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, 2024

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

Commission File Number **001-36019**

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**26-1434750**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
26 Main Street, Suite 101 **Chatham, New Jersey**	**07928**
(Address of principal executive office)	(Zip Code)

(862) 799-8599
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2024, based on the closing sales price of the common stock as quoted on The NASDAQ Global Market was $6,857,126. For purposes of this computation, all officers and directors are deemed to be affiliates. Such determination should not be deemed an admission that such directors, officers, or 5 percent beneficial owners are, in fact, affiliates of the registrant.

As of March 17, 2025, there were 6,434,881 shares of registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

ITEM 1 – BUSINESS

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

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our Management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Risks Factors" below, as well as those discussed elsewhere in this Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We file reports with the Securities and Exchange Commission ("SEC"). You can read and copy any materials we file or will file with the SEC, which, among other places, can be found on the SEC's website at http://www.sec.gov, as well as on our corporate website at www.tonixpharma.com).

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

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

- Our prospects are dependent on the success of TNX 102-SL for the management of Fibromyalgia ("FM") and progressing our pipeline through development stages. To the extent regulatory approval of TNX-102 SL is delayed or not granted or, if approved, TNX-102 SL 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®, as well as delays, challenges and expenses, and unexpected costs associated with integrating and operating this 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;

- Our ability to raise additional capital, 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

Tonix Pharmaceuticals ("Tonix" or the "Company") is a fully-integrated biopharmaceutical company developing and commercializing therapeutics to treat, and vaccines to prevent, disease and alleviate suffering. Tonix's primary focus is to obtain U.S. marketing authorization for TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 5.6 mg (2 x 2.8 mg tablets) for the management of fibromyalgia ("FM") from the U.S. Food and Drug Administration ("FDA"). The FDA assigned a prescription drug user fee act ("PDUFA") goal date of August 15, 2025, for a decision on marketing authorization for TNX-102 SL. In addition, we market two FDA-approved, prescription products for the treatment of acute migraine, and we are developing a robust pipeline of potential new products.

Our pipeline has been generated from internal discovery, as well as licenses, acquisitions and collaborations with academic institutions and non-profit organizations. Our development portfolio is focused on central nervous system ("CNS"), disorders, but also consists of immunology, infectious disease and rare disease, product candidates. The CNS portfolio includes small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions and includes TNX-1300 which is in Phase 2 clinical development to treat cocaine intoxication partially funded by the U.S. National Institute on Drug Abuse (NIDA). Our immunology portfolio includes TNX-1500 (anti-CD40L monoclonal antibody, or mAb), a biologic which has shown encouraging results in Phase 1, which we plan to study to prevent organ transplant rejection and treat autoimmune diseases. Our infectious disease portfolio includes TNX-801 (horsepox, live virus vaccine) a vaccine in development to prevent smallpox and mpox (formerly known as monkeypox) and TNX-4200, which is a discovery program for broad spectrum antiviral drugs funded by a U.S Department of Defense contract for up to $34 million over five years. TNX-4200 is being developed at our R&D facility located in Frederick, Maryland, ("RDC"), which has biosafety level 2 (BSL-2) with BSL-3 components. Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Central Nervous System (CNS) Pipeline

In October 2024, Tonix submitted a New Drug Application ("NDA") to the FDA for TNX-102 SL 5.6 mg for the management of FM, a proprietary sublingual tablet formulation of cyclobenzaprine ("CBP") designed for bedtime administration, and in December 2024, the FDA assigned a PDUFA goal date of August 15, 2025, for a decision on marketing authorization for TNX-102 SL. FM is a chronic pain disorder characterized by widespread pain, non-restorative sleep, fatigue and impaired cognition. TNX-102 SL is a centrally-acting, non-opioid analgesic designed for long-term bedtime use and has been studied in three Phase 3 trials using TNX-102 SL 5.6 mg, two studies reported statistically significant results. The FDA granted TNX-102 SL Fast Track designation in July 2024. We are preparing for a commercial launch of TNX-102 SL in the fourth quarter of 2025, conditional on FDA approval.

In March 2024, Tonix announced it selected two contract manufacturing organizations (CMOs), one of which is Almac Pharma Services, a member of the privately owned Almac Group, as dual supply sources for the potential launch and commercialization of TNX-102 SL in the U.S.

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.

In addition, TNX-102 SL has active INDs for the treatment of PTSD, agitation in Alzheimer's disease ("AAD"), alcohol use disorder ("AUD") and the management of multi-site pain associated with Long COVID (also known as Post-Acute SARS-CoV-2 or PASC). 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. Tonix is continuously evaluating further indications for which TNX-102 SL could potentially provide benefit.

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.

Finally, we are developing TNX-1900 (intranasal potentiated oxytocin) for several CNS disorders through investigator-initiated studies. TNX-1900 is in development through investigator-initiated studies at Massachusetts General Hospital ("MGH") for the treatment of binge eating disorder ("BED"), adolescent obesity, and bone health in pediatric autism. TNX-1900 is in development through an investigator-initiated study at the University of Washington for the treatment of social anxiety disorder.

Immunology Pipeline

Our lead candidate in the immunology pipeline is TNX-1500, an Fc-modified humanized monoclonal antibody ("mAb"), directed against CD40-ligand (CD40L, also known as CD154). TNX-1500 was engineered to modulate binding to Fc receptors with the goal of maintaining the activity of first-generation mAbs, yet with reduced risk of thrombotic complications. TNX-1500 is being developed to prevent organ transplant rejection as well as to treat autoimmune conditions. Topline results from a Phase 1 single ascending dose escalation study at 3 mg/kg, 10 mg/kg and 30 mg/kg of TNX-1500 in healthy volunteers was reported in the first quarter of 2025.

TNX-1500 has also been studied in combination with other immunosuppressive agents in allogeneic transplants in non-human primates at 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.

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 co-stimulation-based immunosuppressive regimen including TNX-1500. The results of these preclinical studies were encouraging and demonstrated the potential of GE 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. Subsequently, several other GE pig kidney transplants have been performed. TNX-1500 treatment has not been used in any human transplant recipient.

Our immunology pipeline also includes TNX-1700, a recombinant Trefoil Factor Family 2 ("hTFF2-HSA") fusion protein that was licensed from Columbia University in 2019. TNX-1700 consists of TFF2 fused to human serum albumin 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. We plan to request an INTERACT meeting with the FDA in 2025 to seek early guidance on program development.

Infectious Disease Pipeline

Our infectious disease portfolio includes vaccines based on our live virus vaccine or recombinant pox vaccine ("RPV") platform. Live virus vaccines are believed to protect against poor clinical outcomes of infectious diseases by eliciting T cell responses in addition to antibody responses.

TNX-801, a live minimally replicative vaccine based on synthesized horsepox, is in the pre-IND stage of development to protect against smallpox and mpox. In 2022 the WHO determined that the upsurge of mpox Clade IIb constituted a public health emergency of international concern (PHEIC). Mpox Clade IIB subsequently has become endemic in the U.S. mostly in populations of men who have sex with men. In August 2024, the WHO determined that the upsurge of mpox clade Ib in a growing number of countries in Africa constituted a PHEIC. The WHO reaffirmed the PHEIC status of mpox clade Ib in February of 2025. Mpox cases of the new clade Ib mpox have been detected in the United States and many other countries outside of Africa. Non-human primates vaccinated with TNX-801 were protected from mpox clade Ia in studies reported in the first quarter of 2020 and published in the peer-reviewed journal *Vaccines* in 2023.

In September 2024, at the DoD's MHSRS conference and in October 2024 at the World Vaccine Congress in Barcelona, Spain, Tonix presented new data on a potential mpox vaccine, TNX-801, demonstrating tolerability and no evidence of spreading to blood or tissues, even at high doses, in immunocompromised animals. After a single-dose vaccination, TNX-801 prevented clinical disease and lesions, and also decreased shedding in the mouth and lungs of animals after a lethal challenge with clade Ia monkeypox. These findings are consistent with TNX-801 inducing mucosal immunity and suggest TNX-801 may block forward transmission. In September 2024, the Company also announced that the WHO's preferred target product profile ("TPP") aligns with the characteristics of TNX-801. Key elements of the WHO draft TPP include single-dose, durable protection, administration without special equipment, and stability at ambient temperature. Other potential beneficial characteristics include the ability to limit forward transmission, use in case-contact vaccination strategies and suitability for use in immunocompromised individuals.

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 minimally replicative than older vaccinia-based smallpox vaccines in both human primary cell lines and immunocompromised mice. In October 2024, at the World Vaccine Congress - Europe, we highlighted positive preclinical efficacy data of TNX-801, demonstrating tolerability in immunocompromised animals and showed that TNX-801 is unable to spread in blood or tissues in these animals, even at an approximately 100-fold higher dose than 20th century vaccinia vaccines in immune-comprised mice. These data were published in the peer-reviewed journal *mSphere* in 2024.

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. The company's Good Manufacturing Practice ("GMP")-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801. The GMP suites are currently decommissioned but are ready to be reactivated in case of a national or international emergency.

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 June 2024, the Company announced preclinical data, demonstrating immunity and tolerability, during an oral keynote talk at the Vaccine Congress 2024. Like TNX-801, TNX-1800 is a live minimally replicative vaccine based on horsepox that is believed to provide immune protection with better tolerability than modern vaccinia viruses. TNX-1800 was selected by the NIH's Project NextGen for inclusion in clinical trials as part of a select group of next generation COVID-19 vaccine candidates with the intent to identify promising vaccine platforms. If Tonix is able to provide TNX-1800 to NIH, they would conduct a Phase 1 trial and cover the full cost. However, Tonix has not prioritized the production of TNX-1800, so it is uncertain whether or how quickly this project will progress. 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 is developing potential broad-spectrum antiviral drugs in three programs: CD45-targeted therapeutics (TNX-4200), cathepsin inhibitors (TNX-3900) and viral glycan-targeted engineered biologics (TNX-4000). 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.

In July 2024 Tonix was awarded a contract with a potential for up to $34 million over five years by the Defense Threat Reduction Agency (DTRA), an agency within the DoD. The objective of the contract is to develop small molecule broad-spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix's program will focus on optimization and development of its TNX-4200 program, to develop an orally available CD45 antagonist with broad-spectrum efficacy against a range of viral families through preclinical evaluation. The program is expected to establish physicochemical properties, pharmacokinetics, and safety attributes to support an IND submission and to fund a first-in-human Phase 1 clinical study. Tonix plans to leverage previous research on phosphatase inhibitors, specifically compounds that target CD45, to optimize lead compounds for therapeutic intervention of biothreat agents and provide the government with a complete and cost-effective solution for a broad-spectrum medical countermeasure. Tonix's premise is that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations, a lower dose, and a better safety profile.

Tonix will utilize its state-of-the-art research laboratory capabilities, including a Biosafety Level 3 (BSL-3) lab and an Animal Biosafety Level 3 (ABSL-3) facility at the RDC, as well as experienced personnel in-house.

Rare Disease Pipeline

Our rare disease portfolio consists of 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 gene mutations.

Marketed Medicines

Our commercial portfolio consists of two FDA-approved prescription products for the treatment of migraine: 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. Tonix Medicines is the only manufacturer with both a branded injectable and nasal spray indicated for the acute treatment of migraine with or without aura in adults.

In September 2024, Tonix announced that the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 12,097,183 to the Company, claiming use of a pre-filled autoinjector comprising a composition of Zembrace® SymTouch® for treating migraines via subcutaneous administration. This patent, excluding possible patent term extensions, is expected to fortify protection and market exclusivity into 2036. Additionally, Tonix announced that the USPTO issued U.S. Patent No. 12,090,139 to the Company, claiming a pharmaceutical composition, a method of treating migraine via intranasal administration, and an intranasal delivery system for Tosymra®. This patent is expected to fortify protection and market exclusivity into 2030.

In June 2024, the Company presented data at the 66th Annual Scientific Meeting of the American Headache Society (AHS) comparing real-world data with real-world usage of non-oral migraine products with the most recent AHS consensus statement. This data stressed the need for customizing treatment of migraine headaches to the needs of patients. Thus far, real world data show that conformity with the guidelines and the consensus statement have yet to be achieved but has the potential to be increased. The data show the use of non-oral drugs for treating an acute migraine attack was only 7% in 2012 and has decreased to below 4% in 2023, when the potential need for such drugs is anticipated to be a more substantial percentage of migraineurs based on epidemiological data. In 2024, Tonix Medicines launched a national educational campaign focusing on the link between migraine, gastroparesis, and the need for non-oral acute migraine therapies.

Facilities

Relating to our development programs, we own and operate the 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 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, clinical and commercial scale manufacturing of live-virus vaccines and biologics to support clinical trials. This facility was decommissioned in 2024 but Tonix has the ability to reactivate it should we choose to do so.

We are led by a management team with significant industry experience in commercialization and 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 and marketing capabilities 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. Our latest stage product candidate is TNX-102 SL 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.

  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 improvement in bone health in 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. 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 TNX-102 SL 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 will seek to enter into collaborations with pharmaceutical or biotechnology companies for commercialization.

  In preparation for the launch of TNX-102 SL, we have added to our team of professionals to market and distribute our products. Our commercial team is engaged in marketing and distributing our products and is also engaged in planning the launch of TNX-102 SL contingent on FDA approval.

- ***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 plan 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, in addition to smallpox and mpox, and for oncology applications.

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)

Fibromyalgia is a common chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system, called central sensitization. Brain imaging studies have localized the functional disorder to the brain's insular and anterior cingulate cortex. Fibromyalgia afflicts more than 10 million adults in the U.S., the majority of whom are women. Symptoms of fibromyalgia include chronic widespread pain, non-restorative sleep, fatigue, and brain fog (or cognitive dysfunction). Other associated symptoms include mood disturbances, including depression, anxiety, headaches, and abdominal pain or cramps. Individuals suffering from fibromyalgia often struggle with their daily activities, have impaired quality of life, and frequently are disabled. Physicians and patients report common dissatisfaction with currently marketed products. Fibromyalgia is now recognized as the prototypic nociplastic syndrome. Nociplastic pain is the third primary type of pain in addition to nociceptive pain and neuropathic pain. Many patients present with pain syndromes that are combinations of the three primary types of pain. Nociplastic syndromes can involve components of both central and peripheral sensitization. Fibromyalgia can occur without any identifiable precipitating event. However, many fibromyalgia cases follow one or more precipitating event(s) including: chronic nociceptive or neuropathic pain states; recovery from an infectious illness; a cancer diagnosis or cancer treatment; a metabolic or endocrine stress; or a traumatic event. In the cases of recovery from an infectious illness, fibromyalgia is considered an Infection-Associated Chronic Condition. In addition to fibromyalgia cases associated with other conditions or stressors, the U.S. National Academies of Sciences, Engineering, and Medicine, has concluded that fibromyalgia is a diagnosable condition that occurs after recovery from COVID-19 in the context of Long COVID. Fibromyalgia is also recognized as a Chronic Overlapping Pain Condition, due to shared symptoms with chronic fatigue syndrome/myalgic encephalomyelitis, irritable bowel syndrome, endometriosis, low back pain, post-concussive syndrome (also known as mild traumatic brain injury), chronic Lyme disease, chronic diabetic neuropathy and chronic post-herpetic neuralgia.

We believe that diagnosing fibromyalgia in Long COVID patients will increase the potential market for TNX-102 SL as compared to market estimates from before the COVID-19 pandemic. Tonix has previously presented its analysis of real-world evidence from the TriNetX claims database suggesting that over 40% of Long COVID patients present with a constellation of symptoms that overlap with fibromyalgia.

According to reports by Frost and Sullivan and Eversana 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, based on U.S. claims data, approximately 50% of patients diagnosed with FM are prescribed opioids within 18 months of diagnosis, despite the lack of evidence for their effectiveness and the risk of addiction and toxicity, including overdose.

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.

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 36.4%. According to 2018-2021 data, approximately 0.8 percent of men and women will be diagnosed with stomach cancer during their lifetime. In 2021, there were an estimated 130,263 people living with stomach cancer in the U.S. As of 2024, there were approximately 26,890 new cases with 10,880 deaths.

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, malignancy begins in the mucosal layer and spreads outwards.

The 5-year relative survival rate with colorectal cancer is 65.0%, per the National Cancer Institute. Based on 2018-2021 data, approximately 4.0 percent of men and women will be diagnosed with colorectal cancer during their lifetime. In 2021, there were an estimated 1,392,445 people living with colorectal cancer in the United States. As of 2024, there were approximately 152,810 new cases with 53,010 deaths. It is the 3rd leading cause of cancer death in women, and 2nd in men.

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 II cases spread rapidly in the U.S. and other countries. The Clade II mpox affects mostly men who have sex with men in the U.S., where it has become endemic. In August 2024, the World Health Organization ("WHO") declared mpox Clade Ib to be a public health emergency of international concern (PHEIC) due to an outbreak in the Democratic Republic of the Congo that spread globally, including to the United States. Clade Ib affects children as well as adults. The WHO reaffirmed the PHEIC status of mpox clade Ib in February of 2025.

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. New variants continue to sweep across the world in successive 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.

Rare Disease

Prader-Willi Syndrome

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

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.

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
TNX-102 SL	Fibromyalgia	NDA submitted and accepted by FDA for review; PDUFA goal date of August 15, 2025
TNX-102 SL	Acute Stress Reaction	Phase 2 ready* – investigator-initiated IND
TNX-1300	Cocaine Intoxication	Mid-Phase 2
TNX-1900	Adolescent Obesity, Binge Eating Disorder, and Bone Health in Pediatric Autism; Social Anxiety Disorder	Phase 2 currently enrolling* Phase 2 clinical phase completed*
TNX-1500	Kidney Transplant Rejection	Phase 1 topline reported 1Q'25
TNX-801	Smallpox and Mpox vaccine	Preclinical, pre-IND
TNX-1800	COVID-19 vaccine	Preclinical, pre-IND
TNX-2900	Prader-Willi Syndrome	Phase 2 ready
TNX-4200	Treatment or Prevention of Viral Disease	Preclinical, pre-IND
TNX-1700	Gastric and colorectal Cancer	Preclinical, pre-IND

*Investigator Initiated Studies

TNX-102 SL

Overview

TNX-102 SL is a proprietary sublingual tablet formulation of cyclobenzaprine ("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, of multi-site pain associated with 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 transmucosal absorption of CBP.

The current TNX-102 SL sublingual tablets each contain 2.8 mg of CBP. 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 a tertiary amine tricyclic, that is the listed 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 or ER 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 (ER) CBP capsules taken once a day mimic, and flatten, the pharmacokinetic profile of three times per day CBP IR tablets.

Both the IR and ER tablet formulations of CBP result in accumulation of the persistent metabolite norcyclobenzaprine ("norCBP") to blood levels that exceed the levels of CBP. NorCBP is a secondary amine tricyclic with a relatively stronger inhibitory activity of the norepinephrine transporter (NET) than the parent CBP. We believe that the accumulation of norCBP is undesirable in a medicine to be taken chronically at bedtime because norCBP accumulates over weeks, potentially interfering with the dynamic receptor effects of CBP and also may interrupt sleep quality by inhibiting the NET.

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 bypasses the "first pass" hepatic metabolism that swallowed medications undergo, results in a higher plasma level of CBP relative to norcyclobenzaprine during sleeping hours when taken at bedtime. We believe the dynamic changes in CBP after TNX-102 SL administration at steady state during chronic use contribute to its activity in treating fibromyalgia. We believe this is the first drug designed to increase the activity of the tertiary amine tricyclic parent and decrease the activity of the secondary amine tricyclic metabolite. 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. The most common adverse event was transient numbness in the mouth after TNX-102 SL administration.

In September 2024, at the 11th Global Conference on Pharmaceutics and Novel Drug Delivery Systems (PDDS 2024), the Company announced data highlighting the proprietary formulation technology and pharmacokinetic properties of TNX-102 SL, including composition and methods patents based on the proprietary eutectic formulation of TNX-102 SL that are expected to provide market exclusivity until at least 2034 in the U.S., EU, Japan, China and other jurisdictions. The eutectic protects cyclobenzaprine HCl from interacting with the basifying agent that is also part of the formulation and required for efficient transmucosal absorption. The formulation of TNX-102 SL was designed specifically for sublingual administration and transmucosal absorption for bedtime dosing to target disturbed sleep, improve pain and other fibromyalgia symptoms, while reducing the risk of daytime somnolence.

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 listed drug. We believe that TNX-102 SL has the potential to provide clinical benefit in fibromyalgia and PTSD and possibly other CNS 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.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets) – FM program

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

Clinical Development Plan

NDA Acceptance and PDUFA Goal Date

In October 2024, Tonix submitted its NDA to the FDA for TNX-102 SL 5.6 mg for the management of fibromyalgia and in December 2024, the FDA assigned a PDUFA goal date of August 15, 2025, for a decision on marketing authorization for TNX-102 SL. We are preparing for a commercial launch of TNX-102 SL in the fourth quarter of 2025, conditional on FDA approval.

Pre-NDA Meetings and Fast Track Designation

In July 2024, Tonix was granted Fast Track designation by the FDA for TNX-102 SL for FM. The designation validates that FM is a serious condition and that TNX-102 SL has the potential to address this unmet medical need. Tonix previously announced alignment with the FDA regarding the content of its proposed NDA submission, following completion of the Company's pre-NDA meetings.

During the second quarter of 2024, Tonix successfully completed two positive pre-NDA meetings with the FDA for TNX-102 SL for the management of fibromyalgia. The first, with minutes announced in June 2024, was a Type B Chemistry, Manufacturing, and Controls (CMC) meeting to seek alignment and agreement with the FDA on key CMC topics to support the planned NDA submission for TNX-102 SL. Based on formal meeting minutes, the Company believes it is aligned with the FDA on proposed drug substance and drug product commercial specifications, shelf life assignment, manufacturing and commercial drug packaging. At the second pre-NDA meeting announced in July 2024, the Company and the FDA aligned on nonclinical, clinical pharmacology and clinical matters and agreed that the proposed data package is sufficient to support the NDA submission.

Completed Phase 3 RESILIENT Study (F307) with Statistically Significant Improvement in Primary Endpoint of Pain Reduction

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 TNX-102 SL 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 TNX-102 SL 2.8 mg (1 tablet) or placebo. Thereafter, all participants increase their dose to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks. The 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 TNX-102 SL 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 ($p \leq 0.001$). 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. TNX-102 SL was well tolerated and consistent with prior trials, with no new safety signals observed. Among participants randomized to the TNX-102 SL and placebo arms, 81.0% and 79.2%, respectively, completed the 14-week dosing period. As expected, based on prior TNX-102 SL studies, administration site reactions were the most commonly reported adverse events and were higher in the TNX-102 SL 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 TNX-102 SL 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 TNX-102 SL arm. Of the two in the TNX-102 SL 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 TNX-102 SL 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 TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients had the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint was daily diary pain severity score change from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation. We reported pre-planned interim analysis results from a Phase 3 study, RALLY (F306), in July 2021. Based on the recommendation from the independent data monitoring committee that the RALLY trial was unlikely to demonstrate a statistically significant improvement in the primary endpoint, we stopped enrollment of new participants but allowed those participants who were already enrolled to complete the study. We reported topline data from the completed study in March of 2022. As expected, based on interim analysis results, TNX-102 SL did not achieve statistical significance over placebo on the primary endpoint of reduction in daily pain. 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 (~80% higher in each), which we believe may have been impacted by conducting the study in the period of highest mortality across the U.S. from the COVID-19 pandemic (September 2020 through March 2021 for the interim analysis sample).

Completed Phase 3 RELIEF Study (F304) with Statistically Significant Improvement in Primary Endpoint of Pain Reduction

In the fourth quarter of 2020, we announced the results of a randomized, double-blind, placebo-controlled, 12-week Phase 3 study of TNX-102 SL in 503 participants with FM, which we refer to as the RELIEF study. The primary objective of this study was to evaluate the potential clinical benefit of using TNX-102 SL to treat FM at a dose of 5.6 mg, administered sublingually once daily at bedtime for 12 weeks. The primary endpoint of the RELIEF trial was the daily diary pain severity score change from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation. The RELIEF study achieved statistical significance on the primary efficacy endpoint: change from baseline in the weekly average of daily diary pain severity numerical rating scale (NRS) scores for TNX-102 SL 5.6 mg (LS mean [SE]: -1.9 [0.12] units) versus placebo (-1.5 [0.12] units), analyzed by mixed model repeated measures with multiple imputation (LS mean [SE] difference: -0.4 [0.16] units, p=0.010).

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

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

Global NDA Requirements

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 Cmax, 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 Cmax, AUC_{0-T} and $AUC_{0-\infty}$, were all within the formal narrow equivalence limit of 0.8 to 1.25 after both the 5.6 mg dose and 2.8 mg dose, respectively. These results support similarity in cyclobenzaprine PK between Asian (pooled Japanese and Chinese) and Caucasian samples.

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 open-label extension studies of the PTSD program. Based on the FDA's guidance, the long-term safety exposure studies in PTSD was used to support the NDA for the management of fibromyalgia.

Manufacturing of TNX-102 SL

TNX-102 SL drug product for Phase 3 and the associated registration batches for the NDA were manufactured at commercial cGMP facilities. We currently have 36-month stability data in the proposed packaging configurations ready for commercialization. The FDA has reviewed the proposed CMC data package to support TNX-102 SL's NDA approval and commercial manufacturing plans as part of the IND process. Tonix is ready to manufacture TNX-102 SL commercial product for the forecasted fibromyalgia market. During the second quarter of 2024, Tonix successfully completed a pre-NDA meeting with the FDA for TNX-102 SL for a Type B Chemistry, Manufacturing, and Controls (CMC) meeting to seek alignment and agreement with the FDA on key CMC topics to support the planned NDA submission for TNX-102 SL. Based on formal meeting minutes, the Company believes it is aligned with the FDA on proposed drug substance and drug product commercial specifications, shelf life assignment, manufacturing and commercial drug packaging. In March 2024, Tonix announced it selected two contract manufacturing organizations (CMOs), one of which is Almac Pharma Services, a member of the privately owned Almac Group, as dual supply sources for the potential launch and commercialization of TNX-102 SL in the U.S.

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 ("ED") after a motor vehicle collision. The trial will enroll approximately 180 individuals who acutely experienced trauma at ED study sites across the U.S. and participants will be randomized in the ED to receive a two-week course of either TNX-102 SL or placebo. We expect enrollment in the OASIS study to begin in the first half of 2025. The OASIS trial will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients in the ED after a motor vehicle collision. A fourteen day course of bedtime TNX-102 SL will be tested in the immediate aftermath of motor vehicle collision trauma. The study will test the potential for TNX-102 SL to target trauma-related sleep disturbance and its ability to facilitate recovery from ASR and to prevent PTSD. The results may ultimately provide military personnel with a new treatment option that, when administered in the early aftermath of a traumatic event to individuals with ASR symptoms, improves warfighter function.

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 first half of 2025. The FDA granted IND clearance in the first quarter of 2024.

In August 2024 at the DoD's MHSRS conference, the Company presented clinical data and rationale supporting the potential for TNX-102 SL to be studied for the treatment of ASR and prevention of PTSD. Prior studies showed that treatment with TNX-102 SL showed effects on sleep and PTSD symptoms in PTSD patients at two and four weeks. This supportive data on the effects of TNX-102 SL on reducing PTSD symptoms suggest early intervention immediately after trauma using TNX-102 SL has the potential to reduce ASR/ASD symptoms which are similar to those of PTSD. Data from these trials support testing of TNX-102 SL within 24 hours of index trauma for effects on ASR symptoms and the subsequent incidence of newly developed PTSD.

TNX-1300 – Cocaine Intoxication

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

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

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

In August 2022, we announced that we received a Cooperative Agreement grant from 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 manufactured Phase 2 drug product clinical supply.

We initiated a Phase 2 clinical trial, CATALYST, of TNX-1300 in the third quarter of 2024. The Phase 2 trial is a single-blind, placebo-controlled, proof-of-concept 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. Because of the challenges of recruiting eligible patients into this study, we are not guiding to a timeline for completion of enrollment or topline data.

TNX-1900 –Adolescent Obesity, Binge Eating Disorder, Social Anxiety and Bone Health in Autism

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.

There are three ongoing Phase 2 investigator-initiated 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, University of Washington is conducting an investigator-initiated study of TNX-1900 in SAD using functional MRI, in which the clinical phase has been completed, and data analyses are in progress.

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.

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

TNX-1500 was engineered to modulate binding to Fc receptors with the goal of maintaining the activity of first-generation monoclonal antibodies (mAbs), yet with reduced risk of thrombotic complications. TNX-1500 is being developed as a prophylaxis against organ transplant rejection as well as to treat autoimmune conditions. The IND was cleared for the prevention of kidney transplant, and a Phase 1 single ascending dose escalation study at 3 mg/kg, 10 mg/kg and 30 mg/kg of TNX-1500 in healthy volunteers was initiated in the second quarter of 2023. The objectives of the Phase 1 trial were to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of intravenous TNX-1500, as well as to support dosing in a planned Phase 2 trial in kidney transplant recipients. We reported positive topline data related to the Phase 1 in February of 2025. TNX-1500 showed suppression of the primary and secondary antibody responses to KLH antigen challenges for the 10 and 30 mg/kg doses. Additionally, preliminary pharmacokinetic results showed mean half-life ($t_{1/2}$) for the 10 mg/kg and 30 mg/kg dose groups of 34-38 days, consistent with monthly dosing. In healthy volunteers, TNX-1500 was generally well-tolerated with a favorable safety profile. Anti-CD40L has multiple potential indications in addition to solid organ and bone marrow transplantation including autoimmune diseases: potential pipeline in a product. Tonix plans to discuss these results with the FDA in an End-of-Phase 1 meeting. Pending alignment with the FDA, a Phase 2 study of TNX-1500 in kidney transplant recipients will be pursued.

TNX-1500 has also been studied in combination with other immunosuppressive agents in allogeneic transplants in non-human primates at 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. In June 2024, at the American Transplant Congress 2024, Tonix announced data demonstrating the combined use of TNX-1500 and anti-CD28 monoclonal antibody, VEL-101 is associated with durable protection and graft survival and function in a nonhuman primate model. Further data demonstrated that TNX-1500 has promise to prevent rejection of 9-, or 10-gene-edited (GE) pig hearts. All research has been directed by the faculty of the Center for Transplantation Sciences at Massachusetts General Hospital.

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.

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 animals. The data demonstrates that TNX-1500 showed activity in preventing organ rejection and was well tolerated in animals. Blockade of CD40L with TNX-1500 monotherapy consistently prevented pathologic alloimmunity in animal models of cardiac and kidney allograft model without evidence of clinical thrombosis.

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

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TNX-1700 — Gastric and Colorectal Cancers

TNX-1700 is a recombinant Trefoil Family Factor 2 (hTFF2-HSA) fusion protein in development to treat gastric and colorectal 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 colorectal cancers. The licensed patents are directed to TFF2 compositions and methods of treatment. The licensed patents U.S. Patent No. 10,124,037 and U.S. Patent No. 11,167,010. The licensed patents provide TNX-1700 with US market exclusivity until April 2033, subject to any patent term extensions. On August 27, 2020, we filed International Patent Application No. PCT/IB2020/000699 entitled "Modified TFF2 Polypeptides." The PCT application is now nationalized in 12 countries.

Preclinical data has shown that mTFF2-CTP augmented the efficacy of mAb anti-PD-1 therapy. Anti-PD-1 in combination with mTFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice. The mechanism of action is to suppress myeloid-derived suppressor cells and activate anti-cancer CD8+ T cells, which is different from checkpoint inhibitors. There is potential synergy with anti-PD-1 or anti-PD-L1 mAbs.

TNX-801 –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 and mpox. 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®, the only non-replicating virus vaccine, is 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 has become endemic in the U.S. since it spread in the U.S. and other countries outside of Africa, mostly in populations of gay men. In August 2024, the WHO determined that the upsurge of mpox in a growing number of countries in Africa constitutes a public health emergency of international concern (PHEIC), the second such declaration in the past two years in response to transmission of the virus. Mpox cases of the new clade Ib mpox have since also been detected in multiple countries outside of Africa, including the U.S.. Animals 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 November 2024, Tonix announced that it has entered into a sponsored research agreement with the Kenya Medical Research Institute (KEMRI) to design, plan and seek regulatory approval for a Phase 1 clinical study in Kenya to test the safety, tolerability, and immunogenicity of TNX-801 as a vaccine to prevent mpox and smallpox. Tonix will be the sponsor and KEMRI will lead the execution of the proposed clinical trial.

In September 2024, at the DoD's MHSRS conference and in October 2024 at the World Vaccine Congress in Barcelona, Spain, Tonix presented new data on potential mpox vaccine, TNX-801, demonstrating tolerability and no evidence of spreading to blood or tissues, even at high doses, in immunocompromised animals. After a single-dose vaccination, TNX-801 prevented clinical disease and lesions, and also decreased shedding in the mouth and lungs of animals after a lethal challenge with clade Ia monkeypox. These findings are consistent with TNX-801 inducing mucosal immunity and suggest TNX-801 has the ability to block forward transmission. In September 2024, the Company also announced that the WHO's preferred TPP aligns with the characteristics of TNX-801. Key elements of the WHO draft TPP include single-dose, durable protection, administration without special equipment, and stability at ambient temperature. Other potential beneficial characteristics include the ability to limit forward transmission, use in case-contact vaccination strategies and suitability for use in immunocompromised individuals.

In August 2024, Tonix and Bilthoven Biologicals, part of the world's largest vaccine manufacturer the Cyrus Poonawalla Group, which includes the Serum Institute of India, announced a collaboration to advance TNX-801.

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 minimally replicative than older vaccinia-based smallpox vaccines in both human primary cell lines and immunocompromised mice. Similar data was also published in the peer-reviewed journal *mSphere* which presented data demonstrating that TNX-801 is less virulent than 20th Century vaccinia vaccines in immune-compromised mice.

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 meeting cGMP quality to support a clinical study.

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.

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.

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. The company's Good Manufacturing Practice (GMP)-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801 and the GMP suites are ready to be reactivated in case of a national or international emergency.

TNX-1800 – COVID-19 Vaccine

TNX-1800 is a minimally replicative, 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. 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. Because of extensive reviews of NIH programs, the future of this program is uncertain.

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 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 an animal 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 began 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 minimally replicative than older VACV-based smallpox vaccines in human primary cell lines and 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.

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 x 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 minimally replicative than older VACV-based smallpox vaccines in human primary cell lines and immunocompromised mice.

TNX-4200 – Broad-Spectrum Antiviral

Tonix is developing CD45-targeted therapeutics (TNX-4200). In July 2024 Tonix was awarded a contract with a potential for up to $34 million over five years by DTRA. The objective of the contract is to develop small molecule broad-spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments.

Tonix's program will focus on optimization and development of its TNX-4200 program, to develop an orally available CD45 antagonist, with broad-spectrum efficacy against a range of viral families through preclinical evaluation. The program is expected to establish physicochemical properties, pharmacokinetics, and safety attributes to support an IND submission and to fund a first-in-human Phase 1 clinical study. Tonix plans to leverage previous research on phosphatase inhibitors, specifically compounds that target CD45, to optimize lead compounds for therapeutic intervention of biothreat agents and provide the government with a complete and cost-effective solution for a broad-spectrum medical countermeasure. Tonix's hypothesis is that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations, a lower dose, and a better safety profile.

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 Inserm. The licensing agreement has been negotiated and signed by Inserm Transfert, the private subsidiary of Inserm, on behalf of Inserm, 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.

Tonix's Facilities Overview

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 is the principal site for the research on TNX-4200, a broad-spectrum antiviral targeting CD45 funded by the U.S. Department of Defense, Defense Threat Agency contract. 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 intended to accelerate development, clinical and commercial scale manufacturing of live-virus vaccines and biologics. ADC includes single-use bioreactors and purification suites with equipment for Good Manufacturing Practice (GMP) production of vaccines and biologics for clinical trials, including the capability of producing sterile vaccines in glass vials.

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. This facility was decommissioned in May 2024 but Tonix has the ability to reactivate it should we choose to do so.

Marketing, Sales and Distribution

Marketing activity for Zembrace Symtouch and Tosymra in the United States is 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.

In 2024, Tonix engaged EVERSANA to support the launch strategy and commercial planning of TNX-102 SL for the management of fibromyalgia. Specifically, EVERSANA worked with Tonix to assess the fibromyalgia landscape and help plan an efficient go-to-market strategy.

