, 2023	2022
Statutory federal income tax	(21.0)%	(21.0)%
Change in valuation allowance	11.7%	9.6%
Foreign loss not subject to income tax	7.2%	7.0%
Attribute reduction from control change	0.9%	4.0%
Other	1.2%	0.4%
Income Tax Provision	<u>0.0%</u>	<u>0.0%</u>

Deferred tax assets (liabilities) and related valuation allowance as of December 31, 2023 and 2022 were as follows (in thousands):

	December 31, 2023	2022
Deferred tax assets/(liabilities):		
Net operating loss carryforward	\$ 32,997	\$ 21,642
Stock-based compensation	10,276	7,353
Other	2,211	1,997
Total deferred assets	45,484	30,992
Valuation allowance	(45,484)	(30,992)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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, 2023 have been reduced to \$0.0 million to reflect IRC section 383 ownership changes through December 31, 2023 and the resulting inability to utilize a portion of the R&D credit prior to its expiration.

TONIX PHARMACEUTICALS HOLDING CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

At December 31, 2023, the Company has \$263.4 million of Ireland NOL carryforwards that do not expire. As of December 31, 2023, the Company's Federal NOL carryforwards of \$0.2 million, which do not expire. The Company has New Jersey NOL carryforwards of \$0.2 million, Massachusetts NOL carryforwards of \$0.01 million, and Montana NOL carryforwards of \$0.05 million, all of which expire in 20 years, are subject to annual limitations in their use in accordance with IRC section 382. The NOL carryforwards at December 31, 2023 have been reduced to reflect IRC section 382 ownership changes through December 31, 2023 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, 2023. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth. As such, the Company has determined that it is not more likely than not that the deferred tax assets will be realized and accordingly, has provided a full valuation allowance against its gross deferred tax assets. The increase/(decrease) in the valuation allowance for the years ended December 31, 2023 and 2022 were \$14.5 million, and \$9.5 million respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2023 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, 2023, the Company's tax returns remain open and subject to examination by the tax authorities for the tax years 2020 and after.

NOTE 23 – SUBSEQUENT EVENTS

On January 25, 2024, the Company filed a Certificate of Amendment to its Articles of Incorporation, as amended, with the Secretary of State of the State of Nevada to increase the number of authorized shares of the Company's common stock from 160,000,000 to 1,000,000,000 shares. The Amendment was approved by the Company's shareholders at a special meeting of shareholders held on January 25, 2024.

On February 27, 2024, the Company granted options to purchase an aggregate of 4,261,104 shares of the Company's common stock to employees with an exercise price of \$0.37, 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 2,860,680 shares of the Company's common stock to certain employees with an exercise price of \$0.46, with a term of ten years, vesting 1/3 on the first anniversary and 1/36th each month thereafter for 24 months. Finally, the Company granted options to purchase 1,309,911 shares of the Company's common stock to an employee with an exercise price of \$0.37, with a term of ten years, vesting in 6 months.

On March 28, 2024, the Company sold 10,766,666 shares of common stock, pre-funded warrants to purchase up to 3,900,000 shares of common stock, and accompanying Series E warrants to purchase up to 14,666,666 shares of common stock with an exercise price of \$0.33 per share and expiring five and a half years from date of issuance in a public offering, which closed on April 1, 2024. The offering price per share of common stock was \$0.30, accompanying warrants was \$0.33, and the offering price per share of pre-funded warrants was \$0.2999.

The Company incurred offering expenses of approximately \$0.5 million, including placement agent fees of approximately \$0.3 million. The Company received net proceeds of approximately \$3.9 million, after deducting the underwriting discount and other offering expenses.

Additionally, the Company entered into warrant amendments with certain holders of its Common Warrants. The exercise price of each Existing Warrant will be amended to \$0.33 upon approval by the Company's stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635, or as otherwise provided in the Amendment if stockholder approval is not obtained by October 1, 2024. Upon stockholder approval, the termination date for Common Warrants to purchase up to an aggregate of 6,950,000 shares will be amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 8,900,000 shares will be April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 8,900,000 shares will be April 1, 2029; the termination date for Series C Warrants to purchase up to an aggregate of approximately 34,823,928 shares will be the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by the Company to the Series C Warrant holder of the Company's public announcement of the FDA's acknowledgement and acceptance of the Company's NDA relating to TNX-102 SL in patients with Fibromyalgia; the termination date for Series D Warrants to purchase up to an aggregate of approximately 34,823,928 shares will be April 1, 2029. The other terms of the Existing Warrants will remain unchanged. If stockholder approval is not obtained on or by October 1, 2024, then the Company has agreed to automatically amend the exercise price of the Existing Warrants to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of the Common Stock on October 1, 2024 if and only if the Minimum Price is below the then current exercise price.

