Fundamental Research Corp.
Investment Analysis for Intelligent Investors

December 11, 2024

NurExone Biologic Inc.

(TSXV: NRX / OTCQB: NRXBF / FSE: J90)

A Potential Breakthrough in Spinal Cord and Optic Nerve Injury Treatment - Initiating Coverage

BUY
Current Price: C$0.77
Fair Value: C$2.61
Risk*: 5

Sector: Biotechnology

Click here for more research on the company

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Head of Research

Highlights

- NRX, an Israeli biotech company founded in 2020, is **developing a novel drug delivery platform** designed to provide minimally invasive, highly targeted solutions to address unmet medical needs.
- The company leverages **exosomes**, tiny, naturally occurring cellular sacs, to deliver medication directly to inflamed or damaged tissues. This **targeted approach offers potential advantages** over traditional gene and cell therapies. While the exosome therapeutics industry is emerging, there are currently no FDA-approved products.
- NRX is focused on **treating central nervous system injuries**, spinal cord injury (SCI), optic nerve injury, brain trauma, and neurological conditions through regenerative medicine. Its **lead product, ExoPTEN**, is an exosome-based therapy that has completed several preclinical studies, and received an **orphan drug designation from the U.S. FDA**, **and the European Medicines Agency (EMA)**, for the treatment of acute SCI. While there is currently no cure for SCI, treatments such as immobilization, surgery, medication, and rehabilitation can help manage symptoms.
- The company has also conducted a pre-Investigational New Drug (**pre-IND**) meeting with the FDA, a necessary step before initiating human clinical trials. ExoPTEN is expected to enter **phase one clinical trials** by the end of 2025.
- We note that the common **exit strategy** for pharma/biotech companies is to either be acquired by larger companies, or enter into licensing agreements with them, following promising clinical trial results.

Risks

- Limited operating history
- **In pre-revenue stage**
- No guarantee that any of its drugs/therapies will be commercialized
- Potential for delays in clinical trials; unfavorable results
- Will **need to pursue equity financings**, implying potential for share dilution

Price Performance (YTD)

	YTD	12M
NRX	157%	148%
TSXV	11%	16%
NBI (Index)	3%	14%

Company Data

52-Week Range	C$0.26 – C$1.19
Shares O/S	71M
Market Cap.	C$55M
Current Yield	N/A
P/E (forward)	N/A
P/B	N/A

Key Financial Data (US$)		
YE: Dec 31	2023	2024 (9M)
Cash	$541,000	$2,523,000
Working Capital	$74,000	$2,388,000
Assets	$2,170,000	$3,614,000
LT-Debt	-	-
Revenue	-	-
Net Income	-$3,639,000	-$3,497,000
EPS	-$0.08	-$0.06

***See last page for important disclosures, rating, and risk definitions. All figures in US$ unless otherwise specified.**

Company Overview

Founded in 2021 and based in Israel

Holds an exclusive worldwide license for the technology

NurExone is developing exosome-based therapies aimed at providing minimally invasive, highly targeted drug delivery, and regenerative medicine solutions. The company **holds an exclusive, worldwide license** from two leading Israeli universities for the development and commercialization of the technology. Under the licensing agreement, the company is **required to pay 20.25% of revenue in royalties and licensing fees.**