In 2024, Tonix hired a new head of Commercial Operations as well as Vice Presidents to run Medical Affairs and Marketing, each with decades of experience successfully launching and commercializing new CNS products. In January 2025, Tonix announced the appointment of a vice president to oversee Market Access. In 2025, we will continue to build out our commercial team and capabilities as we look forward to a targeted launch of TNX-102 SL in the fourth quarter of 2025, contingent on FDA approval.

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. Most recently, Axsome Therapeutics announced FDA approval of SYMBRAVO® (meloxicam and rizatriptan) for the acute treatment of migraine with or without aura in adults. We also note that the PDUFA goal date for Shin Nippon Biomedical Laboratories, Ltd and Satsuma Pharmaceuticals is April 30, 2025 for their intranasal asset STS101 (dihydroergotamine) for the treatment of migraine headaches.

Fibromyalgia

We are currently awaiting an FDA decision on marketing authorization for TNX-102 SL for the management of fibromyalgia. There are 3 products approved for the treatment of fibromyalgia which 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 is still on patent. There has not been a new product approved for this indication in 15 years.

Tonix is aware of multiple companies actively developing treatments for fibromyalgia. Axsome Therapeutics Inc. expects to submit an NDA for AXS-14 (esreboxetine) for the management of fibromyalgia to the FDA for AXS-14 in Q1 2025. Virios Therapeutics, Inc. announced the initiation of a Phase 3 trial in the U.S. for IMC-1 for the treatment of fibromyalgia. IMC-1 is a fixed dose combination of famciclovir + celecoxib, is a 505(b)(2) and has been granted Fast Track Designation by the FDA. Tonix is also focused on developments for fibromyalgia outside of the U.S. and keeps abreast of the progress made by Australian company Tryptamine Therapeutics Ltd who announced positive data from a Phase IIa clinical trial of TRP-8802 for fibromyalgia which was presented in an abstract at the International Association for the Study of Pain (IASP) 2024 World Congress on August 9, 2024.

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

As of now, there are no specific drugs approved by the FDA solely for the treatment of Long COVID (formerly known as Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)). Tonix is aware of several companies developing therapeutics for the treatment of Long COVID including, but not limited to, Direct Biologics, LLC (Phase III for DB-001 was completed in the fourth quarter of 2024 and American CryoStem Corporation. Other developments include Organicell Regenerative Medicine, Inc. is conducting a Phase 2 for Zofin as a potential therapeutic for Long COVID. PaxMedica, Inc. is developing PAX-101 for the treatment of Long COVID and currently conducting a Phase1b in South Africa. In October 2024, Resolve Therapeutics, LLC, announced the results from its Phase II Long COVID study of RSLV-132. Furthermore, GeNeuro announced the data from Phase II GNC-501 clinical trial in patients suffering from Long COVID, testing temelimab against placebo. Finally, in June 2024, Berlin Cures Holding AG announced that it is preparing for a Phase III study in Long COVID and Statera BioPharma, Inc. is comparing STAT-205 with placebo for reducing fatigue in Long COVID.

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

There are no approved drugs for treating ASR or for the prevention of ASD or PTSD. In October 2024, BioXcel Therapeutics announced a Phase IIa efficacy and safety trial of BXCL501 in patients experiencing ASD resulting from motor vehicle collisions to begin in the first half of 2025. BXCL501 is an orally dissolvable film formulation of the α2A adrenergic receptor agonist dexmedetomidine that is FDA approved as IGALMI® for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults.

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. Embera NeuroTherapeutics currently lists EMB-001 in Phase II development for the treatment of cocaine use disorder in its pipeline.

Transplantation Rejection and Autoimmune Treatments with Anti-CD40-ligand Monoclonal Antibodies

We are aware of multiple companies advancing the development of biologics targeting the CD40L molecule including Sanofi, UCB, Eledon Pharmaceuticals, and Amgen Inc. Eledon Pharmaceuticals revealed promising results from the Phase I/II trial of tegoprubart, aimed at preventing islet transplant rejection in individuals with type 1 diabetes. The trial showed that the first human cases of insulin independence were achieved using an anti-CD40L monoclonal antibody therapy, without relying on tacrolimus, the current standard treatment for preventing transplant rejection. Sanofi's SAR441344 (Frexalimab), a second-generation anti-CD40L monoclonal antibody, is being tested in multiple sclerosis. In a Phase II trial involving participants with relapsing multiple sclerosis (NCT04879628), frexalimab demonstrated effectiveness in quickly reducing the number of new gadolinium-enhancing T1-lesions at week 12. Amgen Inc. is currently conducting a Phase III trial to test Dazodalibep for Sjogren's Syndrome (NCT06104124) with an estimated completion date for the first half of 2026. H. Lundbeck is testing Lu AG22515 for Thyroid Eye Disease (TED) and plans to report results from the Phase Ib TED study in the second half of 2026. In 2024, UCB and Biogen announced positive results from a Phase III trial testing Dapirolizumab Pegol for Systemic Lupus Erythematosus. In November 2024, UCB and Biogen announced the initiation of their potentially confirmatory Phase III trial to test Dapirolizumab Pegol for Systemic Lupus Erythematosus (NCT06617325). These are a few key highlights that underscore the focus of major pharmaceutical companies in this area and we monitor the activity of other 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

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. Acadia anticipates the enrollment of the final patient in by the fourth quarter of 2025, with top-line results expected to be announced in the first half of 2026. Soleno is developing diazoxide chloride controlled release (DCCR) which had positive results in a randomized withdrawal study of PWS. The PDUFA goal date for a decision on marketing authorization is in March 2025.

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. 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. At the end of 2024, Neuren Pharmaceuticals Limited announced the suspension of its Phase II open-label study of the safety, tolerability, and pharmacokinetics of oral NNZ-2591 in Prader-Willi syndrome (PWS-001) due to a revised development strategy.

Tonix is knowledgeable about several companies dedicated to developing a therapy for the treatment of PWS including, but not limited to, Aardvark Therapeutics, ConSynance Therapeutics, Lipidio Pharma, Helsinn, Inversago Pharma, Saniona, 9 Meters Biopharma, Neuracle Science, Harmony Biosciences Holding Inc., and Notitia Biotechnologies.

Gastric and Colorectal Cancer

TNX-1700 asset is a recombinant TFF2 (albumin fusion peptide) and has demonstrated that by targeting myeloid derived suppressor cells (MDSCs) using TFF2-MSA fusion protein synergizes well with PD-1 blockade therapy in advanced and metastatic syngeneic mouse models of colorectal cancer. Tonix is aware of several companies that are focused on MDSCs to treat Gastric and Colorectal Cancer. Anbogen announced a drug supply collaboration to evaluate the combination of Anbogen's ABT-301, with BeiGene's tislelizumab, in patients with mismatch repair–proficient or microsatellite stable metastatic colorectal cancer ("mCRC") in a global Phase II trial. Gilead Sciences and Arcus Biosciences announced new data from Cohort B of ARC-9, a Phase Ib/II study evaluating the safety and efficacy of etrumadenant, a dual A2a/b adenosine receptor antagonist, plus anti-PD-1 monoclonal antibody zimberelimab, FOLFOX chemotherapy and bevacizumab (EZFB) in third-line mCRC. In 2023, TriSalus Life Sciences announced it plans to initiate a Phase II trial of SD-101 (Nelitolimod) for colorectal cancer. NextCure, Inc. have NC410 in the clinic for Colorectal Cancer. Faron Pharmaceuticals Oy have Bexmarilimab in the clinic for Colorectal Cancer. Merck & Co., Inc. and Agenus are collaborating on MK-4830 for Colorectal Cancer.

Smallpox / Mpox

BioNTech SE is conducting a Phase I/II study in the U.S. evaluating the safety, tolerability, reactogenicity and immunogenicity of the investigational RNA-based multivalent vaccine candidate BNT166a for active immunization against mpox. The study is expected to complete in the first quarter of 2026. In 2023, Moderna announced it has mRNA-1769 in preclinical development for the treatment of Mpox. Moderna is conducting a P1/2 study of mpox vaccine in the U.K. Emergent BioSolutions, Inc. has enabled the enrolment of the first patients for the MOSA, a pan-African randomized platform adaptive trial to test Tembexa to treat mpox at Mbandaka Hospital in Equateur Province, Democratic Republic of Congo. A first interim analysis is expected by the end of the first quarter of 2025. Other companies we monitor include GeoVax Labs, Inc., NanoViricides, Inc., EpiVax, Inc., Gylden Pharma Limited.

Covid-19

There are many vaccine products in development for the treatment or prevention of Covid-19 globally. Approved products include Pfizer-BioNTech's (BNT162b2), Moderna's (mRNA-1273) and Novavax's (NVX-CoV2373) which are routinely updated to address new variants. CSL and Arcturus announced that the European Commission has granted marketing authorization for KOSTAIVE (ARCT-154), an mRNA COVID-19 vaccine, KOSTAIVE is currently marketed in Japan against COVID-19. Codagenix is developing CoviLiv™ as an intranasal vaccine candidate and in Phase 3 for COVID-19. Other companies working in the area include: Vaxart Inc. which is developing a potentially orally administered vaccine based on the adenovirus serotype 5 (Ad-5) vector to express the spike protein of SARS-CoV-2; CastleVax USA which is developing a potential nasally administered vaccine based on a Newcastle disease virus (NDV) vector to express the Spike protein of SARS-CoV-2.

Intellectual Property

We believe that we have an extensive patent portfolio and substantial know-how relating to 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 10, 2025, the patents we are either the owner of record of or own the contractual right to include 42 issued U.S. patents and 432 issued non-U.S. patents. We are actively pursuing an additional 23 U.S. non-provisional patent applications, 3 international patent applications, and 244 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 February 10, 2025 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 pain, fatigue and sleep disturbances in fibromyalgia, for treating or managing fibromyalgia (early onset response, favorable tolerability, or side effect profile), for alcohol abuse, for disordered sleep, for sexual dysfunction, for depression in fibromyalgia, for fatigue and disordered sleep (e.g., CAP rates), for post-acute sequelae of SARS-CoV-2 infection, for acute stress reaction/acute stress disorder, and for agitation in neurodegenerative conditions, e.g., AD.

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 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 August 4, 2023, Chinese Patent No. ZL201910263541.6, entitled “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride,” issued. The claims recite a eutectics of cyclobenzaprine hydrochloride and beta-mannitol and methods of making those eutectics.

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 after 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 after the February 2022 oral proceedings. Hexal AG did not appeal that decision.

On June 4, 2024, U.S. Patent No. 11,998,516, entitled “Methods and Compositions for Treating Depression Using Cyclobenzaprine,” issued. The claims recite methods for treating major depressive disorder in a fibromyalgia patient using a composition comprising cyclobenzaprine or its salts.

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 and is now nationalized in European Patent Office and U.S. (U.S. Patent Application No. 18/698,483). 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 PCT is now nationalized in 9 countries. 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.

On December 19, 2024, U.S. non-provisional Patent Application No. 18/988,194 and International Patent Application No. PCT/US2024/061125, entitled "Early Onset Response, Favorable Tolerability, and Side Effect Profile in the Treatment of Fibromyalgia," were filed. The claims are directed to methods for treating or managing fibromyalgia and its associated symptoms in subjects characterized by an early onset of one or more of: (1) a reduction in widespread pain; (2) a reduction in sleep disturbance; (3) a reduction in fatigue; or (4) an improved sleep quality. The claims are also directed to methods for preventing or avoiding clinically meaningful changes in mean weight, in mean systolic blood pressure or mean diastolic blood pressure, or a decline in sexual functioning.

On January 23, 2025, International Patent Application No. PCT/US2025/012803, entitled Cyclobenzaprine Treatment for Acute Stress Reaction or Acute Stress Disorder," was filed. The claims are directed to methods for treating or preventing acute stress reaction (ASR) or acute stress disorder (ASD) and associated symptoms thereof using a composition with cyclobenzaprine or its salts in.

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 acquired International Patent Application No. PCT/US2017/027265, filed April 12, 2017, entitled "Magnesium-Containing Oxytocin Formulations and Methods of Use" (nationalized in 9 countries). On December 3, 2024, U.S. Patent No. 12,156,897, entitled "Magnesium-Containing Oxytocin Formulations and Methods of Use," issued. The patent, which claims methods for treating autism spectrum disorder, social anxiety disorder, or a social communication disorder, will expire in April 2037, excluding any patent term extensions.

We also have rights to International Patent Application No. PCT/US2019/020419, filed on April 12, 2017, entitled "Labeled Oxytocin and Method of Manufacture and Use" (nationalized in the U.S., European Patent Office and Japan). On April 30, 2024, U.S. Patent No. 11,970,554, entitled "Labeled Oxytocin and Method of Manufacture and Use," issued.

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).

On August 28, 2024, European Patent No. 3993876, entitled "Anti-CD154 Antibodies and Uses Thereof," issued (validated in 37 countries). The claims recite an isolated antibody that binds CD154, compositions comprising the antibody, and use of the compositions for treating or preventing a transplant rejection.

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 minimally replicative 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 now 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.

TNX-1700 — Recombinant Trefoil Family Factor 2 (rTFF2) to Treat Gastric and Colorectal 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 colorectal 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-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."

TNX-4300 — Estianeptine for Psychiatric and Neurodegenerative Diseases

We are developing TNX-4300, the (S)-isomer of tianeptine, for psychiatric and neurodegenerative diseases. On March 27, 2024, we filed International Patent Application No. PCT/US2024/021799, entitled "(S)-Tianeptine and Use in Treating Disorders and Conditions Associated with Peroxisome Proliferator-Activated Receptor."

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
I590820	Compositions and Methods for Transmucosal Absorption	Taiwan R.O.C.	June 14, 2033
2013274003	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
I642429	Compositions and Methods for Transmucosal Absorption	Taiwan R.O.C.	June 14, 2033
726488	Compositions and Methods for Transmucosal Absorption	New Zealand	June 14, 2033
I683660	Compositions and Methods for Transmucosal Absorption	Taiwan R.O.C.	June 14, 2033
2018241128	Compositions and Methods for Transmucosal Absorption	Australia	June 14, 2033
2876902	Compositions and Methods for Transmucosal Absorption	Canada	June 14, 2033
IDP000076019	Compositions and Methods for Transmucosal Absorption	Indonesia	June 14, 2033
382516	Compositions and Methods for Transmucosal Absorption	Mexico	June 14, 2033
2861223 (AL/P/2022/458 in Albania; P20221325T in Croatia; 602013082236.0 in Germany; 3111421 in Greece; 502022000069474 in Italy; P912561 in North Macedonia; SM-T-202200436 in San Marino; RS63822B1 in Serbia; and 2022-GE-787024 in Turkey)	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
3,118,913	Compositions and Methods for Transmucosal Absorption	Canada	June 14, 2033
10201605407T	Compositions and Methods for Transmucosal Absorption	Singapore	June 14, 2033

CBP – Depression

Patent No.	Title	Country / Region	Expiration Date
11,998,516	Methods and Compositions for Treating Depression Using Cyclobenzaprine	U.S.A.	March 5, 2032
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 (AL/P/2020/15 in Albania; P20200142 in Croatia; MK/P/2020/68 in North Macedonia; 602012066717.6 in Germany; 3103147 in Greece; HU/E048596 in Hungary; 502020000014740 in Italy; 10476 in North Macedonia; SM-T-202000083 in San Marino; 60240 in Serbia; 2773834 in Spain; and 2020-GE-5216 in Turkey)	Methods and Compositions for Treating Depression Using Cyclobenzaprine	European Patent Office – Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Republic of North Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, and Turkey	March 6, 2032

CBP – PTSD

Patent No.	Title	Country / Region	Expiration Date
9,918,948	Methods and Compositions for Treating Symptoms Associated with Post-Traumatic Stress Disorder Using Cyclobenzaprine	U.S.A.	November 18, 2030

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
411601	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Mexico	December 11, 2038
3,083,341	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Canada	December 11, 2038
2020/03243	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	South Africa	December 11, 2038
MY-207073-A	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Malaysia	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
ZL.201580050140.2	Eutectic Formulations of Cyclobenzaprine Hydrochloride	China	September 18, 2035
2014233277	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Australia	March 14, 2034
2015317336	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Australia	September 18, 2035
I661825	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan R.O.C.	March 14, 2034
I740136	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Taiwan R.O.C.	March 14, 2034
IDP000055516	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia	March 14, 2034
IDP000063221	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Indonesia	September 18, 2035
IDP000076872	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Indonesia	March 14, 2034
2968992 (1211591 in Austria, CZ2014-762323 in Czechia, 602014058260.5 in Germany, E018723 in Estonia, P20200055 in Croatia, 201361792757 P in Ireland, 2020.67 in Monaco, P-2020/0094 in Serbia, 201431487 in Slovenia, 33269 in Slovakia, 2020000045 in San Marino, AL/P/2019/906 in Albania, MK/P/2020/67 in Republic of North Macedonia, 3102655 in Greece, 502020000007756 in Italy)	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	European Patent Office - Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Republic of North Macedonia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	March 14, 2034

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, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	March 14, 2034
241353	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Israel	March 14, 2034
251218	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Methods of Producing Same	Israel	September 18, 2035
277814	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Methods of Producing Same	Israel	September 18, 2034
370021	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico	March 14, 2034
387402	Eutectic Formulations of Cyclobenzaprine Hydrochloride	Mexico	September 18, 2035
388137	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Mexico	March 14, 2034
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
3119755	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
40013124	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong	March 14, 2034
40030559	Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride	Hong Kong	March 14, 2034

Analogs of CBP

Patent No.	Title	Country / Region	Expiration Date
11,517,557	Analogs of Cyclobenzaprine and Amitryptilene	U.S.A.	July 13, 2038
12,156,864	Analogs of Cyclobenzaprine and Amitryptilene	U.S.A.	July 13, 2038
7330964	Analogs of Cyclobenzaprine and Amitryptilene	Japan	July 13, 2038

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 (P20231438 in Croatia; 602016083177.5 in Germany; 3114323 in Greece; HU/E065385 in Hungary; 65034 in Serbia; SM-T-202400020 in San Marino; and 2023-GE-778438 in Turkey)	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
2020286221	Magnesium-Containing Oxytocin Formulations and Methods of Use	Australia	January 7, 2036
734097	Magnesium-Containing Oxytocin Formulations and Methods of Use	New Zealand	January 7, 2036
771693	Magnesium-Containing Oxytocin Formulations and Methods of Use	New Zealand	January 7, 2036
10-2677904	Magnesium-Containing Oxytocin Formulations and Methods of Use	Republic of Korea	January 7, 2036
7455402	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan	January 7, 2036
BR112017014545-6	Magnesium-Containing Oxytocin Formulations and Methods of Use	Brazil	January 7, 2036
11,970,554	Labeled Oxytocin and Method of Manufacture and Use	U.S.A.	March 1, 2039
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
12,156,897	Magnesium-Containing Oxytocin Formulations and Methods of Use	U.S.A.	April 12, 2037

417307	Magnesium-Containing Oxytocin Formulations and Methods of Use	Mexico	April 12, 2037
3442560 (602017086259.2 in Germany; and SM/T/2025/000041 in San Marino)	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, and United Kingdom)	April 12, 2037
2575853 (2595251 in Spain)	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 (2526672 in Spain)	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; 2644511 in Spain; 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; 2727851 in Spain; and E1100344 in Austria)	Method for Treating Neurocognitive Dysfunction	European Patent Office – Austria, Belgium, Switzerland, Germany, Spain, France, United Kingdom, Ireland, Luxembourg, Monaco, and Portugal	April 30, 2029

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
2017353868	Synthetic Chimeric Poxviruses	Australia	November 2, 2037
ZL201780078546.0	Synthetic Chimeric Poxviruses	China	November 2, 2037
40014109	Synthetic Chimeric Poxviruses	Hong Kong	November 2, 2037
2022/04981	Synthetic Chimeric Poxviruses	South Africa	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
12,090,139	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 (E760080 in Austria; 502016000000073 in Italy; 602010028995.8 in Germany; and 2553862 in Spain)	Formulations Comprising Triptan Compounds	European Patent Office - Austria, Belgium, Czechia, Denmark, France, Germany, Italy, Spain, Switzerland, and United Kingdom	June 17, 2030
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
12,097,183	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 Sumatripan for Treating Migraine	Canada	February 1, 2036

CD40 and anti-CD154 Therapeutics

Patent No.	Title	Country / Region	Expiration Date
3993876 (E1717312 in Austria; P20241602 in Croatia; 602020036714.4 in Germany; 3116977 in Greece; HU/E069680 in Hungary; 502024000056334 in Italy; 66218 in Serbia; 2994684 in Spain; and SM-T-202400527 in San Marino)	Anti-CD154 antibodies and uses thereof	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, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey, United Kingdom)	July 1, 2040

CBP - ASD and PTSD

Patent No.	Title	Country / Region	Expiration Date
420368	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Mexico	August 20, 2039

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
BR122024022801-7	Anti-CD154 antibodies and uses thereof	Brazil
3145453	Anti-CD154 antibodies and uses thereof	Canada
202080059891.1	Anti-CD154 antibodies and uses thereof (Allowed)	China
24195755.4	Anti-CD154 antibodies and uses thereof	European Patent Office
202217004870	Anti-CD154 antibodies and uses thereof	India
P00202200763	Anti-CD154 antibodies and uses thereof	Indonesia
289354	Anti-CD154 antibodies and uses thereof	Israel
2021-578262	Anti-CD154 antibodies and uses thereof	Japan
PI 2021007835	Anti-CD154 antibodies and uses thereof	Malaysia
PI 2024006778	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
2024/09160	Anti-CD154 antibodies and uses thereof	South Africa
62022063693.5	Anti-CD154 antibodies and uses thereof (Allowed)	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
62024090562.5	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Hong Kong
62024091450.2	Methods of Inducing Immune Tolerance with Modified Anti-CD154 Antibodies	Hong Kong
3136725	Inhibitors of CD40-CD154 Binding	Canada
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
15841528.1	Eutectic Formulations of Cyclobenzaprine Hydrochloride	European Patent Office
18101200.4	Eutectic Formulations of Cyclobenzaprine 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 2023000078	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
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
2024-14696	Compositions and Methods for Transmucosal Absorption	Japan
10202401383X	Compositions and Methods for Transmucosal Absorption	Singapore

CBP – Agitation in Neurodegenerative Condition

Application No.	Title	Country / Region
2018383098	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions (Allowed)	Australia
BR112020011345-0	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Brazil
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
62020022462.9	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
42024101171.7	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	Hong Kong
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
202410396685.X	Cyclobenzaprine Treatment for Agitation, Psychosis and Cognitive Decline in Dementia and Neurodegenerative Conditions	China

Analogs of CBP

Application No.	Title	Country / Region
18/950,382	Analogs of Cyclobenzaprine and Amitriptyline	U.S.A.
3069699	Analogs of Cyclobenzaprine and Amitriptyline	Canada
201880050758.2	Analogs of Cyclobenzaprine and Amitriptyline	China
18831505.5	Analogs of Cyclobenzaprine and Amitriptyline	European Patent Office
2024-027046	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
813830	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
202510112547.9	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
2025-32822	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Japan
10-2024-02502Q	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	Singapore
2021/01121	Methods of Treating Acute Stress Disorder and Posttraumatic Stress Disorder	South Africa

CBP – Fibromyalgia

Application No.	Title	Country / Region
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
62024089847.3	Cyclobenzaprine Treatment for Fibromyalgia	Hong Kong
62024090216.8	Cyclobenzaprine Treatment for Fibromyalgia	Hong Kong
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
524462219	Cyclobenzaprine Treatment for Fibromyalgia	Saudi Arabia
10202403823V	Cyclobenzaprine Treatment for Fibromyalgia	Singapore
2023/06139	Cyclobenzaprine Treatment for Fibromyalgia	South Africa

CBP – Fibromyalgia (Early Onset Response, Favorable Tolerability, and Side Effect Profile)

Application No.	Title	Country / Region
PCT/US2024/061125	Early Onset Response, Favorable Tolerability, and Side Effect Profile in the Treatment of Fibromyalgia	PCT
18/988,194	Early Onset Response, Favorable Tolerability, and Side Effect Profile in the Treatment of Fibromyalgia	U.S.A.

CBP – Acute Stress Reaction or Acute Stress Disorder

Application No.	Title	Country / Region
PCT/US2025/012803	Cyclobenzaprine Treatment for Acute Stress Reaction or Acute Stress Disorder	PCT

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
62024087606.5	Cyclobenzaprine Treatment for Alcohol Use Disorder	Hong Kong
62024089500.8	Cyclobenzaprine Treatment for Alcohol Use Disorder	Hong Kong
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
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 (Allowed)	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
62025103395.2	Cyclobenzaprine Treatment for Sexual Dysfunction	Hong Kong
18/698,483	Cyclobenzaprine for Treatment or Prevention of Sexual Dysfunction Associated with Mental Health Conditions in Female Patients	U.S.A.
22800445.3	Cyclobenzaprine for Treatment or Prevention of Sexual Dysfunction Associated with Mental Health Conditions in Female Patients	European Patent Office

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

Application No.	Title	Country / Region
18/212,500	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	U.S.A.
2023286504	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	Australia
36260042	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	Canada
Not Yet Assigned	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	China
23744274.4	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	European Patent Office
317836	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	Israel
2024-575083	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	Japan
MX/a/2025/000142	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	Mexico
817589	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	New Zealand
2025/00293	Cyclobenzaprine Treatment for Post-Acute Sequelae of (SARS)-CoV-2 Infection (PASC)	South Africa

Oxytocin therapeutics

Application No.	Title	Country / Region
2024203428	Magnesium-Containing Oxytocin Formulations and Methods of Use	Australia
BR122024008322-1	Magnesium-Containing Oxytocin Formulations and Methods of Use	Brazil
2972975	Magnesium-Containing Oxytocin Formulations and Methods of Use	Canada
42024096348.8	Magnesium-Containing Oxytocin Formulations and Methods of Use	Hong Kong
23201255.9	Magnesium-Containing Oxytocin Formulations and Methods of Use	European Patent Office
2024-33983	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan
18/621,985	Labeled Oxytocin and Method of Manufacture and Use	U.S.A.
19710979.6	Labeled Oxytocin and Method of Manufacture and Use	European Patent Office
2020-545532	Labeled Oxytocin and Method of Manufacture and Use	Japan
2024-9405	Labeled Oxytocin and Method of Manufacture and Use	Japan
18/921,777	Magnesium-Containing Oxytocin Formulations and Methods of Use	U.S.A.
3,020,179	Magnesium-Containing Oxytocin Formulations and Methods of Use (Allowed)	Canada
2023100344997	Magnesium-Containing Oxytocin Formulations and Methods of Use	China
24214056.4	Magnesium-Containing Oxytocin Formulations and Methods of Use	European Patent Office
2024-196703	Magnesium-Containing Oxytocin Formulations and Methods of Use	Japan
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 (Allowed)	Taiwan R.O.C.
BR112019008781-8	Synthetic Chimeric Poxviruses	Brazil
3,042,694	Synthetic Chimeric Poxviruses	Canada
17868045.0	Synthetic Chimeric Poxviruses	European Patent Office
201917021814	Synthetic Chimeric Poxviruses	India
PID201904682	Synthetic Chimeric Poxviruses	Indonesia
266399	Synthetic Chimeric Poxviruses (Allowed)	Israel
2019-545700	Synthetic Chimeric Poxviruses	Japan
2024-93677	Synthetic Chimeric Poxviruses	Japan
752893	Synthetic Chimeric Poxviruses	New Zealand
11201903893P	Synthetic Chimeric Poxviruses	Singapore
2024/03393	Synthetic Chimeric Poxviruses	South Africa
2017-000418	Synthetic Chimeric Poxviruses	Venezuela
62020003684.1	Synthetic Chimeric Poxviruses	Hong Kong
792675	Synthetic Chimeric Poxviruses	New Zealand
P00202402600	Synthetic Chimeric Poxviruses	Indonesia
113144133	Synthetic Chimeric Poxviruses	Taiwan

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
2024-28557	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
10202401171Y	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
PI 2024003859	Synthetic Chimeric Vaccinia Virus	Malaysia
810669	Synthetic Chimeric Vaccinia Virus	New Zealand

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

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.
2022-569505	Compositions and Methods for Increasing Efficacy of a Drug	Japan
202217072271	Compositions and Methods for Increasing Efficacy of a Drug	India
62023079383.3	Compositions and Methods for Increasing Efficacy of a Drug	Hong Kong

Triptan Compound – Formulations

Application No.	Title	Country / Region
18/782,922	Formulations Comprising Triptan Compounds	U.S.A.

Triptan Compound – Migraine

Application No.	Title	Country / Region
18/797,812	Methods of Treating Migraine	U.S.A.
18/783,734	Pharmaceutical Composition for Treating Migraine	U.S.A.

Tianeptine – Conditions Associated with Peroxisome Proliferator-Activated Receptor

Application No.	Title	Country / Region
PCT/US2024/021799	(S)-Tianeptine and Use in Treating Disorders and Conditions Associated with Peroxisome Proliferator-Activated Receptor	PCT

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. 98/577945, filed May 31, 2024), ANGSTRO-TECHNOLOGY (Serial No. 98/006538, filed May 22, 2023) and TNX-102 SL (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); TONIX ONE LOGO Design (Serial No. 99/057051, filed February 26, 2025). 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); European Union: TONIX ONE LOGO Design (Application No. 19151272, filed March 4, 2025).

Research and Development

We have approximately 45 employees dedicated to research and development. Our research and development operations are located in Chatham, NJ, 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.

Marketing

We have nine 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. This facility is currently decommissioned. It was designed for the manufacture of nonclinical and clinical investigational products for our Infectious Disease portfolio. The current focus of which is TNX-801 a Smallpox and Mpox Preventing Vaccine and TNX-1800 a COVID vaccine selected by NIH/NIAID Project NextGen for Inclusion in Clinical Trials. This facility was decommissioned in 2024 but Tonix has the ability to reactivate it should we choose to do so.

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. 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. We submitted NDA under Section 505(b)(2) for TNX-102 SL for FM, and plan to submit an 505(b)(2)for 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 SARS-CoV-2.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

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

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

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

Coverage and Reimbursement

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

Other Healthcare Laws

Because of our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors, we will also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both.

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

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

The Impact of New Legislation and Amendments to Existing Laws

The FDCA is subject to routine legislative amendments with a broad range of downstream effects. In addition to new legislation, such as the FDA Reauthorization Act of 2017 or the FDASIA in 2012, Congress introduces amendments to reauthorize drug user fees and address emerging concerns every five years. We cannot predict the impact of these new legislative acts and their implementation of regulations on our business. The programs established or to be established under the legislation may have adverse effects upon us, including increased regulation of our industry. Compliance with such regulation may increase our costs and limit our ability to pursue business opportunities. In addition, the FDA's regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our products.

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

Human Capital Resources

As of March 17, 2025, we had 81 full-time employees, of whom 12 hold M.D. or Ph.D. degrees. We have 45 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, New Jersey, Dartmouth, Massachusetts, 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, and on the success of TNX 102-SL.
- We are exposed to cybersecurity and data privacy risks that, if realized, could harm our business.
- We have a history of operating losses and may never reach profitability. We may struggle to continue operations without facing the risk of liquidation, as we don't expect product sales to cover expenses.
- If novel product candidates are successfully developed, it is uncertain they will receive regulatory approval or successful commercialization.
- We are subject to extensive and costly government regulation, and we do not have, and may never obtain, the regulatory approvals we need to market our product candidates.
- Our product candidates may cause serious adverse events or undesirable side effects, which would delay or prevent approval, or lead to market removal, safety warnings, or sales limitations.
- We may be unable to meet our anticipated development and commercialization timelines for approval of any of our product candidates.
- Changes in the U.S. political and regulatory environment could affect availability of government funding that we may rely on, or cause delays in the development and approval of our product candidates.
- Any 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 be subject to post-approval regulation or may not be accepted by the market.
- We may use our financial and human resources to pursue research programs or product candidates that are less profitable and have a lower likelihood of success than other programs.
- We may need additional capital, and, if unavailable, we may have to delay or scale-back operations.
- Outbreaks of communicable diseases may materially and adversely affect our business.
- Competition and technological change may make our product candidates and technologies less attractive or obsolete, and our product candidates may face competition sooner than expected.
- Failure to protect our intellectual property rights could negatively affect our development of products.

- We may be involved in lawsuits to protect or enforce our patents, which could be costly.
- If we infringe the rights of third parties, we could suffer adverse effects, including defending against litigation.
- We may experience difficulties managing growth when we ultimately expand our operations. Our future success depends on our ability to retain our current executive officers and other key personnel.
- The failure of third parties to manufacture compounds used our studies, and any approved products for sale at sufficient quantities and at acceptable costs could harm our business.
- Failure by our third-party manufacturers to comply with regulatory guidelines set forth by the FDA could harm the development, approval and commercialization of our product candidates.
- Adverse global conditions, including economic uncertainty, may negatively impact our finances.
- Our internal computer systems 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 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.
- If we fail to establish marketing, sales and distribution capabilities, 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 to federal and state healthcare laws and regulations. If we are unable to comply with such laws, including any newly adopted healthcare legislative reform measures, 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.
- Obtaining approval to commercialize products outside the U.S. would expose us to international risk.
- We face the risk of product liability claims and may not be able to obtain insurance.
- We use hazardous chemicals in our business which could expose us to costly and time consuming legal claims.
- 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 our technology is ever considered “dual use” technology, it will 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.
- Sales of additional shares of our common stock could cause the price of our common stock to decline, and the issuance of preferred stock may impair the rights of the holders of common stock.
- The market price of our common stock has been extremely volatile and may continue to be. We expect that our quarterly results of operations will fluctuate, which could cause our stock price to decline.

- We could be delisted from Nasdaq, which could harm the liquidity of our stock and our capital raising.
- If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, our stock price could decline significantly and raising capital could be more difficult.
- 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.
- The Eighth Judicial District Court of Clark County, Nevada as the sole and exclusive forum for certain types of stockholder actions or proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

RISKS RELATED TO OUR BUSINESS

Our prospects are dependent on the success of TNX-102 SL. To the extent regulatory approval of TNX-102 SL is delayed or not granted or, if approved, TNX-102 SL 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 TNX-102 SL, and we believe our prospects are also dependent on our ability to obtain regulatory approval for and successfully commercialize TNX-102 SL in the U.S. The regulatory approval and successful commercialization of TNX-102 SL is subject to many risks, including those discussed in other risk factors, and TNX-102 SL 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 TNX-102 SL do not meet our or others' expectations, the market price of our common stock could decline significantly.

The FDA assigned a PDUFA goal date of August 15, 2025, for a decision on marketing authorization for TNX-102 SL. and retains complete discretion in deciding whether to approve the NDA for TNX-102 SL, 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 TNX-102 SL for the treatment of FM, or that if approved, we will successfully commercialize TNX-102 SL.

Coverage and adequate reimbursement may not be available for our products, which could make it difficult for us to sell our products profitably.

Market acceptance and sales 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, pharmacy benefit managers ("PBMs"), 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. If PBMs other payers or payer affiliates deny formulary inclusion, impose unfavorable tiering, or require burdensome utilization management restrictions, patient access to our products could be significantly limited. Moreover, 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.

Access to prescription drugs in the U.S. commercial market is largely controlled by three dominant entities: Emisar/Optum/United HealthCare, Ascent/Express Scripts/Cigna, and Zinc/CVS Caremark/Aetna, which collectively manage a significant portion of formulary decisions and reimbursement policies. These entities have the ability to deny or restrict formulary access to our products through various techniques, including National Drug Code ("NDC") blocks, exclusion lists, and unfavorable tier placement. Such actions could severely limit patient access to our therapies, reduce sales, and negatively impact our financial performance. Additionally, the consolidation of PBMs and insurers further strengthens their negotiating leverage, increasing the risk of unfavorable pricing and reimbursement terms for our products.

Moreover, PBMs have significant influence over prescription drug access through formulary decisions, reimbursement policies, and utilization management practices. In some cases, PBMs may prioritize lower-cost alternatives, including off-label or unapproved therapies, over our FDA-approved products. This could include steering patients toward opioid-based treatments for fibromyalgia or barbiturates for migraine or other medications that do not meet the same regulatory and safety standards as our products. Such actions may limit patient access to clinically appropriate therapies and negatively impact our sales.

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 authorization 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 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 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.

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.

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 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 will 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.