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.

The acquisition of marketed products from Upsher Smith has had a material impact on the Company's internal control over financial reporting as we are now required and have implemented controls related to revenue and inventory management. Management established controls to mitigate the risk over financial reporting as it relates to the services provided by Upsher Smith under the transition services agreement.

Except as otherwise described above, there was no change in our internal control over financial reporting that occurred during the year ended December 31, 2023, that has materially affected, or is 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	66	President, CEO and Chairman of the Board of Directors
Richard Bagger	64	Director
Margaret Smith Bell	64	Director
David Grange	76	Director
Adeoye Olukotun	79	Director
Newcomb Stillwell	67	Director
Carolyn Taylor	64	Director
James Treco	68	Lead Director
Jessica Morris	46	Chief Operating Officer
Bradley Saenger	50	Chief Financial Officer and Treasurer
Gregory Sullivan	58	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 Plumblinc 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 PPD 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 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 is a member of the board of directors of Arrowhead Pharmaceuticals. Dr. Olukotun's extensive medical background and experience in the pharmaceutical industry was instrumental in his selection as a member of our Board.

Newcomb Stillwell became a director in March 2023. Mr. Stillwell has held positions of varying responsibility at the law firm of Ropes & Gray LLP from 1984 to 2021, including, most recently, as co-managing partner of the Ropes & Gray Boston office. Mr. Stillwell graduated from Harvard Law School and earned an A.B. from Princeton University. Mr. Stillwell's extensive advisory experience on numerous transactions in the life science and healthcare sectors was instrumental in his selection as a member of the 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, Newcomb Stillwell, Carolyn Taylor and James Treco are each an independent director as defined in the Marketplace Rules of The NASDAQ Stock Market.

Board Diversity Matrix

The following matrix is provided in accordance with applicable Nasdaq listing requirements:

Board Diversity Matrix as of March 18, 2024				
Total Number of Directors	8			
Part I: Gender Identity	Female	Male	Non-Binary	Did Not Disclose Gender
Directors	2	5	—	1
Part II: Demographic Background				
African American or Black	—	1	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	—	—	—
Hispanic or Latinx	—	—	—	—
White	2	5	—	1
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+	1			
Did Not Disclose Demographic Background	1			

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 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 has been held by Mr. Treco since March 2021. 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, 2023, the Board held 13 meetings, the Audit Committee held eight meetings, the Compensation Committee held six meetings and the Nominating and Corporate Governance Committee held five meetings. The Board and Board committees also approved certain actions by unanimous written

consent.

Each of the directors attended at least 75% of the aggregate of the total number of meetings of our Board (held during the period for which such directors served on the Board). Each of the directors attended at least 75% of the total number of meetings of all committees of our Board on which the director served (during the periods for which the director served on such committee or committees). Dr. Lederman was the only member of the Board who attended last year's annual meeting of stockholders. The Company does not have a formal policy requiring members of the Board to attend our annual meetings.

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		*	
Newcomb Stillwell	*		
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, Margaret Smith Bell and Newcomb Stillwell. 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, 2023. Our Board has adopted a written charter for the Audit Committee, a copy of which is posted under the “Investors” tab under “Governance” on our website, which is located at www.tonixpharma.com.

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. Our Compensation Committee has engaged Aon plc, an independent executive compensation consultant, to provide guidance with respect to the development and implementation of our compensation programs. Our Board has adopted a written charter for the Compensation Committee, a copy of which is posted under the “Investors” tab under “Governance” on our website, which is located at www.tonixpharma.com.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Richard Bagger, Chair of the Committee, David Grange, Newcomb Stillwell 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, 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. 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. Our Board has adopted a written charter for the Nominating and Corporate Governance Committee, a copy of which is posted under the “Investors” tab under “Governance” on our website, which is located at www.tonixpharma.com.

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.

Prohibition Against Certain Transactions

All of our employees and directors are prohibited from hedging or pledging Tonix stock, or engaging in short sales or trading in standardized options under our Insider Trading Policy.