Established by experienced biotech entrepreneurs

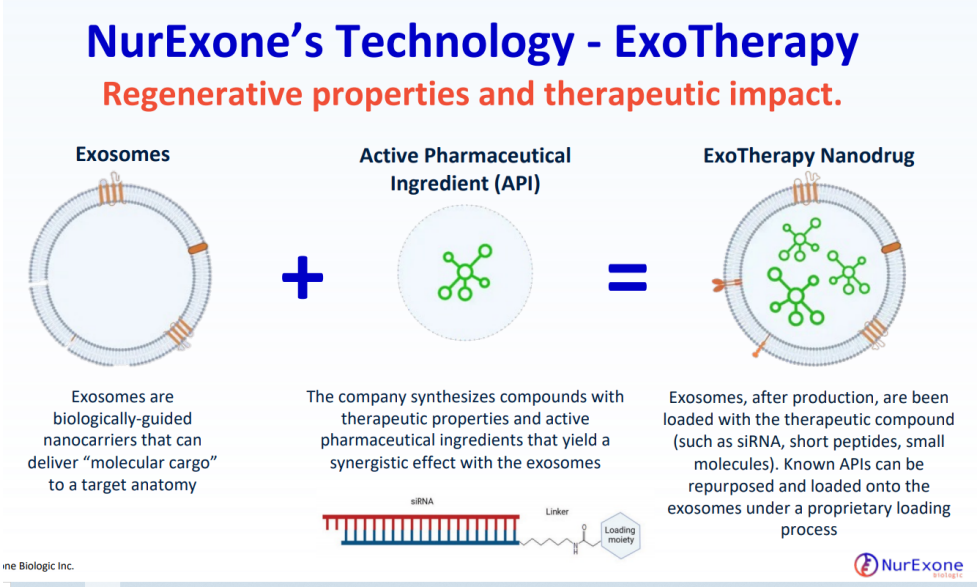
Management owns 6.5% of NRX's equity

Nine full-time and eight part-time employees

Name	Position(s)	# Shares Outstanding	% of Total
Lior Shaltiel, PhD	CEO & Director	425,000	0.58%
Yoram Drucker	Co-Founder, VP Strategic Development & Chairman	3,655,000	5.01%
Eran Ovadya, MBA	CFO	425,000	0.58%
Noa Avni, PhD	R&D Director	-	-
Ina Sarel, PhD	Head of CMC, Quality and Regulation	-	-
Gadi Riesenfeld, PhD	Independent Director	-	-
Oded Orgil, LL.B.	Independent Director	-	-
James Richardson	Independent Director	225,633	0.31%
Total		**4,730,633**	**6.49%**

Source: Company, FRC

Aims to harness the natural properties of exosomes to create effective and targeted treatments for a wide range of diseases



Source: Company

U.S. patent granted in 2023

Exosomes are nano-sized, membrane-bound vesicles (sacs) secreted by cells, and abundantly present in various body fluids, including blood, urine, saliva, semen, vaginal fluid, and breast milk. They **play a pivotal role in intercellular communication**, facilitating the transfer of vital biological molecules, such as DNA, RNA, and proteins, between cells. Various sources suggest that exosomes possess significant therapeutic potential, **to serve as an effective, targeted drug**

delivery system. Exosomes' natural ability to target inflamed or damaged tissues, and their capacity to carry and deliver active pharmaceutical ingredients (APIs), make them a promising platform for targeted drug delivery and regenerative medicine.

In recent years, the exosome therapeutics and diagnostics industry has experienced significant growth, with over 50 companies actively engaged in R&D. However, there are currently **no FDA-approved exosome products.**

Exosome-based therapies are in early stages of development, aiming to improve upon existing gene and cell therapies

Studies indicate that exosomes offer unique advantages, such as reduced immune responses, targeted delivery, and the potential for off-the-shelf treatments