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 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;
- market acceptance of our product candidates;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to obtain and maintain regulatory approval for our product candidate TNX-102 SL for FM, or any of our other product candidates in the United States and foreign jurisdictions;
- delays in the commencement, enrollment and timing of clinical studies;
- the success of our clinical studies through all phases of clinical development, including studies of our most advanced product candidate, TNX-102 SL for FM and potentially other CNS indications;
- any delays in regulatory review and approval of product candidates in clinical development;
- 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;
- competition from existing products or new products that may emerge;
- 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.

Uncertainty in Government Funding and In-Kind Support Policies and Programs may adversely affect our business.

Changes in federal funding policies, including the ongoing review of DoD contracts and NIH grants and in-kind support by the new administration of President Donald Trump, could materially impact our financial resources and the progress of research conducted with U.S.-based university collaborators. While we have secured certain DoD and NIH funding and NIH in-kind support through Project NextGen, there is no guarantee that such funding or in-kind support will not be rescinded or otherwise restricted. Additionally, DoD, NIH and Biomedical Advanced Research and Development Authority ("BARDA") funding for future projects may be delayed, reduced, or denied altogether. Any such changes could adversely affect our research programs, financial condition, and operational plans. Further, certain research projects conducted in collaboration with U.S.-based university collaborators could be slowed or discontinued.

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 COMMERCILAIZATION

Our product candidates are novel and still in development.

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

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

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.

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 our 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.

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 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 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 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.

Our product candidates may cause serious adverse events, or SAEs, or undesirable side effects which may delay or prevent marketing authorization, 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 authorization 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 required to generate additional data related to safety and efficacy in order to obtain approval for TNX-SL for FM under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

We submitted the NDA for TNX-102 SL for FM under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. Some of the data required by the FDA for approval 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 authorization 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.

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 authorization 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.

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.

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 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.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges.

The U. S. biopharmaceutical industry is highly regulated and subject to frequent and substantial changes, including as a result of new judicial or government actions. Legislative and regulatory agendas as they relate to the biopharmaceutical industry are currently uncertain. Changes in the regulatory approval process, or substantial reductions in the personnel who oversee that process, could affect our ability to obtain regulatory approval for our product candidates or the timeline in which we can obtain that approval. We and our current and future third party collaborators rely on government programs and agencies, such as DTRA and the NIH, as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as DTRA and the NIH can fluctuate and is subject to the political process, which is often unpredictable. Reductions in government grants to us or our third party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act ("APA") "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision could have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight and impact of the biopharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies could be subject to increased litigation and judicial scrutiny. We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the biopharmaceutical industry, or the regulatory agencies that oversee the biopharmaceutical industry, will affect our business.

Reductions in staffing and funding at FDA and other federal agencies could cause delays in the development and approval of our products.

Under the Federal Food, Drug, and Cosmetic Act, our products cannot be investigated in humans or marketed without approval from FDA. In addition, companies developing new therapies routinely seek and receive guidance from FDA regarding their methods and plans for developing their products. We and companies like us may also benefit from FDA-administered programs like orphan drug designation and expedited development pathways, e.g., breakthrough designation. Any material reductions in the ability of FDA to perform these and other functions may delay the development and approval of our product candidates. Recent actions by the United States federal government have caused concern in the industry that this may occur. For example, beginning on February 13, 2025, the Department of Health and Human Services began firing a large number of its probationary employees, a category that includes new federal employees and employees recently promoted or transferred to new positions or agencies. Larger layoffs may follow, according to a memorandum issued by the Office of Personnel Management on February 26, 2025. These terminations, if they withstand legal challenges, may significantly delay and impede our interactions with FDA. Similar results may stem from the recent confirmed resignations of some senior FDA employees with responsibility for regulation of drugs and biologics, as well as possible future layoffs and resignations. There are also reports that the United States federal government intends to request Congress to reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of our products.

RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS; COMPETITION

We may be unable to continue to operate without the threat of liquidation for the foreseeable future. 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.

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 first quarter of 2026, 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. In connection with our management's assessment, our report from our independent registered public accounting firm for the fiscal year ended December 31, 2024 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.

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 first quarter of 2026, 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.

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.

Although 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.

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

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.

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

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 authorization 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, 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 fibromyalgia program's Phase 2 AtEase study, Phase 3 RELIEF study, the Phase 3 RALLY study and the Phase 3 RESILIENT 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 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.

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, 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. 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. If the BPCIA is 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, or business may be harmed. 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 new chemical entity ("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 limited experience in marketing or selling pharmaceutical products and currently have a small sales, marketing, and distribution infrastructure. To market any of our products directly, we would need to continue 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.

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 TNX-102 SL 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 $1,500,000 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.

If we are unsuccessful in obtaining a priority review voucher for material threat medical countermeasures, the length of the approval process for our TNX-801 vaccine in development to prevent smallpox and mpox will be longer than the approval process with the priority review voucher.

Section 3086, of the 21st Century Cures Act, or the Act, 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 in some instances for a significant amount of money. If we are not successful in obtaining a priority review voucher for TNX-801, we would not receive the benefit from the voucher.

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

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

RISKS RELATED TO OUR STOCK

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

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

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

Although our common stock is listed on the NASDAQ 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";
- "short sellers";
- 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.

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 arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of our articles of incorporation or bylaws, or

- any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws.

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

ITEM 1B – UNRESOLVED STAFF COMMENTS

There are no unresolved staff comments at December 31, 2024.

ITEM 1C – Cybersecurity

Cybersecurity Risk Management

We 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 $144,745 as of December 31, 2024, and such amount is deposited into the restricted cash account maintained at the bank that issued the letter of credit.

We own and operate a research and development facility in Frederick, Maryland used for process development activities.

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, 2024, the facility was not ready for its intended use.

We own a 45,000 square foot facility in North Dartmouth, Massachusetts that houses our Advanced Development ("ADC"), for accelerated development and manufacturing of vaccines. During the fourth quarter of 2023, the Company engaged CBRE, an international real estate brokerage firm, to potentially find a strategic partner for, or buyer of, its ADC. During the second quarter of 2024, the Company decommissioned its ADC facility. As of December 31, 2024, the Company does not have a commitment in place to sell the ADC.

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

Year Ending December 31,	
2025	$ 299
2026	142
2027	139
2028	101
2029	7
	688
Included interest	(56)
	$ 632

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 17, 2025, the closing sale price of our common stock, as reported by The NASDAQ Stock Market, was $16.28 per share. On March 17, 2025, there were approximately 220 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

In September 2024, the Board of Directors approved a share repurchase program pursuant to which we may repurchase up to $10.0 million in value of our 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. No repurchases occurred during the quarter ended December 31, 2024. Subsequent to December 31, 2024, we repurchased 250,000 of our shares of common stock outstanding under the share repurchase program at prices ranging from $9.98 to $14.33 per share for a gross aggregate cost of approximately $3.0 million.

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 transforming therapies for pain management and vaccines for public health challenges. Our development portfolio is focused on central nervous system (CNS) disorders. Our priority is to advance TNX-102 SL, a product candidate for the management of fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia and for which a PDUFA (Prescription Drug User Fee act) goal date of August 15, 2025 has been assigned for a decision on marketing authorization. The FDA has also granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the National Institute on Drug Abuse. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in infectious disease, including a vaccine for mpox, TNX-801. We recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. We own and operate a state-of-the art infectious disease research facility in Frederick, Maryland. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

Our product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are the property of their respective owners. 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, 2024 Compared to Fiscal year Ended December 31, 2023

The following table sets forth our operating expenses for the fiscal years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
	2024	**2023**
REVENUE		
Product revenue, net	$ 10,094	$ 7,768
COSTS AND EXPENSES:		
Cost of sales	$ 7,765	$ 4,741
Research and development	39,972	86,655
Selling, general and administrative	40,101	34,752
Asset impairment charges	58,957	—
Total operating expenses	146,795	126,148
Operating loss	(136,701)	(118,380)
Grant income	2,594	—
Gain on change in fair value of warrant liabilities	6,150	—
Other (expense) income, net	(2,079)	1,722
Net loss	$ (130,036)	$ (116,658)

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 11 to our financial statements appearing in this Annual Report on Form 10-K. Revenue recognized for the year ended December 31, 2024 and 2023 was $10.1 and $7.8 million, respectively.

The Company's net product revenues are summarized below:

	Year Ended December 31,	
	2024	**2023**
Zembrace Symtouch	$ 8,546	$ 6,304
Tosymra	1,548	$ 1,464
Total product revenues	$ 10,094	$ 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 Laboratories ("Upsher Smith"). See discussion at Note 11 to our financial statements appearing in this Annual Report on Form 10-K. Cost of goods sold during the year ended December 31, 2024, was $7.8 million, including write-downs related to Tosymra and Zembrace finished goods inventory of approximately $1.5 million based on an assessment of inventory on hand and projected sales prior to the respective expiration dates. 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, 2024, were $40.0 million, a decrease of $46.7 million, or 54%, from $86.7 million for the fiscal year ended December 31, 2023. This decrease is predominately due to decreased clinical expenses of $18.8 million, non-clinical expenses of $10.5 million, manufacturing expenses of $3.1 million as a result of fewer trials in the clinic and pipeline prioritization period over period, employee-related expenses of $7.1 and lab supplies of $4.1 million due to a reduction in expenditures, predominately as a result of the decommission of the ADC and reduction in force earlier in 2024.

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, 2024 and 2023, we recorded $1.6 and $2.9 million, respectively 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, 2024, and 2023.

	December 31, (in thousands)		
	2024	2023	Change
Research and development expenses:			
Direct expenses – TNX - 102 SL	$ 4,616	$ 12,250	$ (7,634)
Direct expenses – TNX - 1800	319	1,608	(1,289)
Direct expenses – TNX - 601 ER	577	8,531	(7,954)
Direct expenses – TNX - 801	599	2,931	(2,332)
Direct expenses – TNX - 1500	2,772	7,044	(4,272)
Direct expenses – TNX - 1900	1,427	5,254	(3,827)
Direct expenses – Other programs	1,716	6,826	(5,110)
Internal staffing, overhead and other	27,946	42,211	(14,265)
Total research & development	$ 39,972	$ 86,655	$ (46,683)

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.

Selling, General and Administrative Expenses. Selling, General and administrative expenses for the fiscal year ended December 31, 2024, were $40.1 million, an increase of $5.3 million, or 15%, from $34.8 million incurred in the fiscal year ended December 31, 2023. The increase is primarily due to an increase in financial reporting expenses of $1.2 million, related to the special shareholder meetings in 2024, an increase in sales and marketing of $1.2 million, an increase in professional fees of $2.7 million, an increase in depreciation of property and equipment of $0.4 million and an increase in fees and permits of $0.4 million, related to licenses obtained to sell the migraine products, offset by a decrease in employee-related costs of $1.0 million, due to fewer employees.

Asset impairment charges. We recognized a non-cash impairment charge of $48.8 million related to property and equipment, a non-cash impairment of $1.0 million related to goodwill, and a non-cash impairment charge of $9.2 million related to intangible assets, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

The impairment of the Tosymra and Zembrace inventory, intangibles and goodwill was driven by our delayed investment in the sales personnel required to drive growth in the business as we are focusing our cash resources to further our efforts to bring TNX-102 SL through the approval process and to market. However, we believe that the benefits and long-term value proposition of the 2023 acquisition of Tosymra and Zembrace remain, in that we now have the infrastructure to be ready to manufacture and sell TNX-102 SL under an expedited timeline pending FDA approval for which we expect an FDA decision in 2025.

Net Loss. As a result of the foregoing, the net loss for the year ended December 31, 2024, was $130.0 million, compared to a net loss of $116.7 million for the year ended December 31, 2023.

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, 2024, 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 and Tosymra (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 manage certain government rebates, and Upsher Smith will be reimbursed by us at cost for any rebates they pay on our behalf.

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 royalty 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. Royalty 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, royalty 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 royalty payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable royalty 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 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, 2024, we had working capital of $100.7 million, comprised primarily of cash and cash equivalents of $98.8 million, accounts receivable, net of $3.7 million, inventory of $8.4 million, and prepaid expenses and other of $8.1 million, offset by $4.5 million of accounts payable, $10.7 million of accrued expenses and other current liabilities, $2.8 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.

The following table provides a summary of operating, investing, and financing cash flows for the years ended December 31, 2024, and 2023, respectively (in thousands):

	December 31,	
	2024	2023
Net cash used in operating activities	$ (60,925)	$ (102,003)
Net cash used in investing activities	(120)	(29,070)
Net cash provided by financing activities	134,872	36,517

For the years ended December 31, 2024, and 2023, we used approximately $60.9 million and $102.0 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The decrease in cash outlays principally resulted from a decrease in research and development expense.

Cash used by investing activities for the year ended December 31, 2024, was approximately $0.1 million related to the purchase of property and equipment. 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.

For the year ended December 31, 2024, net proceeds from financing activities were $134.9 million, primarily related to the sale of common stock and warrants. For the year ended December 31, 2023, net proceeds from financing activities were $36.5 million, predominately from the sale of our common stock and warrants; and debt raised which was offset by repurchase of common stock.

We believe that our cash resources at December 31, 2024 and the proceeds that we raised from equity offerings in the first quarter of 2025, will meet our operating and capital expenditure requirements into the first quarter of 2026, 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.

2024 At-the-Market Offering

On July 30, 2024, we entered into a 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 $250.0 million in the ATM. 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, 2024, we sold approximately 4.2 million shares of common stock under the Sales Agreement, for net proceeds of approximately $128.4 million. Subsequent to December 31, 2024, we sold 2.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately $46.3 million.

July 2024 Financing

On July 9, 2024, we entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which we sold 33,936 shares of common stock and pre-funded warrants to purchase up to 37,032 shares of common stock. The offering price per share of common stock was $57.00, and the offering price per share of pre-funded warrant was $56.99.

The offering closed on July 10, 2024. We incurred offering expenses of approximately $0.5 million, including placement agent fees of approximately $0.3 million. We received net proceeds of approximately $3.5 million, after deducting the underwriting discount and other offering expenses.

June 2024 Financings

On June 12, 2024, we entered into a securities purchase agreement with certain investors, pursuant to which we sold 11,995 shares of common stock and pre-funded warrants to purchase up to 25,682 shares of common stock. The offering price per share of common stock was $106.50, and the offering price per share of pre-funded warrant was $106.40.

The offering closed on June 13, 2024. We incurred offering expenses of approximately $0.6 million, including placement agent fees of approximately $0.3 million. We received net proceeds of approximately $3.4 million, after deducting the underwriting discount and other offering expenses.

On June 27, 2024, we entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which we sold 28,339 shares of common stock and pre-funded warrants to purchase up to 42,282 shares of common stock. The offering price per share of common stock was $57.00, and the offering price per share of pre-funded warrant was $56.99.

The offering closed on June 28, 2024. We incurred offering expenses of approximately $0.6 million, including placement agent fees of approximately $0.3 million. We received net proceeds of approximately $3.4 million, after deducting the underwriting discount and other offering expenses.

March 2024 Financing

On March 28, 2024, we entered into an agreement to sell 3,365 shares of common stock, pre-funded warrants to purchase up to 1,219 shares of common stock, and accompanying Series E warrants to purchase up to 4,584 shares of common stock with an exercise price of $1,056.00 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 $960.00 and the offering price per share of pre-funded warrants was $959.68.

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, with the closing of the financing on April 1, 2024, we entered into warrant amendments (collectively, the "Warrant Amendments") with certain holders of our common warrants (referred to herein as the "Existing Warrants"). We agreed to amend the exercise price of each Existing Warrant to $1,056.00 upon approval by our stockholders of a proposal to allow the Existing Warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 or, if stockholder approval is not obtained by October 1, 2024, we agreed to automatically amend the exercise price of the Existing Warrants to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of our common stock on October 1, 2024 if and only if the Minimum Price is below the then current exercise price. Upon stockholder approval on May 22, 2024, the termination date for the warrants issued August 2023 (the "August Warrants") to purchase up to an aggregate of 2,172 shares was amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2025; the termination date for Series C Warrants to purchase up to an aggregate of approximately 10,884 shares is the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by we to the Series C Warrant holder of our 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 10,884 shares is April 1, 2029. The other terms of the Existing Warrants will remain unchanged. On May 22, 2024, at the annual meeting of stockholders, our stockholders approved the proposal to amend the exercise prices of the Existing Warrants to $1,056.00 per share and extend the expiration dates.

December 2023 Financing

On December 20, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with certain institutional investors, pursuant to which we sold and issued (i) 7,920 shares of our common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 8,973 shares of common stock and (iii) Series C warrants to purchase up to 25,338 shares of common stock (the "Series C Warrants"), and (iv) Series D warrants to purchase up to 25,338 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 $1,776.00, and the offering price per Pre-Funded Warrant and accompanying Common Warrants was $1,775.68. 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. At the closing of the offering, 2,034 Pre-Funded Warrants were immediately exercised into shares of common stock for nominal proceeds.

The Pre-Funded Warrants have an exercise price of $0.32 per share, were 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 $1,776.00 per share, and were exercisable on the later of approval by our stockholders of (i) a proposal to approve the filing of an amendment to our 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 initially expired 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 $2,720.00 per share and were exercisable beginning on the Approval Date through the five-year anniversary of the Approval Date.

Upon the closing of the offering, we 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, we determined that the authorized shares were sufficient to settle all remaining Pre-Funded Warrants and 15,917 Series D Warrants and were therefore classified in equity. The remaining 9,422 Series D Warrants and the Series C Warrants associated with the deficit shares were initially classified as liabilities at fair value and presented within non-current liabilities on the consolidated balance sheet as of December 31, 2023.

The $30.0 million in gross proceeds received by us were first allocated to the Series C Warrants and the liability-classified Series D Warrants at their respective fair values, and the residual proceeds were allocated between 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 were allocated between the equity and liability-classified instruments on a relative fair value basis, resulting in issuance costs of $1.4 million recognized as a discount to the equity-classified instruments, and $0.9 million allocated to the liability-classified instruments and immediately expensed within Selling, general and administrative expense on the consolidated statements of operations.

On January 25, 2024, the date our 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, the liability-classified Series D Warrants and the Series C Warrants were adjusted to fair value and reclassified to equity.

September 2023 Financing

On September 28, 2023, we sold 1,266 shares of common stock; pre-funded warrants to purchase up to 1,549 shares of common stock, and accompanying Series A warrants to purchase up to 2,813 shares of common stock with an exercise price of $1,600.00 per share and expiring five years from date of issuance, and Series B warrants to purchase up to 2,813 shares of common stock with an exercise price of $1,600.00 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 $1,600.00, and the offering price per share of pre-funded warrant and accompanying warrants was $1,599.68.

We incurred offering expenses of approximately $0.5 million, including placement agent fees of approximately $0.3 million. 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 791 shares of common stock; pre-funded warrants to purchase up to 1,399 shares of common stock and accompanying common warrants to purchase up to 2,188 shares of common stock with an exercise price of $3,200.00 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 $3,200.00, and the offering price per share of pre-funded warrant and accompanying common warrant was $3,199.68.

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.

2020 At-the-Market Offerings

On April 8, 2020, we entered into a sales agreement with AGP pursuant to which we may issue and sell shares of our 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, we sold approximately 322 shares of common stock under the Sales Agreement, for net proceeds of approximately $3.0 million.

Share Repurchase Program

In September 2024, the Board of Directors approved a 2024 share repurchase program pursuant to which we may repurchase up to $10.0 million in value of our 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. No repurchases occurred during the year ended December 31, 2024. Subsequent to December 31, 2024, we repurchased 250,000 of shares of our common stock outstanding under the 2024 share repurchase at prices ranging from $9.98 to $14.33 per share for a gross aggregate cost of approximately $3.0 million.

During the first quarter of 2023, we repurchased 786 of our shares of common stock outstanding under the 2022 share repurchase program for $12.5 million at prices ranging from $8,800.00 to $27,552.00 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 2023 share repurchase program pursuant to which we may repurchase up to an additional $12.5 million in value of our 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, we repurchased 50 of our shares of common stock outstanding under the new 2023 share repurchase program at $22,784 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, 2024, 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.

During the first quarter of 2025, we paid $9.6 million as a result of a pay-off of the above-mentioned loan. The pay-off amount paid by us in connection with the termination of the Loan Agreement was pursuant to a pay-off letter and includes a prepayment fee of $1.0 million in accordance with the terms and provisions of the Loan Agreement.

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, 2024, no 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' historical stock price volatility.

The weighted average fair value of options granted during the year ended December 31, 2024, was $868.00 per share. The weighted average fair value of options granted during the year ended December 31, 2023, was $12,768.00 per share.

Stock-based compensation expense relating to options granted of $4.8 million, of which $3.4 million and $1.4 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2024. 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.

As of December 31, 2024, the Company had approximately $3.4 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 1.57 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 our stockholders on May 5, 2023.

The 2023 ESPP allows eligible employees to purchase up to an aggregate of 250 shares of our 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 our 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, 2024, 159 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, 2024 and 2023, $27,000 and $34,000, respectively, was expensed. In January 2023, 5 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 had accumulated and had been recorded in accrued expenses. In January 2024, 21 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. As of June 30, 2024, approximately $33,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In July 2024, 70 shares that were purchased as of June 30, 2024, under the 2022 ESPP, were issued. Accordingly, during the third quarter of 2024, approximately $4,000 of employee payroll deductions accumulated at June 30, 2024, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $29,000 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 $12.7 million at December 31, 2024 for future work to be performed.

Operating leases

As of December 31, 2024, future minimum lease payments are as follows (in thousands):

Year Ending December 31,		
2025	$	299
2026		142
2027		139
2028		101
2029		7
Included interest		(56)
	$	632

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.

Asset impairment charges. We test certain assets for impairment, including goodwill, indefinite-lived intangibles, long-lived assets and amortizing intangibles. Goodwill is reviewed for impairment by comparing the carrying value of a reporting unit to its fair value on an annual basis as of June 30, or more frequently if events or changes in circumstances indicate that the carrying amount of goodwill may be impaired. We evaluate long-lived assets for impairment, including property and equipment and finite-lived intangibles assets whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, we compare the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amount. Impairment, if any, is based on the excess of the carrying amount over the fair value, based on market value when available, or discounted expected cash flows, of those assets and is recorded in the period in which the determination is made.

We completed the required annual impairment test for goodwill as of June 30, 2024, primarily using an income approach or discounted cash flow analysis. Additionally, due to a sustained decline in revenues and continued delays in building out the sales team for our commercialized products, we also tested the commercialized products asset group for recoverability as of June 30, 2024, and determined that the carrying value was not recoverable and therefore estimated the fair value of the asset group using a discounted cash flow analysis. The significant assumptions used in the discounted cash flow model included revenue growth, long-term growth rate, and discounts rate. The impairment assessments resulted in full non-cash impairment of $965,000 of goodwill and $9.2 million, consisting of $6.2 million and $3.0 million for the Zembrace and Tosymra developed technology, intangible assets, which are reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

During the second quarter of 2024, we identified certain triggering events related to the ADC and the decommissioning of the ADC. The Company determined that the carrying value of the ADC was not recoverable and that the carrying value exceeded its fair value. We engaged independent appraisers to value the building and land, using sales comparison and income capitalization approaches, and the related equipment using a indirect cost approach and market approach. The assessments resulted in a non-cash impairment charge of $48.8 million, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

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.

The classification of derivative instruments is reassessed at each reporting date. If the classification changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified.

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 November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. Effective January 1, 2024, the Company adopted the new standard on a retrospective basis for annual periods, and interim periods beginning for the first quarter of 2025. The Company does not believe the impact of the new guidance and related codification improvements had a material impact to its financial position, results of operations and cash flows.

Recently Issued Accounting Pronouncements

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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures,* to improve transparency in financial reporting by requiring entities to present more detailed information about the nature of expenses included within the Income Statement. The guidance will first be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2024-03 on our disclosures.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TONIX PHARMACEUTICALS HOLDING CORP.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Tonix Pharmaceuticals Holding Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tonix Pharmaceuticals Holding Corp. and Subsidiaries (the "Company") as of December 31, 2024 and 2023, 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, 2024 and 2023, 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) relate 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 matters below, providing separate opinions 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 $1.8 million is included in accrued expenses and other current liabilities in the December 31, 2024 consolidated balance sheet. The Company also recorded prepaid clinical trial expenses of approximately $0.9 million within prepaid expenses and other in the December 31, 2024 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 a sample of contractual commitments for completeness of the contract listing, as well as confirmation of work 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 Company financial 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 work completed in the current period to work completed in prior-period to identify unusual fluctuations, if any.

Impairment of long-lived assets

As described in Note 2 to the consolidated financial statements, the Company evaluates long-lived assets for impairment, including property and equipment, finite-lived intangible assets and operating lease right-of-use assets whenever events or circumstances indicate that their net book value may not be recoverable. The Company compared the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amount. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets, with the difference recorded as an impairment charge. For the year-ended December 31, 2024, the Company recorded impairment charges related to long-lived assets of $48.8 million associated with the decommissioning of the Advanced Development Center, and $9.2 million associated with Zembrace and Tosymra developed technology intangible assets due to a decline in revenues.

We identified the impairment of long-lived assets as a critical audit matter due to the significant judgment and estimation required by management in estimating the undiscounted cash flows and related fair value estimates of each impaired asset group. 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 the identification of events or changes in circumstances that indicate the carrying amount of an asset or asset group may not be recoverable, as well as management's methodology in determining the fair value estimate when triggering events are identified.

Our procedures related to the Advanced Development Center also included, among others, (i) evaluation of whether management appropriately identified events or changes in circumstances that indicated that the carrying amount of certain asset groups may not be recoverable; (ii) evaluation of management's determination of asset groups at the lowest level of identifiable cash flows; (iii) vouching a selection of invoices to validate acquisition costs, along with physical observation of the underlying land, building, and selected machinery and equipment near the impairment date;

and (iv) testing managements fair value estimates. Testing over the fair value estimates involved the assistance of auditor specialists, which included determining the reasonableness of the valuation methodology applied and assumptions used by Management.

Our procedures related to developed technology intangible assets also included, among others, (i) evaluation of whether management appropriately identified events or changes in circumstances that indicated that the carrying amount of certain asset groups may not be recoverable; and (ii) testing managements recoverability test and fair value estimates. Testing over the fair value estimates involved the assistance of auditor specialists, which included determining the reasonableness of the valuation methodology applied and assumptions used by Management. As part of our evaluation, we also considered whether such assumptions were consistent with evidence obtained in other areas of the audit.

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

EISNERAMPER LLP
Iselin, New Jersey
March 18, 2025

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 98,776	$ 24,948
Accounts receivable, net	3,683	—
Inventory, net	8,408	13,639
Prepaid expenses and other current assets	8,135	9,181
Total current assets	119,002	47,768
Property and equipment, net	42,252	94,028
Intangible assets, net	120	9,743
Goodwill	—	965
Operating lease right-to-use assets	565	824
Other non-current assets	951	1,129
Total assets	$ 162,890	$ 154,457
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,546	$ 3,782
Accrued expenses and other current liabilities	10,667	12,482
Term loan payable, short term	2,820	2,350
Lease liability, short term	274	270
Total current liabilities	18,307	18,884
Term loan payable, long term	4,667	6,561
Series C warrant liabilities	—	14,595
Series D warrant liabilities	—	8,260
Lease liability, long term	358	632
Total liabilities	23,332	48,932
Commitments (See Note 17)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, 0 shares designated as of both December 31, 2024 and 2023; 0 shares issued and outstanding - as of both December 31, 2024 and 2023	—	—
Common stock, $0.001 par value; 1,000,000,000 shares authorized; 4,385,929 and 20,926 shares issued and outstanding as of December 31, 2024 and 2023, respectively and 21 shares to be issued as of December 31, 2023	4	—
Additional paid in capital	870,503	706,415
Accumulated deficit	(730,694)	(600,658)
Accumulated other comprehensive loss	(255)	(232)
Total stockholders' equity	139,558	105,525
Total liabilities and stockholders' equity	$ 162,890	$ 154,457

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,	
	2024	**2023**
REVENUES:		
Product revenue, net	$ 10,094	$ 7,768
COSTS AND EXPENSES:		
Cost of sales	7,765	4,741
Research and development	39,972	86,655
Selling, general and administrative	40,101	34,752
Asset impairment charges	58,957	—
Total Operating Expenses	146,795	126,148
Operating loss	(136,701)	(118,380)
Grant income	2,594	—
Gain on change in fair value of warrant liabilities	6,150	—
Other (expense) income, net	(2,079)	1,722
Net loss available to common stockholders	$ (130,036)	$ (116,658)
Net loss to common stockholders per common share, basic and diluted	$ (176.60)	$ (14,720.25)
Weighted average common shares outstanding, basic and diluted	736,339	7,925

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2024	**2023**
Net loss	$ (130,036)	$ (116,658)
Other comprehensive loss:		
Foreign currency translation loss	(23)	(65)
Comprehensive loss	$ (130,059)	$ (116,723)

See the accompanying notes to the consolidated financial statements

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

	Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance, December 31, 2023	20,926	$ —	$ 706,415	$ (232)	$ (600,658)	$ 105,525
Issuance of common stock upon exercise of prefunded warrants	113,155	—	—	—	—	—
Issuance of common stock under At-the-market offering, net of transactional expenses of $4,977	4,174,122	4	128,363	—	—	128,367
Issuance of common stock, net of transactional expenses of $2,261	77,635	—	14,215	—	—	14,215
Fair value of warrants reclassified from liabilities to equity	—	—	26,682	—	—	26,682
Fair value of warrants classified from equity to liabilities	—	—	(9,977)	—	—	(9,977)
Employee stock purchase plan	91	—	27	—	—	27
Stock-based compensation	—	—	4,778	—	—	4,778
Foreign currency transaction gain	—	—	—	(23)	—	(23)
Net loss	—	—	—	—	(130,036)	(130,036)
Balance, December 31, 2024	4,385,929	$ 4	$ 870,503	$ (255)	$ (730,694)	$ 139,558

See the accompanying notes to the consolidated financial statements

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

	Common stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Gain (loss)	Deficit	Total
Balance, December 31, 2022	6,446	$ —	$ 677,387	$ (167)	$ (470,038)	$ 207,182
Repurchase of common stock under Share Repurchase Program, including transactional expenses of $334	(836)	—	(3)	—	(13,962)	(13,965)
Issuance of common stock under 2022 Purchase agreement	30	—	441	—	—	441
Issuance of common stock under At-the-market offering, net of transactional expenses of $137	322	—	3,024	—	—	3,024
Issuance of common stock and warrants under AGP Financing, net of transactional expenses of $2,663	9,977	—	16,262	—	—	16,262
Issuance of common stock upon exercise of prefunded common warrants	4,982	—	—	—	—	—
Employee stock purchase plan	5	—	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	20,926	$ —	$ 706,415	$ (232)	$ (600,658)	$ 105,525

See the accompanying notes to the consolidated financial statements

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

	Year ended December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (130,036)	$ (116,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,421	4,291
Asset impairment charges	58,957	—
Stock-based compensation	4,778	9,275
Change in fair value of warrant liabilities	(6,150)	283
Offering costs allocated to warrant liabilities	—	903
Inventory write-off	1,490	—
Amortization of debt discounts	840	—
Gain on sale of property and equipment	—	(62)
Changes in operating assets and liabilities:		
Accounts receivable	(3,683)	—
Inventory	3,741	61
Prepaid expenses and other	3,613	1,573
Accounts payable	927	(3,490)
Operating lease liabilities and ROU asset, net	(13)	35
Accrued expenses and other current liabilities	1,190	1,786
Net cash used in operating activities	(60,925)	(102,003)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of business	—	(22,174)
Disposal of property and equipment	—	999
Purchase of property and equipment	(120)	(7,895)
Net cash used in investing activities	(120)	(29,070)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Deferred payment related to purchase of business	(3,000)	—
Proceeds from ESPP	27	29
Repayments of term loan	(2,350)	—
Redemption of convertible preferred stock	—	—
Proceeds from debt financing	—	8,942
Proceeds, net of $7,238 and $2,800 expenses, from sale of common stock and warrants	140,195	18,939
Proceeds from allocated warrant liabilities	—	22,572
Repurchase of common stock	—	(13,965)
Net cash provided by financing activities	134,872	36,517
Effect of currency rate change on cash	4	(65)
Net increase (decrease) in cash, cash equivalents and restricted cash	73,831	(94,621)
Cash, cash equivalents and restricted cash beginning of the period	25,849	120,470
Cash, cash equivalents and restricted cash end of period	$ 99,680	$ 25,849
Supplemental disclosures of cash flow information:		
Interest paid	$ 1,234	$ 88
Purchases of property and equipment included in accounts payable and accrued liabilities	$ —	$ 106
Net ATM proceeds received after year-end	$ 2,387	$ —
Debt financing costs included in accrued liabilities and other current liabilities	$ —	$ 85
Issuance costs included in accrued liabilities and other current liabilities	$ —	117
New operating leases and lease amendments	$ —	898

See the accompanying notes to consolidated financial statements

NOTE 1 – BUSINESS

Tonix Pharmaceuticals Holding Corp. ("Tonix" or the "Company"), through its wholly owned subsidiary Tonix Pharmaceuticals, Inc. ("Tonix Sub"), is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges.

Tonix's priority is to advance TNX-102 SL, a product candidate for the management of fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia and for which a PDUFA (Prescription Drug User Fee act) goal date of August 15, 2025 has been assigned for a decision on marketing authorization. The FDA has also granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the National Institute on Drug Abuse. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, Md. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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, 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, 2024, the Company had working capital of approximately $100.7 million. At December 31, 2024, the Company had an accumulated deficit of approximately $730.7 million. The Company held unrestricted cash and cash equivalents of approximately $98.8 million as of December 31, 2024.

The Company believes that its cash resources at December 31, 2024 and the net proceeds of $46.3 million that it raised from equity offerings in the first quarter of 2025 (See Note 13), will not meet its planned operating and capital expenditure requirements into the first quarter of 2026, but not beyond.

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 or all of its research and development activities or other operations, and potentially delay product development in an effort to maintain sufficient funds to continue operations. If any of these events occurs, the Company's ability to achieve development and commercialization goals will 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 June 10, 2024, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock, The Company accounted for the reverse stock split on a retrospective basis pursuant to ASC 260, Earnings Per Share. All 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 common and preferred stock were not adjusted because of the reverse stock split.

On February 5, 2025, the Company effected a 1-for-100 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 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 common and preferred stock were 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.

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, impairments, 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

The Company adopted Accounting Standard Update ("ASU") 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, as of January 1, 2024.

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company considers its chief executive officer to be the Company's CODM. The CODM manages its operations and allocates resources based on the Company's consolidated results and therefore operates as one segment.

Segment revenue, profit or loss, significant segment expenses and other segment items - The accounting policies of the Company's single operating and reportable segment are the same as those described in the summary of significant accounting policies. The Company's method for measuring segment profitability includes net income (loss), which the CODM uses to assess performance and make decisions for resource allocation, consistent with the measurement principals for net income (loss) as reported on the Company's consolidated statement of operations. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's consolidated statement of operations, and expenses are not regularly reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources. The measure of segment assets is reported.

The Company has two products that each accounted for $8.5 million and $1.6 million, respectively, representing 100% of total revenues during the year ended December 31, 2024 and 2023.

As of December 31, 2024, accounts receivable from four customers accounted for 30%, 26%, 25%, and 9% of accounts receivable. 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, 2024, revenues from five customers accounted for 24%, 23%, 22%, 16% and 10% of net product revenues, respectively. For the year ended December 31, 2023, revenues from four customers accounted for 25%, 21%, 18% and 14% of net product revenues, respectively.

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, 2024 and 2023, cash equivalents, which consisted of money market funds, amounted to $24,000 and $23,000, respectively. Restricted cash, which is included in Other non-current assets on the consolidated balance sheet, at both December 31, 2024 and 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 16) and restricted cash held by vendors in escrow accounts for patient support services.

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, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	$ 98,776	$ 24,948
Restricted cash	904	901
Total	$ 99,680	$ 25,849

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 cash discounts, chargebacks and customer rebates. 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.

As of December 31, 2024, the Company did not have an allowance for credit losses, as the Company's exposure to credit losses is de minimis. An allowance for credit losses 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 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. Acquired inventory was valued at estimated selling price less a reasonable margin. 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. During the year ended December 31, 2024, the Company recorded write-downs related to Tosymra and Zembrace finished goods inventory of approximately $0.3 million and $1.2 million, respectively, based on an assessment of inventory on hand and projected sales prior to the respective expiration dates. 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 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 and amortization is calculated using the straight-line method over the asset's estimated useful life, which ranges from 20 to 40 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 and amortization on assets begin when the asset is placed in service. Depreciation and amortization expense for the years ended December 31, 2024, and 2023 was $2.9 million and $3.8 million, respectively. The Company's property and equipment is 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, LLC ("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 both the years ended December 31, 2024, and 2023, was $0.5 million. The Company recorded a full impairment of its developed technology assets during the second quarter of 2024, discussed further below.