Insider Trading Policies and Procedures

We have adopted a Policy on Insider Trading and a Policy Regarding Special Trading Procedures. These policies and procedures apply to all of our directors, officers and employees.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees which can be found on our website at <https://ir.tonixpharma.com/corporate-governance/governance-documents>.

Involvement in Certain Legal Proceedings

Our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;
4. being found by a court of competent jurisdiction in a civil action, the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a Federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
5. being subject of, or a party to, any Federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any Federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

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

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 2023 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 2023, 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 2023 and 2022.

Name & Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾⁽²⁾	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Seth Lederman	2023	675,000	—	—	1,375,065	—	—	—	2,050,065
Chief Executive Officer	2022	675,000	355,000	—	3,550,167	—	—	—	4,580,167
Jessica Morris	2023	475,000	179,550	—	274,049	—	—	—	928,599
Chief Operations Officer	2022	455,175	155,000	—	781,037	—	—	—	1,391,212
Bradley Saenger	2023	465,000	175,770	—	264,143	—	—	—	904,913
Chief Financial Officer	2022	445,400	152,000	—	639,030	—	—	—	1,236,430
Gregory Sullivan	2023	480,000	181,440	—	290,558	—	—	—	951,998
Chief Medical Officer	2022	461,120	130,000	—	887,541	—	—	—	1,478,661

(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 18 to our audited financial statements.

(2) In lieu of a cash award, Dr. Lederman’s bonus shall be paid in the form of a stock option award granted pursuant to the 2020 Plan, with 100% of such options vesting on the six-month anniversary of issuance, expiring 10 years from date of issuance and having an exercise price per share equal to the closing price of the Company’s common stock on February 27, 2024.

Grants of Plan-Based Awards in Fiscal 2023

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, 2023.

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	2/23/2023	112,000	4.57	465,003
	2/23/2023	112,000	5.71 ⁽²⁾	459,499
Bradley Saenger	2/23/2023	32,000	4.57	137,840
	2/23/2023	32,000	5.71 ⁽²⁾	136,209
Jessica Morris	2/23/2023	33,200	4.57	132,858
	2/23/2023	33,200	5.71 ⁽²⁾	131,285
Gregory Sullivan	2/23/2023	35,200	4.57	146,144
	2/23/2023	35,200	5.71 ⁽²⁾	144,414

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

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

Outstanding Equity Awards at December 31, 2023

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2023.

Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$/Sh)	Option Expiration Date
Seth Lederman	1	—	\$ 3,176,000.00	2/11/2024
	1	—	\$ 1,974,000.00	6/17/2024
	1	—	\$ 1,336,000.00	10/29/2024
	1	—	\$ 1,190,000.00	2/25/2025
	1	—	\$ 1,190,000.00	2/25/2025
	1	—	\$ 1,006,000.00	2/9/2026
	—	1(1)	\$ 1,006,000.00	2/9/2026
	1	—	\$ 110,000.00	3/1/2027
	8	—	\$ 68,000.00	2/13/2028
	8	—	\$ 85,000.00	2/13/2028
	12	—	\$ 3,780.00	2/26/2029
	12	—	\$ 4,720.00	2/26/2029
	65	—	\$ 4,100.00	5/6/2029
	65	—	\$ 5,120.00	5/6/2029
	600	—	\$ 80.00	2/25/2030
	600	—	\$ 100.00	2/25/2030
	10,000	—	\$ 154.00	5/4/2030
	10,000	—	\$ 192.00	5/4/2030
	14,174	826(2)	\$ 244.00	2/23/2031
	14,174	826(2)	\$ 306.00	2/23/2031
	15,284	9,716(3)	\$ 41.38	2/15/2032
	2,500	22,500(3)	\$ 82.75	2/15/2032
	2,500	22,500(3)	\$ 124.06	2/15/2032
	2,500	22,500(3)	\$ 165.44	2/15/2032
	—	112,000(4)	\$ 4.57	2/23/2033
	—	112,000(4)	\$ 5.71	2/23/2033
Jessica Morris	1	—	\$ 3,176,000.00	2/11/2024
	1	—	\$ 1,974,000.00	6/17/2024
	1	—	\$ 1,336,000.00	10/29/2024
	1	—	\$ 1,190,000.00	2/25/2025
	1	—	\$ 1,006,000.00	2/9/2026
	—	1(1)	\$ 1,006,000.00	2/9/2026
	1	—	\$ 110,000.00	3/1/2027
	3	—	\$ 68,000.00	2/13/2028
	3	—	\$ 85,000.00	2/13/2028
	3	—	\$ 3,780.00	2/26/2029
	3	—	\$ 4,720.00	2/26/2029
	15	—	\$ 4,100.00	5/6/2029
	15	—	\$ 5,120.00	5/6/2029
	120	—	\$ 80.00	2/25/2030
	120	—	\$ 100.00	2/25/2030
	1,800	—	\$ 154.00	5/4/2030
	1,800	—	\$ 192.00	5/4/2030
	2,550	150(2)	\$ 244.00	2/23/2031
	2,550	150(2)	\$ 306.00	2/23/2031
	3,364	2,136(3)	\$ 41.38	2/15/2032
	550	4,950(3)	\$ 82.75	2/15/2032
	550	4,950(3)	\$ 124.06	2/15/2032
	550	4,950(3)	\$ 165.44	2/15/2032
	—	33,200(4)	\$ 4.57	2/23/2033
	—	33,200(4)	\$ 5.71	2/23/2033
Bradley Saenger	1	—	\$ 1,974,000.00	6/17/2024
	1	—	\$ 1,336,000.00	10/29/2024
	1	—	\$ 1,190,000.00	2/25/2025
	1	—	\$ 1,006,000.00	2/9/2026
	—	1(1)	\$ 484,000.00	5/27/2026

