November 12, 2024

Tonix Pharmaceuticals Reports Third Quarter 2024 Financial Results and Operational Highlights

Submitted New Drug Application (NDA) to FDA for TNX-102 SL for fibromyalgia based on two statistically significant Phase 3 studies

Granted Fast Track Designation by FDA in July 2024 for TNX-102 SL, a centrally-acting, non-opioid analgesic; Fibromyalgia is a common chronic pain condition that affects mostly women

Expect FDA decision in December 2024 on TNX-102 SL NDA acceptance for review and 2025 PDUFA date; If FDA-approved in 2025, TNX-102 SL would be the first new drug for fibromyalgia in more than 15 years

Presented new data on potential mpox vaccine, TNX-801, in September and October 2024, demonstrating tolerability in immunocompromised animals; Previously reported studies showed a single-dose provided immune protection against a monkeypox challenge

Awarded U.S. Department of Defense (DoD) contract for up to $34 million over five years in July 2024 to develop a broad-spectrum antiviral drug; Received first payment from DTRA

CHATHAM, N.J., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced financial results for the third quarter ended September 30, 2024, and provided an overview of recent operational highlights.

“With our recent NDA submission to the U.S. Food and Drug Administration (FDA), Tonix is excited about the potential of TNX-102 SL to become the first new drug treatment option in more than 15 years for the roughly 10 million adults in the U.S. suffering from fibromyalgia,” said Seth Lederman, M.D., Chief Executive Officer of Tonix. “FDA awarded TNX-102 SL Fast Track designation in the third quarter of 2024, which is intended to expedite FDA review of important new drugs to fill unmet needs for serious conditions. We look forward to next steps with FDA. If the NDA filing is accepted in December, we expect a decision on the marketing approval of TNX-102 SL for fibromyalgia in 2025.”

Dr. Lederman continued, “As we continue to advance key pipeline products through a capital efficient strategy, we are excited to have announced collaborations with world-class institutions to advance the development of TNX-801, a potential mpox vaccine whose single-dose administration and other characteristics align closely with The World Health Organization’s preferred target product profile (TPP) criteria for mpox vaccines. The World

Health Organization (WHO) previously announced the growing number of mpox cases constitutes a public health emergency of international concern (PHEIC), with clade 1b mpox strains now detected in 16 countries in Africa as well as in Sweden, Thailand, Singapore, India, England and Germany."

Key Product Candidates* -- Recent Highlights

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): 5.6 mg, once-daily at bedtime small molecule for the management of fibromyalgia (FM) – a centrally-acting, non-opioid analgesic.

- In October 2024, Tonix announced submission of the TNX-102 SL New Drug Application (NDA) for fibromyalgia to the FDA. The submission was based upon two Phase 3 studies of TNX-102 SL in fibromyalgia that showed statically significant reduction in the chronic, widespread pain associated with fibromyalgia. If approved by the FDA, TNX-102 SL would be the first member of a new class of analgesic drugs for fibromyalgia and the first new drug available for treating fibromyalgia in more than 15 years. Fibromyalgia affects more than 10 million adults in the U.S., most of whom are women.

- 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[1] 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.

- In August 2024, at both the DoD's 2024 Military Health System Research Symposium (MHSRS), and at the International Association for the Study of Pain's (IASP's) 2024 World Congress on Pain, Tonix announced additional data and analyses of TNX-102 SL for the management of fibromyalgia. TNX-102 SL had met the pre-specified primary endpoint in the Phase 3 RESILIENT study, significantly reducing daily pain compared to placebo (p-value=0.00005) in participants with fibromyalgia while demonstrating broad syndromal benefits with statistically significant improvement in all six pre-specified key secondary endpoints, including those related to improving sleep quality, reducing fatigue, and improving patient global ratings and overall fibromyalgia symptoms and function. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies and no new safety signals were observed.

- In July 2024, Tonix noted that, based on the new definition of Long COVID by the U.S. National Academies of Sciences, Engineering and Medicine (NASEM), fibromyalgia is a 'diagnosable condition' in people suffering from Long COVID. The Company believes that diagnosing fibromyalgia in Long COVID patients will increase the potential market for TNX-102 SL following approval as compared to market estimates from before the

COVID-19 pandemic.