Impairment testing of long-lived assets

The Company evaluates long-lived assets for impairment, including property and equipment, finite-lived intangibles assets and operating lease right-to-use assets whenever events or changes in circumstances indicate that their net book value may not be recoverable. When such factors and circumstances exist, the Company compares the projected undiscounted future cash flows associated with the related asset or group of assets over their estimated useful lives against their respective carrying amount. Impairment, if any, is based on the excess of the carrying amount over the fair value, based on market value when available, or discounted expected cash flows, of those assets and is recorded in the period in which the determination is made.

During the second quarter of 2024, the Company identified certain triggering events related to and the decommissioning of the ADC. The Company determined that the carrying value of the ADC was not recoverable and that the carrying value exceeded its fair value. As such, the Company recorded a non-cash impairment charge of $48.8 million, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

Additionally, due to a sustained decline in revenues and continued delays in building out the sales team for its commercialized products, the Company also tested its commercialized products asset group for recoverability during the second quarter of 2024. The Company determined that the carrying value was not recoverable and therefore estimated the fair value of the asset group using a discounted cash flow analysis. The Company recorded a non-cash impairment charge for the amount of $9.2 million, representing the excess carrying value over the fair value, consisting of $6.2 million and $3.0 million for the Zembrace and Tosymra developed technology intangible assets, respectively, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

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. The Company previously recognized goodwill in connection with the USL Acquisition consummated on June 30, 2023 (See Note 5). The Company completed the required annual impairment test for goodwill during the second quarter of 2024, which resulted in full non-cash impairment of the Company's $965,000 of goodwill, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

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

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.

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, 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.

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 and, in certain arrangements. U.S. GAAP does not have specific accounting standards covering government grants to business entities. The Company applies International Accounting Standards 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance by analogy when accounting for government grants. Under IAS 20, government grants are initially recognized when there is reasonable assurance the conditions of the grant will be met and the grant will be received. After initial recognition, government grants received are recognized in earnings in the same period the underlying costs for which the grant is intended to compensate are incurred. The Company classifies government grants received under these arrangements as either a reduction to the related research and development expense or as grant income in the consolidated statements of operations, depending on the fee structure of the arrangement. The Company also applies the disclosure requirements of ASC 832, Government Assistance.

In August 2022, the Company 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, 2024, we received $1.4 million in funding as a reduction of related research and development expense. Included in prepaid expenses and other current assets is an additional $0.2 million which was received in February 2025 and resulted in a further reduction of research and development expense during the year ended December 31, 2024. During the year ended December 31, 2023, we received $2.7 million in funding as a reduction of related research and development expense.

In June 2024, the Company was awarded a prototype Other Transaction Agreement from the Defense Threat Reduction Agency ("DTRA"), an agency within the U.S. Department of Defense, to fund the Company's TNX-4200 program for the development of a small molecule broad-spectrum antiviral for the prevention or treatment of viral infections to improve the medical readiness of military personnel in biological threat environments. The DTRA grant provides for payments totaling up to $34.1 million over five years, which is subject to adjustment based on costs, scope, budget, and other factors as the program advances. Funding under the DTRA grant is earned and recognized under a cost-plus-fixed-fee arrangement in which the Company is reimbursed for all direct costs incurred plus allowable indirect costs and a fixed fee. During the year ended December 31, 2024, $2.6 million was recognized in grant income related to the DTRA grant. As of December 31, 2024, $0.6 million of grant income, included above, was earned but not yet received and is presented in prepaid expenses and other current assets.

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, 2024, 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.

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 15). 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 variable exercise price of the 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.

The classification of derivative instruments is reassessed at each reporting date. If the classification changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified.

Per Share Data

The computation of basic and diluted loss per share for the year ended December 31, 2024 and 2023 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. Prefunded warrants are assumed exercised on date of issuance and are included in the basic earnings per share ("EPS") calculation.

All warrants (See Note 15) issued participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing EPS, these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the year ended December 31, 2024, and 2023, 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, 2024 and 2023, are as follows:

	2024	2023
Warrants to purchase common stock	45,664	65,431
Options to purchase common stock	3,865	774
Totals	49,529	66,205

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. Effective January 1, 2024, the Company adopted the new standard on a retrospective basis for annual periods, and interim periods beginning for the first quarter of 2025. The Company does not believe the impact of the new guidance and related codification improvements had a material impact to its financial position, results of operations and cash flows.

Recently Issued Accounting Pronouncements

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 consolidated 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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures,* to improve transparency in financial reporting by requiring entities to present more detailed information about the nature of expenses included within the Income Statement. The guidance will first be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is in the process of assessing the impact of ASU 2024-03 on our disclosures.

NOTE 3 – INVENTORY

The components of inventory consisted of the following as of December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
	(in thousands)	
Raw Materials	$ 3,071	$ 3,611
Work-in-process	213	2,539
Finished Goods	5,124	7,489
Total Inventory	$ 8,408	$ 13,639

NOTE 4 – PROPERTY AND EQUIPMENT, NET

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

	December 31, 2024	December 31, 2023
	(in thousands)	
Property and equipment, net:		
Land	$ 8,011	$ 8,011
Land improvements	305	326
Buildings	24,504	66,749
Office furniture and equipment	1,371	2,366
Laboratory equipment	12,124	21,904
Leasehold improvements	34	34
Property and equipment gross	46,349	99,390
Less: Accumulated depreciation and amortization	(4,097)	(5,362)
Property and equipment, net	$ 42,252	$ 94,028

During the second quarter of 2024, primarily as a result of the Company's decision to decommission its ADC facility in Dartmouth, Massachusetts, the Company recognized a non-cash impairment charge of $48.8 million, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024. The 45,000 square foot facility was purchased on September 28, 2020, for $4.0 million and incurred approximately $61.6 million to the build-out of the facility.

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, 2023	$ 965
Impairment of goodwill	(965)
Balance at December 31, 2024	$ —

The Company completed its annual impairment test for goodwill during the second quarter of 2024, which resulted in full impairment of the Company's $965,000 of goodwill, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

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

	December 31, 2024	December 31, 2023
	(in thousands)	
Intangible assets subject to amortization		
Developed technology	$ 10,100	$ 10,100
Less: Impairment charge	9,147	—
Less: Accumulated amortization	953	477
Total	$ —	$ 9,623
Intangible assets not subject to amortization		
Internet domain rights	$ 120	$ 120
Total intangible assets, net	$ 120	$ 9,743

During the years ended December 31, 2024 and 2023, the Company recorded amortization of $476,000 and $477,000, respectively.

As a result of certain triggering events identified impacting the Company's commercialized products asset group during the second quarter of 2024, the Company tested the asset group for impairment as of June 30, 2024, resulting in a full impairment of its Zembrace and Tosymra developed technology intangible assets, of $6.2 million and $3.0 million, respectively, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024.

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, 2024, and 2023, the Company used Level 1 quoted prices in active markets to value cash equivalents which were de minimis for both periods presented. The Company did not have any Level 2 or Level 3 assets or liabilities as of December 31, 2024. As of December 31, 2023, Level 3 liabilities included a portion of the Series D Warrants and all Series C Warrants issued in December 2023, which did not meet the criteria for equity classification due to insufficient authorized shares to settle the instruments and were therefore accounted for as liabilities at fair value from the issuance date to January 25, 2024, the date the Company received stockholder approval to increase the number of authorized shares.

Additionally, during the year ended December 31, 2024, Level 3 liabilities included a portion of the Company's outstanding August 2023 Warrants, Series A Warrants, Series B Warrants, Series C Warrants, and Series D Warrants (collectively, the "Existing Warrants"), as a result of certain Warrant Amendments executed on April 1, 2024, which provided for potential adjustments to the exercise prices of the Existing Warrants that were contingent on stockholder approval. As such, the Existing Warrants classified as liabilities from April 1, 2024, through May 22, 2024, the date the Company received stockholder approval to fix the exercise prices at $1,056.00 per share.

The Company uses the Black-Scholes option pricing model to estimate the fair value of warrant liabilities as of the respective issuance dates or reclassification dates, as applicable, using significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. For periods prior to the initial exercise date of the warrants, an additional discount for lack of marketability ("DLOM") was applied. For the Existing Warrants, the Black-Scholes option pricing model was probability weighted for different exercise price scenarios, as applicable.

The following table summarizes the range of significant assumptions used in determining the fair value of liability-classified warrants for the years ended December 31, 2024, and 2023:

	Year ended December 31, 2024	Year ended December 31, 2023
Common stock price	$ 608.00 - 988.80	$ 1,289.60
Risk-free rate	4.01% - 5.37%	3.84% - 4.23%
Expected term (in years)	0.86 - 5.00	1.78 - 5.15
Expected volatility	105.00% - 120.00%	108.00%
Discount for lack of marketability	N/A	5.00%

A reconciliation of the beginning and ending balances for the liability-classified warrants measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the year ended December 31, 2024:

	Warrant liabilities
Balance at December 31, 2023	$ 22,855
Fair value - mark to market adjustment	(7,005)
Warrants reclassified from liabilities to equity	(15,850)
Warrants reclassified from equity to liabilities	9,977
Fair value - mark to market adjustment	855
Warrants reclassified from liabilities to equity	(10,832)
Balance at December 31, 2024	$ —

A reconciliation of the beginning and ending balances for the liability-classified warrants measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows for the year ended December 31, 2023:

	Warrant liabilities
Balance at December 31, 2022	$ —
Warrant liabilities issued	22,572
Fair value - mark to market adjustment	283
Balance at December 31, 2023	$ 22,855

Changes in the fair value of the liability-classified warrants are recognized as a separate component of income and expense in the consolidated statement of operations.

NOTE 7 – OTHER BALANCE SHEET INFORMATION

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

	December 31, 2024	December 31, 2023
Prepaid expenses and other current assets:	(in thousands)	
Contract-related	$ 881	$ 4,590
Government grants	793	199
At-the-market receivable	2,387	—
Non-trade receivables	953	—
Debt interest and fees	180	1,513
Inventory	—	508
Insurance	1,392	143
Other	1,549	2,228
	$ 8,135	$ 9,181
Accrued expenses and other current liabilities:		
Contract-related	$ 1,816	$ 2,980
Upsher Smith obligation	—	3,000
Compensation and compensation-related	4,496	4,361
Gross-to-net deductions	3,658	743
Professional fees and other	697	1,398
	$ 10,667	$ 12,482

NOTE 8 – DEBT FINANCING

Long-term debt consists of the following:

	December 31, 2024	December 31, 2023
Term Loan	$ 8,650	$ 11,000
Less: current portion	(2,820)	(2,350)
Total long-term debt	5,830	8,650
Less: unamortized debt discount and deferred financing costs	(1,163)	(2,089)
Total long-term debt, net	$ 4,667	$ 6,561

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 (collectively, the "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 remaining deposit as of December 31, 2024 totals $0.2 million, which 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 is 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.

During the first quarter of 2025, the Company paid $9.6 million as a result of a pay-off of the above-mentioned loan. The pay-off amount paid by the Company in connection with the termination of the Loan Agreement was pursuant to a pay-off letter and includes a prepayment fee of $1.0 million in accordance with the terms and provisions of the Loan Agreement.

NOTE 9 – STOCKHOLDERS' EQUITY

On June 10, 2024, the Company effected a 1-for-32 reverse stock split of its issued and outstanding shares of common stock, whereby 95,543,805 outstanding shares of the Company's common stock were exchanged for 2,985,924 shares of the Company's common stock. In connection with the reverse stock split, the Company issued an additional 245,205 shares of the Company's common stock due to fractional shares. These numbers represent the split at the time and are not split adjusted for further split adjustments. 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. As a result of the reverse-stock-split, on June 26, 2024, the Company's stock regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(a)(2).

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.

On February 5, 2025, the Company effected a 1-for-100 reverse stock split of its issued and outstanding shares of common stock, whereby 559,044,486 outstanding shares of the Company's common stock were exchanged for 5,590,667 shares of the Company's common stock. 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. As a result of the reverse-stock-split, on February 20, 2025, the Company's stock regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(a)(2).

On February 20, 2025, the Company received a letter from The NASDAQ Stock Market LLC stating that because the Company's shares had a closing bid price at or above $1.00 per share for a minimum of 10 consecutive business days, the Company's stock had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(a)(2), and that the matter is now closed.

NOTE 10 – REVENUES

Disaggregation of Net Revenues

The Company's net product revenues are summarized below:

	Year ended December 31,	
	2024	**2023**
Zembrace Symtouch	$ 8,546	$ 6,304
Tosymra	1,548	1,464
Total product revenues	$ 10,094	$ 7,768

The Company recognized revenue beginning July 1, 2023, as a result of the acquisition of two marketed products.

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 $4.5 million at December 31, 2024, of which $0.8 million was recorded as a reduction to accounts receivable and $3.7 million was recorded as a component of accrued expenses. 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 11 – 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 provided 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 for the management of certain government rebates. Upsher Smith will be reimbursed by the Company at cost for any rebates they pay on the Company's behalf.

The Company has assumed certain obligations of Upsher Smith, including the payment of quarterly royalty 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. Royalty 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, royalty 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 royalty payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable royalty 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 royalty 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 royalty 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. In April 2024, the Company paid the additional deferred payment of $3.0 million in cash.

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	$ 26,522

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 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):

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	$ 26,522

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.

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	$ 10,100	

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.

Due to a sustained decline in revenues and continued delays in building out the sales team for its commercialized products, the Company also tested its commercialized products asset group for recoverability during the second quarter of 2024. The Company determined that the carrying value was not recoverable and therefore estimated the fair value of the asset group using a discounted cash flow analysis. The Company recorded a non-cash impairment charge in the amount of $9.2 million, representing the excess carrying value over the fair value, consisting of $6.2 million and $3.0 million for the Zembrace and Tosymra developed technology intangible assets, respectively, which is reflected in asset impairment charges in the consolidated statements of operations for the year ended December 31, 2024. As the carrying value of these intangibles is $0, there were no further impairment considerations during the year ended December 31, 2024.

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 as if the USL Acquisition had occurred as of January 1, 2023, and gives effect to transactions that are directly attributable to the acquisition, including additional amortization expense related to the fair value of intangible assets acquired and an increase in Cost of Sales related to the acquisition-date fair value adjustment to inventory. On an unaudited pro forma basis, consolidated Net Product Sales and Net Loss for the year ended December 31, 2023, would have been $15.4 million and $119.9 million, respectively. 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 business 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 for the year ended December 31, 2024, is $10.1 million and $17.4 million, respectively.

As described above, in connection with the USL Acquisition, the Company and Upsher Smith entered into a Transition Services Agreement with Upsher Smith 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. Upsher Smith collected 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 Company. On April 1, 2024, the Company amended the transitional services agreement with Upsher Smith so that Upsher Smith will only provide for the management of certain government rebates. Upsher Smith will be reimbursed by the Company at cost for any rebates they pay on the Company's behalf.

NOTE 12 – 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.

NOTE 13 – SALE OF COMMON STOCK

2024 At-the-Market Offerings

On July 30, 2024, the Company entered into a Sales Agreement (the "2024 Sales Agreement"), with AGP pursuant to which the Company may issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $250.0 million in ATM sales. AGP will act as sales agent and will be paid a 3% commission on each sale under the 2024 Sales Agreement. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the year ended December 31, 2024, the Company sold approximately 4.2 million shares of common stock under the Sales Agreement, as defined below, for net proceeds of approximately $128.4 million. Subsequent to December 31, 2024, the Company has sold 2.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately $46.3 million.

July 2024 Financing

On July 9, 2024, the Company entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which the Company sold 33,936 shares of common stock and pre-funded warrants to purchase up to 37,032 shares of common stock. The offering price per share of common stock was $57.00, and the offering price per share of pre-funded warrant was $56.99.

The offering closed on July 10, 2024. 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 $3.5 million, after deducting the underwriting discount and other offering expenses.

June 2024 Financings

On June 12, 2024, the Company entered into a securities purchase agreement with certain investors, pursuant to which the Company sold 11,995 shares of common stock and pre-funded warrants to purchase up to 25,682 shares of common stock. The offering price per share of common stock was $106.50, and the offering price per share of pre-funded warrant was $106.40.

The offering closed on June 13, 2024. The Company incurred offering expenses of approximately $0.6 million, including placement agent fees of approximately $0.3 million. The Company received net proceeds of approximately $3.4 million, after deducting the underwriting discount and other offering expenses.

On June 27, 2024, the Company entered into a securities purchase agreement with certain institutional and retail investors, pursuant to which the Company sold 28,339 shares of common stock and pre-funded warrants to purchase up to 42,282 shares of common stock. The offering price per share of common stock was $57.00, and the offering price per share of pre-funded warrant was $56.99.

The offering closed on June 28, 2024. The Company incurred offering expenses of approximately $0.6 million, including placement agent fees of approximately $0.3 million. The Company received net proceeds of approximately $3.4 million, after deducting the underwriting discount and other offering expenses.

March 2024 Financing

On March 28, 2024, the Company entered into an agreement to sell 3,365 shares of common stock, pre-funded warrants to purchase up to 1,219 shares of common stock, and accompanying Series E warrants to purchase up to 4,584 shares of common stock with an exercise price of $1,056.00 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 $960.00, and the offering price per share of pre-funded warrants was $959.68.

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, with the closing of the financing on April 1, 2024, the Company entered into warrant amendments (collectively, the "Warrant Amendments") with certain holders of its common warrants (referred to herein as the "Existing Warrants"). The Company agreed to amend the exercise price of each Existing Warrant to $1,056.00 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, if stockholder approval is not obtained by October 1, 2024, the Company 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 Company's common stock on October 1, 2024, if and only if the Minimum Price is below the then current exercise price. Upon stockholder approval, the termination date for the warrants issued August 2023 (the "August Warrants") to purchase up to an aggregate of 2,172 shares was amended to April 1, 2029; the termination date for Series A Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2029; the termination date for Series B Warrants to purchase up to an aggregate of approximately 2,782 shares is April 1, 2025; the termination date for Series C Warrants to purchase up to an aggregate of approximately 10,884 shares is the earlier of (i) April 1, 2026 and (ii) 10 trading days following notice by the Company to the Series C Warrant holders 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 10,884 shares is April 1, 2029. The other terms of the Existing Warrants remained unchanged.

The Company evaluated the Warrant Amendments as of April 1, 2024, and determined that the potential adjustment to the exercise price that is contingent on stockholder approval precluded the Existing Warrants from being indexed to the Company's own stock, and as a result, did not meet the criteria for equity classification under ASC 815-40. The Company accounted for the incremental fair value of the Warrant Amendments of $3.0 million as a direct and incremental cost of the March 2024 financing as an offset to the proceeds received. As all of the Existing Warrants were equity-classified prior to the Warrant Amendments, the net impact to the consolidated statement of stockholders' equity was zero. The Company then reclassified the Existing Warrants from equity to liabilities at post-modification fair value on April 1, 2024. On May 22, 2024, the date the Company's stockholders approved the proposal to fix the exercise prices at $1,056.00 per share, the Existing Warrants were adjusted to fair value and reclassified back to equity.

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) 7,920 shares of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 8,973 shares of common stock and (iii) Series C warrants to purchase up to 25,338 shares of common stock (the "Series C Warrants"), and (iv) Series D warrants to purchase up to 25,338 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 $1,776.00, and the offering price per Pre-Funded Warrant and accompanying Common Warrants was $1,775.68. 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, 2,034 Pre-Funded Warrants were immediately exercised into shares of common stock for nominal proceeds.

The Pre-Funded Warrants have an exercise price of $0.32 per share, were 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 $1,776.00 per share, and were 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 initially expired 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 $2,720.00 per share and were 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 determined that the authorized shares were sufficient to settle all remaining Pre-Funded Warrants and 15,917 Series D Warrants and were therefore classified in equity. The remaining 9,422 Series D Warrants and the Series C Warrants associated with the deficit shares were initially classified as liabilities at fair value and presented within non-current liabilities on the consolidated balance sheet as of December 31, 2023.

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, and the residual proceeds were allocated between 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 were allocated between the equity and liability-classified instruments on a relative fair value basis, resulting in issuance costs of $1.4 million recognized as a discount to the equity-classified instruments, and $0.9 million allocated to the liability-classified instruments and immediately expensed within Selling, general and administrative expense on the consolidated statements of operations.

On January 25, 2024, the date 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, the liability-classified Series D Warrants and the Series C Warrants were adjusted to fair value and reclassified to equity.

September 2023 Financing

On September 28, 2023, the Company sold 1,266 shares of common stock; pre-funded warrants to purchase up to 1,549 shares of common stock, and accompanying Series A warrants to purchase up to 2,813 shares of common stock with an exercise price of $1,600.00 per share and expiring five years from date of issuance, and Series B warrants to purchase up to 2,813 shares of common stock with an exercise price of $1,600.00 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 $1,600.00, and the offering price per share of pre-funded warrant and accompanying warrants was $1,599.68.

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 791 shares of common stock; pre-funded warrants to purchase up to 1,399 shares of common stock and accompanying common warrants to purchase up to 2,188 shares of common stock with an exercise price of $3,200.00 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 $3,200.00, and the offering price per share of pre-funded warrant and accompanying common warrant was $3,199.68.

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.

2020 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 322 shares of common stock under the Sales Agreement, for net proceeds of approximately $3.0 million.

Stock repurchases

In September 2024, the Board of Directors approved a 2024 share repurchase program pursuant to which the Company may repurchase up to $10.0 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. No repurchases occurred during the year ended December 31, 2024. Subsequent to December 31, 2024, the Company repurchased 250,000 shares of common stock outstanding under the 2024 share repurchase program at prices ranging from $9.98 to $14.33 per share for a gross aggregate cost of approximately $3.0 million.

During the quarter ended March 31, 2023, the Company repurchased 786 of its shares of common stock outstanding under its 2022 share repurchase program for $12.5 million at prices ranging from $8,800.00 to $27,552.00 per share for a gross aggregate cost of approximately $12.5 million.

In January 2023, the Board of Directors approved a 2023 share repurchase program pursuant to which the Company may repurchase up to $12.5 million in value of its outstanding common stock from time to time on the open market and in privately negotiated transactions subject to market conditions, share price and other factors. During the quarter ended March 31, 2023, the Company repurchased 50 of its shares of common stock outstanding under the new 2023 share repurchase program at $22,784.00 per share for a gross aggregate cost of $1.1 million.

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

NOTE 14 – 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, 2024, no 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, 2024 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2022	435	$ 1,069,056	8.70	$ —
Grants	374	$ 14,763	—	—
Exercised	—	—		
Forfeitures or expirations	(35)	358,117		
Outstanding at December 31, 2023	774	$ 276,359,750	8.75	$ —
Grants	3,461	$ 1,042	—	$ —
Exercised	—	—		
Forfeitures or expirations	(370)	$ 288,965,154		
Outstanding at December 31, 2024	3,865	$ 27,540,609	8.74	$ —
Exercisable at December 31, 2024	936	$ 101,743,715	7.27	$ —

The weighted average fair value of options granted during the year ended December 31, 2024, and December 31, 2023 was $868.00 per share and $12,768.00, 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 years ended December 31, 2024 and 2023 were as follows:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Risk-free interest rate	3.58% to 5.33%	3.42% to 4.35%
Expected term of option	5.25 to 10 years	5.0 to 10 years
Expected stock price volatility	111.89% - 140.42%	122.19% - 142.72%
Expected dividend yield	0.0	0.0

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

Stock-based compensation expense relating to options granted of $4.8 million, of which $3.4 million and $1.4 million, related to General and Administration and Research and Development, respectively was recognized for the year ended December 31, 2024. 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.

As of December 31, 2024, the Company had approximately $3.4 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 1.57 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, 2024, 159 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, 2024 and 2023, $27,000 and $34,000, respectively, was expensed. In January 2023, 5 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 had accumulated and had been recorded in accrued expenses. In January 2024, 21 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. As of June 30, 2024, approximately $33,000 of employee payroll deductions had accumulated and had been recorded in accrued expenses. In July 2024, 70 shares that were purchased as of June 30, 2024, under the 2022 ESPP, were issued. Accordingly, during the third quarter of 2024, approximately $4,000 of employee payroll deductions accumulated at June 30, 2024, related to acquiring such shares, was transferred from accrued expenses to additional paid in capital. The remaining $29,000 was returned to the employees.

NOTE 15 – STOCK WARRANTS

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2024:

Exercise Price	Number Outstanding	Expiration Date
$ 1,056.00	4,585	April 2029
$ 1,056.00	2,782	April 2029
$ 1,056.00	2,782	April 2025
$ 1,056.00	2,172	April 2029
$ 1,056.00	10,884	February 2025
$ 1,056.00	10,884	April 2029
$ 1,600.00	36	October 2028
$ 1,776.00	5,758	January 2025
$ 2,720.00	5,758	December 2028
$ 3,200.00	22	August 2028
$ 364,800.00	1	February 2025
	45,664	

During the year ended December 31, 2024, 113,155 prefunded common warrants were exercised.

For the year ended December 31, 2024, 36 and 1 warrants with an exercise price of $1,600.00 and $320,000.00, respectively, expired.

For the year ended December 31, 2024, 8,700 and 8,700 warrants with an exercise price of $1,776.00 and $2,720.00, respectively, were returned and cancelled.

Subsequent to December 31, 2024, 10,884, 5,758 (as the Company received FDA acceptance of our NDA filing), and 1 warrants with an exercise price of $1,056.00, $1,776.00 and $364,800.00, respectively, expired.

Additionally, with the closing of the financing on April 1, 2024, the Company entered into the Warrant Amendments (as defined in Note 13) with certain holders of its warrants to purchase common stock, agreeing to amend the exercise price of each Existing Warrant to $1,056.00 upon approval by the Company's stockholders of a proposal to allow the warrants to become exercisable in accordance with Nasdaq Listing Rule 5635 or, if stockholder approval is not obtained by October 1, 2024, the exercise price would be automatically amended to the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of the Company's common stock on October 1, 2024, if and only if the Minimum Price is below the then current exercise price. The Company's stockholders approved the proposal to amend the exercise prices of the Existing Warrants to $1,056.00 per share and extend the termination dates at the annual meeting of the Company's stockholders held on May 22, 2024. As such, the table above reflects the modified terms of the Existing Warrants in effect as of December 31, 2024. See Note 13 for further details.

No common warrants were exercised during the year ended December 31, 2023.

For the year ended December 31, 2023, 1 warrant with an exercise price of $22,400,000.00 expired.

NOTE 16 – 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, 2024, the Company has right-of-use assets of $0.6 million and a total lease liability for operating leases of $0.6 million of which $0.3 million is included in long-term lease liabilities and $0.3 million is included in current lease liabilities.

At December 31, 2024, 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,	
2025	$ 299
2026	142
2027	139
2028	101
2029	7
Included interest	(56)
	$ 632

No new leases or amendments were entered into during the year ended December 31, 2024. 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.

Other information related to leases is as follows:

Operating lease expense was $0.3 and $0.6 million for the years ended December 31, 2024, and 2023, respectively.

Other information related to leases is as follows:

Cash paid for amounts included in the measurement of lease liabilities:	**Year Ended December 31, 2024**	**Year Ended December 31, 2023**
Operating cash flow from operating leases (in thousands)	$ 292	$ 556
Weighted Average Remaining Lease Term		
Operating leases	3.10 years	3.78 years
Weighted Average Discount Rate		
Operating leases	4.92%	4.53%

NOTE 17 – COMMITMENTS

Contractual agreements

The Company has entered into contracts with various contract research organizations with outstanding commitments aggregating approximately $12.7 million at December 31, 2024 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 $1.2 million and $1.3 million for the years ended December 31, 2024 and 2023, respectively, for contributions under the 401(k) Plan.

NOTE 18 – INCOME TAXES

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

	Year ended December 31,	
	2024	2023
Foreign	$ (49,444)	$ (98,204)
Domestic	(80,592)	(18,454)
Total	$ (130,036)	$ (116,658)

In 2024, the foreign losses are primarily comprised of $49.4 million related to the Irish operations and $0.09 million related to Canada operations of Tonix International Holding. In 2023, the foreign losses are primarily comprised of the $98.4 million related to the Irish operations and $0.23 million related to the Canadian 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,	
	2024	2023
Statutory federal income tax	(21.0)%	(21.0)%
Change in valuation allowance	14.4%	11.7%
Permanent differences	(1.0)%	0.2%
Foreign loss not subject to income tax	3.2%	7.2%
Attribute reduction from control change	4.3%	0.9%
Other	0.1%	1.0%
Income Tax Provision	0.0%	0.0%

Deferred tax assets (liabilities) and related valuation allowance as of December 31, 2024 and 2023 were as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets/(liabilities):		
Net operating loss carryforward	$ 39,255	$ 32,997
Stock-based compensation	9,170	10,276
Fixed assets	9,617	—
Other	4,829	2,211
Total deferred assets	62,871	45,484
Valuation allowance	(62,871)	(45,484)
Net deferred tax assets	$ —	$ —

The Company has incurred research and development ("R&D") expenses, a portion of which qualifies for tax credits. The Company conducted an R&D credit study to quantify the amount of credits and has claimed an R&D credit on its 2014-2017 tax returns. A portion of these R&D credit carryforwards are subject to annual limitations in their use in accordance with Internal Revenue Service Code ("IRC") section 383. The R&D credit carryforwards at December 31, 2023 have been reduced to $0.0 million to reflect IRC section 383 ownership changes through December 31, 2024 and the resulting inability to utilize a portion of the R&D credit prior to its expiration.

At December 31, 2024, the Company has $314.0 million of Ireland NOL carryforwards that do not expire. As of December 31, 2024, the Company's Federal NOL and state net operating losses are fully limited in accordance with IRC section 382. As such, there are no NOL carryforwards available as of December 31, 2024.

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, 2024. 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, 2024 and 2023 were $17.4 million, and $14.5 million respectively.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. However, as of December 31, 2024 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, 2024, the Company's tax returns remain open and subject to examination by the tax authorities for the tax years 2021 and after.

NOTE 19 – SUBSEQUENT EVENTS

On February 3, 2025, the Company paid $9.6 million as a result of a pay-off of its outstanding loan facility. The pay-off amount paid by the Company in connection with the termination of the Loan Agreement was pursuant to a pay-off letter and includes a prepayment fee of $1.0 million in accordance with the terms and provisions of the Loan Agreement.

On February 20, 2025, the Company received a letter from The NASDAQ Stock Market LLC stating that because the Company's shares had a closing bid price at or above $1.00 per share for a minimum of 10 consecutive business days, the Company's stock hadregained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(a)(2), and that the matter is now closed.

On February 25, 2025, the Company granted options to purchase an aggregate of 449,708 shares of the Company's common stock to employees with an exercise price of $8.05. Additionally, the Company granted options to purchase 221,558 shares of the Company's common stock to certain employees with an exercise price of $10.06.

Subsequent to December 31, 2024, the Company has sold 2.3 million shares of common stock under the Sales Agreement, for net proceeds of approximately $46.3 million.

Subsequent to December 31, 2024, the Company repurchased 250,000 of its shares of common stock outstanding under the 2024 share repurchase program at prices ranging from $9.98 to $14.33 per share for a gross aggregate cost of approximately $3.0 million.

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

None.

ITEM 9A – CONTROLS AND PROCEDURES

Management's evaluation of disclosure controls and procedures

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

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

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, 2024, 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.

Previously Reported Material Weakness in Internal Control Over Financial Reporting

In the 2024 Form 10-Q, filed with the SEC on August 16, 2024, management concluded that our internal control over financial reporting was not effective as of June 30, 2024. In the evaluation, we did not maintain an effective control environment over the internal control activities to ensure the proper recognition and measurement related to the accounting for complex and non-routine transactions. We did not have adequate supervision and review controls over the complex accounting related to the non-cash impairment of intangibles, non-cash equity transactions and the recoverability of inventory. As a result, management review of asset impairment calculations did not identify errors in the associated cash flow projections which led to an error in the conclusion of the initial impairment assessment. We also did not properly assess the realizability of inventory based upon the projections utilized and our assessment of an amendment to existing warrants that were reclassified into equity in the same period did not include a quantitative evaluation of the potential materiality of revaluation adjustments.

In connection with the material weakness as it relates to the accounting for complex and non-routine transactions related to the non-cash impairment of intangibles, non-cash equity transactions and the recoverability of inventory, management re-evaluated the effectiveness of such controls as of December 31, 2024, and concluded that such controls were remediated and operating effectively as of December 31, 2024. The remediation of the material weakness over the complex accounting related to the non-cash impairment of intangibles, non-cash equity transactions was as a result of no material balances related to these financial statement captions as of December 31, 2024, and consequently there was no risk of material misstatements for these financial statement captions. While there were no material balances for the intangible assets as of December 31, 2024 and no non-cash equity transactions for the period July 1, 2024 to December 31, 2024, management's testing of internal controls over financial reporting as of December 31, 2024 included controls that were similar in nature to the controls that were not operating effectively as of June 30, 2024 and noted such controls were operating effectively as of December 31, 2024.

In relation to the realizability of inventory, the remediation of this material weakness constituted implementing new controls with expanded review processes including but not limited to the assessment of additional data points for the assessment and additional personnel included to evaluate our ability to realize inventory balances.

Changes in internal control over financial reporting.

Other than as described above, there were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B – OTHER INFORMATION

During the fiscal quarter ended December 31, 2024, none of our officers or directors, as those terms are defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

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	67	President, CEO and Chairman of the Board of Directors
Richard Bagger	64	Director
Margaret Smith Bell	65	Director
David Grange	77	Director
Adeoye Olukotun	80	Director
Newcomb Stillwell	68	Director
Carolyn Taylor	65	Director
James Treco	69	Lead Director
Jessica Morris	47	Chief Operating Officer
Bradley Saenger	51	Chief Financial Officer and Treasurer
Gregory Sullivan	59	Chief Medical Officer and Secretary
Siobhan Fogarty	56	Chief Technical Officer

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 was a Manager of L&L Technologies LLC, or L&L, from 1996 to March 2025. In addition, Dr. Lederman has been the Managing Member of Seth Lederman Co, LLC since 2007 and was the Managing Member of Lederman & Co, LLC, or Lederman & Co, from 2002 to March 2025, 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 was a Managing Member of Plumbline LLC from 2002 to March 2025. 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 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. Previously, Ms. Bell was a Vice President at Standard Life Investments where she was a portfolio manager and health care equity analyst. Ms. Bell was also a Managing Director at Putnam Investments and served as a senior health care analyst and a portfolio manager of the Putnam Health Sciences Trust. Ms. Bell was an analyst and vice president at State Street Research and a research analyst at Alex. Brown & Sons, Inc. Ms. Bell is a past member of the Board of Overseers at Beth Israel Deaconess Medical Center. Ms. Bell holds a B.A. from Wesleyan University and an M.B.A. from the Wharton School at the University of Pennsylvania. Ms. Bell's extensive healthcare and investment banking experience were instrumental in her selection as a member of the Board.

Major General David Grange (U.S. Army, retired) became a director in February 2018. MG Grange has been President and founder of Osprey Global Solutions, LLC ("OGS"), a Service Disabled Veterans Organization, since 2011. MG Grange was Chief Executive Officer of Pharm-Olam International, Ltd. ("Pharm-Olam"), a contract research organization, from April 2017 to October 2019. Prior to founding OGS, MG Grange was a member of the Board of Pharmaceutical Product Development, Inc. (Nasdaq: PPDI), a contract research organization, from 2003 to 2009, and Chief Executive Officer from 2009 to 2011.

Prior to PPDI he served in the McCormick Tribune Foundation for 10 years most recently as Chief Executive Officer and President, where he also oversaw the support of Veteran Programs. MG Grange served 30 years in the U.S. Army as a Ranger, Green Beret, Aviator, Infantryman and a member of special operating units. At the Pentagon, he was Director of Army Current Operations, Readiness, and Mobilization. MG Grange commanded the Ranger Regiment and the First Infantry Division (the Big Red One). MG Grange holds a master's degree in Public Service from Western Kentucky University. MG Grange's extensive experience in the pharmaceutical industry and service with the U.S. military was instrumental in his selection as a member of our Board.

