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SECURITIES • RESEARCH

NurExone Biologic Inc.

March 2025

OTCPK: NRXBF
TSXV: NRX

Rating: BUY
Target: C$2.52

Market Cap +/- $52M~	Outstanding Shares +/- 70M	2025 Range: 0.54-0.78	CEO: Lior Shaltiel

Introduction

NurExone Biologic Inc. (NRX) is an Israeli biotechnology company developing exosome-based therapies for central nervous system (CNS) injuries, including spinal cord injury (SCI). Its lead candidate, ExoPTEN, has received Orphan Drug Designation from both the U.S. FDA and EMA, granting potential regulatory and commercial benefits such as market exclusivity and tax incentives. The company has completed a pre-IND meeting with the FDA, with Phase 1 clinical trials expected to begin by late 2025

Research Objectives:
This report provides an in-depth analysis of NurExone Biologic Inc., examining its technology, market potential, financial outlook, and competitive positioning. The key objectives of this research are to:

- Assess NurExone's exosome-based drug delivery platform and its potential for treating CNS injuries
- Analyze the market size, growth trends, and competitive landscape within the exosome therapeutics sector
- Evaluate the company's financial position, investment risks, and valuation
- Identify strategic opportunities, including potential partnerships or acquisitions

Scope and Methodology:
This report focuses on NurExone's role in the biotechnology and regenerative medicine industries, particularly in exosome-based therapeutics for CNS disorders. The analysis covers:

- Industry focus: Exosome-based drug delivery and regenerative medicine
- Geographical scope: Primarily the U.S. and European markets, where regulatory approvals are targeted
- Timeframe: Market trends and projections through 2025 and beyond

The research is based on secondary data sources, including company filings, investor presentations, industry reports, regulatory documents, and competitive benchmarking. The objective is to provide a data-driven evaluation of NurExone's growth potential and investment considerations.

Highlights

- Plans to uplist from OTC, TSXV listed
- Rapid, Non-invasive, Cell free
- No immune response in patients
- Intranasal spray, off the shelf
- Being studied as glaucoma treatment

★75% of Test Subjects Recovered Motor Function & Bladder Control Following Short Treatment With ExoPTEN Administered Intranasally

- FDA Orphan Drug Designation
- R&D Facility in Haifa, Israel
- Nearing human clinical trials
- Large Scale Preclinical Testing
- Large geographical patent coverage

Recent Developments in 2025

- Completed preclinical study towards Investigational New Drug ("IND") submission, which advances path towards first-in-human trials
- Plans to pursue uplisting from the OTC to a major U.S. exchange, subject to requisite regulatory approval, to strengthen market position and broaden investor access
- Appointed Dr. Tali Kizhner as its new Director of R&D as it advances toward clinical trials. Dr. Kizhner has 15 years of R&D, chemistry, manufacturing and controls expertise and has led groundbreaking initiatives in therapeutic protein development and dietary supplements
- Acquired a master cell bank from a U.S. manufacturer, ensuring a stable and scalable supply chain for production of exosome therapies for clinical needs and eventual patient treatment
- Significant findings from an expanded preclinical study of the potential of its portfolio drug, ExoPTEN, for repairing optic nerve damage, strengthening the suggestion of a promising treatment pathway for glaucoma, the leading cause of irreversible blindness globally
- European Medicines Agency (the "EMA") has granted Orphan Medicinal Product Designation for the Company's ExoPTEN therapy, marking a significant step towards making this potential treatment available for acute spinal cord injury patients across Europe

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Exo-PTEN

Born in the labs of Israel, ExoPTEN is NurExone's first nanodrug. Being developed for patients who have suffered acute spinal cord injury. ExoPTEN uses exosomes loaded with a specific and proprietary sIRNA sequence as the active pharmaceutical ingredient. **Studies have demonstrated that ExoPTEN facilitates nerve regeneration, regrowth, and functional recovery following a brief intranasal administration in laboratory animals**

Spinal Cord Injury Treatments (SCI)	Intranasal ExoPTEN Technology	Autologous Stem Cell	Allogeneic Stem Cell	Epidutal Electrical Stimulation
Potential to repair full transection	✓	✓	✓	X
Immune Evasion	✓	✓	X	✓
Off the shelf use	✓	X	✓	✓
Non Invasive	✓	X	X	X

Initial indications from a pre-clinical study have demonstrated the potential for an **off-the-shelf therapy for non-invasive administration** shortly after spinal cord trauma. The product, which would not require personalization, is expected to reduce damage from a spinal-cord injury and to improve the chance of functional recovery.

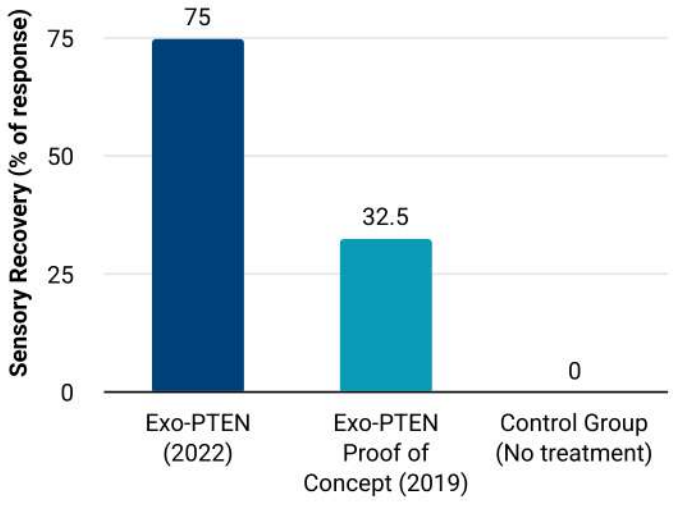
The aim is to be able to recover function after any acute or traumatic SCI. Introducing any level of recovery, partial or complete, would bring significant relief to the patient and direct improvement of their quality of life.

Preclinical Trials - ExoPTEN

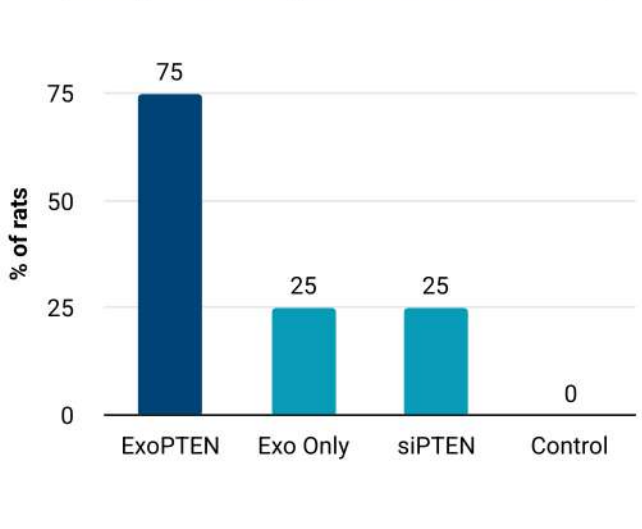
Preclinical studies in rats with NurExone's proprietary Exo-PTEN for the treatment of spinal cord injury

**Motor rehabilitation assessed by the evaluation of the BBB score (Blood Brain Barrier)*

Sensory Recovery 4 weeks after treatment



Tail & paw recovery 2 weeks after treatment



Nurexone's product includes a complete bioprocess, starting with isolation from 3D cultured BM-derived mesenchymal stem cells with an increased yield, followed by loading of the exosomes with PTEN-siRNA) and **intranasal administration** in rats for in vivo studies. These results have **signifcant clinical therapeutic application for SCI and other neurological diseases with neuroinflammation**.

