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Zacks Small-Cap Research

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Nurexone Biologic (OTCQB:NRXBF—TSXV:NRX)

NRXBF: Tests Confirm Potential for Spinal Cord Injury Recovery

NRXBF is a preclinical stage biotech company developing a treatment for spinal cord injuries. We value NRXBF at $3.05/share using the discounted cash flow method and a 20% discount rate.

OUTLOOK

NurExone (OTC-NRXBF) is a preclinical stage biotech company that is developing a breakthrough treatment for spinal cord injuries that has the potential to dramatically improve lives. The technology involved also has the potential to more efficiently get other treatments to the needed area.

The company announced that a preclinical study demonstrated that ExoPTEN treatment led to motor function recovery and improvements in blood flow—both positive signs for an IND submission.

Current Price (03/14/25)	$0.42
Valuation	**$3.05**

SUMMARY DATA

52-Week High	**$0.59**
52-Week Low	**$0.38**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**3,666**
Shares Outstanding (mil)	**74**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Cap**
Industry	**Biotech**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	NA	NA	NA	NA	0 A
2024	0 A	0 A	0 A	0 E	0 E
2025	0 E	0 E	0 E	0 E	0 E
2026	0 E	0 E	0 E	0 E	0 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	NA	NA	NA	NA	-0.08 A
2024	-0.02 A	-0.04 A	-0.02 A	-0.02 E	-0.10 E
2025	-0.02 E	-0.03 E	-0.01 E	-0.02 E	-0.08 E
2026	-0.04 E	-0.04 E	-0.03 E	-0.03 E	-0.14 E

Update

NurExone is developing a product known as ExoPTEN that is designed to treat patients with acute spinal cord injuries, while also conducting preclinical tests for other conditions that ExoPTEN may be able to treat. On that latter point, the company, late last year, announced some preclinical test results that have the potential to benefit thousands of patients and increase the value of NRXBF to investors. More recently, however, the company announced preclinical results that are encouraging for the first condition mentioned above.

Company management announced that its preclinical study on ExoPTEN for the treatment of spinal cord injuries demonstrated that the treatment led to motor function recovery and significant improvements in blood flow at the site of the spinal cord injury, which are both crucial components for tissue healing and recovery. We believe these results will prove to be a crucial part of the upcoming IND submission to the FDA and increase the probability that the study will be approved.

We also want to point out that investors in Canada appear to already be recognizing the potential that NRXBF has. NurExone just announced that it has been included in the 2025 TSX Venture 50, which is a well-thought-of annual ranking of top-performing companies on the TSX Venture Exchange. The TSX Venture 50 recognizes the top 50 performing issuers out of the 1,605 listed issuers on the TSXV, across all sectors. This recognition highlights NurExone's strong market performance and strategic advances in the past year including 110% share price appreciation and 209% market cap growth on the exchange.

This follows other actions by NurExone to expand its presence in the United States. The company recently announced that it is forming a US-based subsidiary, known as Exo-Top Inc. Management characterizes the establishment of Exo-Top as "a key step towards an independent and scalable supply of high-quality exosomes for the company's future nanodrug pipeline and collaboration opportunities."

Finally, the company announced that it is going to be presenting at the International Society for Cell & Gene Therapy (ISCT) 2025 Annual Meeting ("ISCT 2025"), a major global cell and gene therapy translation conference, taking place from May 7-10, 2025 in New Orleans, Louisiana, United States. This is another chance for United States investors to hear some of the potential breakthrough treatments the company is pursuing.

In addition to the above results, company management recently announced significant findings from an expanded study of ExoPTEN for repairing optic nerve damage. Using a rodent model of optic nerve crush to simulate damage associated with conditions such as glaucoma. Analysis of the data showed clear recovery of signal transmission in treated eyes compared to untreated controls, which showed no significant response.

According to the company, the study also showed significantly enhanced the survival of retinal ganglion cells, which are key neurons responsible for transmitting visual information to the brain.

We were also encouraged to hear comments from the lead investigator at the Goldschleger Eye Institute, part of a top hospital the company is collaborating with, when Dr. Ifat Sher said, "the results from this expanded study are extremely encouraging. ExoPTEN demonstrates potential as a treatment that restores functionality and offers neuroprotection. The study shows clear signal recovery, healthier optic nerve structures and preserved retinal ganglion cells. These results suggest that ExoPTEN could fundamentally change how we approach conditions like glaucoma and optic nerve trauma."