Adeoye Olukotun, MD became a Director in September 2018. Dr. Olukotun is a board member of Arrowhead Pharmaceuticals (ARWR), a publicly traded biopharmaceutical company. Dr. Olukotun has been the Chief Executive Officer of CR Strategies, LLC, a medical products consulting company, since 2000. Dr. Olukotun was the Chief Executive Officer of Genesis Unicorn Corporation, a special acquisition company listed on Nasdaq (GENQU) that became Genesis Unicorn Capital Corp. (GENQ), and later became ESGL Holdings Ltd trading on Nasdaq (ESGL). Dr. Olukoton 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.

R. 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 continues to be involved with several small clinical research companies operating out of the Hanover, New Hampshire area. Mr. Treco has been a Managing Partner at First Chicago Advisors, Inc., a boutique financial advisory firm where he advised 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 2024. 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.

Siobhan Fogarty became our Chief Technical Officer in February 2025. Siobhan has worked for Tonix Pharma Limited, a wholly-owned subsidiary of the Company, since September 2016, holding roles with increasing responsibility, most recently as Executive Vice President, Product Development, since February 2021, and prior to that as Vice President, Product Development, since February 2019. Ms. Fogarty started her career with Elan Corporation as a formulation scientist. Ms. Fogarty moved to Glaxo SmithKline as a manufacturing strategist post the merger of Glaxo and SmithKline Beecham. Ms. Fogarty established European product development sites for Fuisz Technologies and Biovail Corporation. Subsequently Ms. Fogarty started her own consultancy company, *e*MSc, continuing to consult with pharmaceutical companies in product development and implementation of a phased approach to quality. Ms. Fogarty earned a Bachelor of Science in Industrial Chemistry from the University of Limerick, and a Masters in Pharmaceutical Science from the School of Pharmacy, Trinity College Dublin.

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 Leadership Structure

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

We have established the position of lead director, which 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, 2024, the Board held 11 meetings, the Audit Committee held 10 meetings, the Compensation Committee held six meetings and the Nominating and Corporate Governance Committee held four 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, 2024. 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 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 engaged Aon plc, an independent executive compensation consultant, to provide advice and recommendations on the structure, amount and form of executive and director compensation and the competitiveness thereof. At the request of the Compensation Committee, the compensation consultant provided, among other things, comparative data from selected peer companies. The compensation consultant reports directly to the Compensation Committee. The Compensation Committee's decision to hire the compensation consultant was not made or recommended by Company management. The compensation consultant has not performed any work for the Company except with respect to the work that it has done directly for 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 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.

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 Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures (the "Insider Trading Policy").

Insider Trading Policies and Procedures

We have adopted the Insider Trading. These policies and procedures apply to all of our directors, officers and employees. We believe that the Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of the Insider Trading Policy is filed as Exhibit 19.01 to this Form 10-K.

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 them from or otherwise limiting their 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.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who beneficially own more than 10% of our outstanding common shares to file reports with the SEC regarding their share ownership and changes in their ownership of our common shares. Based on our records and representations from our directors and executive officers, we believe that all Section 16(a) filing requirements applicable to our directors and executive officers were complied with during the fiscal year ended December 31, 2024.

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 2024 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 2024, 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 2024 and 2023.

Name & Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) [1]	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Seth Lederman	2024	675,000	417,656	—	717,111	—	—	—	1,809,767
Chief Executive Officer	2023	675,000	—	—	1,375,065	—	—	—	2,050,065
Jessica Morris	2024	494,000	180,310	—	213,431	—	—	—	887,741
Chief Operations Officer	2023	475,000	179,550	—	274,049	—	—	—	928,599
Bradley Saenger	2024	483,600	176,514	—	189,867	—	—	—	849,981
Chief Financial Officer	2023	465,000	175,770	—	264,143	—	—	—	904,913
Gregory Sullivan	2024	499,200	182,208	—	241,036	—	—	—	922,444
Chief Medical Officer	2023	480,000	181,440	—	290,558	—	—	—	951,998

(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.

Grants of Plan-Based Awards in Fiscal 2024

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, 2024.

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	2/27/2024	410	1,177.60	398,408
	2/27/2024	74	1,177.60	79,637
	2/27/2024	595	1,472.00[2]	637,474
Bradley Saenger	2/27/2024	89	1,177.60	95,435
	2/27/2024	89	1,472.00[2]	94,432
Jessica Morris	2/27/2024	100	1,177.60	107,279
	2/27/2024	100	1,472.00[2]	106,152
Gregory Sullivan	2/27/2024	112	1,177.60	121,155
	2/27/2024	112	1,472.00[2]	119,881

(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.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

We do not have any formal policy that requires us to grant, or avoid granting, stock options at particular times. Consistent with our annual compensation cycle, if options are to be granted, the Compensation Committee generally seeks to grant annual stock option awards in connection with their conducting and completing such annual review, which typically occurs in approximately February of each year. Options are awarded to our non-employee directors pursuant to our Amended and Restated 2020 Plan, which is awarded on the date of our annual meeting of stockholders. The timing of any stock option grants in connection with new hires, promotions, or other non-routine grants may be tied to the event giving rise to the award (such as an employee's commencement of employment or promotion effective date), and in other cases such grants may be awarded at the same time with other annual grants. As a result, in all cases, the timing of grants of stock options occurs independent of the release of any material nonpublic information, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

No stock options were issued to executive officers in 2024 during any period beginning four business days before the filing of a periodic report or current report disclosing material non-public information (other than a current report on Form 8-K disclosing a material new option award grant under Item 5.02(e) of that form) and ending one business day after the filing or furnishing of such report with the SEC.

Outstanding Equity Awards at December 31, 2024

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2024.

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	—	$ 3,808,000,000.00	2/25/2025
	1	—	$ 3,808,000,000.00	2/25/2025
	1	—	$ 3,219,200,000.00	2/9/2026
	—	1(1)	$ 3,219,200,000.00	2/9/2026
	1	—	$ 352,000,000.00	3/1/2027
	1	—	$ 217,600,000.00	2/13/2028
	1	—	$ 272,000,000.00	2/13/2028
	1	—	$ 12,096,000.00	2/26/2029
	1	—	$ 15,104,000.00	2/26/2029
	1	—	$ 13,120,000.00	5/6/2029
	1	—	$ 16,384,000.00	5/6/2029
	1	—	$ 256,000.00	2/25/2030
	1	—	$ 320,000.00	2/25/2030
	4	—	$ 492,800.00	5/4/2030
	4	—	$ 614,400.00	5/4/2030
	5	—	$ 780,800.00	2/23/2031
	5	—	$ 979,200.00	2/23/2031
	7	1(2)	$ 132,416.00	2/15/2032
	2	6(2)	$ 264,800.00	2/15/2032
	2	6(2)	$ 396,992.00	2/15/2032
	2	6(2)	$ 529,408.00	2/15/2032
	22	13(3)	$ 14,624.00	2/23/2033
	22	13(3)	$ 18,272.00	2/23/2033
	410	—(4)	$ 1,177.60	2/27/2034
	—	74(5)	$ 1,177.60	2/27/2034
	—	595(5)	$ 1,472.00	2/27/2034
Jessica Morris	1	—	$ 3,808,000,000.00	2/25/2025
	1	—	$ 3,219,200,000.00	2/9/2026
	—	1(1)	$ 3,219,200,000.00	2/9/2026
	1	—	$ 352,000,000.00	3/1/2027
	1	—	$ 217,600,000.00	2/13/2028
	1	—	$ 272,000,000.00	2/13/2028
	1	—	$ 12,096,000.00	2/26/2029
	1	—	$ 15,104,000.00	2/26/2029
	1	—	$ 13,120,000.00	5/6/2029
	1	—	$ 16,384,000.00	5/6/2029
	1	—	$ 256,000.00	2/25/2030
	1	—	$ 320,000.00	2/25/2030
	1	—	$ 492,800.00	5/4/2030
	1	—	$ 614,400.00	5/4/2030
	1	—	$ 780,800.00	2/23/2031
	1	—	$ 979,200.00	2/23/2031
	1	1(2)	$ 132,416.00	2/15/2032
	1	1(2)	$ 264,800.00	2/15/2032
	1	1(2)	$ 396,992.00	2/15/2032
	1	1(2)	$ 529,408.00	2/15/2032
	7	4(3)	$ 14,624.00	2/23/2033
	7	4(3)	$ 18,272.00	2/23/2033
	—	100(5)	$ 1,177.60	2/27/2034
	—	100(5)	$ 1,472.00	2/27/2034
Bradley Saenger	1	—	$ 3,808,000,000.00	2/25/2025
	1	—	$ 3,219,200,000.00	2/9/2026
	—	1(1)	$ 1,548,800,000.00	5/27/2026
	1	—	$ 1,548,800,000.00	5/27/2026
	1	—	$ 352,000,000.00	3/1/2027

	1	—	$	217,600,000.00	2/13/2028
	1	—	$	272,000,000.00	2/13/2028
	1	—	$	12,096,000.00	2/26/2029
	1	—	$	15,104,000.00	2/26/2029
	1	—	$	13,120,000.00	5/6/2029
	1	—	$	16,384,000.00	5/6/2029
	1	—	$	256,000.00	2/25/2030
	1	—	$	320,000.00	2/25/2030
	1	—	$	492,800.00	5/4/2030
	1	—	$	614,400.00	5/4/2030
	1	—	$	780,800.00	2/23/2031
	1	—	$	979,200.00	2/23/2031
	1	1(2)	$	132,416.00	2/15/2032
	1	1(2)	$	264,800.00	2/15/2032
	1	1(2)	$	396,992.00	2/15/2032
	1	1(2)	$	529,408.00	2/15/2032
	7	3(3)	$	14,624.00	2/23/2033
	7	3(3)	$	18,272.00	2/23/2033
	—	89(5)	$	1,177.60	2/27/2034
	—	89(5)	$	1,472.00	2/27/2034
Gregory Sullivan	1	—	$	3,808,000,000.00	2/25/2025
	1	—	$	3,219,200,000.00	2/9/2026
	—	1(1)	$	3,219,200,000.00	2/9/2026
	1	—	$	352,000,000.00	3/1/2027
	1	—	$	217,600,000.00	2/13/2028
	1	—	$	272,000,000.00	2/13/2028
	1	—	$	12,096,000.00	2/26/2029
	1	—	$	15,104,000.00	2/26/2029
	1	—	$	13,120,000.00	5/6/2029
	1	—	$	16,384,000.00	5/6/2029
	1	—	$	256,000.00	2/25/2030
	1	—	$	320,000.00	2/25/2030
	1	—	$	492,800.00	5/4/2030
	1	—	$	614,400.00	5/4/2030
	2	—	$	780,800.00	2/23/2031
	2	—	$	979,200.00	2/23/2031
	1	1(2)	$	132,416.00	2/15/2032
	1	1(2)	$	264,800.00	2/15/2032
	1	1(2)	$	396,992.00	2/15/2032
	1	1(2)	$	529,408.00	2/15/2032
	7	4(3)	$	14,624.00	2/23/2033
	7	4(3)	$	18,272.00	2/23/2033
	—	112(5)	$	1,177.60	2/27/2034
	—	112(5)	$	1,472.00	2/27/2034

(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 $3,840,000,000.00, $4,480,000,000.00 and $5,120,000,000.00 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 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.

(3) 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.

(4) The shares subject to this stock option were 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.

(5) The shares subject to this stock option vested as to 1/3 of the shares on February 23, 2025, 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, 2024.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2024.

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]	3,865	$ 27,540,609.31	159
Equity compensation plans not approved by security holders	—	—	—
Total	3,865	$ 27,540,609.31	159

(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, 0 shares of common stock were available for issuance under the Amended and Restated 2020 Plan and 159 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 March 1, 2025, the base salary is $702,000. 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 March 1, 2025, the base salary is $519,168. 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 $502,944 per annum as of March 1, 2025. 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 $522,912 per annum as of March 1, 2025. 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 2024, each of our non-employee directors received stock options to purchase shares of our common stock valued at $16,499 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 2024 for services to our Company.

Name	Cash Compensation ($)	Option Awards ($)[1]	Total ($)
Richard Bagger	$ 55,000	$ 16,499[2]	$ 71,499
Margaret Smith Bell	$ 55,000	$ 16,499[2]	$ 71,499
David Grange	$ 55,000	$ 16,499[2]	$ 71,499
Adeoye Olukotun	$ 55,000	$ 16,499[2]	$ 71,499
Newcomb Stillwell	$ 55,000	$ 16,499[2]	$ 71,499
Carolyn Taylor	$ 55,000	$ 16,499[2]	$ 71,499
James Treco [3]	$ 75,000	$ 16,499[2]	$ 91,499
Total:	$ 405,000	$ 115,493	$ 520,493

(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) The aggregate number of shares of common stock underlying stock options outstanding as of December 31, 2024 held by the directors was 33.

(3) 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 14, 2025:

- 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)
Directors and Executive Officers			
Seth Lederman	Common Stock	772(3)	*
Jessica Morris	Common Stock	288(4)	*
Bradley Saenger	Common Stock	273(5)	*
Gregory Sullivan	Common Stock	312(6)	*
Richard Bagger	Common Stock	42(7)	*
Margaret Smith Bell	Common Stock	45(8)	*
David Grange	Common Stock	45(9)	*
Adeoye Olukotun	Common Stock	43(10)	*
Newcomb Stillwell	Common Stock	41(11)	*
Carolyn Taylor	Common Stock	41(12)	*
James Treco	Common Stock	44(13)	*
Officers and Directors as a Group (11 persons)	Common Stock	1,946(14)	*%

* Denotes less than 1%
(2) Percentage based upon 6,434,881 shares of common stock issued and outstanding as of March 14, 2025.
(3) Includes 765 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days, 1 share of common stock owned by Lederman & Co, and 1 share owned through an IRA account. Seth Lederman, as the Managing Member of Lederman & Co has investment and voting control over the shares held by these entities.
(4) Includes 288 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.
(5) Includes 273 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.
(6) Includes 312 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days.
(7) Includes 42 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.
(8) Includes 45 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.
(9) Includes 45 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.
(10) Includes 43 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.
(11) Includes 41 shares of common stock underlying options and restricted stock units which are currently exercisable or vested or become exercisable within 60 days.

(12) Includes 41 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days
(13) Includes 44 shares of common stock underlying options which are currently exercisable or become exercisable within 60 days
(14) Includes 1,939 shares of common stock underlying options which are currently exercisable or vested or become exercisable within 60 days, 1 share of common stock owned by Lederman & Co, and 1 share owned through an IRA account of Dr. Lederman.

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, 2024 and 2023, including review of our interim financial statements as well as registration statement filings with the SEC and comfort letters issued to underwriters were $648,375 and $522,533, 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, 2024 and 2023.

(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, 2024 and 2023.

(4) All Other Fees

None.

Pre-Approval Policies and Procedures

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

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(c) Index to Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
3.01	Articles of Incorporation, filed as an exhibit to the Registration Statement on Form S-1, filed with the Securities and Exchange Commission (the "Commission") on April 9, 2008 and incorporated herein by reference.
3.02	Articles of Merger between Tamandare Explorations Inc. and Tonix Pharmaceuticals Holding Corp., effective October 11, 2011, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 17, 2011 and incorporated herein by reference.
3.03	Third Amended and Restated Bylaws, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 3, 2016 and incorporated herein by reference.
3.04	Certificate of Change of Tonix Pharmaceuticals Holding Corp., dated March 13, 2017 and effective March 17, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 16, 2017 and incorporated herein by reference.
3.05	Certificate of Amendment to Articles of Incorporation, effective June 16, 2017, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 16, 2017 and incorporated herein by reference.
3.06	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.'s Articles of Incorporation, as amended, filed with the Secretary of State of the State of Nevada on May 3, 2019.
3.07	Form of Certificate of Designation of Series A Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
3.08	Form of Certificate of Designation of Series B Convertible Preferred Stock, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022 and incorporated herein by reference.
3.09	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.
3.10	Certificate of Amendment to Tonix Pharmaceuticals Holding Corp.'s Articles of Incorporation, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on January 25, 2024 and incorporated herein by reference
4.01	Specimen Common Stock Certificate of the Registrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 24, 2018 and incorporated herein by reference.
4.02	Form of Warrant, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on November 14, 2019 and incorporated herein by reference.
4.03	Form of Warrant Agency Agreement, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on November 14, 2019 and incorporated herein by reference.
4.04	Form of Warrant, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on February 6, 2020 and incorporated herein by reference.
4.05	Form of Warrant Agency Agreement, filed as an exhibit to the Registration Statement on Form S-1, filed with the Commission on February 6, 2020 and incorporated herein by reference.
4.06	Description of Registrant's Securities, filed herewith.
4.07	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.
4.08	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.
4.09	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.
4.10	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.
4.11	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.

4.12	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 29, 2024, and incorporated herein by reference.
4.13	Form of Series E Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on March 29, 2024, and incorporated herein by reference.
4.14	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 13, 2024, and incorporated herein by reference.
4.15	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 28, 2024 and incorporated herein by reference.
4.16	Form of Pre-Funded Warrant, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 10, 2024 and incorporated herein by reference.
10.01	Tonix Pharmaceuticals Holding Corp. 2012 Amended and Restated Incentive Stock Option Plan, incorporated herein by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A (File No. 000-54879), filed with the Commission on April 3, 2013.*
10.02	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Seth Lederman, dated February 11, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 14, 2014 and incorporated herein by reference.*
10.03	Tonix Pharmaceuticals Holding Corp. 2014 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on May 2, 2014.*

10.04	Lease Amendment and Expansion Agreement, dated February 11, 2014, by and between 509 Madison Avenue Associates, L.P. and Tonix Pharmaceuticals, Inc., filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on February 27, 2015 and incorporated herein by reference.
10.05	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Gregory Sullivan, dated June 3, 2014, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on June 3, 2014 and incorporated herein by reference.*
10.06	Tonix Pharmaceuticals Holding Corp. 2016 Stock Incentive Plan, incorporated herein by reference to Annex A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 25, 2016.*
10.07	Tonix Pharmaceuticals Holding Corp. 2017 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on May 2, 2017.*
10.08	Tonix Pharmaceuticals Holding Corp. 2018 Equity Incentive Plan, incorporated herein by reference to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on April 19, 2018.*
10.09	Purchase Agreement, dated October 18, 2018, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on October 24, 2018 and incorporated herein by reference.
10.10	Tonix Pharmaceuticals Holding Corp. 2019 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 18, 2019.*
10.11	Tonix Pharmaceuticals Holding Corp. 2019 Employee Stock Purchase Plan, incorporated herein by reference to Appendix B to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 18, 2019.*
10.12	License Agreement, dated May 20, 2019, between Tonix Pharmaceuticals Holding Corp. and The Trustees of Columbia University in the City of New York, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on August 12, 2019 and incorporated herein by reference.
10.13	Purchase Agreement, dated August 20, 2019, between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on August 23, 2019 and incorporated herein by reference.
10.14	Asset Purchase Agreement, dated August 19, 2019, between Tonix Pharmaceuticals Holding Corp. and TRImaran Pharma, Inc., filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 8, 2019 and incorporated herein by reference.
10.15	First Amended and Restated Exclusive License Agreement, dated August 19, 2019, between Tonix Pharmaceuticals Holding Corp. and Wayne State University, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 8, 2019 and incorporated herein by reference.
10.16	Exclusive License Agreement, dated September 16, 2019, between Tonix Pharmaceuticals Holding Corp. and The Trustees of Columbia University in the City of New York, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 8, 2019 and incorporated herein by reference.

10.17	Tonix Pharmaceuticals Holding Corp. 2020 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on December 13, 2019.*
10.18	Research Collaboration Agreement between Tonix Pharmaceutical, Inc. and Southern Research Institute, dated November 7, 2018, filed as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 24, 2020 and incorporated herein by reference.
10.19	License Agreement, dated May 5, 2020, between Tonix Pharmaceuticals (Canada) Inc. and The Governors of the University of Alberta, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference.†
10.20	Asset Purchase Agreement, dated June 11, 2020, between Tonix Pharmaceuticals, Inc. and Trigemina, Inc., filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on May 12, 2020 and incorporated herein by reference.†
10.21	Amended and Restated Exclusive License Agreement, dated June 11, 2020, between Tonix Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference.
10.22	Assignment and Agreement, dated June 11, 2020, between Tonix Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference.
10.23	Purchase and Sale Agreement, dated July 1, 2020, between Tonix Pharmaceuticals Holding Corp. and Seller named therein, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on August 10, 2020 and incorporated herein by reference.†
10.24	Real Property Purchase and Sale Agreement, dated October 14, 2020, between Tonix Pharmaceuticals Holding Corp. and the Seller named therein, filed as an exhibit to the Quarterly Report on Form 10-Q, filed with the Commission on November 9, 2020 and incorporated herein by reference. †
10.25	Tonix Pharmaceuticals Holding Corp. Amended and Restated 2020 Stock Incentive Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A (File No. 001-36019), filed with the Commission on March 30, 2020.*
10.26	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Jessica Morris, dated February 23, 2021, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 26, 2021 and incorporated herein by reference.*
10.27	Employment Agreement, between Tonix Pharmaceuticals Holding Corp. and Bradley Saenger, dated February 23, 2021, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on February 26, 2021 and incorporated herein by reference.*
10.28	Purchase and Sale Agreement, dated March 5, 2021, between Tonix Pharmaceuticals Holding Corp. and the Seller named therein, filed as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 15, 2021 and incorporated herein by reference.†
10.29	License Agreement, dated April 14, 2021, between the Company and OyaGen, Inc., filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on May 10, 2021 and incorporated herein by reference.†
10.30	Purchase Agreement, dated May 14, 2021, by and between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on May 14, 2021, and incorporated herein by reference.

10.31	Purchase and Sale Agreement, dated July 26, 2021, between the Company and Southern Research, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on August 9, 2021, and incorporated herein by reference.
10.32	Purchase Agreement, dated August 16, 2022, by and between Tonix Pharmaceuticals Holding Corp. and Lincoln Park Capital Fund, LLC, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on August 17, 2022, and incorporated herein by reference.
10.33	Tonix Pharmaceuticals Holding Corp. 2022 Employee Stock Purchase Plan, incorporated herein by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A, filed with the Commission on March 18, 2022.*
10.34	Form of Securities Purchase Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022, and incorporated herein by reference.
10.35	Form of Side Letter between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022, and incorporated herein by reference.
10.36	Form of Registration Agreement between Tonix Pharmaceuticals Holding Corp. and the investors thereto, dated October 25, 2022, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on October 25, 2022, and incorporated herein by reference.
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	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.

10.41	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.
10.42	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.
10.43	Placement Agent Agreement, dated March 28, 2024, 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 March 29, 2024 and incorporated herein by reference.
10.44	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.
10.45	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.
10.46	Placement Agent Agreement, dated March 28, 2024, 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 March 29, 2024 and incorporated herein by reference.
10.47	Placement Agency Agreement, dated June 12, 2024, between Tonix Pharmaceuticals Holding Corp. and Dawson James Securities Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 13, 2024, and incorporated herein by reference.
10.48	Warrant Agent Agreement, dated June 13, 2024, between Tonix Pharmaceuticals Holding Corp. and VStock Transfer, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 13, 2024 and incorporated herein by reference.
10.49	Placement Agency Agreement, dated June 27, 2024, between Tonix Pharmaceuticals Holding Corp. and Dawson James Securities Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 28, 2024 and incorporated herein by reference.
10.50	Warrant Agent Agreement, dated June 28, 2024, between Tonix Pharmaceuticals Holding Corp. and VStock Transfer, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on June 28, 2024 and incorporated herein by reference.
10.51	Placement Agency Agreement, dated July 9, 2024, between Tonix Pharmaceuticals Holding Corp. and Dawson James Securities Inc., filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 10, 2024 and incorporated herein by reference.
10.52	Warrant Agent Agreement, dated July 10, 2024, between Tonix Pharmaceuticals Holding Corp. and VStock Transfer, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 10, 2024 and incorporated herein by reference.
10.53	Form of Security Purchase Agreement, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on July 10, 2024 and incorporated herein by reference.
10.54	Sales Agreement, dated July 30, 2024, 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 July 30, 2024 and incorporated herein by reference.
10.55	Pay-Off Letter, dated February 3, 2025, by and among the Loan Parties, the Lenders and the JGB Agent, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on February 3, 2025 and incorporated herein by reference.†
10.56	Base Agreement between Advanced Technology International (ATI) and Tonix Pharmaceuticals, Inc., dated July 17, 2023.
10.57	Project Agreement No. 1 by and between Advanced Technology International and Tonix Pharmaceuticals, Inc., dated June 28, 2024†.
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: March 18, 2025

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

Date: March 18, 2025

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

POWER OF ATTORNEY

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

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

Name	Position	Date
/s/ SETH LEDERMAN Seth Lederman	Chief Executive Officer, President and Director (Principal Executive Officer)	March 18, 2025
/s/ BRADLEY SAENGER Bradley Saenger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2025
/s/ RICHARD BAGGER Richard Bagger	Director	March 18, 2025
/s/ MARGARET SMITH BELL Margaret Smith Bell	Director	March 18, 2025
/s/ DAVID GRANGE David Grange	Director	March 18, 2025
/s/ ADEOYE OLUKOTUN Adeoye Olukotun	Director	March 18, 2025
/s/ NEWCOMB STILLWELL Newcomb Stillwell	Director	March 18, 2025
/s/ CAROLYN TAYLOR Carolyn Taylor	Director	March 18, 2025
/s/ JAMES TRECO James Treco	Director	March 18, 2025

Exhibit 4.06

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

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

Common Stock

We are authorized to issue up to 1,000,000,000 shares of our common stock, par value $0.001 per share.

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

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

Transfer Agent and Registrar

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

DESCRIPTION OF PREFERRED STOCK

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

Preferred Stock

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

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

We summarize below some of the provisions that will apply to the preferred stock that we may offer to you unless the applicable prospectus supplement provides otherwise. This summary may not contain all information that is important to you. You should read the prospectus supplement, which will contain additional information and which may update or change some of the information below. Prior to the issuance of a new series of preferred stock, we will further amend our articles of incorporation, as amended, designating the stock of that series and the terms of that series. We will file a copy of the certificate of designation that contains the terms of each new series of preferred stock with the Nevada Secretary of State and the SEC each time we issue a new series of preferred stock. Each certificate of designation will establish the number of shares included in a designated series and fix the designation, powers, privileges, preferences and rights of the shares of each series as well as any applicable qualifications, limitations or restrictions. You should refer to the applicable certificate of designation as well as our articles of incorporation, as amended, before deciding to buy shares of our preferred stock as described in the applicable prospectus supplement.

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

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

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

- the designation, stated value and liquidation preference of such preferred stock;
- the number of shares within the series;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of such series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;
- the terms and conditions, if any, on which shares of such series shall be convertible or exchangeable for shares of our stock of any other class or classes, or other series of the same class;

- the voting rights, if any, of shares of such series; the status as to reissuance or sale of shares of such series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us or any subsidiary, of the common stock or of any other class of our shares ranking junior to the shares of such series as to dividends or upon liquidation;
- the conditions and restrictions, if any, on the creation of indebtedness by us or by any subsidiary, or on the issuance of any additional stock ranking on a parity with or prior to the shares of such series as to dividends or upon liquidation; and
- any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of such preferred stock.

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

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

Exhibit 10.56

BASE AGREEMENT

BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL (ATI)
315 SIGMA DRIVE
SUMMERVILLE, SC 29486

AND

Tonix Pharmaceuticals. Inc.
26 Main Street
Suite 101
Chatham, NJ 07928

Unique Entity Identifier (UEI): JYPLHNCHF675

MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) BASE AGREEMENT NO.: 2023-493

Authority: MCDC Other Transaction Agreement (OTA) No. W15QKN-16-9-1002 and 10 U.S.C. § 4022.

This Agreement is entered into between the Advanced Technology International hereinafter referred to as the "Consortium Management Firm (CMF)," and Tonix Pharmaceuticals, Inc., hereinafter referred to as "Project Agreement Holder." This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

ADVANCED TECHNOLOGY INTERNATIONAL	TONIX PHARMACEUTICALS, INC.
Rebecca Harmon, CFCM Sr. Contracts Manager Advanced Technology International	/s/ Jessica Morris
(Signature)	(Signature) Jessica Morris, COO
(Name & Title)	(Name & Title) July 17, 2023
(Date)	(Date)

Article I. SCOPE OF THE AGREEMENT

Section 1.01 Background

The U.S. Army Contracting Command-New Jersey (ACC-NJ) is entering into an Other Transaction Agreement (OTA) under the authority of 10 U.S.C. § 4022(f0, with the Medical CBRN Defense Consortium (MCDC). The Joint Project Manager for Chemical, Biological, Radiological, Nuclear - Medical (JPM-CBRN Medical), through the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), will collaborate with the MCDC to carry out a coordinated research and development program designed to develop prototype medical, pharmaceutical, and diagnostic technologies directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components or materials in use by the armed forces. An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance the mission effectiveness of military personnel, collaborating with industry partners for the advanced development of Medical Countermeasures (MCM) for chemical and biological defense. The OTA will allow JPM-CBRN Medical to partner with other agencies in the Department of Defense (DoD) chemical and biological defense enterprise, as well as collaborate with industry on applied research on candidate MCMs and supporting technologies. The MCDC was formed in response to the Government's expressed interest to engage with an industry consortium comprised of traditional and nontraditional Government contractors, small and large business, for-profit and not-for-profit entities, academic organizations and their affiliates for the purpose of entering into an OTA to develop and mature medical, pharmaceutical, and diagnostic technologies through the execution of prototype projects.

Under the OTA and associated awards, the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the areas contained within the scope of the OTA as listed in Article I, Section 1.03 herein.

Section 1.02 Definitions

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreement" refers to the MCDC Base Agreement.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final OTA for the Government.

"Agreements Officer's Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of the specific project; the AOR shall only assist in agreement administration of the specific project to the extent delegated such administration authority in writing, in the AOR delegation letter by the responsible AO.

"Base Agreement" or "OTA" refers to the Prototype OTA under the authority of 10 U.S.C. § 4022(f), between the Government and the MCDC, Agreement No. W15QKN-16-9-1002.

"Basket" is an electronic file containing proposals that have been submitted by MCDC Members in response to requests for prototype proposals, reviewed by the Government, and favorably evaluated in accordance with the procedures outlined in Section 1.03 of this Article.

"Cash Contribution" means a Project Agreement Holder's (PAH) financial resources expended to conduct a project awarded under a Project Agreement (PA). The cash contribution can be derived from PAH funds or outside sources, or may also come from non-federal contract or grant revenues, or from profit or fee on a federal procurement contract. A PAH's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds, or any other indirect cost pool allocation. New or concurrent IR&D funds can be utilized as a cash contribution, provided those funds identified by the PAH are to be spent on the conduct of a project's Statement of Work (SOW). Prior IR&D will not be considered as part of the PAH's cash or in kind contributions, nor will fee be considered on the PAH's cost sharing portion. Cash contributions include the funds a PAH will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), subcontractor efforts expended on a project, and restocking the parts and material consumed under a project.

“Consortium Management Firm (CMF)” refers to the organization acting on behalf of the MCDC to execute and administer the efforts under the OTA for this program, as defined in the specific agreement entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

“Contracting Activity” means an element of an agency designated by the agency head, and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency, which has been delegated contracting authority through its agency charter.

“Cost Share” means resources expended by the PAH on the proposed project SOW, and subject to the direction of the AOR. There are two kinds of cost share: cash contribution and in-kind contribution. Cost Share may only be proposed and collected on cost-reimbursement type agreements.

“Date of Completion” is the date on which all work is completed, or the date on which the period of performance ends.

“Development” means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service), for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

“Effective Date” means the date of last signature of this MCDC Base Agreement.

“Government” means the U.S. Government and its departments and agencies.

“Government Fiscal Year” means the period commencing on October 1 and ending September 30 of the following calendar year.

“In Kind Contribution” means the PAH’s nonfinancial resources expended by the PAH to conduct a project, such as wear and tear on in-place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of the project.

“JPEO-CBRND” means the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, created to manage our nation’s investments in chemical, biological, radiological, and nuclear defense. The JPEO-CBRND is also the parent organization of JPM-CBRN Medical. The JPEO-CBRND includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

“JPM-CBRN Medical” means the Joint Project Manager for Chemical, Biological, Radiological, Nuclear - Medical Office, created for the advanced development of medical countermeasures for chemical and biological defense. The JPM-CBRN Medical is also the program management office for this overall effort. The JPM-CBRN Medical includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

“Medical CBRN Defense Consortium (MCDC)” is the consortium formed by industry in response to the Government’s expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions.

“MCDC Base Agreement” means the agreement between the MCDC’s CMF and the MCDC Member that serves as the baseline agreement for all future PAs, and flows down applicable terms and conditions from this OTA.

“MCDC Executive Committee” is the Executive Committee, comprised of Traditional and Nontraditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions.

“MCDC Members” means the Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions that are members in good standing of the MCDC.

“MCDC Enhanced White Paper (EWP)” means the paper (proposal) submitted by MCDC member that describes a specific technology idea or concept for an indicated research area, in a Government-specified format, as delineated in the Request for Prototype Proposals (RPP). As part of the EWP RPP process, MCDC EWPs are evaluated by the Government to determine selection.

“MCDC White Paper” means the paper submitted by MCDC member that describes a specific technology idea or concept for an indicated research area in a Government-specified format, as delineated in the RPP. As part of the two-step RPP process, MCDC White Papers are evaluated by the Government to determine whether submission of a full proposal on the summarized concept or idea might be warranted.

“Milestone” means a scheduled event signifying the completion of a major deliverable or a set of related deliverables.

“Nonprofit Research Institution” means a university or other institution of higher learning, or an organization of the type described in Section 501(c)(3) of the Internal Revenue Code of 1954 that is exempt from taxation under Section 501(a) of the Internal Revenue Code, or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

“Nontraditional Defense Contractor” means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the RPP, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41, and the regulations implementing such section. A nontraditional defense contractor can be at the prime level, team members, subcontractors, lower tier vendors, or “intra-company” business units (provided the business unit makes a significant contribution to the prototype project). Examples of what might be considered a significant contribution include supplying new key technology or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

“Other Transactions for Prototype Projects” refers to the type of OTA this MCDC Base Agreement is under. This type of OTA is authorized by Department of Defense (DoD) Authorization Acts, and is found in the U.S. Code as a Note in 10 U.S.C. § 4022. 10 U.S.C. § 4022, “Authority of the DoD to carry out certain prototype projects,” authorizes the Secretary of a military department to carry out prototype projects directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. This type of OTA is treated by the DoD as an acquisition instrument, commonly referred to as an “other transaction” for a research prototype project or 4022 “other transaction.”

“Parties” means the Consortium Management Firm, ATI, and the PAH where collectively identified and “Party” where each entity is individually identified.

“Payable Milestone” means that once a milestone has been met (see definition of “milestone”), the Government can approve payment to the PAH of a predetermined dollar amount in relation to performance of a particular project under the OTA.

“Program Manager” means the Technical Administrator for the Program (located at the JPM-CBRN Medical) responsible for Government oversight of the MCDC OTA program.

“Project” refers to the scope of work being completed under a PA.

“Project Agreement (PA)” means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms, and conditions for the MCDC member entity’s performance and payment under the Government funded project. PAs shall comply with all provisions contained within the OTA and any other supporting documents referenced therein. The PA is initiated by the CMF based on the Technical Direction Letter (TDL) sent by the Government to the CMF.

“Project Agreement Holder (PAH)” means the MCDC member entity issued a PA by the CMF.

“Request for Prototype Proposals (RPP)” means the announcement(s) by the Government to the MCDC, instructing and requesting submissions for an indicated research area.

“Selection Announcement Letter (SAL)” means the Government document to be issued to the MCDC via the CMF, documenting the Government’s decision to make the award of a PA and/or place one (1) or more proposal(s) in the “Basket” and/or reject one (1) or more proposal(s).

“Technical Direction Letter (TDL)” is a Government document to be issued to the CMF, reflecting the Government’s decision to select and fund all or part of a particular proposal submitted by a MCDC member or team of MCDC members, through the RPP process conducted under this OTA. The TDL shall establish the scope of work, terms and conditions for performance and payment, and include the MCDC member proposal selected for Government funding. Where a specific Government agency laboratory, test facility, center or other location will be used by the MCDC member entity or team of MCDC member entities in performance of the PA, it will be identified, and the cost of such use, whether Government-contributed or MCDC member reimbursed, will be identified in the TDL.

“United States Army Contracting Command – New Jersey (ACC-NJ)” means the contracting activity who is designated as the lead Government organization in charge of executing the program.