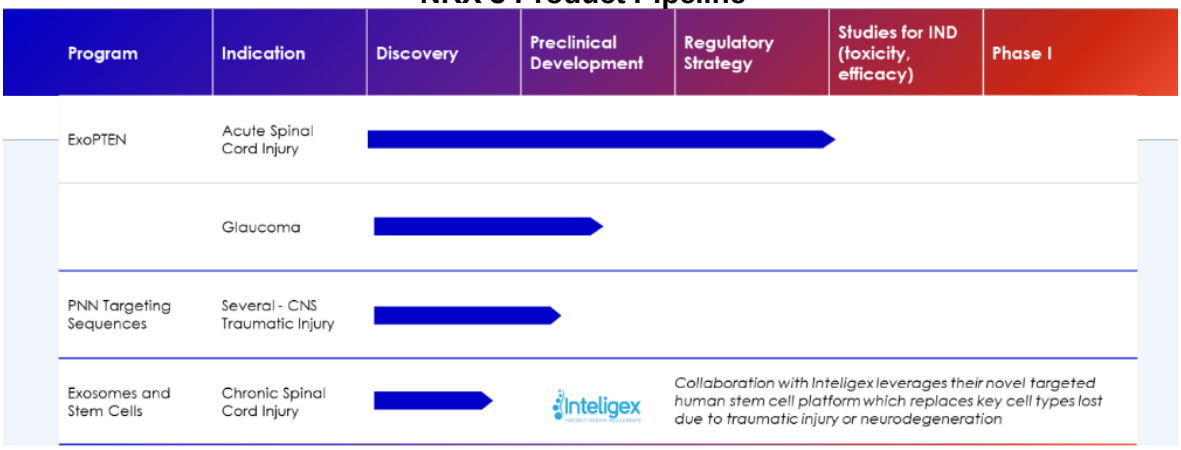
Exosome vs Competing Therapies

Feature	Exosomes	Gene Therapy	Cell Therapy
Stage of Development	Early-stage clinical trials	Established (approved therapies available)	Established (approved therapies available)
Method of Delivery	Indirect (through exosomes)	Direct (viral or non-viral vectors)	Direct injection of cells
Risk of Immune Rejection	Lower	Moderate to high	Moderate to high
Complexity of Treatment	Simpler	Moderate	Complex
Potential for Off-the-Shelf Use	Higher	Lower	Lower
Therapeutic Applications	Diverse (e.g., regenerative medicine, cancer treatment)	Diverse (e.g., genetic disorders, cancer)	Diverse (e.g., regenerative medicine, blood disorders)
Cost of Treatment	Potentially lower (due to simpler production and delivery)	High (due to complex production and delivery)	High (due to complex procedures and potential for multiple treatments)

Source: FRC/Various

NRX is focusing on a broad range of applications within the central nervous system, including spinal cord injury (SCI), optic nerve injury, brain trauma, and various neurological disorders

NRX's Product Pipeline

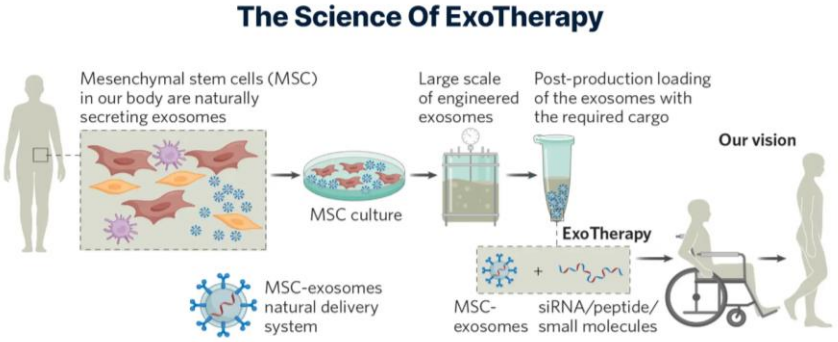


Source: Company

NRX's Lead Product - ExoPTEN

The company is developing ExoTherapy, an exosome-based therapy designed to stimulate neuroregeneration for the **treatment of acute SCIs**.

ExoPTEN utilizes exosomes loaded with a unique and proprietary special code (siRNA) as its active pharmaceutical ingredient



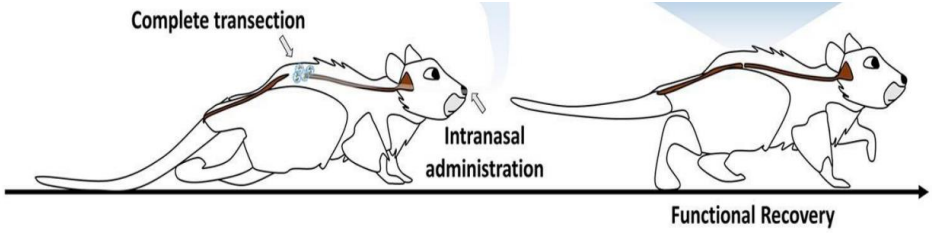
MSC is a type of stem cell that has the potential to differentiate into various cell types, such as bone, cartilage, fat, and muscle. They are found in various tissues, including bone marrow, adipose tissue (fat), and umbilical cord blood.