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Roadmap

Nurexone's pipeline develops therapies and nanodrugs to address medical needs and to improve patient outcomes across various indications

Program	Indication	Discovery	Regulatory Strategy	Preclinical Development	Studies for IND	Clinical	Commercial
ExoPTEN	Acute Spinal Cord Injury	→	→	→			
	Glaucoma	→	→				
PNN Targeting Sequences	Several - CNS Traumatic Injury	→	→	→			
Exosomes & Stem Cells	Chronic Spinal Cord Injury	→	→	→			

Collaboration with Inteligex leverages their novel targeted human stem cell platform which replaces key cell types lost due to traumatic injury or neurodegeneration

- **Q1-2023** — Establish scaled up ExoPTEN Production
- **Q2-2023** — Finalize product characterization
- **Q4-2023** — Orphan Drug Designation Approval
- **Q2-2024** — Preclinical experiments for IND Application
- **Q4-2024** — QC/QA & IND preparation
- **Q4-2025** — IND submission Phase I/IIa Human trials
- **Q2-2026** — Phase I/IIa SCI Phase I/IIa Glaucoma EXO-Therapy JV/licensing
- **Q2-2026** — Initiate Nasdaq Uplisting
- **Q2-2026** — Nasdaq Uplisting Complete

*IND=Investigational New Drug Application

Patents, Designations & Intellectual Property

Patents	Description
Vesicles Comprising a PTEN Inhibitor and Uses of Same	The present invention provides pharmaceutical compositions comprising membrane vesicles, including extracellular vesicles including those referred to as exosomes, loaded with an exogenous Phosphatase and tensin homolog (PTEN) inhibitor
Anti-PTEN RNA Interference Oligonucleotides and Uses Thereof	The present invention provides RNA interference (RNAi) oligonucleotides inhibiting expression of Phosphatase and tensin homolog (PTEN), extracellular vesicles comprising the RNAi oligonucleotides, pharmaceutical compositions including the RNAi oligonucleotides

Patent Coverage	Status
United States of America	**Granted**
Russia	**Granted**
Japan	**Granted**

Designations	Status
U.S Food and Drug (FDA) Orphan Drug Designation	**Granted**
European Orphan Drug Designation	**Granted**

Designation Benefits
Tax Benefits
7-12 Years Market Protection
Shortened Approval Process

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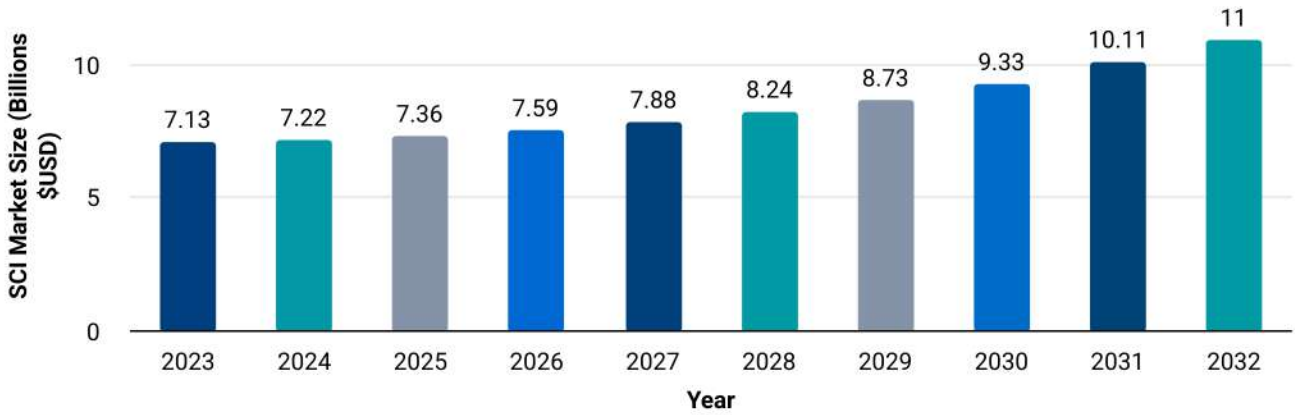
Total Adressable Market

ExoPTEN is targeted at patients who have recently suffered an acute spinal cord injury, e.g., vehicle, work, sports-related injuries. Globally, an estimated **250,000–500,000 people suffer from spinal cord injuries (SCIs) annually**, with 90% of these injuries stemming from traumatic causes such as vehicle accidents, workplace incidents, or sports-related mishaps. In the United States alone, this accounts for approximately **17,000 new cases per year**, while in Europe, there are around **10,000 new cases annually**. This suggests a **potential market for ExoPTEN of approximately 50,000 new cases per year**.

The financial burden on both patients and the healthcare system is considerable. It involves immediate expenses, such as emergency surgeries, followed by prolonged rehabilitation periods. Additionally, many individuals with spinal cord injuries require ongoing financial support to accommodate various disabilities and cope with unemployment. The **spinal cord injury treatment market size achieved a value of USD 7.13 billion in 2023 and is anticipated to reach USD 11.00 billion by 2032**. Projections suggest a compound **annual growth rate (CAGR) of 4.8% for the period of 2024 to 2032**.



The emerging **exosome therapeutics market is projected to reach $2.9 billion by 2030**, growing at a **CAGR of 30%**. Nurexone differentiates itself by focusing on CNS disorders, while many competitors target oncology and dermatology. Given its regulatory progress and strong market potential, NurExone could be a candidate for future licensing deals or acquisition by a larger pharmaceutical company.

Spinal Cord Injury Facts

Source: https://www.who.int/news-room/fact-sheets/detail/spinal-cord-injury https://pmc.ncbi.nlm.nih.gov/articles/PMC9554757/