Section 1.03 Scope

The purpose of this MCDC Base Agreement is to streamline the process for project awards related to prototype medical, pharmaceutical, and diagnostic technologies. Under this MCDC Base Agreement and associated Project Agreements (PA), the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the following three (3) objective areas:

- Detection: Systems and devices to identify Chemical, Biological, Radiological, and Nuclear (CBRN) agents and assist in making medical decisions.
- Prevention: Prophylaxis, pretreatment, and post-exposure prophylaxis
- Treatment: Therapeutics (post-exposure, post-symptomatic).

The Government shall determine which research and development endeavors to pursue and projects to fund. The Government shall provide the MCDC, through the Consortium Management Firm (CMF), with a competitive request for prototype proposals, either utilizing Enhanced White Papers (EWP) or White Papers and Full Proposals. The CMF shall make those RPPs available to MCDC Members, who will then decide whether to submit in response to such RPPs and, if so, will prepare their individual documentation or will individually establish a team comprised of MCDC Members to prepare a team proposal(s). The Government shall be solely responsible for evaluation and selection of proposals for project funding from among the proposals submitted. At any time throughout the term of this MCDC Base Agreement, the Government may address the needs for the desired Joint Project Manager for Chemical, Biological, Radiological, Nuclear - Medical (JPM-CBRN Medical) objective areas or other related Government needs, as they arise. The Parties agree that other organizations and agencies within the U.S. Government may participate in the collaborative activities through a Memorandum of Agreement, or other such arrangement. It is anticipated that these other organizations may include the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), Defense Threat Reduction Agency (DTRA), and Biomedical Advanced Research and Development Authority (BARDA).

Request for Prototype Proposals (RPP) Process:

Once the Government identifies a need under one of the goal/objective areas above, the Government will issue a RPP. The RPP will either utilize the EWP or White Paper and Full Proposal approach, via the CMF. Under the White Paper and Full Proposal approach, the Government may require the submission of an initial White Paper for review, prior to the submission of a Full Proposal. Due dates will be indicated for each. The CMF shall in turn issue a similar request to MCDC member entities, for which the Government will review and evaluate all responses. The Government will be solely responsible for evaluation of the submissions, in accordance with the criteria. If the RPP requires a standard MCDC white paper, only members submitting white papers will be permitted to submit full proposal submissions. Based on the evaluation of the white papers, the Government will make a recommendation on whether the member should or should not submit a full proposal submission. However, any member submitting a white paper, regardless of the Government's recommendation, may submit a full proposal.

MCDC member white papers and proposals shall be submitted to the CMF in accordance with the RPP instructions, which will include evaluation criteria and a Statement of Work (SOW) template, along with applicable due dates. The CMF will review white paper and proposal submissions for completeness and format compliance. The CMF shall in turn prepare and transmit MCDC member's white papers and proposals to the Government for evaluation. The Government will be responsible for technical evaluation and selection of the projects from the white papers and proposals submitted. Upon completion of Government evaluations, a Selection Announcement Letter (SAL) will be issued to the MCDC via the CMF, documenting the Government's decision to make the award of a PA and/or place one (1) or more proposal(s) in the "Basket" and/or reject one (1) or more proposal(s). Once selected by the Government for award, the MCDC member entity will prepare an updated cost proposal in accordance with RPP instructions. The CMF will provide a copy of the member's initial cost proposal reasonably upon receipt. Ultimately, the CMF will provide an assessment summary to the Government for review, to include back-up documentation. The Government Agreements Officer (AO) will review the documentation and complete any necessary negotiations, as well as make the final determination regarding whether the negotiated project cost is fair and reasonable. All PAs will be subject to discussions/negotiations and proposal updates, as appropriate, prior to execution.

Once all steps are complete, the Government will issue a Technical Direction Letter (TDL) to the CMF for the authorization and execution of the prototype project to be performed by the selected MCDC member entity(ies). Once the CMF receives notification of selection of a project for funding via TDL, the CMF will enter into a PA with the MCDC member.

A modification will be executed separately by the Government, which will include the funding for the negotiated and agreed-upon project. After receipt of the TDL, and review and execution of the funding modification, the CMF shall enter into a PA with the MCDC member whose project was selected. The MCDC CMF shall administer the Government-funded PAs. The Government's designated Agreements Officer's Representative (AOR) for the specific project, will supervise the technical work performed by the MCDC member entity in execution of the PA. The Government reserves the right to revise the terms and conditions of these projects in accordance with Article III, Section 3.04. The above process is subject to change based on annual review meetings.

Placement in the Electronic "Basket File":

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. The RPP will contain the available ratings and their definitions to be assigned to proposals as a result of the technical evaluation, as well as which specific ratings will qualify a proposal for inclusion in the basket. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria.

Once in the basket, a proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1.) Request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2.) Fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the basket, the CMF will receive notification of the award decision through a TDL, whereupon the CMF will enter into a PA with the indicated MCDC member, as required.

A selected proposal will reside in the Basket for thirty-six (36) months from the date the corresponding RPP is closed, unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

Small Business Innovation Research (SBIR) Phase III Project Requests:

It will be incumbent upon the MCDC member, on their own, with some general support and guidance from the CMF, to find a Government Technical Point of Contact (POC) with both (1) available funding and (2) an interest in furthering technology developed under a current or prior SBIR project. Upon doing so, the Government Technical POC will coordinate the feasibility of placing the award under the Base Agreement with the Government AO and OTA Program Manager (PM), and the following areas will be considered when making a determination for appropriateness of award under the Base Agreement:

- How the proposed effort derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements;

- How the proposed effort fits within the definition of a prototype effort related to medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel, in accordance with the statutory requirement;

- How the proposed effort fits within the overall scope of work and the goals and objectives of the Base Agreement.

Should the Government AO and the OTA PM determine it is appropriate to award the SBIR Phase III under the Base Agreement, the Government AO will send a proposal request to the MCDC member through the CMF, as is standard for any Government request under the Base Agreement. The CMF will provide a cost summary to the Government AO for consideration in the Government's award determination. The Government will evaluate the proposal, conduct any necessary negotiations, and make an award determination. If the Government makes the determination to award to the MCDC member, the Government AO will issue a TDL letter to the CMF, resulting in the issuance of a PA between the CMF and MCDC member.

SBIR Phase III awards under the Base Agreement shall include the data rights provisions and data rights granted to the MCDC member, contained within Article XI of this MCDC Base Agreement. All administrative, reporting, and other aspects of awards made for SBIR Phase III efforts under this MCDC Base Agreement, will be in accordance with the terms and conditions of the OTA. MCDC Members must have been awarded and performed under a previous SBIR Phase I and/or Phase II contract, in order to qualify for SBIR Phase III award under the Base Agreement.

Section 1.04 Goals/Objectives

The Government, in conjunction with the MCDC, shall perform coordinated research and development projects that focus on the following:

- Accelerate the development of mission critical technologies in the areas of concern from applied research into advanced development.

- Deliver therapeutic Medical Counter Measure (MCM) prototypes targeting viral, bacterial, and biological toxin targets of interest to the Department of Defense (DoD). MCM prototypes are drug products that have completed all or part of the activities required to support Food and Drug Administration (FDA) licensure. This may include meeting warfighter requirements of protection against an aerosolized route of exposure.
- Deliver enabling technologies that will support the development and regulatory review of MCM prototypes. The enabling technologies can include animal models of viral, bacterial or biological toxin disease and pathogenesis (multiple routes of exposure), assays, diagnostic technologies or other platform technologies applicable to development and regulatory review of MCMs.
- Develop prototype candidates for the prophylaxis, treatment, and diagnosis of chemical threats. This will include diagnosis of, and prophylaxis and treatment for, exposure to traditional and emerging chemical nerve agent threats, as well as other emerging chemical threat agents, other than nerve agents.
- Develop prototype candidates for the prophylaxis, treatment, and diagnosis of radiological and nuclear threats. This will include prototype candidates for diagnosis of, and prophylaxis and treatment for, Acute Radiation Syndrome.
- Develop soldier-carried autoinjector delivery devices for single drug administration. Develop soldier-carried autoinjector delivery devices for administration of two (2) or more drugs.
- Develop vaccine-manufacturing platforms that offer early stage manufacturing flexibility and diversity, using a deep knowledge of protein(s) expression in a biological system that is reproducible and scalable, and preferably with direct FDA experience. The goal is to manufacture and test identified protective molecule(s) and target molecule(s) (along with associated reagents and standards) in multiple scalable, flexible manufacturing platforms, encompassing a diverse array of manufacturing systems (e.g., insect, mammalian, live viral, plant, *E.coli*, yeast, etc.) for use in appropriate animal model(s) and in Phase 1 trials.
- Pharmaceutical development will address the FDA Animal Rule, as appropriate.
- Utilize adjuvants and excipients supporting the ability to develop up to approximately 300,000 equivalent doses within sixty (60) days at clinical quality.
- Support a family of systems diagnostic approach that increases the speed, accuracy, and confidence of agent identification and disease diagnosis. Diagnostic areas include those for organisms that circulate freely, and at relatively high numbers at or near the onset of symptoms, organisms that circulate in low numbers early in infection, but then integrate with host cells, organisms that have significant genomic diversity from strain to strain, and non-Biological Warfare (BW) agents such as toxins and chemical/radiological agents that do not replicate, and require low quantities to cause illness.
- Support the Defense Biological Products Assurance Office (formally the Critical Reagents Program), the principal DoD resource of high quality, validated, and standardized biological reference materials, reagents, and assays, as necessary.
- DoD Advanced Development and Manufacturing Capabilities: To facilitate lessons learned and to ensure DoD MCM product development schedules are not impacted, the consortium will consider Advanced Development and Manufacturing (ADM) capability contractors for biologics manufacturing activities for monoclonal antibodies, vaccines, and recombinant proteins, who may utilize the DoD funded facility.
- Pursue collaborative research with non-traditional technology providers in a manner that enables effective transition of technologies to Government prototyping programs during any phase of life cycle support (affordability, manufacturability, sustainment, etc.).

Section 1.05 Reports

The MCDC member organizations conducting projects in accordance with this MCDC Base Agreement shall maintain records of the activities performed and funding expended under the projects, as well as the results of any studies analyses, tests, and other investigations conducted. Based on the progress of the funded projects and other information known to the AO or authorized designee, the Government Program Office shall review the relevant projects throughout the period to determine if any changes to planning or budget are required. If such a change is expected, which will cause a need to modify the Base Agreement, the TDL or an individual PA may be modified to incorporate such changes. The AO is the only authorized representative of the Government who may make modifications to the Base Agreement. Project Agreement Holders (PAH) shall submit the following reports to the CMF for each PA they have been awarded:

a.) Quarterly Report. The report will have two (2) major sections, Technical Status and Business Status.

(i) Technical Status Report. The technical status report will detail technical progress to date of the PA, and report on all problems, technical issues, or major developments during the reporting period. At a minimum, each report shall include:

1. A comparison of actual accomplishments with the goals and objectives established for the reporting period.

2. Reasons why established goals and objectives were not met, if appropriate.

3. Other pertinent information, including, when appropriate, analysis and explanation of cost variances.

4. New discoveries, inventions or potential patents, as well as the specific applications or technology transfers stemming from the discoveries, inventions or potential patents. Such disclosures shall be in the form that does not compromise any intellectual property or patent rights,

5. A cumulative chronological list of written publications in technical journals. Include those in press, as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors, and titles.

6. Papers presented at meetings, conferences, seminars, etc.

(ii) Business Status Report. The business status report will provide summarized details of the resource status of the PA, including the status of the contributions by all project participants. This report will include a quarterly accounting of current expenditures, as well as any participant cost share contributions. Any major deviations from the agreed to PA plans shall be explained with discussion of proposed actions to address the deviations.

b.) Annual Technical Report. Annual technical reports are required for projects whose periods of performance are greater than one (1) year. The PAH's report will provide a concise and factual discussion of the significant accomplishments and progress during the year covered by the report.

a) Final Technical Report. The PAH shall submit a Final Technical Report to the CMF within thirty (30) calendar days of completion of the PA. The Final Technical Report will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of performance. Each of the topics described above shall be addressed as appropriate. The CMF shall submit the Final Report to the AO and cognizant AOR, who will have thirty (30) calendar days to provide comments or request that additional information be included for final approval.

b) Final Business Status Report. The Final Business Status Report shall provide summarized details of the resource status of the PA, including the status of the contributions by all participants. This report will include a final accounting of cumulative expenditures, including the status of the cost share contributions of all project participants.

The Final Technical and Business Status Reports are also required in the event of a termination in accordance with Article II, if sufficient funding is available.

Note: Deficiencies in regulatory reports must be adequately assessed by the Government, MCDC and the individual performer, or consortium as a whole, to come to resolution. The Government will notify the MCDC if reporting and/or performance are not sufficient, and work collaboratively with the MCDC toward a resolution.

Article II. TERM

Section 2.01 The Term of this MCDC Base Agreement

The period of performance for this MCDC Base Agreement is from the effective date, which is the date of last signature, to April 7, 2036, unless extended by mutual agreement of the Parties. If at any time funds expended exceed the amount obligated on a PA prior to the expiration of the term, the Parties have no obligation to continue performance and may elect to cease their efforts at that point. Provisions of this MCDC Base Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

Section 2.02 Termination of the Base Agreement by Mutual Agreement of the Government and MCDC

Except for the rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government, the CMF and the MCDC member organizations, unless extended by mutual written agreement of the Parties, the Base Agreement shall automatically terminate by written agreement of the Government and MCDC. Unless otherwise directed by the AO through the CMF, individual PAs pursuant to this MCDC Base Agreement shall also terminate upon the termination of the Base Agreement.

Section 2.03 Termination Provisions

Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA or a specific project, in whole or in part, if the AO determines that a termination is in the Government's interest. The AO shall terminate by delivering to the MCDC through its CMF, a Notice of Termination specifying the extent of termination and the effective date.

After receipt of a Notice of Termination, and except as directed by the CMF, the PAH shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its subawardees to stop work, as specified in the notice.

(2) Place no further PAs or orders (referred to as orders in this Article) for materials, services, or facilities, except as necessary to complete the continued portion of the project.

(3) Terminate all orders to the extent they relate to the work terminated.

(4) Assign to the Government, as directed by the AO, all right, title, and interest of the PAH under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.

(5) With approval or ratification to the extent required by the AO, the CMF may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this Article.

(6) Provide CMF, and/or obtain from the PAHs under the terminated portion of the PA, a transfer of title to the following where applicable, and deliver to the Government --

(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.

(7) Complete performance of any work not terminated, if applicable.

(8) Take any action that may be necessary, or that the AO may direct through the CMF, for the protection and preservation of the property related to this project, that is in the possession of the PAH(s) or any subawardee and in which the Government has or may acquire an interest.

(9) Use commercially reasonable efforts to sell, as directed or authorized by the CMF, any property of the types referred to under Article II, Section 2.03 Termination Provisions, (6)(i) and (ii); provided, however, that the PAH:

(i) is not required to extend credit to any purchaser and

(ii) may arrange for the PAH who was performing the terminated work, to acquire the property under the conditions prescribed by, and at prices approved by, the CMF.

(iii) will in no event be required to continue with such efforts for more than three (3) months after notice by the CMF to sell or disposition such property.

(10) The PAH has no obligation to continue to cost share on the terminated project or terminated portion of the project.

The requirement for at least 1/3 cost share of the total project cost by the PAH is assessed prior to award. In the event that during the course of the performance of the PA, any of the parties to the PA believe the cost sharing funds available will be insufficient, the PAH shall notify the CMF within twenty-five (25) days of the event that gave rise to the insufficient cost sharing funds. CMF will notify the Government within five (5) days of receiving such notice from the PAH. The Government will determine whether it is in its best interest to either renegotiate the scope and/or terms of the PA to meet the cost share requirement, or terminate the PA in whole or in part.

The proceeds of any transfer or disposition of project property, will be applied to reduce any payments to be made by the Government under that particular project, including credited to the price or cost of the work, or paid in any other manner directed by the CMF.

In the event of a termination of the PA, the Government shall have patent rights as described in Article X, Patent Rights, and rights in data as described in Article XI, Data Rights. Failure of the PAH and Government to agree to an equitable adjustment shall be resolved pursuant to Article VII, Disputes.

Section 2.04 Termination Cost

The CMF will negotiate with the Government and PAH in good faith, equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects. The Government will allow full credit for the Government share of the obligations properly incurred by a PAH prior to termination. Costs incurred by a PAH during a suspension or after termination of a project are not allowable unless the CMF expressly authorizes them in either the notices of suspension, termination, or subsequently. Other PAH's costs incurred during a suspension or after termination, which are necessary, and not reasonably avoidable, are allowable if:

(a) The costs result from obligations which were properly incurred by the PAH before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

Section 2.05 Close-out Procedure

If the Government funds an individual PA and then subsequently terminates the agreement, or the requirements of the agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by the PAH.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto, on which the period of performance ends.

(iii) "Disallowed Costs" – those charges that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this MCDC Base Agreement.

(b) Upon request, the Government shall make prompt payments to the PAH through the CMF for allowable reimbursable costs under the PA being closed out.

(c) The PAH shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by the PAH for use in the performance of the PA.

(d) The CMF shall obtain from the PAH, within ninety (90) calendar days after the date of completion of a PA, all financial, performance, and other reports required as a condition of the PA. Subject to Government concurrence, the CMF may grant extensions when requested by the PAH.

(e) When authorized, the CMF shall make a settlement for any upward or downward adjustments to the Government's share of costs after these reports are received, based on final, actual expenditures in accordance with the Termination Costsprovision of this MCDC Base Agreement.

(f) Quick close-out procedures similar to FAR 42.708, shall be followed.

(g) The PAH shall account for any property received from the Government.

Section 2.06 Stop Work

As directed by the AO, the CMF may, at any time, by written order to the PAH, require the PAH to stop all, or any part, of the work called for under this MCDC Base Agreement or any PA for a period of ninety (90) days after the written order is delivered to the PAH, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this section. Upon receipt of the order, the PAH shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of ninety (90) days after a stop-work is delivered to the PAH, or within any extension of that period to which the parties shall have agreed, the CMF shall either:

(a) Cancel the stop-work order; or

(b) Terminate the work covered by the PA as provided in Article II, Term.

If a stop work order issued under this Article is canceled, the PAH shall resume work. The CMF shall make an equitable adjustment in the delivery schedule or PA estimated cost/price, or both, and the Government's share of the PA shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the PAH's cost properly allocable to, the performance of any part of the PA; and

(2) The PAH asserts its right to the adjustment within thirty (30) days after the end of the period of work stoppage; provided that, if the Government decides the facts justify the action, the Government through the MCDC CMF, may receive and act upon a proposal submitted at any time before final payment under the PA.

If a stop work order is not canceled and the work covered by the PA is terminated in accordance with Article II, the MCDC CMF shall work with the PAH to negotiate an equitable reimbursement in accordance with Article II. Section 2.03, Termination Provisions.

Article III. MANAGEMENT, MODIFICATION, AND ADMINISTRATION

Section 3.01 The Medical CBRN Defense Consortium (MCDC)

The MCDC, as defined in this MCDC Base Agreement, was formed to work with the Government and provide input in developing medical, pharmaceutical, and diagnostic technologies to enable advanced development of MCM for chemical and biological defense, which are related to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces, ultimately resulting in fully executed research and development prototype projects selected by the Government. Every Member in this MCDC is independent of the other, and there is no affiliation between the MCDC Members within the definition of 13 C.F.R. 121.103 of the Federal Small Business Regulations, and no such affiliation is intended either by the formation or implementation of the MCDC.

As appointed by the MCDC Executive Committee, the CMF has the authority to manage this OTA on behalf of the MCDC, and has the responsibility for day-to-day overall administration of this MCDC Base Agreement, subject to the supervision of the MCDC Executive Committee.

Section 3.02 The following MCDC decisions are subject to ACC-NJ approval:

1. Changes to the MCDC Articles of Collaboration, if such changes substantially alter the relationship of the MCDC and the Government as originally agreed upon when the OTA was executed;

2. Changes to, or elimination of, any ACC-NJ funding allocation to any MCDC Member, as technically and/or financially justified.

Section 3.03 Management and Project Structure

Technical and project management of the coordinated research program established under this MCDC Base Agreement shall be accomplished through the management structures and processes detailed in this Article.

The Government competitively selected the MCDC, organized by its CMF, Advanced Technology International (ATI), a Section 501(c)(3) nonprofit organization. The MCDC has entered into an agreement with ATI, authorizing ATI to enter into the OTA as the consortium manager, engage in overall day-to-day management of the MCDC under the guidance of and as designated by the MCDC Executive Committee, including technical, programmatic, reporting, financial, administrative and contractual matters, and administer PAs required for performance under the OTA.

As established by funded projects under the OTA, the Government Program Manager shall fully participate in the appropriate program technical meetings held by the MCDC. The AORs and other Government personnel, as deemed appropriate, also may participate in the technical portion of these meetings.

Section 3.04 Modifications

As a result of scheduled meetings, end of program reviews, or at any time during the term of the OTA, research progress or results may indicate that a change in the OTA's scope, objectives or Term would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the OTA Scope, will be documented in a letter and submitted by the PAH to the CMF, who will then forward it to the Program Manager with a copy to the AO. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the OTA. The Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the OTA Scope or other proposed changes to the terms and conditions of the OTA and subsequently this MCDC Base Agreement.

With regard to projects the Government determines to fund as a result of the RPP process specified in the MCDC Base Agreement scope, any PAH recommendations for modifications, including justifications to support any changes to the funded PAs, will be documented in a letter and submitted by the CMF to the AO, with a copy to the Government AOR designated for the particular project. The AO shall be responsible for review of proposed changes, and for all modifications to the terms and conditions of the PA(s). The CMF shall modify the PA(s) in the event of any such modifications or changes to the project.

For minor or administrative Base Agreement modifications, the CMF will issue a written Base Agreement modification. The Government and the CMF, along with the PAH, shall approve in writing all other Base Agreement modifications.

Management of Projects

(1) Performance of the work on each project is subject to the technical direction of the AOR designated in the PA. For the purposes of this Article, technical direction includes the following:

   a. Direction to the PAH, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the SOW;
   b. Guidelines to the PAH that assist in the interpretation of drawings, specifications or technical portions of work description.
   c. Review and, where required by the PA, approval of technical reports, drawings, specifications, or technical information to be delivered by the PAH under the PA.

   The AOR shall monitor the PAH's performance with respect to compliance with the technical requirements of the PA.

(2) Technical direction must be within the general scope of work stated in the PA. Technical direction may not be used to
   a. Assign additional work under the PA;
   b. Increase or decrease the estimated PA cost, fee (if any), or the time required for the project performance;
   c. Change any of the terms, conditions or specifications of the PA; or
   d. Accept non-conforming work.

   As such, no verbal or written request, notice, authorization, direction or order received by the PAH shall be binding upon the MCDC, CMF or Government, or serve as the basis for a change in the PA cost, or any other provision of the PA, unless issued (or confirmed) in writing by the MCDC CMF.

(3) The PAH shall immediately notify the MCDC CMF whenever a written change notification has been received from anyone other than the MCDC CMF, which would affect any of the terms, conditions, cost, schedules, etc. of the PA. The PAH is to perform no work or make any changes in response to any such notification or make any claim on the MCDC through its CMF or Government, unless the MCDC CMF directs the PAH, in writing, to implement such change notification.

Article IV. AGREEMENT ADMINISTRATION

Administrative and contractual matters under this MCDC Base Agreement shall be referred to the following representatives of the parties:

MCDC: Advanced Technology International
MCDC Contracts
315 Sigma Drive
Summerville, SC 29486
contracts.mcdc@ati.org

Project Agreement Holder: Tonix Pharmaceuticals, Inc. _____
26 Main Street, Suite 101 _____
_____ Chatham, NJ 07928 _____
_____ Sina Bavari _____
____ sina.bavari@tonixpharma.com _____
_____

Each party may change its representatives named in this Article by written notification to the other parties.

Agreements Officer Representative (AOR): AOR will be designated by the Government on a per project basis.

Article V. OBLIGATION AND PAYMENT

Section 5.01 Obligation:

Except as specified in Article VII, Disputes, the CMF's liability to make payments to the PAH is limited only to those funds obligated under the PA(s). The CMF may incrementally fund the PA(s). If modification becomes necessary in performance of projects, pursuant to Article V of this MCDC Base Agreement, the CMF and the PAH shall establish and execute a revised Schedule of Payable Milestones consistent with the current PA.

Section 5.02 Project Payments:

The detailed instructions for project payments will be included in the TDL to be issued by the CMF on a project by project basis.

Section 5.03 Accounting System Requirements:

Prior to the submission of invoices, the PAH shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this MCDC Base Agreement. The PAH shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds under this MCDC Base Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

For expenditure-based or resource-sharing projects, the capability of the MCDC Member's accounting system will be considered prior to award. Although the Government will not impose requirements that will cause a MCDC Member to revise or alter its existing accounting system, the Government will not enter into a PA that provides for payment based on amounts generated from the MCDC Member's financial or cost records, if the MCDC Member does not have an accounting system capable of identifying the amounts/costs to individual agreements/contracts.

Allowable Costs: Although OTAs are not subject to the FAR, the principles included in FAR Part 31 may be applied to determine price reasonableness for individual projects. MCDC Members who are selected for awards under the Base Agreement may refer to FAR Part 31 for guidance on allowable costs in preparing their final cost proposal for a project award.

Section 5.04 Invoicing Instructions:

Project Payable Milestones: The PAH shall segregate and track all individual project costs separately and shall document the accomplishments of each Payable Milestone under each PA. A Payable Milestones report shall be detailed on a project basis and submitted with each request to the AOR or designee for approval.

Section 5.04a. Payment Method Types

Project Agreements will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

(a) *Fixed Price Milestone Payment Method:* Payments shall be made in accordance with the Payable Milestone Schedule of each Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Project Agreement. Quarterly reviews by the AOR and the CMF will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone; and

(iii) lists the milestone cost negotiated and contained in each Project Agreement

(b) *Cost Reimbursable Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Task Assignment):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(c) *Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The PAH will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base t Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(d) *Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;

(iv) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(v) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(vi) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

Section 5.04b. Submission of Invoices

Invoices may be submitted no more frequently than monthly. The PAH shall submit invoices and any necessary supporting documentation via email to MCDC-invoices@ati.org.

For Cost type Project Agreements, the PAH's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

Section 5.04c. Payment Terms

Payment terms are NET 30 days after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Article V Section 5.04a. Payment Method Types.

Section 5.05 Advance Payments:

On a per project basis, advance payments may be approved by the AO. If the AO has approved advance payments, there will be a requirement to establish a separate interest bearing account. The PAH sets up and maintains funds in a separate interest bearing account, unless one of the following applies:

(1) The PAH receives less than $120,000.00 in Federal awards per year;

(2) The best reasonably available interest bearing account would not expect to earn interest in excess of $250.00 per year on such cash advances;

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected cash resources for the project; or

(4) The advance payments are made one time to reduce financing costs for large up-front expenditures, and the fund will not remain in the PAH's account for any significant period of time.

Where a separate interest bearing account is set up, any interest earned should be remitted annually to the CMF. CMF shall forward the funds to the Government as directed by the AO. Interest payments shall be made payable to the U.S. Treasury.

Section 5.06 Limitation of Funds:

Except as set forth in Article VII, the Government's financial liability will not exceed the amount obligated for projects and available for payment.

Section 5.07 Financial Records and Reports:

The PAH shall maintain adequate records to account for Federal funds received under this MCDC Base Agreement and shall maintain adequate records to account for PA funding provided under this MCDC Base Agreement, should cost sharing procedures be implemented for funding a particular project. PAH's relevant financial records are available and subject to examination or audit on behalf of the ACC-NJ for a period not to exceed three (3) years after final payment of the PAH's project. The AO or designee shall have direct access to sufficient records and information of the PAH to ensure full accountability for all funding under this MCDC Base Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Government using Government auditors or, at the request of the PAH, by the requesting PAH's external CPA accounting firm at the expense of the requesting PAH.

Article VI. APPROPRIATE USE OF OTHER TRANSACTION AUTHORITY

In accordance with provisions of 10 USC 4022, the DoD has authority to enter into transactions *other than* contracts, grants, or cooperative agreements. The DoD has the authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the DoD, or the improvement of platforms, systems, components, or materials in use by the armed forces.

Per 10 U.S.C. § 4022, each prototype project awarded under this Base Agreement must meet one of the following conditions:

- There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- All significant participants in the transaction, other than the Federal Government, are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.
- At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.
- The senior procurement executive for the agency determines in writing that exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a contract, or would provide an opportunity to expand the defense supply base in a manner that would not be practical or feasible under a contract.

Throughout the period of performance of any PA, the AO and AOR will actively monitor projects to ensure compliance with this statutory requirement. The Government will take into account any implementation guidance from the Department of the Army and the Office of the Under Secretary of Defense for Acquisition and Sustainment, which includes but is not limited to, the most recent Other Transactions Guide. The MCDC Member awarded a PA will be given the opportunity to become compliant with this statutory requirement should they be found non-compliant by the AO and AOR and as communicated to the PAH by the CMF. Failure to comply may result in termination.

If significant nontraditional / nonprofit participation cannot be fulfilled, the PAH must provide at least one third cost share of the value of the PA awarded to the PAH. Proposals that fail to comply with this requirement, will not be awarded under the OTA.

Cost Sharing is not required under the OTA for projects that contain significant nontraditional / nonprofit participation. Where the Government and PAH agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by them, and in accordance with the most recent Other Transactions Guide.

Article VII. DISPUTES

Section 7.01 General

For the purposes of this Article, “Parties” means the CMF, the PAH and the Government where collectively identified and “Party” where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

Section 7.02 Dispute Resolution Procedures

Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this MCDC Base Agreement and whether or not involving an alleged breach of this MCDC Base Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this Article constitute the basis for relief under this article unless the ACC-NJ Division Chief for Emerging Technologies, in the interest of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing, documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the ACC-NJ, Center Director for Emerging Technologies. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ACC-NJ Divison Chief for Emerging Technologies, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days, request further review as provided by this article.

If requested within thirty (30) calendar days of the ACC-NJ Division Chief for Emerging Technologies' decision, further review will be conducted by the Chair of the MCDC Executive Committee and the ACC-NJ Associate Director. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Chair of the MCDC Executive Committee and the ACC-NJ, Associate Director (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law, including but not limited to the right to seek extraordinary relief under Public Law 85-804. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

Section 7.03 Limitation of Liability and Damages

In no event shall the liability of the MCDC PAH or any other entity performing research activities under a Project Agreement exceed the funding such entity has received for their performance of the specific PA under which the dispute arises.

No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Article VIII. CONFIDENTIAL INFORMATION

Section 8.01 Definitions

(1) "Disclosing Party" means CMF, MCDC PAHs, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) "Receiving Party" means CMF, MCDC PAHs, or the Government who receives Confidential Information disclosed by a Disclosing Party.
(3) "Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret, if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information, and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the PAH. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, regardless of how it is stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Section 8.02 Exchange of Information:

The Government may from time to time, disclose Government Confidential Information to the MCDC for use by the MCDC member entities or MCDC PAHs, their subcontractors or suppliers, in connection with Government solicitations and similar processes or particular projects. The CMF, on behalf of the MCDC, MCDC member entities, or MCDC PAHs, their subcontractors or suppliers, may from time to time disclose information that is Trade Secret or Confidential Information to the Government in connection with this MCDC Base Agreement, a project proposal, or performance under a PA. Neither Party shall be obligated to transfer Confidential Information or Trade Secrets independently developed by the Parties, absent an express written agreement between the Parties providing the terms and conditions for the disclosure.

Section 8.03 Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties, or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article VIII, entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof, as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information, as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Section 8.04 Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media, as well as magnetic and digital storage media.

Section 8.05 Term:

The obligations of the Receiving Party under this Article shall continue for a period of five (5) years from conveyance of the Confidential Information.

Section 8.06 Flow Down

The PAH shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, and subawardees (including employees) at all levels, receiving such Confidential Information under this OTA.

Article IX. PUBLICATION AND ACADEMIC RIGHTS

Section 9.01 Use of Information.

For the purposes of this Article, “Parties” means the PAH and the Government where collectively identified and “Party” where each entity is individually identified.

Subject to the provisions of Article VIII, Confidential Information, Article IX, Publication and Academic Rights, and Article XI Data Rights, the PAH and the Government shall have the right to publish or otherwise disclose information and/or data developed by the Government and/or the respective MCDC PAH under the Research Project. The PAH and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Projects by the Government and the MCDC PAH in such publication or disclosure. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Base Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or the PAH.

Section 9.02 Publication or Public Disclosure of Information

(a) Classified Project Agreements

If a release of Confidential Information or Trade Secrets is for a classified Project Agreement, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply.

(b) Review or Approval of Technical Information for Public Release

(1) At least thirty (30) days prior to the scheduled release date, the PAH shall submit to the CMF a copy of the information to be released. In turn, CMF shall submit to the Government AOR a copy of the information to be released.

The Government AOR is hereby designated as the approval authority for the AO for such releases.

(2) Where the PAH is an Academic Research Institution performing fundamental research on campus. PAH shall provide papers and publications for provision to the CMF for provision to the Government AOR for review and comment thirty (30) days prior to formal paper/publication submission. However, if that Academic Research Institution incorporates into its research results or publications artifacts produced by and provided to these institutions on behalf of other (non-educational institution) MCDC PAHs (or has authors listed on the paper who are not employees or students of the Academic Research Institution), then the procedures in Section 9.01 above must be followed.

(3) Parties to this MCDC Base Agreement are responsible for assuring that an acknowledgment of government support will appear in any publication of any material based on or developed under this OTA, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002 between the MCDC, and the Government**.** The US Government is authorized to reproduce and distribute reprints for Governmental purposes, notwithstanding any copyright notation thereon."

(4) Parties to this MCDC Base Agreement are also responsible for assuring that every publication of material based on or developed under this project contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

The PAH shall flowdown these requirements to its subawardees, at all tiers.

(c) Notices. To avoid disclosure of Confidential Information or Trade Secrets belonging to an MCDC member entity or PAH and/or the Government, and the loss of patent rights as a result of premature public disclosure of patentable information, the PAH that is proposing to publish or disclose such information, shall provide advance notice to the MCDC, through its CMF, and identify such other parties that may have an interest in such Confidential Information. The CMF shall notify such parties at least thirty (30) calendar days prior to any PAH's submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the parties during the term of and pursuant to this MCDC Base Agreement. The Government must notify the MCDC, through its CMF, of any objection to disclosure within this thirty (30) day period, or else the PAH, shall be deemed authorized to make such disclosure.

(d) Filing of Patent Applications. During the course of any such thirty (30) calendar day period, the PAH shall provide notice to the CMF as to whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that a PAH and/or the Government, desires that such a patent be filed, the PAH or the Government proposing to publish or disclose such materials, agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

(1) Filing of a patent application covering such invention, or

(2) Written agreement, from the AO and the CMF (on behalf of the PAH to whom such Confidential Information belong) that no patentable invention is disclosed in such materials.

(3) Further, during the course of any such ninety (90) calendar day period, the PAH shall notify the AO and the Government, through the CMF, if PAH believes any of its Confidential Information has been included in the proposed publication or disclosure, and shall identify the specific Confidential Information or Trade Secrets that need to be removed from such proposed publication. The Government and the CMF on behalf of the PAH proposing the publication or disclosure of such materials, agrees to remove from the proposed publication or disclosure all such Confidential Information so identified by the CMF.

Article X. PATENT RIGHTS

Section 10.01 Definitions

"Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

"Made" when used in relation to any invention, means the conception or first actual reduction to practice of such invention.

"Practical Application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

"Subject Invention" means any invention of the MCDC's PAH or its subcontractors of any tier conceived or first actually reduced to practice in the performance of work on a Project Agreement under this MCDC Base Agreement.

"Background Invention" means any invention, or improvement to any invention, other than a Subject Invention, made by a PAH (or their subcontractors of any tier), which was conceived, designed, developed, produced, and/or actually reduced to practice prior to execution of the PA or outside the scope of work performed under the PA under this MCDC Base Agreement.

Section 10.02 Allocation of Principal Rights

The PAH, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C. § 202. In the event that a PAH consists of more than one entity or person, those entities or persons may allocate such right, title, and interest between themselves or others, as they may agree in writing. With respect to any Subject Invention in which the PAH retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States, the Subject Invention throughout the world. The PAH may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government.