With a market size of approximately $5.5 billion currently, based on estimates cited by the company, and a projected growth rate of over 8% annually, the potential for this treatment is extensive and is an exciting addition to the company's portfolio.

As a reminder, the company also recently announced that its ExoPTEN therapy has received the Orphan Medicinal Product Designation by the European Medicines Agency (EMA). According to the company, the EMA's Orphan Medicinal Product Designation offers incentives, including ten years of market exclusivity upon approval, access to grants and incentives from the European Commission and member states. Additionally, the company may benefit from free or reduced-cost scientific advice and assistance with clinical trial design, which can streamline the regulatory process and reduce development costs. Lastly, some European Union countries also provide tax credits and other financial incentives to support orphan drug development.

As we've noted before, the company received the Orphan Drug Designation for ExoPTEN in 2023 from the FDA in the United States. This designation was created by the FDA which noted that supporting the development and evaluation of new treatments for rare diseases is a key priority for the agency. The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. Orphan drug designation qualifies sponsors for incentives including:

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential seven years of market exclusivity after approval

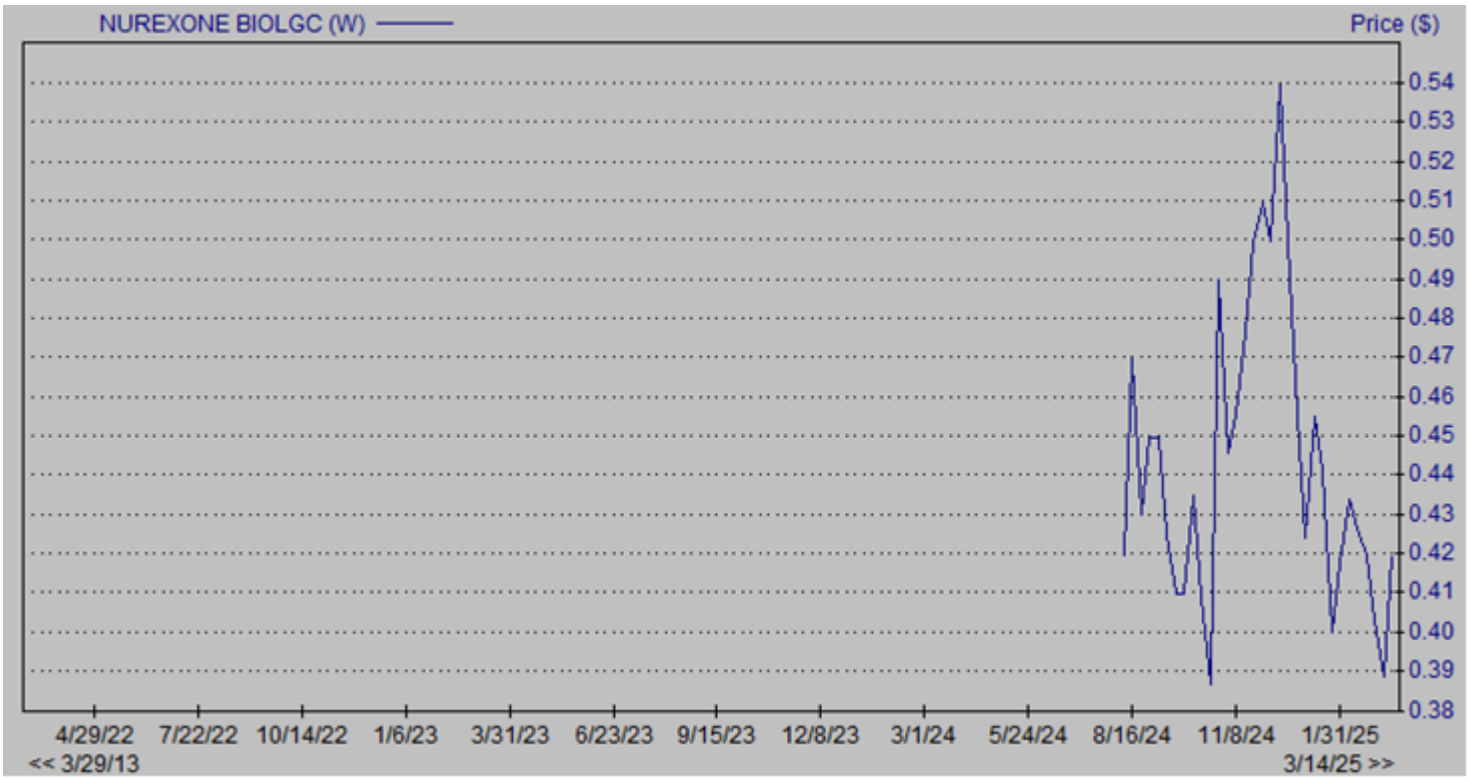
As a reminder, it was earlier test results from the use of ExoPTEN that sparked our enthusiasm for the company, because the initial test results are, in our view, truly remarkable. This isn't a potential treatment that was arrived at quickly or easily as research began at the University level and was conducted between January 2017 and May 2020, including testing the use of intranasal administration of exosomes driven from mesenchymal stem cells loaded with siRNA (a process that is described in more detail below). Testing targeted a complete spinal cord transection in rats, which is the strictest animal testing model, successfully demonstrating significant functional recovery. The company notes that the technology is successfully proven in additional preclinical studies, demonstrating that intranasal administration of ExoPTEN led to significant motor improvement, sensory recovery, and faster urinary reflex restoration. As mentioned, the research began at the University level and the Company has been granted an exclusive worldwide license from the Technion and Tel Aviv University, which includes a patent application, to develop and commercialize the technology. In addition, the Company has developed its own intellectual property and now has five families of patents.