*Important disclosures can be found at the end of this report

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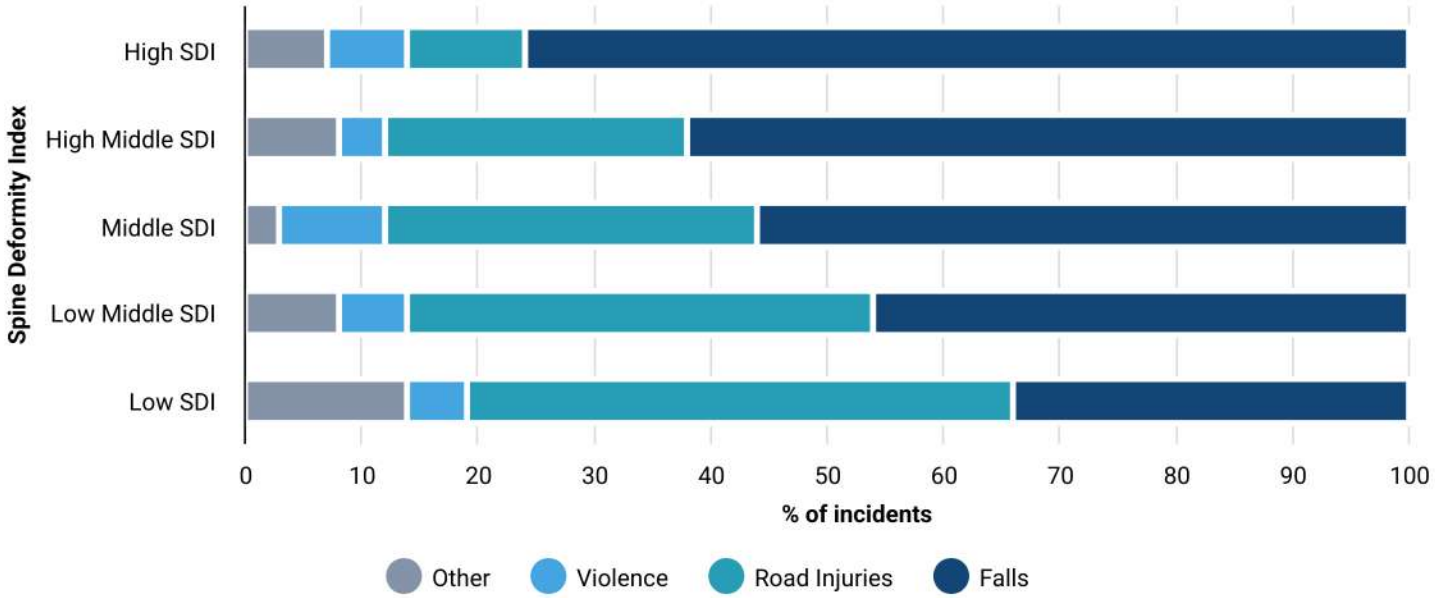
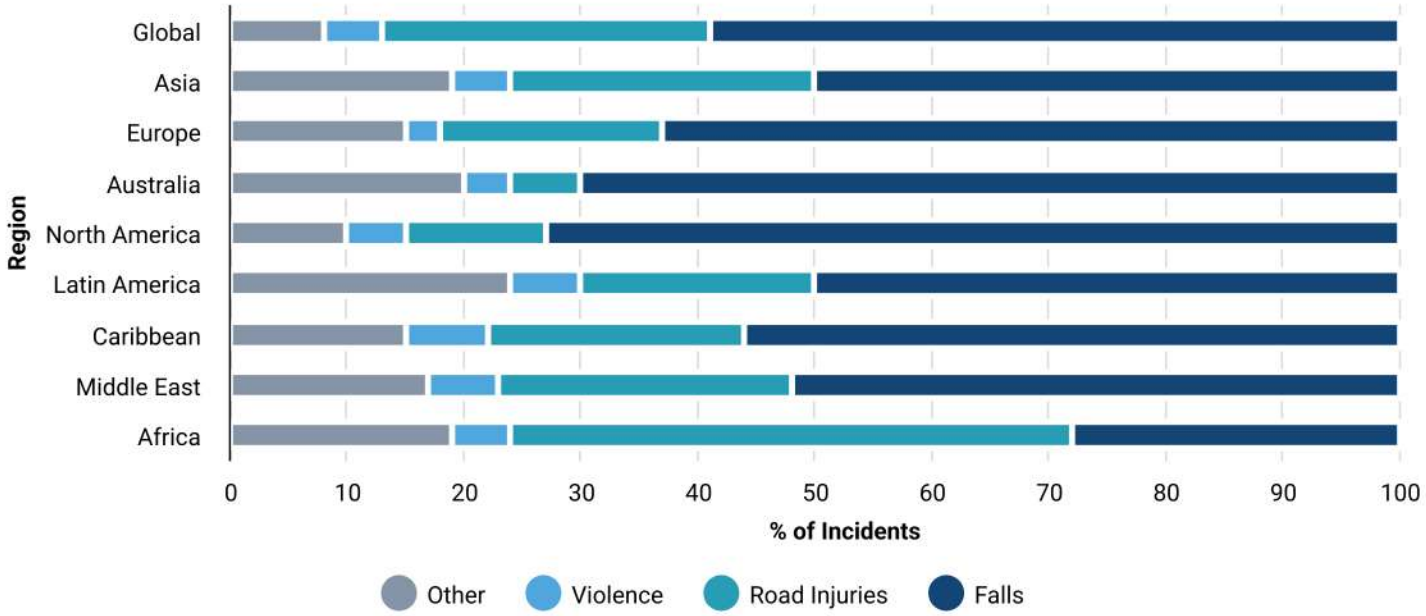
Spinal Cord Injury Statistics

The semiquantitative spinal deformity index (SDI) is a summary measure of the vertebral fracture status of the spine incorporating both the number and severity of vertebral fractures



In 2019, it was estimated that there were 9 million cases of spinal cord injuries worldwide, marking a 52.7% increase compared to estimates in 1990



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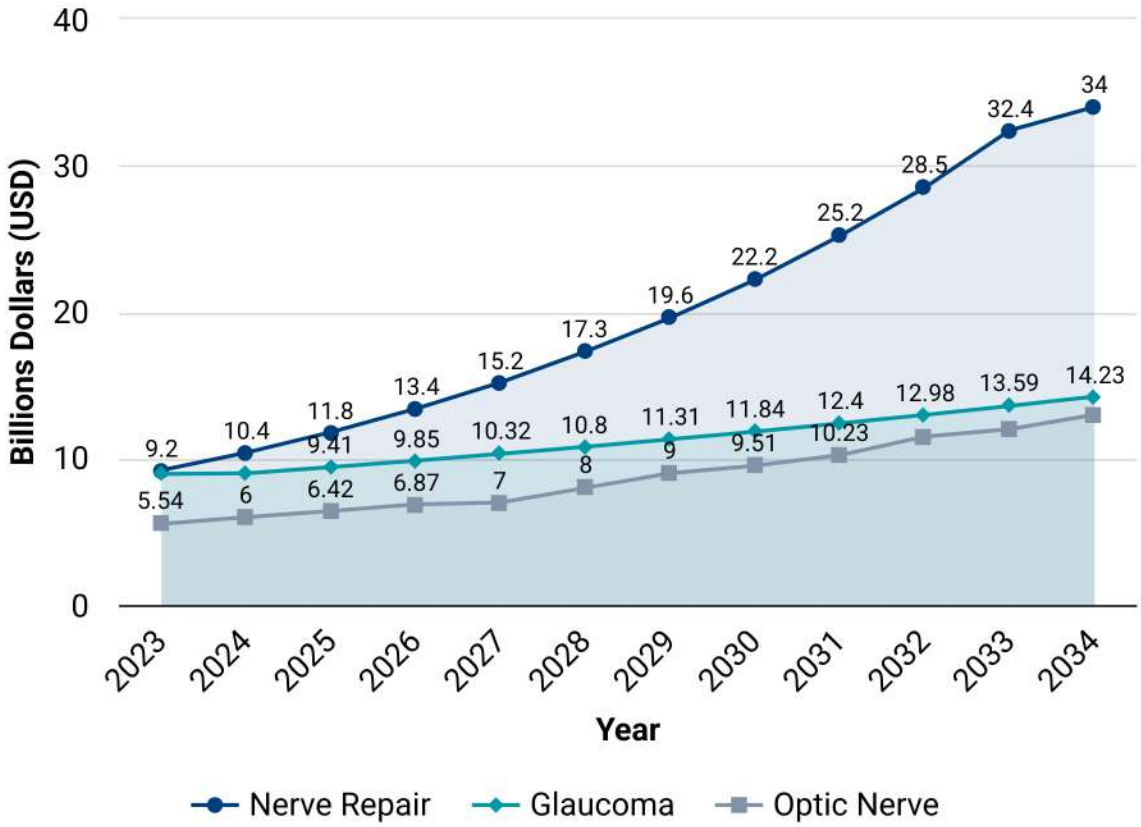
Glaucoma Potential