TNX-102 SL for the treatment of acute stress reaction (ASR) and acute stress disorder (ASD), and prophylaxis against development of posttraumatic stress disorder (PTSD)

- 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[1]. 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[2,3]. 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 PTSD.

- The DoD-funded Optimizing Acute Stress Reaction Interventions (OASIS) trial will be conducted by the University of North Carolina under an investigator-initiated investigational new drug (IND) application. The OASIS trial will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients in the emergency department (ED) after a motor vehicle collision. Fourteen days of bedtime TNX-102 SL will be dosed and tested in the immediate aftermath of motor vehicle collision. 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.

TNX-1300 (recombinant double mutant cocaine esterase): biologic for life-threatening cocaine intoxication

- Tonix announced the first patient in the Phase 2 CATALYST study of TNX-1300 for the treatment of cocaine intoxication was enrolled in August 2024. CATALYST is a Phase 2 single-blind, placebo-controlled, proof-of-concept study in patients presenting to the emergency department. Topline results are expected in the first half of 2025.

- The National Institutes of Health (NIH)'s National Institute of Drug Abuse (NIDA) previously awarded Tonix a Cooperative Agreement grant for approximately $5 million from to support development of TNX-1300.

- TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

Infectious Disease Pipeline

TNX-801 (recombinant horsepox virus, live vaccine): potential vaccine to protect against mpox disease and smallpox.

- 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. TNX-801 is an

attenuated live-virus vaccine based on synthesized horsepox that has been shown to provide single-dose immune protection against a monkeypox challenge. After a single-dose vaccination, TNX-801 prevented clinical disease and lesions, and also decreased shedding in the mouth and lungs of non-human primates 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 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 1b mpox have since also been detected in Sweden, Thailand, Singapore, India, Germany and England.

- In September 2024, the Company 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.

Footnotes:

1. *The TNX-102 SL eutectic is a composition of matter based on co-penetration of cyclobenzaprine HCl and mannitol crystals and protected by 5 issued U.S patents: Nos. 9,636,408; 9,956,188; 10,117,936; 10,864,175; 11,839,594; 9,918,948; 11,826,321.*

2. *Sullivan GM, et al. Randomized clinical trial of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related PTSD and the role of sleep quality in treatment response. Psychiatry Res. 2021 Jul;301:113974.*

3. *Parmenter ME, et al. A phase 3, randomized, placebo-controlled, trial to evaluate the efficacy and safety of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related posttraumatic stress disorder. Psychiatry Res. 2024 (In Press). https://doi.org/10.1016/j.psychres.2024.115764*

Corporate and Partnerships – Recent Highlights

- In November 2024, the Company 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 I clinical study in Kenya to test the safety, tolerability, and immunogenicity of TNX-801 (horsepox, live virus) as a vaccine to prevent mpox and smallpox. Tonix is expected be the sponsor and KEMRI is expected to lead the execution of the proposed clinical trial.

- In October 2024, the Company announced it entered into an artificial intelligence and machine learning drug discovery collaboration with X-Chem, Inc., a leader in small molecule drug discovery, to accelerate the development of small molecules as orally available host-targeted broad-spectrum medical countermeasures. Tonix's TNX-4200 antiviral program focuses on the development of oral CD45 phosphatase inhibitors,

with broad-spectrum activity against a range of viral families.

- In September 2024, Tonix announced the appointment of Thomas Englese as its new Executive Vice President, Commercial Operations. Mr. Englese brings significant leadership to Tonix across several functions, including commercial operations, sales and marketing, and launching and managing major brands through all stages of commercialization.

- In August 2024, the Company announced a collaboration with Bilthoven Biologics (Bbio) to develop GMP manufacturing processes for TNX-801 as a potential mpox vaccine. Bbio is part of the world's largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

- In July 2024, Tonix announced it had been awarded a DoD contract with a potential for up to $34 million over five years by DoD's Defense Threat Reduction Agency (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 IIND submission and to fund a first-in-human Phase 1 clinical study.

Marketed Products – Recent Highlights

- 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.

- 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.

Tonix Medicines launched a national educational campaign focusing on the link between migraine, gastroparesis, and the need for non-oral acute migraine therapies. 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.