Source: Company

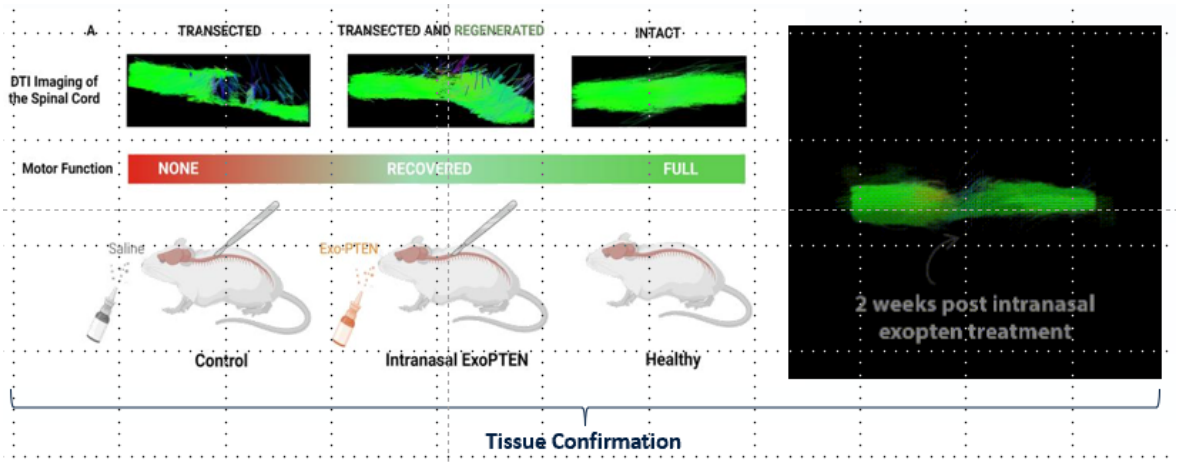
Management's goal is to develop ExoPTEN as a versatile treatment that can address a broad range of nerve injuries, including both acute SCIs, and optic nerve injuries. The technology has been validated in preclinical studies conducted on rats in 2018 and 2019. Key results include:

Intranasal administration of MSC-derived exosomes loaded with siRNA-PTEN (ExoPTEN) was presented to rats with complete spinal cord lesions, resulting in significant functional recovery

- **Penetration of the Blood-Brain Barrier:** Exosomes derived from MSC were shown to cross the blood-brain barrier, and migrate to the injured spinal cord region.
- **Promising Results:** ExoPTEN significantly improved motor function, sensory recovery, and urinary reflex restoration. Over 75% of laboratory rats treated with ExoPTEN recovered motor function. In cases of complete spinal cord lesions, some rats were able to walk again.
- **Neuroregeneration:** The study demonstrated the ability of ExoPTEN to promote the formation of new neural connections, partially repairing the damaged spinal cord.
- **Off-the-Shelf Potential:** Initial findings suggest that ExoPTEN may have the potential to be developed as a readily available therapeutic option.



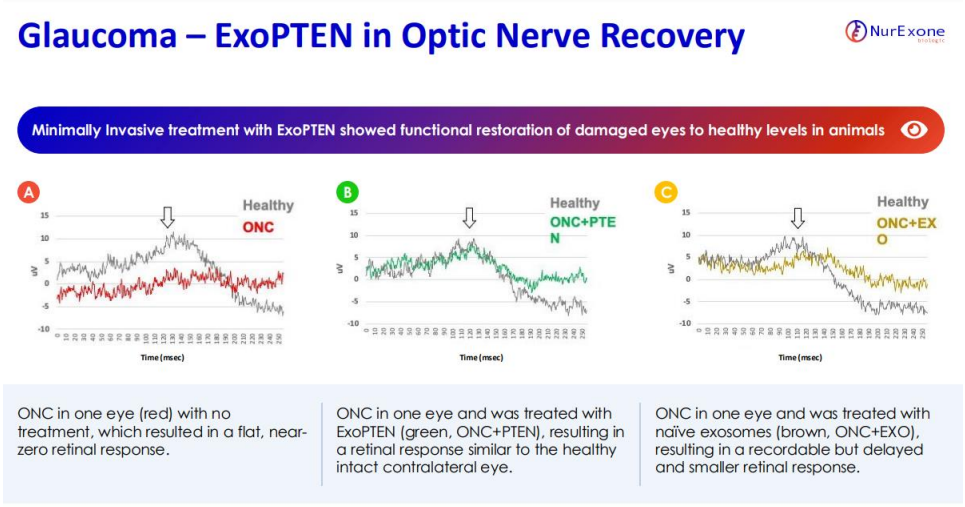
Source: Company



Source: Company

NurExone is also exploring **the potential for treating glaucoma**. Preclinical studies have demonstrated promising results in restoring vision following optic nerve damage—a key characteristic of glaucoma. Current treatments are primarily focused on preventing further damage, with limited options for regenerating or repairing damaged nerves.