Currently, there is no cure for glaucoma, but it can be managed to slow down its progression. The optic nerve, a critical component of the visual system, transmits visual information from the retina to the brain. Since the optic nerve, part of the central nervous system, does not regenerate spontaneously, and damage thereto, whether due to injury, glaucoma, or other conditions, can result in significant vision loss and blindness. According to experts, **current treatments are limited and focus on preventing additional damage rather than regenerating or repairing damaged nerves**.



Based on NurExone's trials on the spinal cord, which is also part of the central nervous system, **exosome-loaded drugs may be able to change this paradigm with their potentially regenerative properties with respect to damaged nerves**. Nurexone has the ability to load a wide range of API, such as siRNA, miRNA, small peptides and small molecules.

In addition to conditionally-expressed protein cargos, miRNA is another key component and regulatory factor of exosomes that have been revealed to alter the gene expression of the TM and Schlemm's canal, playing a **significant role in glaucoma** pathogenesis. Compared with cell-based therapy, **exosome-based therapy shows superiorities of great tissue compatibility, better penetration capacity, better immune tolerance, and the freedom to be modified** with specific cargos to regulate target cells.

As a cutting-edge research focus for glaucoma, exosome-based therapy demonstrates potential benefits in 3 basic aspects: **modulation of neuroinflammation, protection of RGCs and retinal neurons, and promotion of tissue regeneration**. However, currently, all evidence comes from ex vivo studies and animal models, with no clinical data available. With boosting applications of exosomes in clinical trials in several other fields, there is great potential that exosome-based therapy may become readily available for clinical translation in the near future.

Sources: https://pmc.ncbi.nlm.nih.gov/articles/PMC10388248/ https://www.marketresearchfuture.com/reports/optic-nerve-disorders-treatment-market-30051

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Competitive Analysis

NurExone operates in the emerging exosome therapeutics market, which remains highly specialized with few direct competitors. Over 70 companies are engaged in exosome R&D, primarily in oncology, dermatology, and regenerative medicine. However, there are currently no FDA-approved exosome-based therapies.

NurExone stands out by focusing on Central Nervous System injuries, particularly spinal cord injury (SCI), whereas most competitors target oncology and cardiovascular diseases. Several publicly traded companies are developing exosome-based therapeutics, making them key benchmarks for NurExone's market positioning.

*Market Cap as of March 13th, 2025

Company	Symbol	*Mkt Cap (USD)	Focus	Stage	Partnership
Avalon Globocare	NASDAQ:ALBT	~5M	Exosome based diagnostics & drug delivery	Preclinical	MIT
Nurexone Biologic	TSXV:NRX OTCPK:NRXBF	~50M	SCI, CNS glaucoma	Preclinical	Intelegix Nanometrix
Coya Therapeutics	NASDAQ:COYA	~109.43M	treg-derived exosomes, ALS, neuro inflammation	Clinical	HMRI, ADDF ARScience Dr. Reddy's
Lineage Cell (cell-based therapy)	NYSE: LCTX	~118M	Vision Loss, SCI, Hearing Loss	Clinical	Roche Genentech
Capricor Therapeutics	NASDAQ:CAPR	~594M	Vaccines, Muscular Dystrophy	Clinical	Nippon Shinyaku
BioArctic	OMX:BIOAB	~1.85B	CNS, Parkinson's	Preclinical	Eisai

Partnerships:

- NurExone is the only company specializing in therapy for spinal cord injury with the use of exosomes, while others focus on oncology, cardiovascular disease, and gene therapy. This gives NurExone a unique positioning in an underserved market.
- Capricor Therapeutics is the most advanced, with Phase 1/2 clinical trials and a strategic partnership with Nippon Shinyaku Co., Ltd. Its higher market capitalization (~$594.3M) reflects investor confidence
- Aruna Bio also focuses on CNS disorders, but on stroke recovery and neurodegenerative diseases. Unlike NurExone, Aruna has not yet secured Orphan Drug Designation, giving NurExone a regulatory advantage. Additionally, Aruna Bio remains a private company, limiting publicly available valuation metrics
- Avalon GloboCare develops exosome-based drug delivery systems but does not focus on therapeutics. Its MIT partnership strengthens its technology potential, though its market capitalization is significantly lower (~$5M), reflecting its early-stage nature.

Strategic Partnerships Are Key:

- Capricor Therapeutics: Partnered with Nippon Shinyaku Co., Ltd., securing a $30M upfront payment to advance its exosome-based vaccine program
- Avalon GloboCare: Collaborates with MIT on mRNA-based exosome drug delivery, leveraging academic innovation
- NurExone: Collaboration with Inteligex, aims to combine Inteligex's more than twenty years of experience in cell-based therapies. Nurexone will use their platform to produce and load exosomes from Inteligex's cell line to deliver combination regenerative therapy for SCI's

Mergers & Acquisitions

The exosomes research space has gained significant attention in recent years due to its potential to revolutionize healthcare, particularly in diagnostics, drug delivery, and regenerative medicine. The mergers and acquisitions (M&A) activity in this field reflects both its competitive nature and its importance to the future of biomedicine.

Lonza's Acquisition of Exosomics
Lonza, a Swiss multinational specializing in life sciences, acquired Exosomics, an Italian company focused on exosome-based diagnostics and research tools. Exosomics had developed proprietary technology for isolating tumor-derived exosomes, which could enhance cancer diagnostics. Exosomics had a small but specialized team and a portfolio of patents related to exosome isolation. Lonza's acquisition added this capability to its broader bioprocessing and diagnostics offerings. This move signaled Lonza's intent to expand into precision diagnostics, leveraging exosomes as a next-generation tool. It reflects the competitive rush to secure intellectual property (IP) and expertise in this emerging field. The exact financial terms were not publicly disclosed, as is common in private transactions. However, industry estimates suggest the deal was likely in the range of $50–100 million, given Lonza's typical acquisition scale and Exosomics' niche but high-potential technology.