	1	—	\$	484,000.00	5/27/2026
	1	—	\$	110,000.00	3/1/2027
	3	—	\$	68,000.00	2/13/2028
	3	—	\$	85,000.00	2/13/2028
	3	—	\$	3,780.00	2/26/2029
	3	—	\$	4,720.00	2/26/2029
	15	—	\$	4,100.00	5/6/2029
	15	—	\$	5,120.00	5/6/2029
	120	—	\$	80.00	2/25/2030
	120	—	\$	100.00	2/25/2030
	1,800	—	\$	154.00	5/4/2030
	1,800	—	\$	192.00	5/4/2030
	2,550	150(2)	\$	244.00	2/23/2031
	2,550	150(2)	\$	306.00	2/23/2031
	2,750	1,750(3)	\$	41.38	2/15/2032
	450	4,050(3)	\$	82.75	2/15/2032
	450	4,050(3)	\$	124.06	2/15/2032
	450	4,050(3)	\$	165.44	2/15/2032
	—	32,000(4)	\$	4.57	2/23/2033
	—	32,000(4)	\$	5.71	2/23/2033
Gregory Sullivan					
	1	—	\$	1,974,000.00	6/17/2024
	1	—	\$	1,336,000.00	10/29/2024
	1	—	\$	1,190,000.00	2/25/2025
	1	—	\$	1,006,000.00	2/9/2026
	—	1(1)	\$	1,006,000.00	2/9/2026
	1	—	\$	110,000.00	3/1/2027
	4	—	\$	68,000.00	2/13/2028
	4	—	\$	85,000.00	2/13/2028
	5	—	\$	3,780.00	2/26/2029
	5	—	\$	4,720.00	2/26/2029
	22	—	\$	4,100.00	5/6/2029
	22	—	\$	5,120.00	5/6/2029
	196	—	\$	80.00	2/25/2030
	196	—	\$	100.00	2/25/2030
	2,500	—	\$	154.00	5/4/2030
	2,500	—	\$	192.00	5/4/2030
	3,550	201(2)	\$	244.00	2/23/2031
	3,550	201(2)	\$	306.00	2/23/2031
	3,824	2,427(3)	\$	41.38	2/15/2032
	625	5,625(3)	\$	82.75	2/15/2032
	625	5,625(3)	\$	124.06	2/15/2032
	625	5,625(3)	\$	165.44	2/15/2032
	—	35,200(4)	\$	4.57	2/23/2033
	—	35,200(4)	\$	5.71	2/23/2033

(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 \$1,200,000.00, \$1,400,000.00 and \$1,600,000.00 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 23, 2022, 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 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.

(4) The shares subject to this stock option vested as to 1/3 of the shares on February 23, 2024, with the remaining shares vesting on an equal monthly basis over the following 24 months.

Option Exercises and Stock Vested

No options were exercised by any of the named executive officers and no named executive officers held restricted stock units during the fiscal year ended December 31, 2023.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2023.