We believe the expansion into the glaucoma market could significantly enhance NurExone's therapeutic portfolio, and address a critical unmet medical need

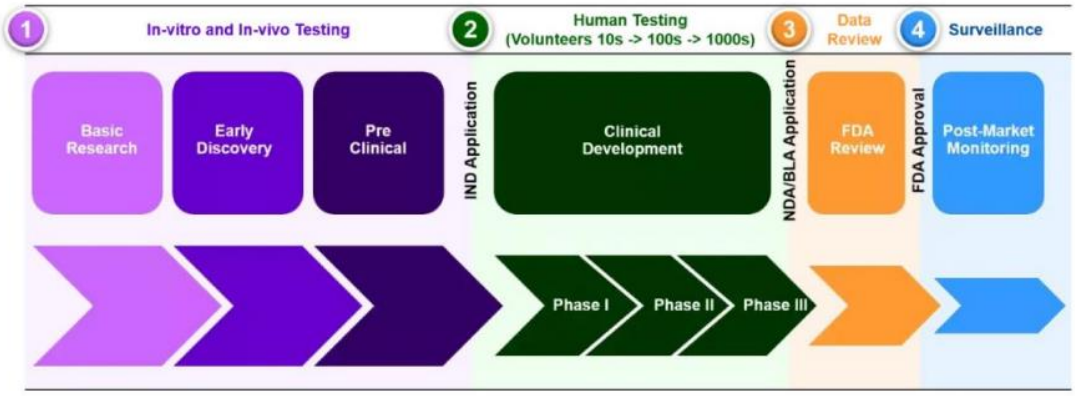


Source: Company

Upcoming Tests/Catalysts

The typical timeframe from phase I to approval is five to 10 years, costing $200M to $1B+

Source: Frost and Sullivan



Source: NorthEast BioLab

Historically, 75% of drug candidates have moved from phase I to II, 50% from II to III, 59% from III to approval, and 88% of those have received final approval (Source: National Library of Medicine), implying that **19% of candidates have advanced from phase I to approval.**

ExoPTEN has received an Orphan Drug Designation from both the FDA and the EMA, potentially accelerating development and approval

NRX has also conducted a pre-IND meeting with the FDA, necessary for starting human clinical trials

NRX's Road Map

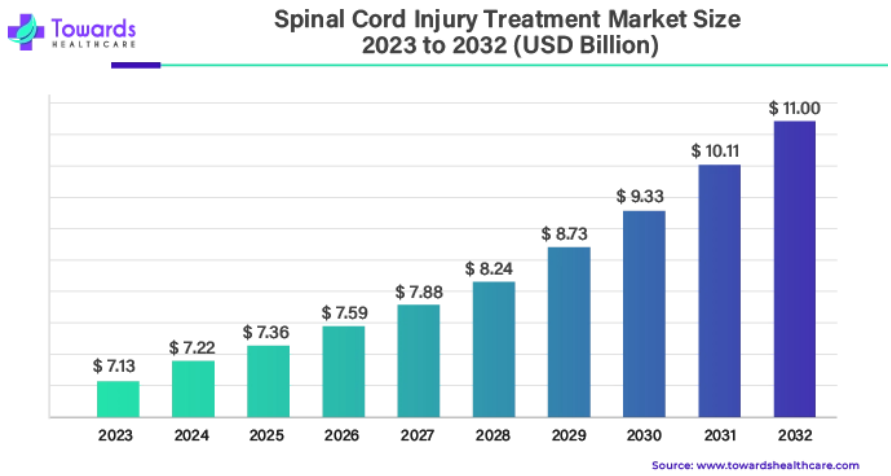
Source: Company

The company expects to **start phase one clinical trials** by the end of 2025.

Market Potential

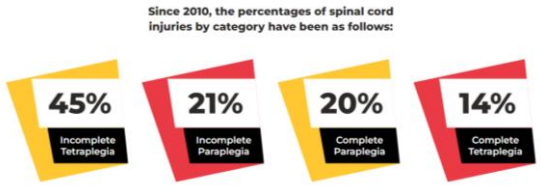
SCIs are complex conditions caused by trauma, such as motor vehicle crashes and falls, or non-traumatic factors like malignancy and degeneration, leading to severe morbidity and permanent disability.