Thermo Fisher Scientific's Attempted Acquisition of QIAGEN
While not exclusively an exosome-focused deal, Thermo Fisher's $11.5 billion bid for QIAGEN included access to QIAGEN's exosome research tools and technologies. QIAGEN had been developing exosome isolation kits widely used in academic and clinical research. QIAGEN's exosome kits were part of a broader molecular diagnostics business generating annual revenues of approximately $1.6 billion at the time. The exosome tools were a growing segment within this. Thermo Fisher's interest underscored the competitive importance of exosome technologies within larger diagnostic platforms. Even though the deal didn't proceed, it highlighted how major players view exosomes as a key growth area. The proposed deal was valued at $11.5 billion, though it ultimately fell through due to shareholder pushback. The exosome-related segment was a smaller but strategically important part of QIAGEN's portfolio.

Evox Therapeutics' Funding and M&A Speculation
Evox Therapeutics, a private UK-based company developing exosome-based therapeutics, has been a rumored M&A target due to its robust pipeline targeting rare diseases. While not yet acquired, it raised significant capital, positioning it as a key player. Evox has a team of around 50–60 employees and a pipeline targeting diseases like Niemann-Pick disease. Its IP includes novel exosome engineering techniques. Evox exemplifies the private-side competition, where venture-backed firms are prime targets for larger pharma companies seeking to bolster their exosome portfolios. Evox raised $95.4 million in a Series C round in 2021, valuing the company at an estimated $300–400 million. Industry speculation suggests a potential acquisition could exceed $500 million if a breakthrough emerges.

Avalon GloboCare and Exosome Diagnostics
Details: Avalon GloboCare, a smaller public biotech, has pursued exosome-based diagnostics and therapeutics, while Exosome Diagnostics (acquired by Bio-Techne in 2018) represents an earlier benchmark. Bio-Techne's acquisition of Exosome Diagnostics marked a significant entry into the exosome diagnostics market. Exosome Diagnostics had developed the ExoDx Prostate IntelliScore, a commercialized exosome-based test, generating early revenue streams that justified the high valuation. Bio-Techne acquired Exosome Diagnostics for $250 million upfront, with up to $325 million in potential earn-outs based on milestones—a sizable investment for a private company focused on exosome-based cancer diagnostics.

AstraZeneca's Interest
While not yet an exosome acquirer, AstraZeneca's $39B Alexion buyout (2021) for rare diseases signals a broader appetite for novel platforms—exosomes could be next.

NurExone's SCI treatment could redefine healthcar by targeting treatments for intractable diseases. Big Pharma needs these wins to justify their scale; acquiring exosome firms positions them to capitalize on this potential $2B+ market while smaller players lack the resources to go it alone. M&A in the exosome space is a linchpin for innovation, speed, and risk management, driving the field toward commercialization. For Big Pharma, it's essential to counter patent cliffs, bridge innovation gaps, and secure precision medicine leadership. Without M&A, their pipelines risk stagnation, while acquiring exosome pioneers ensures they remain at the forefront of a transformative healthcare frontier. The competitive stakes are high—those who move decisively could dominate, while laggards may miss a generational opportunity.

Mergers & Acquisitions-Case Study

Date Announced: June 25, 2018

Acquirer: Bio-Techne Corporation, a **publicly traded biotechnology company** (NASDAQ: TECH) headquartered in Minneapolis, Minnesota, known for its **reagents, instruments, and services in the life sciences and diagnostics markets**

Target: Exosome Diagnostics, Inc., a **privately held company** based in Waltham, Massachusetts, **focused on developing exosome-based diagnostic technologies, particularly for cancer and other diseases**

Purpose: The acquisition aimed to bolster Bio-Techne's position in the growing field of **non-invasive** diagnostics, specifically liquid biopsies. Exosome Diagnostics had pioneered **exosome-based tests**, **leveraging the ability of exosomes—small extracellular vesicles**—to carry disease-specific biomarkers like RNA and proteins from biofluids such as urine or blood

Upfront Payment: Bio-Techne acquired Exosome Diagnostics for $250 million in cash. **This initial payment reflected the value of Exosome Diagnostics' existing technology, intellectual property, and early commercial traction**

Contingent Earn-Outs: The deal included up to an **additional $325 million in potential milestone payments, contingent on achieving specific future performance targets, such as regulatory approvals, revenue milestones, or advancements in the product pipeline**

Total Potential Value: If all milestones are met, the total acquisition cost could reach **$575 million**

Funding: Bio-Techne funded the **upfront $250 million payment using a combination of cash on hand and a revolving line of credit, showcasing its financial commitment to the exosome space**

Key Metrics and Context
Exosome Diagnostics' Technology: At the time of acquisition, Exosome Diagnostics had developed the ExoDx Prostate IntelliScore (EPI) test, a non-invasive urine-based diagnostic for prostate cancer risk assessment. Launched in 2016, this test was the **first exosome-based liquid biopsy to gain commercial traction**, **targeting a market with significant unmet needs**—prostate cancer diagnostics **traditionally relied on invasive biopsies**. The EPI test had received CE marking in Europe and was in the process of seeking broader regulatory approvals, including from the FDA.

Revenue and Growth: While exact revenue figures for Exosome Diagnostics were not publicly disclosed (typical for a private company), industry analysts estimated that the EPI test was generating modest but growing sales, likely in the single-digit millions annually by 2018. The potential for expansion into other cancers (e.g., lung, bladder) and diseases drove the high valuation.

Strategic Fit: Bio-Techne saw Exosome Diagnostics as a **complementary addition to its diagnostics division**, which already included protein analysis and molecular diagnostic tools. The acquisition aligned with Bio-Techne's **goal to expand into precision medicine** and capitalize on the liquid biopsy market, **projected to grow from $1 billion in 2018 to over $5 billion by the mid-2020s**.

Market Impact: The **$250 million upfront price, with a potential total of $575 million**, was a significant investment for Bio-Techne, whose market cap at the time hovered around $7 billion (currently 9.83B). It **signaled strong confidence in exosomes** as a transformative diagnostic platform and **set a benchmark for valuations in the exosome research space**.

Healthcare Potential: Exosome Diagnostics' technology promised to shift diagnostics toward earlier, **less invasive detection, potentially reducing healthcare costs and improving patient outcomes**. For instance, the EPI test aimed to reduce unnecessary prostate biopsies, which carry risks and **cost the U.S. healthcare system hundreds of millions annually**.

Since the acquisition, Bio-Techne has integrated Exosome Diagnostics into its diagnostics portfolio, continuing to develop and market the EPI test while exploring broader applications. By March 16, 2025, the exosome diagnostics market has continued to grow, and Bio-Techne's investment appears to have strengthened its foothold in this space, though specific milestone achievements tied to the $325 million earn-outs remain less publicly detailed.