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⁾	1,375,539	\$ 89.62	1,805,240
Equity compensation plans not approved by security holders	—	—	—
Total	<u>1,375,539</u>	<u>\$ 89.62</u>	<u>1,805,240</u>

(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, 2023, 1,071,599 shares of common stock were available for issuance under the Amended and Restated 2020 Plan and 733,641 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, 2024, the base salary is \$675,000. The Lederman 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 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. 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 indirectly, at least 60% of the combined voting power of the successor entity's outstanding voting securities immediately after the transaction, and
 - after which no person or group beneficially owns voting securities representing 40% or more of the combined voting power of the Company or its successor; provided, however, that no person or group is treated as beneficially owning 40% or more of combined voting power of the Company or its successor solely as a result of the voting power held in the Company prior to the consummation of the transaction.

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

Employment Agreement with Gregory Sullivan

On June 3, 2014, the Company entered into an employment agreement (the "Sullivan Agreement") with Dr. Gregory Sullivan 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, 2024, the base salary is \$499,200. 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, Dr. 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 Mr. Saenger under the Saenger Agreement was \$483,600 per annum as of January 1, 2024. 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), Mr. 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 Mr. 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, Mr. 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 Operating Officer. The base salary for Ms. Morris under the Morris Agreement was \$494,000 per annum as of January 1, 2024. 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), Ms. 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 Ms. 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, Ms. 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

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 \$75,000. In addition, during 2023, each of our non-employee directors received stock options to purchase shares of our common stock valued at \$27,475 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 2023 for services to our Company.

Name	Cash		Option Awards \$(1)	Total (\$)
	Compensation (\$)			
Richard Bagger	\$ 55,000	\$ 27,475	\$	82,475
Margaret Smith Bell	\$ 55,000	\$ 27,475	\$	82,475
David Grange	\$ 55,000	\$ 27,475	\$	82,475
Adeoye Olukotun	\$ 55,000	\$ 27,475	\$	82,475
Newcomb Stillwell	\$ 43,542	\$ 69,511	\$	113,053
Carolyn Taylor	\$ 55,000	\$ 27,475	\$	82,475
James Treco (2)	\$ 75,000	\$ 27,475	\$	102,475
Total:	<u>\$ 393,542</u>	<u>\$ 234,361</u>	<u>\$</u>	<u>627,903</u>

(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 27, 2024:

- 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)
<i>5% Holders</i>			
Sabby Management, LLC	Common Stock	5,205,348(3)	6.4
<i>Directors and Executive Officers</i>			
Seth Lederman	Common Stock	176,003(4)	*
Jessica Morris	Common Stock	42,631(5)	*
Bradley Saenger	Common Stock	40,247(6)	*
Gregory Sullivan	Common Stock	48,916(7)	*
Richard Bagger	Common Stock	22,008(8)	*
Margaret Smith Bell	Common Stock	22,037(9)	*
David Grange	Common Stock	22,008(10)	*
Adeoye Olukotun	Common Stock	22,032(11)	*
Newcomb Stillwell	Common Stock	22,880(12)	*
Carolyn Taylor	Common Stock	21,446(13)	*
James Treco	Common Stock	22,274(14)	*
Officers and Directors as a Group (11 persons)	Common Stock	462,482(15)	*%

* Denotes less than 1%

(2) Percentage based upon 80,882,754 shares of common stock issued and outstanding as of March 27, 2024, including 7,158,558 shares underlying prefunded warrants.

(3) Based solely on a Schedule 13G filed with the SEC on January 3, 2024, by Sabby Volatility Warrant Master Fund Ltd., Sabby Management LLC and Hal Mintz share voting and dispositive power over these shares. The mailing address for Sabby Management, LLC and Mr. Mintz is 115 Hidden Hills Drive, Spicewood TX 78669. The mailing address for Sabby Volatility Warrant Master Fund Ltd. is 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands.

(4) Includes 171,557 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 2 shares of common stock owned by Lederman & Co, 1 share of common stock owned by L&L, 1 share 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, 3,878 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 42,630 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(6) Includes 40,148 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(7) Includes 48,419 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.