We continue to be enthusiastic about the prospects for NurExone and suggest that US investors follow the Canadians and look into NRXBF. We urge investors with a higher risk tolerance to take a look at NRXBF and consider whether this compelling story may be of interest.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Nurexone Biologic Income Statement and Balance Sheet							
(US $ in thousands, except per share data)							
		2023A	**1Q2024A**	**2Q2024A**	**3Q2024A**	**4Q2024E**	**2025E**
Revenues							
Operating Expenses							
	General and administrative	2,116	695	1,507	782	798	3,191
	Research and development	1,541	225	733	503	513	2,052
Loss from operations		3,657	920	2,240	1,285	1,311	5,243
Other income and (expenses)							
	Finance (income)/expense	(18)	2	28	2	2	2
	Other income, net	(28)	45	-21	-69	-72	-76
Total other (income) and expenses, net		(46)	47	7	(67)	(70)	(74)
Net loss		3,611	967	2,247	1,218	1,240	5,169
Basic and diluted loss per share		$ 0.08	$ 0.02	$ 0.04	$ 0.02	$ 0.02	$ 0.08
Basic and diluted wtd avg common shares		44,722,288	56,528,121	61,488,044	63,528,644	64,799,217	66,095,201
Assets							
Current Assets:							
	Cash	541	3,255	2,385	2,523	2,573	2,625
	Securities and other current assets	1,441	422	399	300	309	318
Total Current Assets		1,982	3,677	2,784	2,823	2,882	2,943
Property, Plant and Equipment, net		158	394	445	736	810	891
Right-of-use assets		30	71	63	55	57	58
Other assets		-	-	-	-	-	-
Total Assets		2,170	4,142	3,292	3,614	3,749	3,892
Liabilities and stockholder equity							
Current liabilities:							
	Accounts Payable	317	102	371	263	268	274
	Other current liabilities	1,591	260	175	172	181	190
Total Current Liabilities		1,908	362	546	435	449	463
Long-term Liabilities:							
	Royalty Payments	71	78	64	71	73	75
	Liability Assoc. With Gov't Grants	-	-	-	149	149	149
	Lease Liability	2	71	107	31	33	34
Total long-term liabilities		73	149	171	251	255	259
Total liabilities		1,981	511	717	686	704	722
Stockholders Equity							
	Equity reserves	2,084	2,113	1,197	2,699	2,712	2,726
	Additional Paid-in capital	12,162	16,497	17,682	17,783	18,300	18,834
	Accumulated Deficit	(14,057)	(14,979)	(16,304)	(17,554)	(17,968)	(18,389)
Total stockholders equity		189	3,631	2,575	2,928	3,045	3,170
Total liabilities and stockholder equity		2,170	4,142	3,292	3,614	3,749	3,892

HISTORICAL STOCK PRICE



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