Financial - Recent Highlight

As of September 30, 2024, Tonix had approximately $28.2 million of cash and cash equivalents, compared to approximately $24.9 million as of December 31, 2023. Additionally, Tonix had inventory totaling approximately $7.9 million as of September 30, 2024. Net cash used in operations was approximately $46.3 million for the nine months ended September 30, 2024, compared to approximately $79.7 million for the same period in 2023. Cash used in investing activities for the nine months ended September 30, 2024 was approximately

$117,000 compared to $28.6 million for the same period in 2023.

In July 2024, Tonix received net proceeds of approximately $3.5 million in a securities offering with certain institutional and retail investors. Additionally, during the three months ended September 30, 2024, Tonix sold approximately 134.5 million shares of common stock under the 2024 ATM Sales Agreement for net proceeds of approximately $41.8 million.

Third Quarter 2024 Financial Results

Net product revenue for the third quarter 2024 was approximately $2.8 million. Net product revenue consisted of combined net sales of Zembrace® SymTouch® and Tosymra®, which were acquired from Upsher-Smith Laboratories, LLC on June 30, 2023. Cost of sales for the third quarter 2024 was approximately $1.6 million.

During the three months ended September 30, 2024, Tonix received its first payment from DTRA as part of its previously announced award from DTRA for up to $34 million over five years.

Research and development expenses for the third quarter 2024 were approximately $9.1 million, compared to $21.0 million for the same period in 2023. This decrease is predominantly due to lower clinical, non-clinical and manufacturing expenses aligned with the Company's capital efficient strategy.

Selling, general and administrative expenses for the third quarter 2024 were approximately $7.7 million, compared to $8.7 million for the same period in 2023. The decrease was primarily due to lower employee-related expenses, transactional services and sales and marketing expenses partially offset by an increase in professional fees.

Net loss available to common stockholders was approximately $14.2 million, or $0.23 per share, basic and diluted, for the third quarter 2024, compared to net loss available to common stockholders of $28.0 million, or $38.63 per share, basic and diluted, for the same period in 2023. The basic and diluted weighted average common shares outstanding for the third quarter 2024 was 62,122,283 compared to 724,190 shares for the same period in 2023.

Tonix Pharmaceuticals Holding Corp.*
Tonix is a fully-integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders. 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. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. We expect an FDA decision on the acceptance of the NDA for review and a PDUFA date in December and if accepted, a decision on NDA approval in 2025. 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 U.S. National Institute of Drug Abuse and Addiction. 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 the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and 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.

* Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
REVENUE:				
Product revenue, net	$ 2,822	$ 3,989	$ 7,512	$ 3,989
COSTS AND EXPENSES:				
Cost of revenue	1,555	2,374	6,582	2,374
Research and development	9,114	21,050	31,675	69,535
Selling, general and administrative	7,707	8,712	24,519	23,131
Asset impairment charges	—	—	58,957	—
	18,376	32,136	121,733	95,040
Operating loss	(15,554)	(28,147)	(114,221)	(91,051)
Grant income	1,668	—	1,668	—
Gain on change in fair value of warrant liabilities	—	—	6,150	—
Other (expense) income, net	(327)	172	(1,525)	1,715
Net loss available to common stockholders	$ (14,213)	$ (27,975)	$ (107,928)	$ (89,336)

Net loss per common share, basic and diluted	$ (0.23)	$ (38.63)	$ (4.66)	$ (143.47)
Weighted average common shares outstanding, basic and diluted	62,122,283	724,190	23,136,172	622,684

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands)
(Unaudited)

	September 30, 2024	December 31, 2023[1]
Assets		
Cash and cash equivalents	$ 28,233	$ 24,948
Accounts Receivable, net	4,013	-
Inventory	7,931	13,639
Prepaid expenses and other	10,366	9,181
Total current assets	50,543	47,768
Other non-current assets	44,446	106,689
Total assets	$ 94,989	$ 154,457
Liabilities and stockholders' equity		
Total liabilities	$ 20,778	$ 48,932
Stockholders' equity	74,211	105,525
Total liabilities and stockholders' equity	$ 94,989	$ 154,457

[1]The condensed consolidated balance sheet for the year ended December 31, 2023 has been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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