It is estimated that the global SCI treatment market will grow from $7.1B in 2023, to $11B by 2032, reflecting a CAGR of 4.8%



The Dana and Christopher Reeve Foundation reports that **treating SCI can be extremely costly**, especially for severe cases like high tetraplegia. In addition to substantial initial costs, ongoing care and rehabilitation expenses remain significant throughout a patient's lifetime.

Less than 1% of affected people experience complete neurological recovery by the time of hospital discharge



Severity of Injury	First Year	Each Subsequent Year
High Tetraplegia (C1-C4) ASIS ABC	$1,064,716	$184,891
Low Tetraplegia (C5-C8)	$769,351	$113,423
Paraplegia	$518,904	$68,739
Incomplete motor function (any level)	$347,484	$42,206

Estimated Lifetime Costs

Severity of Injury	25 Years Old	50 Years Old
High Tetraplegia (C1-C4) ASIS ABC	$4,724,181	$2,596,329
Low Tetraplegia (C5-C8) ASIS ABC	$3,451,781	$2,123,154
Paraplegia ASIS ABC	$2,310,104	$1,516,052
Incomplete motor function (any level) ASIS D	$1,578,274	$1,113,990

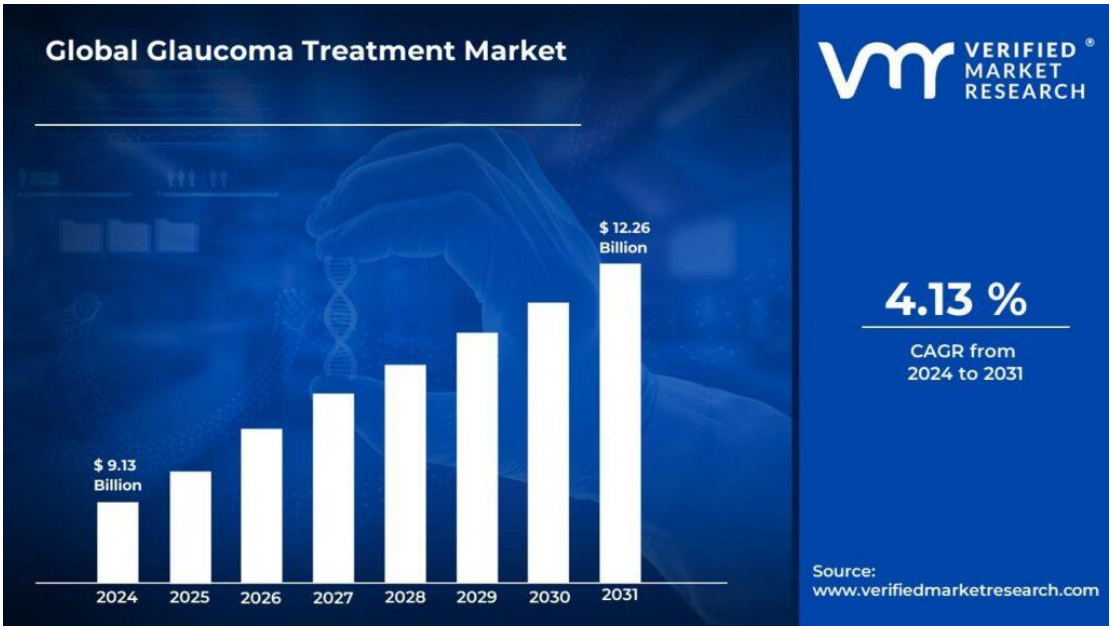
*The tables above outline potential expenses related to treatment and healthcare.
Source: Dana and Christopher Reeve Foundation

Globally, 40-80 people per million experience SCI annually (Source: WHO)

The National Library of Medicine reports that **250k-500k patients globally** suffer from SCIs each year. In the U.S., about 17k new cases arise annually, with an estimated 282k people living with SCIs.