Section 10.03 Invention Disclosure, Election of Title, and Filing of Patent Application

(1) The PAH shall disclose each Subject Invention to the CMF within four (4) months after the inventor discloses it in writing to their company personnel responsible for patent matters. The disclosure to the CMF shall be in the form of a written report and shall identify the PA under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

(2) If the PAH determines that it does not intend to retain title to any such invention, the PAH shall notify the CMF, in writing, within nine (9) months of disclosure. However, in any case where publication, sale or public use has initiated the one (1) year statutory period, wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the ACC-NJ through CMF to a date that is no more than six (6) months prior to the end of the project.

(3) The PAH shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The MCDC PAH may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks, to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

(4) After considering the position of the CMF on behalf of the PAH, a request for extension of the time for disclosure election, and filing under Section 10.03 of this Article X, may be approved by ACC-NJ, which ACC-NJ approval shall not be unreasonably withheld.

Section 10.04 Conditions When the Government May Obtain Title

Upon written request to the CMF, the PAH shall convey to the Government title to any Subject Invention under any of the following conditions:

(1) If the PAH fails to disclose or elects not to retain title to the Subject Invention within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that the Government may only request title within sixty (60) days after learning of the failure of the PAH to disclose or elect within the specified times.

(2) In those countries in which the PAH fails to file patent applications within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that if the PAH has filed a patent application in a country after those times specified in Section 10.03 of this Article X, Patent Rights, but prior to its receipt of the written request by the Government through the CMF, the PAH shall continue to retain title in that country; or

(3) In any country in which the PAH decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

Section 10.05 Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File

The Parties agree that:

(1) The PAH shall retain a non-exclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the PAH fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. The PAH's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the PAH within the corporate structure of which the PAH is a party, and includes the right to grant licenses of the same scope to the extent that PAH was legally obligated to do so at the time the PA was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

(2) The PAH domestic license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention, pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the PAH has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the Government to the extent the PAH, its licensees, or the subsidiaries or affiliates, have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the Government shall furnish the CMF, and the CMF shall forward to the PAH, a written notice of the Government's intention to revoke or modify the license, and the PAH shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

Section 10.06 Action to Protect the Government's Interest

(1) The PAH shall execute or have executed and promptly deliver to CMF all instruments necessary to (i) establish or confirm the rights the Government, has throughout the world in those Subject Inventions to which the PAH elects to retain title, and (ii) convey title to the Government when requested under Section 10.04 of this Article X, Patent Rights, and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

(2) The PAH agrees to require, by written agreement, that its employees working on Project Agreements, other than clerical and non-technical employees, agree to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format acceptable to the CMF, each Subject Invention made under this Agreement in order that the CMF on behalf of the PAH can comply with disclosure provisions of Section 10.03 of the Article X, Patent Rights, and to execute all papers necessary to file the patent applications on the Subject Invention and to establish the Government's rights in the Subject Invention. The PAH acknowledges and shall instruct its employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The PAH shall notify the CMF of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) days before the expiration of the response period required by the relevant patent office.

(4) The PAH shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with U.S. Government support under Base Agreement No. W15QKN-16-9-1002, awarded by the ACC-NJ to the MCDC. The Government has certain rights in the invention."

Section 10.07 Lower Tier Agreements

The PAH shall include the Article X, Patent Rights, suitably modified to identify the parties, in all lower tier PAs, regardless of tier, for experimental, development, or research work.

Section 10.08 Reporting on Utilization of Subject Inventions

The PAH shall submit, on request during the term of the PA, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the PAH or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the PAH, and such other data and information as the agency may reasonably specify. The PAH also agrees to provide additional reports, as may be requested by the Government, through CMF, in connection with any march-in proceedings undertaken by the Government in accordance with Section 10.10 of this Article X, Patent Rights. Consistent with 35 U.S.C. § 205, the Government agrees it shall not disclose such information to persons outside the Government without permission of the MCDC on behalf of the PAHs.

Section 10.09 Preference for American Industry

Notwithstanding any other provision of the Article X, Patent Rights, the PAH is not to grant to any person the exclusive right to use or sell any Subject Invention in the United States or Canada, unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention, shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by the Government upon a showing by the PAH that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

Section 10.10 March-In Rights

The PAH agrees that, with respect to any Subject Invention in which its PAH has retained title, the Government, through CMF, has the right to require the PAH to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the PAH refuses such a request, the Government has the right to grant such a licensee itself if the Government determines that:

(1) Such action is necessary because the PAH or assignee has not taken effective steps, consistent with the intent of this MCDC Base Agreement, to achieve practical application of the Subject Invention;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the PAH, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use, and such requirements are not reasonably satisfied by the PAH, assignee, or licensees; or

(4) Such action is necessary because the agreement required by Section 10.09 of this Article X, Patent Rights, has not been obtained or waived or because a licensee who has the exclusive right to use or sell any Subject Invention in the United States is in the breach of such an agreement.

Section 10.11 Opportunity to Cure

Certain provisions of this Article X, Patent Rights, provide that the Government may gain title or license to a Subject Invention by reason of the PAH's action, or failure to act, within the times required by this Article X, Patent Rights. Prior to claiming such rights (including any rights under Article X, Section 10.10 March-In Rights), the Government will give written notice to the MCDC, through its CMF, and CMF will convey such written notice to PAH, of the Government's intent, and afford the PAH a reasonable time to cure such action or failure to act. The length of the cure period will depend on the circumstances, but in no event will be more than sixty (60) days. PAH may also use the cure period to show good cause why the claiming of such title or right would be inconsistent with the intent of the Base Agreement in light of the appropriate timing for introduction of the technology in question, the relative funding and participation of the parties in the development, and other factors.

Section 10.12 Background Information

In no event shall the provisions set forth in this Article X apply to any Background Inventions or Patents. The PAHs or their subcontractors, shall retain the entire right, title, and interest throughout the world to each such Inventions and Patents that each party has brought through MCDC to the project issued under this MCDC Base Agreement and the Government shall not have any rights under this MCDC Base Agreement. Projects to be funded under this MCDC Base Agreement will list Background Inventions and Patents anticipated to be used on the project; such listing may be amended by the parties, as appropriate, to reflect changes in such plans.

Section 10.13 Survival Rights

Provisions of this Article X shall survive termination of this MCDC Base Agreement under Article II.

Notwithstanding the terms of this Article, differing rights in patents may be negotiated among the Parties to each individual project on a case-by-case basis.

Article XI. DATA RIGHTS

This is a Data Rights Article specifically tailored for this OTA to address respective rights of the Government and MCDC on behalf of its actual or prospective MCDC PAHs to such Data as is owned, developed, to be developed or used by an actual or prospective MCDC member entity or PAH, (1) as identified in a MCDC member entity(ies) proposal submitted to the Government through the CMF in response to a competitive Government OTA RPP, and (2) when such proposal is selected by the Government for funded performance and the PA is issued by the CMF to that MCDC member entity for performance of such Government OTA project.

Section 11.01 Definitions

(1) “Commercial Computer Software” as used in the Article, is defined in DFARS 252-227-7014(a)(1) (FEB 2014).

(2) “Commercial Computer Software License” means the license terms under which commercial computer software and Data (as defined in this OTA) is sold or offered for sale, lease or license to the general public.

(3) “Computer Data Base” as used in this MCDC Base Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) “Computer Program” as used in this MCDC Base Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) “Computer Software” as used in this MCDC Base Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) “Computer Software Documentation” means owner’s manuals, user’s manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) “Data” as used in this Article of the MCDC Base Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) “Form, Fit and Function Data” means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) “Government Purpose Rights” means the rights to use, modify, duplicate or disclose the “Data” licensed with such rights under this OTA within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this MCDC Base Agreement, the period of Government purpose rights shall be no less than ten (10) years, and during such time the MCDC member entity or PAH developing or providing such Data to the Government with government purpose rights, shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another project issued to that MCDC member entity or PAH under this OTA during this ten (10) year period, the period of government purpose rights shall be extended an additional ten (10) years, starting with the date of completion of performance of the additional project.

(10) “Limited Rights” as used in this Article, is as defined in DFARS 252.227-7013(a)(14) (FEB 2014).

(11) “Restricted Rights” as used in this Article, is as defined in DFARS 252.227-7014(a)(15) (FEB 2014).

(12) “Specifically Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the MCDC, on behalf of the member entity or PAH whose proposal is selected by the Government under an RPP issued under the OTA.

(13) “Technical Data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) “Unlimited Rights” as used in this Article, is as defined in DFARS 252.227-7013(a)(16).

Section 11.02 Data Categories

(1) Category A is the Data developed and paid for totally by private funds, or the PAH's (or its subcontractor's) IR&D funds, and it is Data to which the PAH (or its subcontractor) retains all rights. Category A Data shall include, but not be limited to,

(a) Data as defined in this Article and any designs or other material provided by the PAH for a project under this MCDC Base Agreement which was not developed in the performance of work under that project, and for which the PAH retains all rights.

(b) Any initial Data or technical, marketing, or financial Data provided at the onset of the project by any of the MCDC member entities or PAHs. Such Data shall be marked “Category A” and any rights to be provided to the Government for such Data under a specific project shall be as identified in the proposal submitted to the Government, and incorporated into PAs.

(2) Category B is any Data developed under this OTA with mixed funding, i.e. development was accomplished partially with costs charged to a PAH’s indirect cost pools and/or costs not allocated to a PAH’s PA under this OTA, and partially with Government funding under this OTA. Any Data developed outside of this OTA, whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract, shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(3) Category C is any Data developed exclusively with Government funds under this OTA. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

(a) the Government shall have Government Purpose Rights in Data developed exclusively with Government funds under a project funded by the Government under this OTA that is:

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the OTA that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

The Government can only order such Data as is developed under the OTA project, where the order request is made within one (1) year following OTA project completion. In the event the Government orders such Data, it shall pay the PAH the reasonable costs for all efforts to deliver such requested Data, including, but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

(b) The Government shall have Unlimited Rights in Data,

(i) Otherwise publicly available or that has been released or disclosed by PAH without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party, or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Data in which the Government has obtained unlimited rights under another Government contract, or as a result of negotiations; or

(iii) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with—

(1) Government Purpose Rights or limited rights, and the restrictive condition(s) has/have expired; or

(2) Government Purpose Rights and the PAH's exclusive right to use such Data for commercial purposes under such contract or subcontract, has expired.

(c) However, any Data developed outside of this OTA, whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract, shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(d) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this OTA, and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

(4) The parties to this MCDC Base Agreement understand and agree that the CMF shall require PAHs stamp all documents in accordance with this Article, and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

Section 11.03 Allocation of Principal Rights

(2) The Government shall have no rights to Category A Data.

(2) The Government shall have immediate Government Purpose Rights to Category B or C Data, upon delivery or project/PA completion (whichever is earlier), except that

(a) Where the PAH, whose Data it is, is a small business as defined under the Small Business Innovation Research Program (SBIR) under 15 U.S.C. 638, and such data was developed under a project designated by the Government in the RPP as a SBIR program project, such PAH automatically shall be entitled to a delay in the start of the Government Purpose Rights period for at least five (5) years from project completion, or such longer period as may be negotiated among the Government and MCDC on behalf of the PAH, and

(b) The CMF, at the request of small business or an other than small business MCDC member entity or PAH, may request on such member entity's or PAH's behalf, a delay of the start of Government Purpose Rights in Category B or C Data for a period not to exceed five (5) years from project/PA completion (whichever is earlier). Such requests will only be made in those cases where the CMF has provided information from the affected actual or prospective PAH demonstrating the need for this additional restriction on Government use, and shall be submitted to the ACC-NJ AO for approval, which approval shall not be unreasonably withheld. In the event of any dispute regarding approval of this request, the parties agree to treat this as a dispute and shall follow the provisions of Article VII, Disputes.

(c) For Article XI.Section 11.02 3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(d) For Article XI.Section 11.02 3(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

(3) Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific project award funded under this MCDC Base Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(4) Each proposal submitted by the MCDC member entities in response to a Government RPP under this OTA, shall include a list of the Category A, B, and C Data to be used or developed under the proposal, if selected. Rights in such Data shall be as established under the terms of this MCDC Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The Government AO will incorporate the list of Category A, B, and C Data, and the identified rights therefor in the award document.

Following issuance of a TDL and subsequent CMF issuance of the PA to the PAH, the PAH shall update the list to identify any additional, previously unidentified Data, if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this MCDC Base Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

Section 11.04 Marking of Data

Except for Data delivered with unlimited rights, Data to be delivered under this MCDC Base Agreement subject to restrictions on use, duplication or disclosure, shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Base Agreement between the U.S. Government and the MCDC, Agreement No. W15QKN-16-9-1002, Project Title and the MCDC PA [insert name of company] No. _____.

It is not anticipated that any Category A Data will be delivered to the Government under this MCDC Base Agreement.

In the event commercial computer software and Data is licensed under a commercial computer software license under this OTA, a Special License rights marking legend shall be used as agreed to by the parties.

The Government shall have unlimited rights in all unmarked Data. In the event that a PAH learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CMF on behalf of the member entity or PAH, will have the opportunity to cure such omission going forward by providing written notice to the Government AO within three (3) months of the erroneous release.

Section 11.05 Copyright

The PAHs reserve the right to protect by copyright original works developed under this MCDC Base Agreement. All such copyrights will be in the name of the individual PAH. The PAH(s) hereby grant to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for Governmental purposes, any copyrighted materials developed under this MCDC Base Agreement, and to authorize others to do so.

In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work, and it is also indicated on the Data that such Data existed prior to, or was produced outside of this MCDC Base Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the copyright holder.

Copyrighted Data that existed or was produced outside of this MCDC Base Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this MCDC Base Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.

The PAHs are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this MCDC Base Agreement.

The Government agrees not to remove any copyright notices placed on Data, and to include such notices on all reproductions of the Data.

Section 11.06 Data First Produced by the Government

As to Data first produced by the Government in carrying out the Government's responsibilities under this OTA, and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CMF on behalf of any PAH, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CMF and any PAH to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period, such Data may be disclosed and used by the CMF or any PAH, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Section 11.07 Prior Technology

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the CMF or any MCDC member entity or PAH, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this MCDC Base Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this MCDC Base Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by the CMF, PAHs, PAH subcontractors of any tier and their respective employees to whom such Data is provided for use under the OTA. Upon completion of activities under this MCDC Base Agreement, such Data will be disposed of, as requested by the Government.

(2) CMF and PAH Prior Technology: In the event it is necessary for the CMF or any PAH to furnish the Government with Data which existed prior to, or was produced outside of this MCDC Base Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees, that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under the Base Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by such Government Contractors or contract employees. Neither the CMF nor any PAH, shall be obligated to provide Data that existed prior to, or was developed outside of this MCDC Base Agreement to the Government. Upon completion of activities under this MCDC Base Agreement, such Data will be disposed of as requested by the CMF on behalf of itself or PAHs.

(3) Oral and Visual Information: If information which the PAH (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential, is expressly disclosed orally or visually directly to the Government and/or CMF, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government and/or CMF within ten (10) calendar days after such oral or visual disclosure, or the Government and/or CMF shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government and/or CMF request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor the CMF shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article VIII, entitled "Confidential Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or CMF or is generated by the Government or CMF independent of carrying out responsibilities under this MCDC Base Agreement, is rightfully received from a third party without restriction, or is included in Data which the PAH has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this MCDC Base Agreement shall be marked with a suitable notice or legend.

Notwithstanding the paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual project on a case-by-case basis.

Section 11.08 Lower Tier Agreements

The PAH shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier PAs, regardless of tier, or experimental, developmental, or research work.

Section 11.09 Survival Rights

Provisions of this Article shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual PA on a case-by-case basis.

Article XII. EXPORT CONTROL

Export Control

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR).

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act, and that such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- This document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401, et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown.

The PAH shall include this Article, suitably modified, to identify all Parties, in all PAs or lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

Article XIII. TITLE AND DISPOSITION OF PROPERTY

Section 13.01 Definitions

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this MCDC Base Agreement.

Section 13.02 Title to Property

No significant items of property are expected to be acquired under this MCDC Base Agreement by the PAH. Title to any item of property valued $10,000.00 or less that is acquired by the PAH pursuant to a PA with the MCDC, in performance of the project issued to the PAH under this OTA, shall vest in the PAH upon acquisition with no further obligation of the Parties unless otherwise determined by the Government AO. Should any item of property with an acquisition value greater than $10,000.00 be required, the PAH through the CMF shall obtain prior written approval of the Government AO. Title to this property shall also vest in the MCDC member entity or PAH upon acquisition. That PAH shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this Article shall not be considered as in exchange for services in performance of the project, but shall be considered a Government contribution to the project.

Section 13.03 Government Furnished Property (GFP)

The Government may provide the PAH GFP to facilitate the performance of individual projects under this OTA Such GFP will be specifically identified to a particular project and incorporated into the applicable PA. The GFP shall be utilized only for the performance of that individual project, unless a specific exception is made in writing by the AO.

The PAH shall assume the risk of and be responsible for any loss or destruction of, or damage to, any GFP while in its possession or control, with the exception of reasonable wear and tear or reasonable and proper consumption. All property shall be returned at the end of the Project Agreement in as good as condition as when received, with the exception of said reasonable wear and tear or in accordance with the provisions of the PA regarding its use. The PAH shall obtain explicit written authorization for any transfer or disposition of GFP.

Article XIV. CIVIL RIGHTS ACT

This MCDC Base Agreement and any resulting PA is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. It is the responsibility of each PAH to assure the PAH has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (Attachment 1).

Article XV. NO SMALL BUSINESS AFFILIATION

Reserved

Article XVI. ANTITRUST

In the MCDC Articles of Collaboration, members agree to comply with all applicable U.S. laws, including U.S. antitrust laws. The MCDC is recognized under the National Cooperative Research and Production Act of 1993, and the MCDC will be similarly filing under the Act.

Article XVII. SECURITY & OPSEC

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, when applicable.

Covered Defense Information (CDI) will be identified at the PA level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

This MCDC Base Agreement is Unclassified, however work performed by a PAH under a PA may involve access to Classified Information, including but not limited to, information classified as Controlled Unclassified Information (CUI), Confidential, Secret, or Top Secret. As such, DoD Manual 5200.01 (DoD Information Security Program: Protection of Classified Information) shall apply and all appropriate measures shall be followed. MCDC Members shall also comply with Distribution Statements, as mandated by DoDI 5230.24 (Distribution Statements on Technical Documents). If a project involves a classified or CUI effort, the below listed Department of Defense Directives, FAR/DFARS Clauses, and supplemental clauses/guidance will be incorporated into the PAs by reference with the same force and effect as if they were given in full text.

The following process shall be utilized in determining Security / Operations Security (OPSEC) requirements, prior to project award:

(1) Each project Scope of Work will be provided by the AOR to the customer Program Office for dissemination to the appropriate security officer prior to award, for review.

(2) Each project Scope of Work will be subject to customer policy and procedure, according to DoD 5220.22-M, (National Industrial Security Program Operating Manual, NISPOM), as deemed applicable and appropriate during the security review process and prior to award. Additional Communications Security (COMSEC) requirements may be required at other locations/facilities (based on service/command requirements).

(3) Specific applicable policies, instructions, and regulations will be identified in each project. Throughout the life of the MCDC Base Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
   a) DoDM 5200.01, DoD Information Security Program, 24 Feb 12, Volumes 1-4
   b) DoD 5200.2-R, Personnel Security Program, Jan 87
   c) DoDD 5220.22, National Industrial Security Program, 28 Feb 06
   d) DoD 5400.7-R, DoD Freedom of Information Act, Sept 98
   e) DoDI 2000.12, DoD Antiterrorism Program, 01 Mar 12
   f) FAR Clause 4.402, Safeguarding Classified Information Within Industry
   g) FAR Clause 52.204-2, Security Requirements, Aug 1996

(4) For all PAs, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the PAs.

   a) Classification guidance for requirement: “The security level for this agreement is UNCLASSIFIED.”

(5) Anti-Terrorism Level I Training. This provision is for PAH employees with an area of performance within an Army controlled installation, facility or area. All PAH employees, to include subcontractor employees, requiring access to Army installations, facilities and controlled access areas, shall complete AT Level I Awareness Training within sixty (60) calendar days after project start date or effective date of incorporation of this requirement into the project, whichever is applicable. PAH(s) shall submit certificates of completion for each affected employee and PAH employee, to the AOR or to the AO, if an AOR is not assigned, within thirty (30) calendar days after completion of training by all employees or personnel. AT Level I Awareness Training is available at the following website: https://jko.jten.mil/.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is for PAH employees with an area of performance within an Army controlled installation, facility or area. PAH and all associated subcontractor employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DoD, HQDA, and/or local policy. In addition to the changes otherwise authorized by the changes Article of this Base Agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

(7) Anti-Terrorism Awareness Training for PAH Personnel Traveling Overseas. This standard language text requires U.S.-based PAH and associated subcontractor employees, to make available and to receive Government provided Area of Responsibility (AoR) specific AT Awareness Training as directed by AR 525-13. Specific AoR training content is directed by the combatant commander with the unit Anti- Terrorism Officer (ATO) being the local point of contact.

(8) iWATCH Training. This standard language is for PAH employees with an area of performance within an Army controlled installation, facility or area. The PAH and all associated subcontractors, shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This local developed training will be used to inform employees of the types of behavior to watch for, and instruct employees to report suspicious activity to the AOR. This training shall be completed within sixty (60)-calendar-days of a Project Agreement award and within sixty (60) calendar days of new employees’ commencing performance, with the results reported to the AOR NLT thirty (30) calendar days after PA award.

(9) Impact on PAH Performance with Increased FPCON Level. During FPCONs Charlie and Delta, services may be discontinued / postponed due to a higher threat. Services will resume when the FPCON level is reduced to Bravo or lower.

(10) Random Antiterrorism Measures Program (RAMP) Participation. PAH personnel working on an installation are subject to participation in the installation RAMP security program (e.g. vehicle searches, wearing of ID badges, etc.).

(11) For PAH Employees who Require Access to Government Information Systems. All PAH employees with access to a Government information system, must be registered in the ATCTS (Army Training Certification Tracking System) at commencement of services, and must successfully complete the DoD Information Assurance Awareness Training prior to access to systems, and then annually thereafter.

(12) For Projects that require an OPSEC Standing Operating Procedure (SOP)/Plan. The PAH shall develop an OPSEC SOP/Plan within ninety (90) calendar days of project award, to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security. This plan will be submitted by MCDC on behalf of the PAH(s) to the AOR/AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it, and how to protect it. In addition, MCDC shall identify an individual who will be an OPSEC Coordinator. MCDC will ensure this individual becomes OPSEC Level II certified per AR 530-1.

(13) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new PAH employees assigned by the PAH to perform under a MCDC PA must complete Level I OPSEC Awareness Training within thirty (30) calendar days of their reporting for duty. All PAH employees performing under an OPSEC-designated project must complete annual Level I OPSEC Awareness Training. Level I OPSEC Awareness Training is available at the following website: https://www.cdse.edu/catalog/elearning/GS130.html.

(14) For Information Assurance (IA)/Information Technology (IT) Training. All PAH employees must complete the DoD IA Awareness Training before issuance of network access and annually thereafter. All PAHs working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M and AR 25-2 within six (6) months of employment.

(15) For IA/IT certification. Per DoD 8570.01-M, DFARS 252.239-7001, and AR 25-2, the PAH employees supporting IA/IT functions shall be appropriately certified upon PA award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon PA award.

(16) For PAH Personnel Authorized to Accompany the Force. DFARS Clause 252.225-7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States. The clause shall be used in projects that authorize PAH personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance) and personnel data required.

(17) For Projects Requiring Performance or Delivery in a Foreign Country. DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S. The clause shall be used in projects that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national PAH personnel to comply with theater clearance requirements, and allows the combatant commander to exercise oversight to ensure the PAH's compliance with combatant commander and subordinate task force commander policies and directives.

(18) For projects requiring the PAH to obtain U.S. Government Common Access Cards, installation badges, and/or access passes, the PAH shall return all issued U.S. Government Common Access Cards, installation badges, and/or access passes to the AOR when the project is completed, or when the PAH employee no longer requires access to the installation or facility.

(19) For projects that require access to Potential Critical Program Information (PCPI) / Critical Program Information (CPI):

a) The PAH shall comply with the associated Interim Program Protection Plan (IPPP) / Program Protection Plan (PPP) / or Technology Protection Plan (TPP). The PAH shall comply with DoD and DA technology protection requirements in DoDI 5200.39, AR 70-1, DA PAM 70-3, and AR-380-13.

(20) Work by the CMF and PAH under PAs may involve access to CUI, as well as information classified as "Confidential," "Secret," or "Top Secret." The CMF, PAH, and their employees who work on such PAs shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DoD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the PAH security classification specification (DD form 254), if included, and (4) all security requirements, including but not limited to, OPSEC plans and those security requirements specific to the individual projects. During the course of the PA, the Parties may determine that information developed by the PAH and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DoD 5220.22M.

a) Each project Scope of Work will be provided by the AOR to their local Security Office prior to award, for an in-depth review. For classified efforts, the Security Office will provide the overall Security Classification Specification (DD Form 254). The PAH will be responsible for providing a copy of any Subcontract Security Classification Specification (DD Form 254) to lower tier awards.

b) Specific applicable policies, instructions, and regulations will be identified in each PA, based on the reviews conducted. Throughout the life of the Base Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply.

c) Base Agreement Structure

i) Research and Development under these PAs will be in accordance with the OTA between the ACC-NJ and the MCDC, in care of its CMF, ATI.

ii) Within the PAs, sharing of classified information will be on a need to know basis, as directed in required PAs.

iii) Upon PA completion or termination, the PAH must:

(1) Return ALL classified information received or generated under the PA;
(2) Destroy all of the classified information; or,
(3) Request retention for a specified period of time.

Flowdown for OPSEC/Security Requirements:

MCDC shall include the aspects of this Article as they pertain to each project requirement. Each project will include specific OPSEC / Security requirements within each SOW and RPP. The requirements delineated within each project, in turn, shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

Article XVIII. SAFETY

The PAH shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non-hazardous occupational environment throughout the duration of the project. At a minimum, the PAH shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The PAH shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage, may be involved; identifying a potential hazard requiring corrective action. The PAH shall prepare the report for each incident, in accordance with DI-SAFT- 81563.

Material Safety Data Sheets (MSDS): The PAH shall prepare and maintain MSDS for all materials used and generated in support of this project.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, executive orders, treaties, and agreements. The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under the project.

Hazardous Waste Report: The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the project. The PAH shall submit a Hazardous Waste Report, in accordance with DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The PAH shall dispose of all residual and scrap materials generated under the project, including high explosives. The PAH shall specify the anticipated quantities, methods, and disposal costs.

Article XIX. REPRESENTATIONS AND WARRANTIES

Section 19.01 Representations and Warranties of All Parties

Each Party to this MCDC Base Agreement represents and warrants to the other Parties that, (1) it is free to enter into this MCDC Base Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all actions necessary to authorize the execution and delivery of this MCDC Base Agreement, and the performance of its obligations under this MCDC Base Agreement.

Section 19.02 Limitations

Except as expressly provided herein, no party to this MCDC Base Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to, (1) any research conducted under this MCDC Base Agreement, or (2) any invention conceived and/or reduced to practice under this MCDC Base Agreement, or (3) any other intellectual property developed under this MCDC Base Agreement, and each party to this MCDC Base Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

Article XX. LIABILITY OF THE PARTIES

Section 20.01 Waiver of Liability

With regard to the activities undertaken pursuant to this MCDC Base Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.

Section 20.02 Damages

The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Section 20.03 Extension of Waiver of Liability

The PAH agrees to extend the waiver of liability as set forth above subawardees at any tier under a PA, by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this MCDC Base Agreement.

Section 20.04 Applicability

Notwithstanding the other provisions of this Article, this Waiver of Liability shall not be applicable to:

(1) Claims between the PAH and the CMF regarding a material breach, noncompliance, or nonpayment of funds;

(2) Claims for damage caused by willful misconduct; and

(3) Intellectual property claims.

Section 20.05 Limitation of Liability

In no case shall the CMF, or the PAH's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a MCDC member entity under a PA. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

Article XXI. GENERAL PROVISIONS

Section 21.01 Fees

The PAH will not be constrained from the payment of an appropriate fee or profit for the effort being conducted on a PA when cost share is not being contributed. The fees shall be specific to the individual PAs and negotiated on a project by project basis.

Section 21.02 Waiver

No waiver of any rights shall be effective unless assented to in writing by the party (Government, MCDC, CMF, or PAH) to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

Section 21.03 Section Headings

The headings and subheadings of the sections of this MCDC Base Agreement are intended for convenience of reference only, and are not intended to be a part of, or to affect the meaning or interpretation of this MCDC Base Agreement.

Section 21.04 Severability

In the event that any provision of this MCDC Base Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this MCDC Base Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this MCDC Base Agreement to the Parties.

Section 21.05 Force Majeure

No failure or omission by the CMF or the MCDC PAH in the performance of any obligation of this MCDC Base Agreement, shall be deemed a breach of this MCDC Base Agreement, or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: Acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion, and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

Section 21.06 Regulatory Affairs

Development and production of medical products and processes fall under the purview of the FDA and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. Project Awards under this MCDC Base Agreement that involve work in support of or related to FDA regulatory approval, will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

The Government shall ensure performance includes regulatory expertise and guidance for candidate medical countermeasure development efforts:

(1) This includes allowing the Government to discuss/negotiate in partnership with the consortium, how to assume appropriate risk in regulatory strategies. The Government will review, negotiate, and come to consensus with the PAH on product-specific risk-based decisions.

(2) PAHs will use all regulatory programs to accelerate the pace of candidate medical countermeasure development, including fast-track status, and as appropriate meeting requirements for priority review vouchers, applying for breakthrough therapy and accelerated approval, as appropriate (see FDA Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics).

(3) PAH will provide FDA submissions to the Government such as all documentation requested by the FDA and all proposals to FDA.

(4) PAH will allow the Government to monitor all FDA communications by listening to teleconferences and attending meetings.

(5) PAH will allow the Government to attend regulatory site visits and audits, and actively participate in all third-party audits.

(6) PAH will comply with Quality Assurance according to negotiated standards with the Government on reports, material for Interim Fielding Capability (such as Emergency Use Authorization or Expanded Access Protocols), product for trials, prototypes, etc.

(7) PAH will provide strategies to address contingencies that could arise from regulatory directives, and regulatory failures.

Section 21.07 Radioactive Materials

PAH shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

Section 21.08 Recombinant DNA

The PAH shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/ (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

Section 21.09 Required Compliance for Use of Laboratory Animals

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the PAH is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the U.S. Army Medical Research and Development Command, Animal Care and Use Review Office (ACURO). The PAH shall receive written approval to begin research under the applicable protocol proposed for a PA from the U.S. Army Medical Research and Development Command, Animal Care and Use Review Office, ACURO, under separate letter to the PAH and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this Article may result in the termination of award. Information is provided at the following website https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro. The PAH will conduct advanced development/pivotal studies, including human safety studies, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies, as defined by FDA guidance (21 CFR Parts 210-211). The PAH shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

Section 21.10 Required Compliance for Use of Human Subjects

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Development Command's Office of Research Protections, Human Research Protection Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award, will be issued from the U.S. Army Medical Research and Development Command, HRPO, under separate letter, to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this Article may result in withholding of funds and/or the termination of the award. Information is provided at the following website: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo. The PAH shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

Section 21.11 Required Compliance for use of Human Anatomical Substances

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Development Command's Office of Research Protections, Human Research Protections Office, HRPO, approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award, will be issued from the U.S. Army Medical Research and Development Command, HRPO, under separate letter, to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this Article may result in withholding of funds and/or the termination of the award. Information is provided at the following web site: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo. The PAH shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

Section 21.12 Compliance with current Good Manufacturing Processes (cGMP)

Manufacturing Standards, as appropriate for the level of prototype material used for clinical trials, pivotal non-clinical studies, consistency lots, and other uses, as defined in regulatory plans, should be compliant with current cGMP, as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH fails to comply with cGMP in the manufacturing, processing and packaging of this product, and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure), as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. The PAH shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

Section 21.13 Registration with Select Agent Program

Where required, consortium members performing studies and tasks using select biological agent or toxins, should be registered with the program with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS), or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied. Listings of select agents and toxins, biologic agents and toxins, and overlap agents or toxins, as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/. The PAH shall coordinate with the Government in determining the applicability of requirements, based on the specific project.

Section 21.14 Duty-Free Entry

(a) *Definitions*. As used in this Article –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.
(2) "Customs territory of the United States," means the 50 States, the District of Columbia, and Puerto Rico.
(3) "Eligible product," means –
  (i) "Designated country end product," as defined in the Trade Agreements clause;
  (ii) "Free Trade Agreement country end product" other than a "Bahrainian end product," a "Moroccan end product," a "Panamanian end product," or a "Peruvian end product," as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program clause; or
  (iii) "Canadian end product," as defined in Alternate I of the Buy American Act – Free Trade Agreements – Balance of Payments Program clause
  (iv) "Free Trade Agreement country end product," other than a "Bahrainian end product," "Korean end product," "Moroccan end product," "Panamanian end product," or "Peruvian end product," as defined in of the Buy American—Free Trade Agreements—Balance of Payments Program clause.
(4) "Qualifying country" and "qualifying country end product," have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program clause.

(b) Except as provided in Paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a PA or the applicable subcontract, the price of this PA shall not include any amount for duty on-
  (1) End items that are eligible products or qualifying country end products;
  (2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated into U.S – made end products to be delivered under an PA; or
  (3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States.

(c) The PAH shall –
(1) Claim duty-free entry only for supplies that the PAH intends to deliver to the Government under a PA, either as end items or components of end items; and
(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –
  (i) Scrap or salvage; or

(ii) Competitive sale made, directed, or authorized by the AO.

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –
(1) For which no duty is included in the PA price in accordance with Paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in Paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –
(1) Consign the shipments to the appropriate –
(i) Military department in care of the PAH, including the PAH's delivery address; or
(ii) Military installation; and
(2) Include the following information:
(i) Prime agreement number and, if applicable, delivery order number.
(ii) Number of the subcontract for foreign supplies, if applicable.
(iii) Identification of the carrier.
(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 201 Varick Street, Room 905C, New York, New York, 10014, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."
(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty-free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the PAH shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)
(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)
(vi) Estimated value in U.S. dollars.
(vii) Activity address number of the contract administration office administering the prime agreement, e.g., for DCMA Dayton, S3605A.

(f) *Preparation of customs forms.*
(1)(i) Except for shipments consigned to a military installation, the PAH shall –
(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this agreement; and
(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.
(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.
(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –
(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two (2) of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;
(2) Consign the shipment as specified in Paragraph (e) of this clause; and
(3) Mark on the exterior of all packages –
(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and
(ii) The activity address number of the contract administration office administering the prime agreement.

(h) The PAH, through the MCDC CMF, shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH, through the MCDC CMF, shall furnish the notice to the ACO immediately upon award to the supplier, and shall include in the notice –
(1) The PAH's name, address, and Commercial and Government Entity (CAGE) code;
(2) Prime agreement number and PA number;
(3) Total dollar value of the prime agreement or PA number;
(4) Date of the last scheduled delivery under the prime agreement or PA number;
(5) Foreign supplier's name and address;
(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
(i) Scrap of salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this agreement if –
(1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
(2) It is not economical or feasible to account for such supplies, so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this agreement.

(j) The PAH shall –
(1) Insert the substance of this clause, including this Paragraph (j), in all subcontracts for –
(i) Qualifying country components; or
(ii) Non-qualifying country components for which the PAH estimates that duty will exceed $200 per unit;
(2) Require subcontractors to include the number of this agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
(3) Include in applicable subcontracts –
(i) The name and address of the ACO for this agreement;
(ii) The name, address, and activity address number of the contract administration office specified in this agreement; and
(iii) The information required by Paragraphs (h)(1), (2), and (3) of this clause.

Section 21.15 Follow-On Production

10 U.S.C. § 4022(f) authorizes the use of a follow-on production contract (FAR) or transaction (OTA). In order to be eligible for follow-on production, the following criteria is required: (1) the follow-on shall be awarded to the same participants named in the PA; (2) competitive procedures were used to award the PA in question; and (3) the PA was successfully completed. This MCDC Base Agreement was the result of competitive procedures, and competitive procedures are used to award individual projects under this MCDC Base Agreement. The AO shall be responsible for documenting whether or not a PA was successfully completed. Follow-on production efforts shall be strictly limited to the scope of the successfully completed prototype. This MCDC Base Agreement will not be used to award follow-on production efforts; Government customers will be responsible for working with their contracting personnel.