In summary, Bio-Techne acquired Exosome Diagnostics for an upfront payment of $250 million in June 2018, with up to $325 million more in potential earn-outs, totaling a possible $575 million. **This acquisition underscored the strategic importance of exosome-based diagnostics and marked a pivotal moment in the commercialization of exosome technologies.**

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Drivers of M&A

The exosomes research space is highly competitive due to its transformative potential and the race to establish intellectual property and market leadership. Key drivers of M&A activity include:

- **Scarcity of Expertise:** The field requires specialized knowledge, making companies with proven teams or technologies prime acquisition targets. Larger firms like Lonza and Thermo Fisher use M&A to bypass years of internal R&D.Intellectual Property: Companies are racing to secure patents for exosome isolation, engineering, and therapeutic applications. M&A activity often centers on acquiring IP to gain a competitive edge.
- **Market Positioning:** The global exosome market is projected to grow from $200 million in 2023 to over $2 billion by 2030, driven by applications in oncology, neurology, and infectious diseases. M&A allows companies to secure a first-mover advantage.
- **Capital Intensity:** Developing exosome-based products is expensive and time-consuming, with clinical trials often costing hundreds of millions. Larger firms acquire smaller players to pool resources and mitigate risk, as seen with Codiak's partnership strategy.
- **Big Pharma Involvement:** Companies like Pfizer, Novartis, and Amgen are increasingly interested in exosomes, often through partnerships or acquisitions of smaller innovators. This dynamic heightens competition as smaller firms become stepping stones for larger players.
- **Patent Cliffs:** Big Pharma faces revenue gaps from expiring patents, and exosomes offer a novel therapeutic modality. Acquiring exosome-focused biotechs is a strategic move to bolster pipelines, similar to trends in the broader biotech M&A landscape.

The importance of these M&As lies in their potential to consolidate cutting-edge technologies under well-resourced entities capable of scaling clinical development. The competitive nature is underscored by the fact that both public companies and private firms are targets or acquirers, reflecting a mix of consolidation and speculative investment. The high premiums paid—such as Bio-Techne's $250 million for Exosome Diagnostics—indicate the perceived value of early entrants.

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Catalysts

Positive Preclinical Data Releases: NurExone is currently in the preclinical stage with ExoPTEN, an exosome-based therapy for acute spinal cord injury (SCI). Upcoming data from animal studies demonstrating nerve regeneration, motor function recovery, or safety could validate the approach. A strong dataset could boost the stock 50-100% overnight by reducing scientific risk and attracting investor attention. For example, proof of efficacy in a peer-reviewed journal could push the probability of success (PoS) from 8-15% to 20-30%, lifting my prior rNPV valuation from $0.28 CAD to $0.50-$0.75 CAD.

Initiation of Phase I Clinical Trials: Transitioning ExoPTEN to human trials (Phase I) would mark a major milestone, testing safety and dosing in SCI patients. This requires an Investigational New Drug (IND) approval from the FDA or equivalent from the EMA. Successful IND filing or Phase I initiation could significantly increase the share price, as it signals human validation potential. Even modest safety data could draw Big Pharma interest.

Regulatory Milestones: FDA fast-track designation, orphan drug status (SCI qualifies due to its rarity), or positive pre-IND meetings could streamline ExoPTEN's path to market, cutting 1-2 years off the timeline. Fast-track status could increase investor confidence, driving the share price as it signals a shorter payback period and higher PoS.

Manufacturing Scale-Up Success: NurExone's lease of a state-of-the-art facility in Israel aims to establish GMP-compliant exosome production. Updates on scalable, cost-effective manufacturing could address a key industry bottleneck. Proof of reliable production could attract partners and boost the share price by derisking commercialization. It might also position NurExone as an M&A target.

Pipeline Expansion: Applying ExoTherapy to new indications with preclinical proof-of-concept could broaden NurExone's appeal. A second indication could add $50-100M to rNPV, pushing the share price higher, as it diversifies revenue streams.

Clinical Breakthroughs by Peers: Success from competitors could prove exosomes' therapeutic viability, lifting sentiment across the sector. A rising tide could boost NurExone's share price significantly by association, even without company-specific news, as investors pile into exosome plays.

Big Pharma M&A Activity: A high-profile acquisition—say, Pfizer buying Evox or Novartis snapping up Capricor—would signal Big Pharma's commitment to exosomes, sparking a wave of investment and speculation. Could drive a rally and position NurExone as a takeover candidate.

Regulatory Precedents: FDA or EMA approval of an exosome-based therapy would set a clear regulatory framework, reducing uncertainty for all players. Clarified guidelines could lift its PoS by 5-10%, adding to valuations and accelerating its own regulatory path.

Technological Advancements: Innovations in exosome isolation or cargo-loading by firms like Lonza or Thermo Fisher could lower costs and improve efficacy industry-wide. Cheaper production could enhance ExoPTEN's margins, boosting DFE earnings estimate and reinforce licensing appeal.

Funding Environment: A biotech funding boom (e.g., spurred by lower interest rates or a blockbuster IPO) could flood the exosome space with capital, enabling faster development. Easier access to financings could reduce dilution risk, supporting a stock rise and accelerating trials.

M&A Feedback Loop: Industry M&A could make NurExone a target, while its own catalysts could attract buyers, creating a virtuous cycle.

Exchange Uplisting: Should Nurexone achieve an uplisting on either the NASDAQ or NYSE, the valuation gap should in theory close, we see this as a valuation catalyst for a multiple re-rate.

NurExone Biologic Inc.

OTCPK: NRXBF
TSXV: NRX

Rating: BUY
Target: C$2.52

Market Cap +/- $52M	Outstanding Shares +/- 70M	2025 Range: 0.54-0.78	CEO: Lior Shaltiel

Risks

Clinical and Scientific Risks: Preclinical Uncertainty: NurExone's lead candidate, ExoPTEN, remains in preclinical development. Positive animal model results (e.g., nerve regeneration in rodents) may not translate to humans due to biological differences. Failure to demonstrate efficacy or safety in upcoming human trials could greatly affect the share price.

Novelty of Exosomes: Exosome-based therapies are unproven at scale. The field lacks long-term clinical data, and unexpected challenges—like immune rejection, off-target effects, or inconsistent exosome potency—could derail ExoPTEN or the ExoTherapy platform.

High Attrition Rates: Biotech drugs have a ~90% failure rate from preclinical to approval. For NurExone, this risk is amplified by the complexity of SCI, a condition with no widely effective treatments, suggesting a steep scientific hurdle.

Uncharted Regulatory Path: Exosomes are a new therapeutic class, and agencies like the FDA or EMA may impose stringent requirements for approval, such as larger trials or novel endpoints (e.g., functional recovery in SCI). Delays or denials could push timelines beyond 2032, eroding investor confidence.

Manufacturing Standards: Producing exosomes consistently at scale is challenging. Regulatory bodies may demand rigorous Good Manufacturing Practices (GMP) compliance, and any shortfall (e.g., batch variability) could halt progress. NurExone's recent facility lease in Israel is a step forward, but execution risks remain.

Cash Burn and Dilution: NurExone's cash reserves are limited, with an estimated burn rate of $5-10M/year for preclinical work and trial preparation. Without revenue, it will need to raise capital soon, likely diluting shareholders by 20-40%. This could depress the stock price.

Funding Dependence: Biotech funding is cyclical. A market downturn or shift in investor sentiment away from speculative assets could dry up capital, forcing NurExone to accept unfavorable terms or pause development.

Crowded Exosome Space: Larger players, plus Big Pharma entrants, have deeper pockets and more advanced pipelines. If a competitor's SCI or exosome therapy reaches the market first, NurExone's niche could shrink, capping its 2-5% market share assumptions.

Alternative Therapies: Stem cell therapies, neurostimulation, and small-molecule drugs for SCI or glaucoma could outpace exosomes in efficacy or cost, reducing ExoPTEN's relevance. For example, Neuralink's brain-computer interfaces might offer a competing SCI solution.