Approximately 80 million people worldwide are currently living with glaucoma

It is estimated that the global glaucoma treatment market will grow from $9.1B in 2024, to $12.3B by 2031, reflecting a CAGR of 4.1%, driven by an aging population, and increasing awareness and screening programs



Financials

In pre-revenue stage

Current monthly burn rate : $400k/month

Raised $15M since inception

In-the-money options and warrants can generate up to C$9.2M; therefore, we do not anticipate any equity financings in the near term

Key Financial Data (US$)		
YE: Dec 31	2023	2024 (9M)
Cash	$541,000	$2,523,000
Working Capital	$74,000	$2,388,000
Assets	$2,170,000	$3,614,000
LT-Debt	-	-
Revenue	-	-
Net Income	-$3,639,000	-$3,497,000
EPS	-$0.08	-$0.06

	Options	Strike Price (C$)	Value (C$)	Warrants	Strike Price (C$)	Value (C$)
Total Outstanding	7,399,424	$0.37	$2,743,851	14,313,424	$0.45	$6,421,079
In-the-Money	**7,399,424**	**$0.37**	**$2,743,851**	**14,313,424**	**$0.45**	**$6,421,079**

Source: FRC / Company

FRC Projections and Valuation

The following table lists major M&A deals in cell therapy and related fields.

Majors have acquired leading treatments for billions of dollars

Major M&A Deals in Cell Therapy and Related Fields

Acquiring Company	Acquired Company	Year	Therapeutic Area	Deal Amount (US$)	Stage of Acquired Company
Gilead Sciences	Kite Pharma	2017	CAR-T cell therapy for hematological malignancies	$11.9 billion	Phase II/III
Celgene Corporation	Juno Therapeutics	2018	CAR-T cell therapy for hematological malignancies	$9 billion	Phase II/III
Novartis	AveXis	2018	Gene therapy for spinal muscular atrophy (SMA)	$8.7 billion	Phase II/III
Pfizer	Sangamo Therapeutics	2019	Gene therapy and genome editing	$3.1 billion	Phase I/II
Takeda Pharmaceutical	Shire plc	2019	Hemophilia and other rare diseases	$62 billion	Commercial-stage
Bluebird Bio	21st Century Cures	2020	Gene therapy for sickle cell disease and beta-thalassemia	$3 billion	Phase II/III
Bristol-Myers Squibb	Celgene Corporation	2019	Multiple myeloma, lymphoma, and other blood cancers	$74 billion	Commercial-stage
Roche	Spark Therapeutics	2019	Gene therapy for inherited retinal diseases	$4.8 billion	Commercial-stage

Source: Various / FRC

Our DCF model is based on the assumption that NRX will capture 3% of the SCI treatment market in North America, and Western Europe, by the sixth year of commercialization

Modelling $200M in CAPEX for advancing towards commercialization

We arrived at a DCF valuation of C$2.55/share

DCF Valuation (US$M)	2029E	2030E	2031E	2032E	2032E	2033E
# of SCI Patients in North America and Europe	625,000					
# of New SCI Patients in North America and Europe (60 patients per million population)	35,000	35,000	35,000	35,000	35,000	35,000
NRX's Projected Market Share	0.2%	0.6%	0.9%	1.3%	1.6%	3.0%
# of Patients Treated	1,320	3,696	6,072	8,448	10,824	19,800
Projected Treatment Price per Patient (US$)	$150,000	$150,000	$150,000	$150,000	$150,000	$150,000
Total Revenue, net of Royalties and Fees	**$157,905,000**	**$442,134,000**	**$726,363,000**	**$1,010,592,000**	**$1,294,821,000**	**$2,368,575,000**
Gross Profit (sector avg margin - 45%)	$71,057,250	$198,960,300	$326,863,350	$454,766,400	$582,669,450	$1,065,858,750
EBITDA (sector avg margin - 17%)	**$26,843,850**	**$75,162,780**	**$123,481,710**	**$171,800,640**	**$220,119,570**	**$402,657,750**
AT-Net Income	$21,475,080	$60,130,224	$98,785,368	$137,440,512	$176,095,656	$322,126,200
Probability of Success (Phase 1 to approval)	**19%**					
Discount Rate/WACC	**15%**					

	CAPEX (2025-2028E)	2029E	2030E	2031E	2032E	2032E	2033E	Terminal
CAPEX and Net Income Forecasts (US$)	-$200,000,000	$21,475,080	$60,130,224	$98,785,368	$137,440,512	$176,095,656	$322,126,200	
Present Value @ 15% (US$)	-$142,748,918	$10,676,910	$25,995,955	$37,137,079	$44,929,547	$50,057,376	$79,624,670	$683,445,085
Cash-Debt (US$)	$2,388,000							
Fair Value (US$) - risk adjusted	**$150,386,084**							
Shares Outstanding	82,703,940.29							
Value/Share (C$)	**$2.55**							

Source: FRC

Key Assumptions:

- We are applying a probability of success of 19%, consistent with the sector's average success rate.
- We are using a relatively high discount rate of 15%; our typical range for valuing pre-revenue companies is 10% - 15%.
- We are assuming an average treatment price of $150K, which aligns with that of conventional cell therapies and orphan drugs. Note that this price is

significantly lower than the current treatment options for SCI, as shown in the tables presented earlier in this report.