(8) Includes 21,957 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(9) Includes 22,009 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(10) Includes 22,008 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(11) Includes 22,005 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(12) Includes 22,880 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(13) Includes 21,446 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days

(14) Includes 22,223 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days

(15) Includes 457,282 shares of common stock underlying options which are currently exercisable or vested or become exercisable within 60 days, 2 shares of common stock owned by Lederman & Co, 1 share of common stock owned by L&L, 1 share of common stock owned by Targent, 1 share of common stock owned by Leder Labs, 1 share of common stock owned by Starling, 3,878 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 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, 2023 and 2022, including review of our interim financial statements as well as registration statement filings with the SEC and comfort letters issued to underwriters were \$522,533 and \$383,880, 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, 2023 and 2022.

(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, 2023 and 2022.

(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
<u>3.01</u>	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.
<u>3.02</u>	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.
<u>3.03</u>	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.
<u>3.04</u>	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.
<u>3.05</u>	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.
<u>3.06</u>	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.
<u>3.07</u>	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.
<u>3.08</u>	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.
<u>3.09</u>	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.
<u>4.01</u>	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.
<u>4.02</u>	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.
<u>4.03</u>	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.
<u>4.04</u>	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.
<u>4.05</u>	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.
<u>4.06</u>	Description of Registrant’s Securities, filed herewith.
<u>10.01</u>	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.*
<u>10.02</u>	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.*
<u>10.03</u>	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.
- [10.37](#) Asset Purchase Agreement, dated as of June 23, 2023, by and among Upsher-Smith Laboratories, LLC, Tonix Medicines, Inc. and Tonix Pharmaceuticals Holding Corp., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 26, 2023, and incorporated herein by reference.
- [10.38](#) Transition Services Agreement, dated as of June 30, 2023, by and among Upsher-Smith Laboratories, LLC and Tonix Medicines Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 3, 2023, and incorporated herein by reference.
- [10.39](#) Placement Agent Agreement, dated July 27, 2023, among Tonix Pharmaceuticals Holding Corp., A.G.P./Alliance Global Partners and Brookline Capital Markets, a division of Arcadia Securities, LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 28, 2023, and incorporated herein by reference.
- [10.40](#) Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 18, 2023 and incorporated herein by reference.
- [10.41](#) Form of Common Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 28, 2023 and incorporated herein by reference.
- [10.42](#) Placement Agent Agreement, dated September 28, 2023, among Tonix Pharmaceuticals Holding Corp., A.G.P./Alliance Global Partners and Brookline Capital Markets, a division of Arcadia Securities, LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023, and incorporated herein by reference.
- [10.43](#) Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023, and incorporated herein by reference
- [10.44](#) Form of Series A Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023, and incorporated herein by reference
- [10.45](#) Form of Series B Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on September 29, 2023, and incorporated herein by reference
- [10.46](#) Loan and Guaranty Agreement, dated as of December 8, 2023, by and among the Loan Parties, the Lenders and the JGB Agent, filed with the Commission on December 8, 2023, and incorporated herein by reference

- [10.47](#) Placement Agent Agreement, dated December 20, 2023, between Tonix Pharmaceuticals Holding Corp. and A.G.P./Alliance Global Partners, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 and incorporated herein by reference.
- [10.48](#) Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 and incorporated herein by reference.
- [10.49](#) Form of Series C Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 and incorporated herein by reference.
- [10.50](#) Form of Series D Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 21, 2023 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.
- [19.01](#) Tonix Pharmaceuticals Holding Corp. Insider Trading Policy, filed herewith.
- [21.01](#) List of Subsidiaries, filed herewith.
- [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, filed herewith.
- [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, filed herewith.
- [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, filed herewith.
- [97.01](#) Tonix Pharmaceuticals Holding Corp. Compensation Recovery Policy, filed herewith.
- 101 The following materials from Tonix Pharmaceuticals Holding Corp.'s Annual Report on Form 10-K for the year ended December 31, 2023, 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: April 1, 2024

By: /s/ SETH LEDERMAN

Seth Lederman

Chief Executive Officer (Principal Executive Officer)

Date: April 1, 2024

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)	April 1, 2024
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 1, 2024
/s/ RICHARD BAGGER Richard Bagger	Director	April 1, 2024
/s/ MARGARET SMITH BELL Margaret Smith Bell	Director	April 1, 2024
/s/ DAVID GRANGE David Grange	Director	April 1, 2024
/s/ ADEOYE OLUKOTUN Adeoye Olukotun	Director	April 1, 2024
/s/ NEWCOMB STILLWELL Newcomb Stillwell	Director	April 1, 2024
/s/ CAROLYN TAYLOR Carolyn Taylor	Director	April 1, 2024
/s/ JAMES TRECO James Treco	Director	April 1, 2024