Furthermore, successful completion can occur prior to the conclusion of a prototype project, in order to allow the Government to transition any aspects of the prototype project determined to provide utility, into production, while other aspects of the prototype project have yet to be completed.

All PAs shall include the following statement:

"In accordance with 10 U.S.C. § 4022(f), and upon a determination that this competitively awarded prototype project has been successfully completed, this prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures."

Section 21.16 Public Readiness and Emergency Preparedness Act (PREP Act)

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

Prior to award of individual projects under the program, current declarations will be reviewed by the Government via PHE.gov. If upon review, it is determined that a current declaration is applicable to the project to be awarded, appropriate PREP Act language will be incorporated into the SOW in coordination with the prospective PAH.

Article XXII. ASSIGNMENT OF AGENCY

Section 22.01 Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party.

Article XXIII. ORDER OF PRECEDENCE

In the event of any inconsistency between the general terms of this MCDC Base Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Base Agreement; (2) this MCDC Base Agreement; and (3) Attachments to this MCDC Base Agreement; However, specifically negotiated PA terms and conditions and PA attachments will control over the general terms and conditions of this MCDC Base Agreement.

Article XXIV. EXECUTION

This MCDC Base Agreement constitutes the entire MCDC Base Agreement of the Parties, and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This MCDC Base Agreement may be revised only by written consent of the PAH and the CMF Contracting Representative designated in this Agreement.

Article XXV. USE OF UNDEFINITIZED PROJECT ACTIONS

The Government, when it is in its best interest, has the authority to award prototype projects on an undefinitized basis. The exact terms of the Undefinitized Project Action (UPA), to include the Scope, Not to Exceed Amount, and Definitization Schedule, will be provided on a project-by-project basis.

Attachment I – Assurance of Compliance with Title VI of the Civil Rights Act of 1964

Statement of Assurance of Compliance with
Title VI of the Civil Rights Act of 1964
For MCDC Member Organizations

The Tonix Pharmaceuticals, Inc. hereby agrees that it will comply with the provisions of the Title VI Civil Rights Act of 1964 as amended (42 U.S.C 2000-d) and all requirements imposed pursuant thereto, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any MCDC Project for which the MCDC member organization receives Federal financial assistance from the Government.

The MCDC member organization agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the MCDC member organization, its successors, transferees and assignees for the period during which such assistance is provided.

The MCDC member organization further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the MCDC member organization to the above provisions.

/s/ Jessica Morris

Signature of Authorized Official

COO

Title of Authorized Official
Tonix Pharmaceuticals, Inc.

Name of MCDC Member Organization

July 17, 2023

Date

Exhibit 10.57

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS PRIVATE OR CONFIDENTIAL. THE OMISSIONS HAVE BEEN INDICATED BY "[***]."

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

PROJECT AGREEMENT NO.: 01

MCDC BASE AGREEMENT NO.: 2023-496

PROJECT TITLE: MCDC2215-006; Development of a Small Molecule CD45 Antagonist as a Broad-Spectrum Antiviral

UEI: JYPLHNCHF675

PARTIES: Advanced Technology International ("MCDC CMF") and Tonix Pharmaceuticals, Inc. ("Project Agreement Holder")

This Project Agreement is awarded under the authority of MCDC Other Transaction Agreement No. W15QKN-16-9-1002 and herein incorporates all the terms and conditions of MCDC Base Agreement No. 2023-496.

1. PAYMENT METHOD
The Payment Method for this Project Agreement is Cost Plus Fixed Fee with a not to exceed ceiling.

2. TERM OF THE PROJECT AGREEMENT
The period of performance for this Project Agreement is from the effective date, which is the date of the last signature through July 31, 2029.

3. OBLIGATION
The MCDC CMF's liability to make payments to the Project Agreement Holder is limited to only those funds obligated under this Project Agreement or by modification to the Project Agreement. MCDC CMF may incrementally fund this Project Agreement.

4. ESTIMATED COST AND FIXED FEE
The total estimated cost and fixed fee for the services to be provided by the Project Agreement Holder is as follows:

	ESTIMATED COST
Estimated Cost	$31,585,164
Fixed Fee	$ 2,526,813
Total Cost	**$34,111,977**

5. INCREMENTAL FUNDING
The total amount of funding currently available for payment and allotted to this Project Agreement is **$2,695,785**. The amount specified, or as such amount may be increased from time to time, shall apply irrespective of any other provisions of this Project Agreement and any work performed in excess thereof shall be at the Project Agreement Holder's risk. If at any time the Project Agreement Holder has reason to believe that the Total Estimated Cost which will accrue in the performance of this Project Agreement in the next succeeding sixty (60) days, when added to all other payments previously accrued, will exceed seventy-five percent (75%) of the then current total authorized funding, the Project Agreement Holder shall notify the MCDC CMF to that effect, advising the estimate of additional funds required for the period specified. The Project Agreement Holder is not obligated to continue performance under this Project Agreement (including actions under the Termination clause of the MCDC Base Agreement) or otherwise incur costs in excess of the amount allotted to the Project Agreement by the MCDC CMF.

6. MILESTONE PAYMENT SCHEDULE
The Project Agreement Holder shall segregate and track all Project Agreement costs separately and shall document the accomplishments of each Project Payable Milestone under each Project Agreement. Acceptance of Milestones shall be contingent upon approval from the Government Agreements Officer Representative (AOR) detailed in Clause No. 10, Technical and Administrative Representatives. Milestone payments will be paid in the amount indicated in the attached Milestone Payment Schedule (Attachment A) and are adjustable based on actual expenditures.

7. PAYMENT OF FIXED FEE
The fixed fee specified herein, subject to any adjustments required by other provisions of this Project Agreement will be paid in installments at the time of each provisional payment on account of the allowable costs. The amount of fixed fee paid will be based upon the ratio that the Project Agreement Holder's incurred allowable costs bear to the total estimated cost. In the event the work cannot be completed within the estimated cost, the MCDC CMF may increase the estimated cost without increasing the fixed fee.

8. APPROACH TO MEETING THE OTHER TRANSACTION AUTHORITY
In accordance with provision contained in 10 U.S.C. 4022 governing the use Other Transaction Agreements each MCDC Member Organization must meet at least one of the following conditions: have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the performance of an awarded Project Agreement; all significant participants in the Project Agreement other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors; or provide a cost share of no less than one third of the value of the Project Agreement awarded to the Member Organization. The Project Agreement Holder's approach to meeting the Other Transaction Authority requirement is identified below. Throughout the period of performance of any Project Agreement, the CMF and the Government will actively monitor the award to ensure compliance with this provision in accordance with implementation guidance from Headquarters – Department of the Army (HQDA) and/or Office of the Secretary of Defense (OSD). The Project Agreement Holder will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

The signed certifications submitted as part of the proposal are hereby incorporated into this Project Agreement. The Project Agreement Holder was proposed as a nontraditional defense contractor and determined to be providing a significant contribution.

9. STATEMENT OF WORK
The Statement of Work, Attachment A, provides a detailed description of the work to be accomplished and reports and deliverables required by this Project Agreement. All changes to Attachment A must be incorporated via written modification to this Project Agreement. Additional guidance on report requirements is in Attachment B, Report Requirements.

10. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES
The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:
MCDC Contracts
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email: contracts.mcdc@ati.org
Phone: (843) 760-3240

Project Agreement Holder's Representatives:

Technical Representative:
Sina Bavari
26 Main Street, Suite 101
Chatham, NJ 07928
Email: sina.bavari@tonixpharma.com
Phone: (240) 337-2443

Contractual Representative:
Jessica Morris
26 Main Street, Suite 101
Chatham, NJ 07928
Email: jessica.morris@tonixpharma.com
Phone: (862) 904-8182

MCDC Representatives:
Agreements Officer Representative (AOR) and Alternate AOR are identified in Section 11 of Attachment A, Statement of Work.

11. MARKING OF DELIVERABLES
Any Data delivered under this Project Agreement, by the Project Agreement Holder, shall be marked with a suitable notice or legend.

12. SECURITY ADMINISTRATION
The security level for this project is UNCLASSIFIED.

13. ATTACHMENTS
Attachments listed herein are hereby incorporated by reference into this Project Agreement.

A. Statement of Work, "Development of a Small Molecule CD45 Antagonist as a Broad-Spectrum Antiviral"
B. Report Requirements
C. Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment

14. GOVERNMENT FURNISHED PROPERTY
At this time, Government Furnished Property is not provided for use under this Project Agreement.

15. FOLLOW-ON PRODUCTION PROVISION
In accordance with 10. U.S.C. 4022(f), and upon a determination that this competitively awarded prototype project has been successfully completed, this prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures. Furthermore, successful completion can occur prior to the conclusion of a prototype project, in order to allow the Government to transition any aspects of the prototype project determined to provide utility, into production, while other aspects of the prototype project have yet to be completed.

16. ENTIRE AGREEMENT
This Project Agreement and the MCDC Base Agreement under which it is issued constitute the entire understanding and agreement between the parties with respect to the subject matter hereof.

Except as provided herein, all Terms and Conditions of the MCDC Base Agreement and its modifications remain unchanged and in full force and effect.

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Tonix Pharmaceuticals, Inc.

By: /s/ Jessica Morris

Name: Jessica Morris

Title: COO

Date: June 27, 2024

Advanced Technology International

By: /s/ Harmon, Rebecca

Name: Rebecca Harmon, CFCM

Title: Sr. Contracts Manager
Advanced Technology International

Date: 2024.06.28

Attachment A

Statement of Work

[***]

Exhibit 19.01

STATEMENT OF COMPANY POLICY ON INSIDER TRADING AND POLICY REGARDING SPECIAL TRADING PROCEDURES

TONIX PHARMACEUTICALS HOLDING CORP.

STATEMENT OF COMPANY POLICY ON INSIDER TRADING AND POLICY REGARDING SPECIAL TRADING PROCEDURES

Two copies of this Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures (collectively, this "Policy") are being provided to you. You should read this Policy, address questions to Bradley Saenger, our Chief Financial Officer of. (the "Company") and return one signed copy to:

Bradley Saenger
Chief Financial Officer
Tonix Pharmaceuticals Holding Corp.
bradley.saenger@tonixpharma.com

I. POLICY STATEMENT ON INSIDER TRADING

The Company has adopted a policy on insider trading (the "Policy") that applies to each officer, director and employee of the Company*. A statement regarding such policy has been distributed to all officers, directors and employees. It is the policy of the Company that no director, officer or other employee (or any other person designated by this Policy or the Company's Chief Financial Officer) who is aware of material nonpublic information related to the Company may, directly or indirectly, through family members or other persons or entities:

1. engage in transactions in the securities of the Company (except as otherwise expressly provided in this Policy);

2. recommend that any other person engage in transactions in the securities of the Company;

3. disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information or to persons outside of the Company, including, but not limited to, family, friends, business associates, investors and expert consulting firms, unless such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

4. assist anyone engaged in the above activities.

In addition, it is the policy of the Company that no director, officer or other employee (or any other person designated as subject to this Policy) who, in the course of working for the Company, learns of material nonpublic information about a company with which the Company does business, including a customer or supplier of the Company, may trade in that company's securities until the information becomes public or is no longer material.

* The term "Company" refers to Tonix Pharmaceuticals Holding Corp., any subsidiaries and its affiliates, collectively or individually, as the context requires.

This Policy applies to all directors, officers and employees of the Company, its subsidiaries and its affiliates. You must read, sign and retain this Policy statement and, upon request by the Company, re-acknowledge it.

II. DISCUSSION: WHAT IS "INSIDER TRADING"?

Insider trading is, in addition to being a violation of this Policy, a violation of securities laws. The penalties for insider trading are discussed herein.

The term "insider trading" generally is used to refer to the use of material, nonpublic information to trade in securities or to communications of material, nonpublic information to others who may trade on the basis of such information.

While the law concerning insider trading is not static, it is generally understood that the law prohibits insiders of the Company from doing the following:

1. Trading in the Company's securities while in possession of material, nonpublic information concerning the Company.

2. Having others trade on the insider's behalf while he or she is in possession of material, nonpublic information.

3. Communicating nonpublic information concerning the Company or other companies that the Company does business with to others who may then trade in the Company's securities or pass on the information to others who may trade in the Company's securities. Such conduct, also known as "tipping," violates laws that impose strict penalties upon both companies and individuals, including both financial sanctions and prison. Tipping results in civil and criminal liability for the insider of the Company who communicates such information, even if such insider does not actually trade himself, and for the person who received the information if the person has reason to know that it was an improper disclosure and acts on such information or passes it on to others who may act on it.[1]

The elements of insider trading and the potential penalties for such unlawful conduct are discussed herein.

A. Who is an Insider?

The concept of "insider" generally includes any person who possesses nonpublic information about the Company and who has a duty to the Company to keep this information confidential. This Policy applies to all directors, officers and employees of the Company and its subsidiaries. In addition, the Company may determine that other persons should be subject to this Policy, such as service providers, contractors or consultants who have access to material nonpublic information in connection with such service. Outsiders who could be subject to this Policy include, among others, the Company's attorneys, accountants, consultants, advisory board members, investment bankers and the employees of such organizations.

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1 When calculating the civil and criminal liability of a tipper, a tipper may be held responsible for the profits of her "tippees." This means that the tipper may be required to pay back the government all of the profits received by his tippee (and others in the chain of the tip), even if the tipper did not actually profit. Similarly, the profits of a tippee may be used to calculate the prison sentence of the tipper, which may extend the length of any sentence.

This Policy also applies to your family members who reside with you (including a spouse, child, child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members whose transactions in the Company securities are directed by you or are subject to your influence or control (collectively referred to as "family members"). This Policy further applies to any entities that you influence or control, including any corporations, partnerships or trusts (collectively referred to as "controlled entities").

B. What is Material Information?

"Material Information" generally is defined as information for which there is a substantial likelihood that a reasonable investor would consider such information important in making his or her investment decisions, or information that could be reasonably expected to affect the price of a company's securities, whether it is positive or negative. It is important to remember that materiality will always be judged with the benefit of hindsight.

Although there is no precise definition of materiality, information is likely to be "material" if it relates to:

- earnings or expectations for the quarter or the year;
- forecasts or projections of future earnings or losses, or other earnings guidance;
- changes to previously announced earnings guidance or the decision to suspend earnings guidance;
- clinical development milestones;
- changes in dividends, the declaration of a stock split or an offering of additional securities;
- proposals or agreements involving a merger, acquisition, tender offer, joint venture, divestiture or leveraged buy-out;
- changes in relationships with major customers, or obtaining or losing important contracts;
- development of a significant new product, process or service;
- bank borrowings or other financing transactions out of the ordinary course;
- important product developments;
- major financing developments;
- major personnel changes;
- criminal indictments or material civil litigation or government investigations;
- significant disputes with major suppliers or customers;
- labor disputes including strikes or lockouts;
- substantial change in accounting methods;
- debt service or liquidity problems;
- bankruptcy or insolvency;
- public offerings or private sales of debt or equity securities;
- calls, redemptions or repurchases of the Company's securities; or
- change in auditors or notification that the auditor's reports may no longer be relied upon.

"Inside" information could be material because of its expected effect on the price of the Company's securities, the securities of another company or the securities of several companies. Moreover, the resulting prohibition against the misuse of "inside" information includes not only restrictions on trading in the Company's securities but restrictions on trading in the securities of other companies affected by the inside information.

C. What is Nonpublic Information?

In order for information to qualify as "inside" information it must not only be "material," it must be "nonpublic." "Nonpublic" information is information which has not been made available to investors generally. This includes information received from sources or in circumstances indicating the information has not yet been generally circulated.

At such time as material, nonpublic information has been released to the investing public, it loses its status as "inside" information. However, for "nonpublic" information to become public information it must be disseminated through recognized channels of distribution designed to reach the securities marketplace or public disclosure documents filed with the SEC that are available on EDGAR, and sufficient time must pass for the information to become available in the market.

To show that "material" information is public, it is generally necessary to point to some fact verifying that the information has become generally available, such as disclosure by filing of an Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other report with the Securities and Exchange Commission or disclosure by press release to a national business and financial wire service (such as Dow Jones or Reuters), a national news service or a national newspaper (such as The Wall Street Journal). The circulation of rumors or "talk on the street," even if accurate, widespread and reported in the media, does not constitute the requisite public disclosure.

Material, nonpublic information is not made public by selective dissemination. Material information improperly disclosed only to institutional investors or to a favored analyst or a group of analysts retains its status as "nonpublic" information, the use of which is subject to insider trading laws. Similarly, partial disclosure does not constitute public dissemination. So long as any material component of the "inside" information has yet to be publicly disclosed, the information is deemed "nonpublic" and may not be misused.

It is the policy of the Company to not consider material information public until the second business day after appropriate public dissemination.

D. What Transactions Are Subject to this Policy?

This Policy applies to transactions in the Company's securities, including common stock, options or warrants to purchase common stock, or any other securities that the Company may issue, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company securities.

This Policy does not apply to the following transactions, except as specifically noted:

1. Stock Option Exercises. This Policy does not apply to the exercise of any employee stock option acquired pursuant to the Company's equity plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

2. Restricted Stock Awards. This Policy does not apply to the vesting of restricted stock, or of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. This Policy, however, does apply to any market sale of restricted stock.

3. Transactions with the Company. This Policy does not apply to the purchase of the Company securities from the Company or the sale of the Company securities to the Company.

E. What Are the Consequences of Violations of This Policy?

Engaging in securities transactions while aware of material, nonpublic information, or the disclosure of material, nonpublic information is illegal.

Penalties for the purchase or sale of securities, while aware of material, nonpublic information, or communicating material, nonpublic information to others who then trade in such securities, are severe, both for the individuals involved in such unlawful conduct and, potentially, for their employers. A person can be subject to some or all of the penalties below even if he or she does not personally benefit from the violation (i.e., if the violation was one for tipping information). Penalties include:

- jail sentences of up to 10 years;
- disgorgement of profits;
- fines for the person who committed the violation of up to three times the profit gained or loss avoided, whether or not the person actually benefited;
- criminal fines (no matter how small the profit) up to $1 million; and
- fines for the employer or other controlling person, such as a supervisor, of up to the greater of $1,000,000 or three times the amount of the profit gained or loss avoided.

In addition, a violation of this Policy can be expected to result in serious sanctions by the Company, which may include dismissal for cause of the person involved, whether or not the employee's failure to comply with this Policy results in a violation of law.

III. POLICY REGARDING SPECIAL TRADING PROCEDURES

The following Special Trading Policies are applicable to all directors, officers and employees of the Company.

A. Trading Windows and Pre-Clearance.

There are times when the Company may be engaged in a material, nonpublic development. Although you may not know the specifics of the development, if you engaged in a trade before such development was disclosed to the public or resolved you might expose yourself and the Company to a charge of insider trading that could be costly and difficult to refute. In addition, a trade by you during such a development could result in significant adverse publicity for the Company.

Therefore, except pursuant to paragraph 3 below, you, your family members and controlled entities may only purchase or sell securities of the Company during the three or four "trading windows" that occur each year and only after pre-clearing your intent to trade with the Company's Chief Financial Officer.

The trading windows consist of the period that begins on the second business day after issuance of a press release or other announcement by the Company disclosing quarterly or annual earnings through the date which is the quarter or fiscal year end. To the extent a second trading window begins during the duration of an existing trading window, the trading window will continue for the duration of the trading window that expires on the latest date. In accordance with the procedure for waivers described below, in special circumstances a waiver may be given to allow a trade to occur outside of a trading window.

If you intend to engage in a trade during a trading window you must first receive permission to engage in a trade from the Company's Chief Financial Officer*. The Company's Chief Financial Officer may refuse to permit any transaction if he or she determines that it could give rise to a charge of insider trading. The Company's Chief Financial Officer may seek advice of outside counsel as he or she may consider appropriate.

After receiving permission to engage in a trade, you should either complete your trade within three business days or make a new trading request.

The exercise of options to purchase for cash and hold common stock of the Company or the purchase from the Company of common stock of the Company is not subject to the Special Trading Procedures outlined above, but the shares so acquired may not be sold except during a trading window, after authorization from the Company's Chief Financial Officer has been received and after all other requirements of this Policy have been satisfied. Accordingly, the exercise of options and immediate sale of some or all of the shares through a broker is covered by these Special Trading Procedures.

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* If the Company's Chief Financial Officer will be absent from the office or unavailable for a significant period of time, he or she will designate another executive officer of the Company to handle trading requests.

B. Event-Specific Black-out Procedures.

From time to time, an event may occur that is material to the Company and is known by only a few directors or officers. So long as the event remains material and nonpublic, the persons who are aware of the event, as well as other persons covered by these Special Trading Procedures, may not trade in the Company's securities. The existence of an event-specific blackout will not be announced, other than it may be announced to those who are aware of the event giving rise to the blackout. If, however, a person whose trades are subject to pre-clearance requests permission to trade in the Company's securities during an event-specific blackout, the Company's Chief Financial Officer will inform the requesting person of the existence of a blackout period, without disclosing the reason for the blackout. Any person made aware of the existence of an event-specific blackout should not disclose the existence of the blackout to any other person. The failure of the Company's Chief Financial Officer to designate a person as being subject to an event-specific blackout will not relieve that person of the obligation not to trade while aware of material, nonpublic information.

C. Rule 10b5-1 Plans.

The Securities and Exchange Commission has established regulations under which individuals may purchase and sell securities in compliance with "insider trading" laws (more specifically, Rule 10b5-1 of the Securities Exchange Act of 1934) if such purchases or sales are made pursuant to (i) a binding contract to purchase or sell the security, (ii) instructions provided to a third person to execute the trade for the instructing person or entity's account or (iii) an adopted written plan for trading securities; provided, that at the time of the decision to enter into such contract or plan or decision to provide such instructions, you were not aware of material, nonpublic information. In addition to other requirements set forth in such regulations, the contract, instructions or plan must (a) specify the amount, price and date of the purchase or sale or (b) provide a written formula or algorithm or computer program for determining the amounts, prices and dates of such purchases or sales.

Under the Company's policy, you, your family members and your controlled entities may only enter into a contract or plan or provide instructions for the purchase or sale of securities of the Company in compliance with these regulations after receiving written pre-clearance from the Company's Chief Financial Officer. A copy of the Rule 10b5-1 Plan should be submitted for approval at least three business days prior to the entry into the Rule 10b5-1 Plan.

D. Post-Trade Reporting.

You are required to report to the Company's Chief Financial Officer any transaction in securities of the Company by you, your family members or controlled entities not later than the business day following the date of your transaction. Each report you make to the Company's Chief Financial Officer should include the date of the transaction, quantity, price and broker through which the transaction was effected. This reporting requirement may be satisfied by sending (or having your broker send) duplicate confirmations of trades to the Company's Chief Financial Officer if such information is received by the required date.

The foregoing reporting requirement is designed to help monitor compliance with the Special Trading Procedures set forth herein and to enable the Company to help those persons who are subject to reporting obligations under Section 16 of the Securities Exchange Act of 1934 to comply with such reporting obligations. Each officer and director, however, and not the Company, is personally responsible for ensuring that his or her transactions do not give rise to "short swing" liability under Section 16 and for filing timely reports of transactions with the Securities and Exchange Commission.

E. Compliance with the Company's Statement of Company Policy on Insider Trading.

Even if you receive pre-clearance and it is during a trading window, you, your family members and your controlled entities may not trade in securities of the Company if you are in possession of material, nonpublic information about the Company. The procedures set forth herein are in addition to the general insider trading policy and are not a substitute therefor.

IV. PROHIBITION AGAINST CERTAIN TRANSACTIONS

1. **Prohibition on Short Sales.** Neither you, your family members nor your controlled entities may sell any securities of the Company that are not owned by such person at the time of the sale (a "short sale") including a "sale against the box" (a sale with delayed delivery).

2. **Trading in Standardized Options**. An "option" is the right either to buy or sell a specified amount or value of a particular underlying interest at a fixed exercise price by exercising the option before its specified expiration date. An option which gives a right to buy is a "call" option, and an option which gives a right to sell is a "put" option. Standardized options (which are so labeled as a result of their standardized terms) offer the opportunity to invest using substantial leverage and therefore lend themselves to significant potential for abusive trading on material inside information. Standardized options also expire soon after issuance and thus necessarily involve short-term speculation, even where the date of expiration of the option makes the option exempt from certain Securities and Exchange Commission restrictions.

The writing of a call or the acquisition of a put also involves a "bet against the company" and therefore presents a clear conflict of interest for you. As a result, neither you, your family members nor controlled entities may trade in standardized options relating to the Company securities at any time.

3. **Hedging Transactions**. Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow "insiders" to lock in much of the value of his or her stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow "insiders" to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the "insiders" may no longer have the same objectives as the Company's other shareholders. Therefore, neither you, your family members nor your controlled entities may engage in any such transactions.

4. **Margin Accounts and Pledges.** Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged or hypothecated as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when you are aware of material, nonpublic information or otherwise are not permitted to trade in the Company securities, neither you, your family members nor your controlled entities may hold the Company securities in a margin account or pledge the Company securities as collateral for a loan unless such transaction has been pre-approved by the Company's Chief Financial Officer.

V. POST-TERMINATION TRANSACTIONS

This Policy continues to apply to any and all transactions in the Company's securities following termination of your employment or other services to the Company. If you are in possession of material nonpublic information when you are terminated, you may not trade in the Company's securities until that information has become public or is no longer material. The pre-clearance procedures specified above, however, will cease to apply to transactions in the Company's securities upon the expiration of any blackout period applicable at the time of the termination of service.

VI. REPORTING OF VIOLATIONS

If you know or have reason to believe that this Policy or the Special Trading Procedures described above have been or may be violated, you should bring the actual or potential violation to the attention of the Company's Chief Financial Officer.

VII. TRAININGS REGARDING INSIDER TRADING

All directors and employees of the Company are required to annually attend trainings hosted or recommended by the Company regarding the laws governing insider trading.

VIII. MODIFICATIONS; WAIVERS

The Company reserves the right to amend or modify the procedures set forth herein at any time. Waiver of any provision of this Policy or the Special Trading Procedures in a specific instance may be authorized in writing by the Company's Chief Financial Officer (or his or her designee).

IX. QUESTIONS

If you have any questions regarding this Policy or the Special Trading Procedures described above, you should contact the Company's Chief Financial Officer.

ACKNOWLEDGMENT

I have read and understand Tonix Pharmaceuticals Holding Corp.'s Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures. I understand that, if I am an employee of the Company or one of its subsidiaries, my failure to comply in all respects with the Company's policies, including the Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures set forth herein, is a basis for termination for cause of my employment from the Company and any subsidiary thereof to which my employment now relates or may in the future relate. I will comply with the Policy for as long as I am subject to the Policy.

Signature: _____

Printed Name: _____ Date: _____

This document states a policy of Tonix Pharmaceuticals Holding Corp. and is not intended to be regarded as the rendering of legal advice. This policy statement is intended to promote compliance with existing law and is not intended to create or impose liability that would not exist in the absence of the policy statement.

[*Acknowledgement to Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures*]

Exhibit 21.01

SUBSIDIARIES OF THE COMPANY

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

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Tonix Pharmaceuticals Holding Corp. on Form S-3 (Nos. 333-266982 and 333-282270) and Form S-8 (Nos. 333-202006, 333-212300, 333-219928, 333-226776, 333-232137, 333-239152, 333-257437, 333-265705, 333-272746, and 333-283651) of our report dated March 18, 2025, on our audits of the consolidated financial statements as of December 31, 2024 and 2023 and for each of the years then ended, which report is included in this Annual Report on Form 10-K. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
March 18, 2025

Exhibit 31.01

CERTIFICATION

I, Seth Lederman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 18, 2025

/s/ SETH LEDERMAN
Seth Lederman
Chief Executive Officer

Exhibit 31.02

CERTIFICATION

I, Bradley Saenger, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 18, 2025

/s/ BRADLEY SAENGER
Bradley Saenger
Chief Financial Officer

Exhibit 32.01

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

I, Seth Lederman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: March 18, 2025

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

I, Bradley Saenger, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Tonix Pharmaceuticals Holding Corp. on Form 10-K for the fiscal year ended December 31, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Tonix Pharmaceuticals Holding Corp.

Date: March 18, 2025

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

Exhibit 97.01

TONIX PHARMACEUTICALS HOLDING CORP.

COMPENSATION RECOVERY POLICY

(Adopted and approved on November 14, 2023)

1. Purpose

Tonix Pharmaceuticals Holding Corp. (collectively with its subsidiaries, the "**Company**") is committed to promoting high standards of honest and ethical business conduct and compliance with applicable laws, rules and regulations. As part of this commitment, the Company has adopted this Compensation Recovery Policy (this "**Policy**"). This Policy is designed to comply with the requirements of Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated thereunder and the rules of the national securities exchange on which the Company's securities are traded and explains when the Company will pursue recovery of Incentive Compensation awarded or paid to a Covered Person. Please refer to Exhibit A attached hereto (the "**Definitions Exhibit**") for the definitions of capitalized terms used throughout this Policy.

2. Recovery of Recoverable Incentive Compensation

In the event of a Restatement, the Company will pursue, reasonably promptly, recovery of all Recoverable Incentive Compensation from a Covered Person without regard to such Covered Person's individual knowledge or responsibility related to the Restatement. Notwithstanding the foregoing, if the Company is otherwise required by this Policy to undertake a Restatement, the Company will not be required to recover the Recoverable Incentive Compensation if the Compensation Committee determines, after exercising a normal due process review of all the relevant facts and circumstances, that (a) a Recovery Exception exists and (b) it would be impracticable to seek such recovery under such facts and circumstances.

If such Recoverable Incentive Compensation was not awarded or paid on a formulaic basis, the Company will pursue recovery of the amount that the Compensation Committee determines in good faith should be recovered.

3. Other Actions

The Compensation Committee may, subject to applicable law, pursue recovery of Recoverable Incentive Compensation in the manner it chooses, including by pursuing reimbursement from the Covered Person of all or part of the compensation awarded or paid, by electing to withhold unpaid compensation, by set-off, or by rescinding or canceling unvested stock or option awards.

In the reasonable exercise of its business judgment under this Policy, the Compensation Committee may in its sole discretion determine whether and to what extent additional action is appropriate to address the circumstances surrounding a Restatement to minimize the likelihood of any recurrence and to impose such other discipline as it deems appropriate.

4. No Indemnification or Reimbursement

As required by applicable law, notwithstanding the terms of any other policy, program, agreement or arrangement, in no event will the Company or any of its affiliates indemnify or reimburse a Covered Person for any loss of Recoverable Incentive Compensation under this Policy and, to the extent prohibited by law, neither the Company nor any of its affiliates will pay premiums on any insurance policy that would cover a Covered Person's potential obligations with respect to Recoverable Incentive Compensation under this Policy.

5. Administration of Policy

The Compensation Committee will have full authority to administer this Policy. The Compensation Committee will, subject to the provisions of this Policy and Rule 10D-1 of the Exchange Act, and the Company's applicable exchange listing standards, make such determinations and interpretations and take such actions in connection with this Policy as it deems necessary, appropriate or advisable. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1 thereunder and any applicable rules or standards adopted by the Securities and Exchange Commission or any national securities exchange on which the Company's securities are listed. All determinations and interpretations made by the Compensation Committee will be final, binding and conclusive.

6. Other Claims and Rights

The requirements of this Policy are in addition to, and not in lieu of, any legal and equitable claims the Company or any of its affiliates may have or any actions that may be imposed by law enforcement agencies, regulators, administrative bodies, or other authorities. Further, the exercise by the Compensation Committee of any rights pursuant to this Policy will not impact any other rights that the Company or any of its affiliates may have with respect to any Covered Person subject to this Policy.

7. Acknowledgement by Covered Persons; Condition to Eligibility for Incentive Compensation

The Company will provide notice and seek acknowledgement of this Policy from each Covered Person, provided that the failure to provide such notice or obtain such acknowledgement will have no impact on the applicability or enforceability of this Policy. After the Effective Date (and also with respect to any Incentive Compensation Received on or after October 2, 2023 pursuant to a preexisting contract or arrangement), any grant of Incentive Compensation to a Covered Person will be deemed to have been made subject to the terms of this Policy, whether or not such Policy is specifically referenced in the documentation relating to such grant and this Policy shall be deemed to constitute an integral part of the terms of any such grant. All Incentive Compensation subject to this Policy will remain subject to this policy, even if already paid, until the Policy ceases to apply to such Incentive Compensation and any other vesting conditions applicable to such Incentive Compensation are satisfied.

8. Amendment; Termination

The Board or the Compensation Committee may amend or terminate this Policy at any time. In the event that Section 10D of the Exchange Act, Rule 10D-1 thereunder or the rules of the national securities exchange on which the Company's securities are traded are modified or supplemented, whether by law, regulation or legal interpretation, such modification or supplement shall be deemed to modify or supplement this Policy to the maximum extent permitted by applicable law.

9. Effectiveness

Except as otherwise determined in writing by the Compensation Committee, this Policy will apply to any Incentive Compensation that is Received by a Covered Person on or after the Effective Date. This Policy will survive and continue notwithstanding any termination of a Covered Person's employment with the Company and its affiliates.

10. Successors

This Policy shall be binding and enforceable against all Covered Persons and their successors, beneficiaries, heirs, executors, administrators, or other legal representatives.

Exhibit A

TONIX PHARMACEUTICALS HOLDING CORP.

COMPENSATION RECOVERY POLICY

DEFINITIONS EXHIBIT

"**Applicable Period**" means the three completed fiscal years of the Company immediately preceding the earlier of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes (or reasonably should have concluded) that a Restatement is required or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. The "Applicable Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence.

"**Board**" means the Board of Directors of the Company.

"**Compensation Committee**" means the Company's committee of independent directors responsible for executive compensation decisions, or in the absence of such a committee, a majority of the independent directors serving on the Board.

"**Covered Person**" means any person who is, or was at any time, during the Applicable Period, an Executive Officer of the Company. For the avoidance of doubt, a Covered Person may include a former Executive Officer that left the Company, retired, or transitioned to an employee role (including after serving as an Executive Officer in an interim capacity) during the Applicable Period.

"**Effective Date**" means December 1, 2023.

"**Executive Officer**" means the Company's president, principal executive officer, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person (including an officer of the Company's parent(s) or subsidiaries) who performs similar policy-making functions for the Company.

"**Financial Reporting Measure**" means a measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure (including but not limited to, "non-GAAP" financial measures, such as those appearing in the Company's earnings releases or Management Discussion and Analysis). Stock price and total shareholder return (and any measures derived wholly or in part therefrom) shall be considered Financial Reporting Measures.

"**Recovery Exception:**" A recovery of Recoverable Incentive Compensation shall be subject to a "Recovery Exception" if the Compensation Committee determines in good faith that: (i) pursuing such recovery would violate home country law of the jurisdiction of incorporation of the Company where that law was adopted prior to November 28, 2022 and the Company provides an opinion of home country counsel to that effect acceptable to the Company's applicable listing exchange; (ii) the direct expense paid to a third party to assist in enforcing this Policy would exceed the Recoverable Incentive Compensation and the Company has (A) made a reasonable attempt to recover such amounts and (B) provided documentation of such attempts to recover to the Company's applicable listing exchange; or (iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

"**Incentive Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive Compensation does not include any base salaries (except with respect to any salary increases earned wholly or in part based on the attainment of a Financial Reporting Measure performance goal); bonuses paid solely at the discretion of the Compensation Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a Financial Reporting Measure performance goal; bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period; non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures; and equity awards that vest solely based on the passage of time and/or attaining one or more non-Financial Reporting Measures. Incentive Compensation includes any Incentive Compensation Received on or after October 2, 2023 pursuant to a preexisting contract or arrangement.

"**Received:**" Incentive Compensation is deemed "Received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period.

"**Recoverable Incentive Compensation**" means the amount of any Incentive Compensation (calculated on a pre-tax basis) Received by a Covered Person during the Applicable Period that is in excess of the amount that otherwise would have been Received if the calculation were based on the Restatement. For Incentive Compensation based on (or derived from) stock price or total shareholder return where the amount of Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in the applicable Restatement, the amount will be determined by the Compensation Committee based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive Compensation was Received (in which case, the Company will maintain documentation of such determination of that reasonable estimate and provide such documentation to the Company's applicable listing exchange).

"**Restatement**" means an accounting restatement of any of the Company's financial statements filed with the Securities and Exchange Commission under the Exchange Act, or the Securities Act of 1933, as amended, due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, regardless of whether the Company or Covered Person misconduct was the cause for such restatement. "Restatement" includes any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as "Big R" restatements), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as "little r" restatements).