Licensing Challenges: The ExoTherapy platform's value hinges on partnerships. If Big Pharma opts for in-house exosome R&D or prefers established players, NurExone's licensing revenue could fall short.

Management Execution: NurExone's small team must navigate complex science, trials, and partnerships. Any missteps—delays in preclinical data, trial design flaws, or failure to secure GMP certification—could jeopardize timelines and credibility.

Market Sentiment: Biotech stocks are volatile, often swinging 20-50% on news. Negative sector trends could drag NurExone down, even if its fundamentals remain intact.

Economic Downturn: Rising interest rates or a recession could tighten capital markets, increasing NurExone's cost of capital and pressuring its valuation.

Geopolitical Exposure: Based in Israel, NurExone faces risks from regional instability, which could disrupt operations, supply chains, or investor confidence.

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Finances

- Jan. 21, 2025: Recent warrant exercises and private placement have generated slightly more than C$1.2 million, these funds will allow Nurexone to accelerate their R&D activities and drive forward key collaborations (Figures in USD)

Key Information	Q4-22	Q1-23	Q2-23	Q3-23	Q4-23	Q1-24	Q2-24	Q3-24
Cash & Equivalents	2.643M	1.588M	880k	1.143M	541k	3.255M	2.385M	2.523M
Equity	2.096M	1.394M	690k	721k	189k	3.631M	2.575M	2.928M
Debt	0	0	0	0	1.197M	0	0	0
Total Liabilities	769k	809k	650k	521k	690k	511K	717k	686K
Total Assets	4.51M	3.51M	2.04M	1.21M	1.41M	4.14M	3.29M	3.61M

Ownership

*Top 4 shareholders own 6.39% of the company

Name	Title	Ownership	Shares	Current Value
Yorum Drucker	Co-Founder	4.95%	3,655,000	2.3M CA
Lior Shaltiel	CEO & Dir.	0.58%	425,000	267.7k CA
Eran Ovadya	n/a	0.58%	425,000	267.7k CA
James Richardson	Ind. Dir.	0.29%	214,133	134.9k CA

Earnings & Revenue History (USD/yr)

Key Information	Q1-23	Q2-23	Q3-23	Q4-23	Q1-24	Q2-24	Q3-24
Revenue	0	0	0	0	0	0	0
Earnings	-6.559M	-3.800M	-3.916M	-3.639M	-3.856M	-4.141M	-4.234M
Free Cash Flow	-3.607M	-3.196M	-3.144M	-3.061M	-3.892M	-4.125M	-4.456M
Cash From Operations	-3.503M	-3.139M	-3.097M	-2.941M	-3.583M	-3.757M	-3.786M
Operating Expenses	4.032M	3.608M	3.782M	3.657M	3.858M	4.118M	4.241M

Outstanding Shares

Time Period	Q4-2022	Q4-2023	Q1-2024	Q2-2024	Q3-2024	Present
Shares	42,855,159	48,249,707	65,814,822	67,162,428	70,517,003	~70,894,000

Valuation Methodology

To provide a price target for NurExone using the Discounted Future Earnings (DFE) model , we will incorporate the specific inputs Nurexone provides for spinal cord injury (SCI) treatment, add a conservative estimate for glaucoma treatment potential, and apply cautious assumptions about market share, costs, and risks. The DFE model will project future earnings, discount them to present value, and derive a per-share price target based on NurExone's current share structure as of March 16, 2025.

Model Inputs and Assumptions

1. SCI Treatment Market
- Treatment Price: $140,000 per patient
- Current SCI Population: 250,000 people in the U.S. and Europe.
- Annual New Cases: 37,000 per year in the U.S. and Europe.
- Market Penetration: Conservatively assume NurExone's ExoPTEN captures 2% of existing patients (5,000 people) over the first 5 years post-launch (1,000/year) and 5% of new cases (1,850/year) annually thereafter. This reflects competition from existing therapies and slow adoption of a novel exosome treatment.
- Revenue Timeline: Assume market entry in 2032 (8 years from now, allowing for preclinical, clinical, and regulatory phases).

2. Glaucoma Treatment Potential
- Market Size: Glaucoma affects ~3 million people in the U.S. and ~7 million in Europe (10 million total in these regions), with ~120,000 new cases/year combined (based on prevalence data from NIH and European studies).
- Treatment Price: Conservatively assume $50,000 per treatment, lower than SCI due to a larger patient pool and less severe pricing pressure for a chronic condition.
- Market Penetration: Assume 1% of existing patients (100,000 people, or 20,000/year over 5 years) and 2% of new cases (2,400/year) post-launch in 2034 (10 years from now, reflecting a later pipeline expansion).
- Rationale: Glaucoma is exploratory for NurExone, so I'm assuming minimal contribution until SCI proves the platform.

3. Earnings Projections
- **Revenue:**
  - SCI: Year 1 (2032): 1,000 patients × $140,000 = $140M.
    - Years 2-5: 1,000 existing + 1,850 new = 2,850 patients × $140,000 = $399M/year.
    - Years 6-10: 1,850 new patients × $140,000 = $259M/year (steady state).
  - Glaucoma: Year 1 (2034): 20,000 patients × $50,000 = $1B (spread over 5 years, $200M/year).
    - Years 6-10: 2,400 new patients × $50,000 = $120M/year.
- **Costs:**
  - R&D to market: $100M for SCI, $50M for glaucoma ($150M total over 8-10 years, ~$15M/year).
  - Cost of Goods Sold (COGS): 30% of revenue (exosome production is complex).
  - Operating Expenses: 20% of revenue (sales, marketing, admin).
  - Tax Rate: 25% (once profitable).
- Net Earnings Margin: ~25% of revenue after costs and taxes (biotech average for successful drugs).

4. Discount Rate and Timeline
- Discount Rate: 15%, reflecting biotech risk and long timeline.
- Projection Period: 10 years post-launch (2032-2041 for SCI, 2034-2043 for glaucoma, but capped at 2041 for simplicity).

5. Current Financials
- Market Cap: $50M CAD ($35M USD at 1.43 CAD/USD).
- Shares Outstanding: ~70M.
- Dilution: Assume 25% dilution (17.5M new shares) for $10M CAD (~$7.5M USD) financing, totaling 87.5M shares.