- Sector-average EBITDA margins have been applied.
- For conservatism, we are not accounting for any value from the company's other target applications.

Our real options valuation is C$2.67/share

We believe a real options valuation model is valid when valuing development-stage biotech companies, as the model takes into account management's ability to pursue, abandon, or delay drug development

Real Options Valuation

Inputs	
PV of Future Cash Flows ($M)	$931,866,622
Sector average std. dev.	60%
PV of CAPEX ($M)	$142,748,918
Expiration (in years)	5
Risk-free Rate	3.5%

Output			
Stock Price	$931,866,622	T.Bond rate	3.5%
Strike Price	$142,748,918	Variance	0.36
Expiration (in years)	5	Annualized div yield	0%
d1 =	2.200		
N(d1) =	0.986	Value of Option ($)+Cash-Debt	$221,169,710.55
d2 =	0.858	Shares Outstanding	82,703,940.29
N(d2) =	0.805	**Value/Share (C$)**	**$2.67**

Source: FRC

We are **initiating coverage with a BUY rating**, and a **fair value estimate of C$2.61 per share** (the average of our DCF and real options valuations). While NRX faces the inherent risks of an R&D-focused biotech, and exosome therapy remains a nascent field with no FDA-approved products, we view it as an innovative player in developing treatments for neurological disorders. Its lead candidate, ExoPTEN, has shown encouraging preclinical results, and received an Orphan Drug Designation. The typical exit strategy for pharma and biotech companies is acquisition by larger firms upon the successful completion of promising clinical trials.

Risks

We believe the company is exposed to the following key risks (not exhaustive):

As with all R&D stage biotech companies, we are assigning a risk rating of 5 (Highly Speculative)

- Limited operating history
- **In pre-revenue stage**
- No guarantee that any of its drugs/treatments will be commercialized
- Potential for delays in trials; unfavorable results
- Will **need to pursue equity financings**, implying potential for share dilution

Fundamental Research Corp. Equity Rating Scale:
Buy – Annual expected rate of return exceeds 12% or the expected return is commensurate with risk
Hold – Annual expected rate of return is between 5% and 12%
Sell – Annual expected rate of return is below 5% or the expected return is not commensurate with risk
Suspended or Rating N/A— Coverage and ratings suspended until more information can be obtained from the company regarding recent events.

Fundamental Research Corp. Risk Rating Scale:
1 (Low Risk) - The company operates in an industry where it has a strong position (for example a monopoly, high market share etc.) or operates in a regulated industry. The future outlook is stable or positive for the industry. The company generates positive free cash flow and has a history of profitability. The capital structure is conservative with little or no debt.

2 (Below Average Risk) - The company operates in an industry where the fundamentals and outlook are positive. The industry and company are relatively less sensitive to systematic risk than companies with a Risk Rating of 3. The company has a history of profitability and has demonstrated its ability to generate positive free cash flows (though current free cash flow may be negative due to capital investment). The company's capital structure is conservative with little to modest use of debt.

3 (Average Risk) - The company operates in an industry that has average sensitivity to systematic risk. The industry may be cyclical. Profits and cash flow are sensitive to economic factors although the company has demonstrated its ability to generate positive earnings and cash flow. Debt use is in line with industry averages, and coverage ratios are sufficient.

4 (Speculative) - The company has little or no history of generating earnings or cash flow. Debt use is higher. These companies may be in start-up mode or in a turnaround situation. These companies should be considered speculative.

5 (Highly Speculative) - The company has no history of generating earnings or cash flow. They may operate in a new industry with new, and unproven products. Products may be at the development stage, testing, or seeking regulatory approval. These companies may run into liquidity issues and may rely on external funding. These stocks are considered highly speculative.

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