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DFE Calculation

Step 1: Project Future Earnings

SCI Earnings	Glaucoma Earnings	Combined
2032: $140M revenue × 25% margin = $35M 2033-2036: $399M × 25% = $99.75M/year 2037-2041: $259M × 25% = $64.75M/year	2034-2038: $200M × 25% = $50M/year 2039-2041: $120M × 25% = $30M/year	2032: $35M (SCI only). 2033: $99.75M (SCI only). 2034-2036: $99.75M + $50M = $149.75M/year 2037-2038: $64.75M + $50M = $114.75M/year 2039-2041: $64.75M + $30M = $94.75M/year

Step 2: Discount Earnings to Present Value

- Discount factor = 1 / (1 + 0.15)^n, where n = years from 2025.
  - Present Value (PV) of earnings:
    - 2032 (n=7): $35M × 0.376 = $13.16M.
    - 2033 (n=8): $99.75M × 0.327 = $32.62M
    - 2034 (n=9): $149.75M × 0.284 = $42.53M
    - 2035 (n=10): $149.75M × 0.247 = $36.98M
    - 2036 (n=11): $149.75M × 0.215 = $32.20M
    - 2037 (n=12): $114.75M × 0.187 = $21.46M
    - 2038 (n=13): $114.75M × 0.163 = $18.70M
    - 2039 (n=14): $94.75M × 0.141 = $13.36M
    - 2040 (n=15): $94.75M × 0.123 = $11.65M
    - 2041 (n=16): $94.75M × 0.107 = $10.14M

Total Present Value of Earnings $232.80M USD

Step 3: Adjust for Costs and Cash

- R&D Costs (PV): $15M/year × 8 years (SCI) + $10M/year × 2 years (glaucoma pre-2034) = $140M total
- Discounted over 2025-2033 (average n=4): $140M × 0.572 = ~$80M USD
- Net PV: $232.80M - $80M = $152.80M USD
- Add Cash: ~$2M USD = $154.80M USD

Step 4: Convert to Price Target

- Valuation in CAD: $154.80M USD × 1.43 = $221.364,000M CAD
- Price per Share: $208.98M ÷ 87.5M shares = **$2.52 CAD**

Conservative Considerations

- Low Market Share: 2% for SCI existing patients, 5% for new cases, 1% for glaucoma existing, and 2% for new cases are conservative given competition (e.g., stem cell therapies, other exosome players)
- High Discount Rate: 15% penalizes long-term cash flows heavily
- No Licensing Revenue: Excludes ExoTherapy platform licensing to focus solely on drug sales
- Delayed Launch: 2032 for SCI and 2034 for glaucoma assume slow development

Comparison to Current Price

- Current Price: ~$0.74 CAD (market cap 52.46$M CAD)
- Upside: $2.52 CAD represents a 240% increase, suggesting the market undervalues NurExone's potential even under conservative assumptions

Using the Discounted Future Earnings model, a conservative price target for NurExone Biologic is **$2.52 CAD** per share, based on $140,000 SCI treatment for 250,000 existing and 37,000 new patients annually, plus a glaucoma expansion at $50,000 per treatment, with low market shares (2-5% for SCI, 1-2% for glaucoma). This assumes a 2032 SCI launch, 2034 glaucoma entry, and significant discounting for risk and time. While well above the current $0.70 CAD, it reflects a plausible floor for long-term value if NurExone executes successfully, though near-term volatility and funding risks remain.

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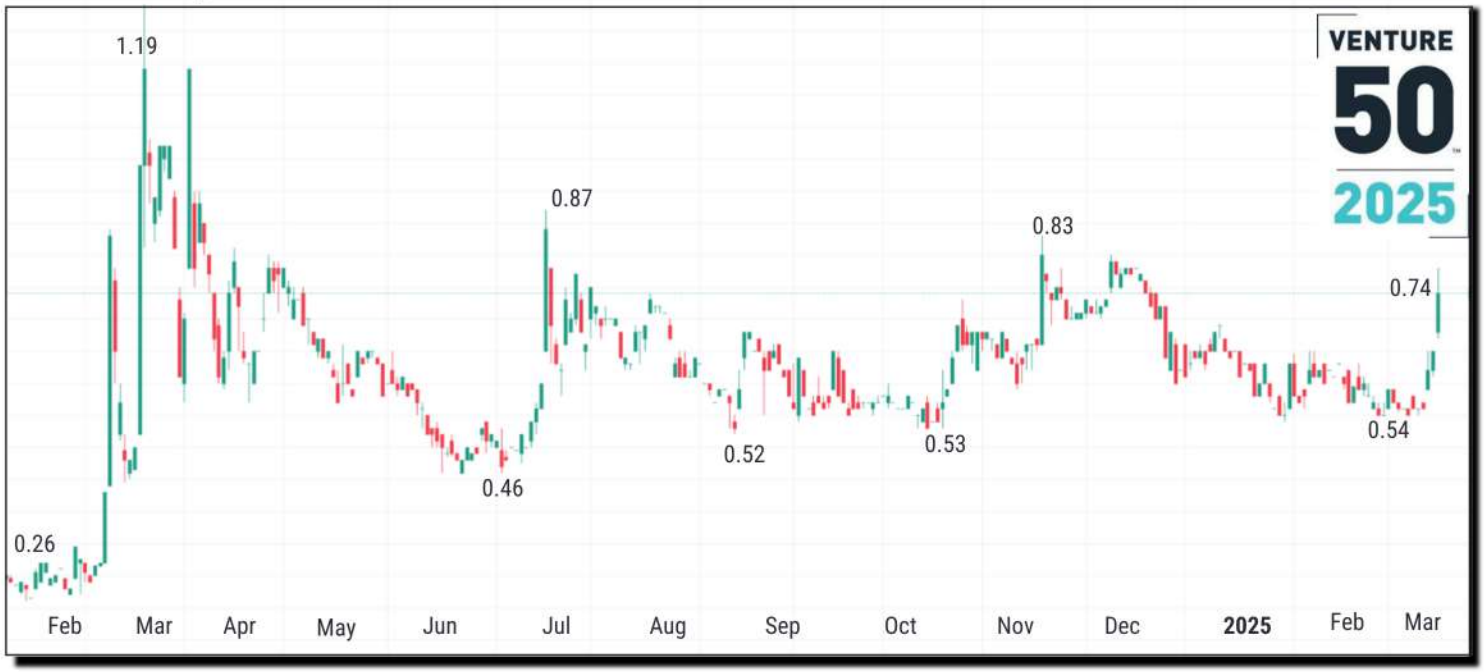
Nurexone - TSXV:NRX

Daily Chart since December 27th, 2024 to March 17th, 2025

Top-50 Performing Companies ON TSX VENTURE EXCHANGE



- 52 week low: 0.46
- 52 week high: 0.87
- 50 day MA: 0.58
- 200 day MA: 0.60
- Avg. volume (3M): 30,307
- Volume 03/17/25: 493,906

Recent Headlines

March 14, 2025

ExoPTEN Preclinical Study Demonstrates Significant Potential For Enhancing Motor Function, Blood Flow, And Spinal Cord Injury Recovery

February 19, 2025

NurExone Biologic Recognized As A 2025 TSX Venture 50™ Top Performing Stock

February 5, 2025

NurExone Forms Exo-Top Inc. In The U.S. For Exosome Manufacture And Commercialization

January 21, 2025

NurExone Secures C$1.2 Million Through Warrant Exercises & Completion Of Private Placement & Appoints New R&D Director

January 8, 2025

NurExone Biologic Secures Master Cell Bank

December 6, 2025

NurExone Announces Promising Preclinical Results In Restoring Vision After Optic Nerve Damage

November 13, 2025

NurExone Biologic Secures EMA Orphan Status For ExoPTEN In Spinal Cord Injury, Accelerating Pathway To European Markets

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SELL: We expect the stock to have a negative total return of more than 15% within a 12-month period.
Total return is defined as price appreciation plus dividend yield.

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