

NurExone Biologic, Inc.

NRX: From Preclinical Promise to Clinical Execution - De-Risking the Exosome Opportunity in CNS

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KEY POINTS

- At the WTR Insights Conference, we hosted a fireside chat with CEO Dr. Lior Shaltiel.** This report contains a transcript of the conversation, which can be accessed [on demand](#). Those wishing to request a meeting with NurExone Biologic can do so through the conference portal.
- Differentiated, minimally invasive technology platform.** NurExone's lead product candidate, ExoPTEN, uses exosomes loaded with siRNA to promote neural regeneration after central nervous system trauma such as acute spinal cord injury or optic nerve injury. Unlike competing approaches (e.g., stem cell transplants or electrical stimulation), ExoPTEN is cell-free, crosses the blood-brain barrier naturally, and can be administered with minimal invasiveness, all of which bring a significant clinical and operational advantage.
- Strong preclinical results across multiple CNS indications.** The company's preclinical studies have demonstrated functional recovery in three distinct animal models—spinal cord injury (following full transection and compression), optic nerve damage (glaucoma model), and facial nerve injury. Notable results include rats regaining mobility after a complete spinal cord severance and restoration of normal optic nerve activity after 18 days, bolstering confidence in the drug's translational potential to humans.
- Clinical development timeline targeting 2027.** NurExone has secured Orphan Drug Designation in both the US and Europe for acute spinal cord injury, completed a pre-IND meeting with the FDA, and is planning a follow-up with a Type C meeting in 2026. The company targets IND submission by late 2026/early 2027 and patient enrollment initiated in 2027, with compassionate use cases potentially providing early human data ahead of formal trials. The company believes its acute spinal cord injury trial design is advantaged by a relatively broad treatment window of up to 72 hours after injury and by orphan-drug status, which could make enrollment more workable than in programs requiring treatment within 24 hours.
- Strategic US manufacturing partnership to accelerate commercialization.** The recently announced non-binding LOI with Florida-based BioXtek (via US subsidiary Exo-TOP) aims to scale GMP-grade naive exosome production. Surplus manufacturing capacity could generate near-term revenue in FDA-permitted Florida markets (pain management, wound healing, orthopedics)—reducing dependence on dilutive financing even before NurExone's internal clinical milestones are reached.
- Planned transition to US markets to unlock institutional capital.** Having raised more than \$20 million, supported by a loyal shareholder base, and been recognized among the top 50 TSXV companies, NurExone is now targeting a US listing to access a broader institutional investor base. Management sees a combination of advancing clinical catalysts and a recovering biotech IPO environment as key to funding Phase 1/2a trials and reducing reliance on small private placements and accelerated warrant conversions.

KEY STATISTICS

Ticker:Exchange	NRX:TSXV
Current Price	C\$0.63
52-Week Range	C\$0.55-C\$1.14
Average Volume (30-Day)	26,817
Shares Outstanding (MM)	73.4
Market Cap (C\$MM)	C\$46.2
Enterprise Value (C\$MM)	C\$56.4
Fiscal Year-End	December

PRICE PERFORMANCE



ABOUT THE EXECUTIVE



Dr. Lior Shaltiel
CEO

Dr. Lior Shaltiel is an entrepreneur and an award-winning scientist with extensive multidisciplinary international experience, specializing in chemical engineering, molecular biology, electrophysiology, pharmacology and drug delivery systems. Lior has years of experience in accelerating Israeli start-ups. Lior has worked in several nano-drug delivery companies such as LipoCure and Ayana Pharma. Before joining NurExone, Lior was a VP and Partner at a boutique Chinese investment bank operating in Israel mapping the investment landscape and opportunities in the Israeli pharmaceutical industry. Lior is the initiator and head of the BioMed-MBA program at the Hebrew University.

EXECUTIVE DISCUSSION

Robert Sassoon: Good morning and welcome. Thank you for participating in this session of the WTR Insights Conference featuring NurExone Biologic (TSVX: NRX/OTCQB: NRXBF). My name is Robert Sassoon, Managing Director of Healthcare, Neurosciences, and Special Situations at Water Tower Research. We are pleased to be hosting Dr. Lior Shaltiel, CEO of NurExone Biologic. Welcome, Lior.

Before proceeding, I must note that NurExone's safe harbor statements are available in its latest presentation and financial filings on its website. Also, this fireside chat is not to be reproduced, nor may a transcript be distributed without prior written consent from Water Tower Research. As always, investor questions are encouraged. Please enter them in the chat box and we will address as many as possible in a follow-up email or within our forthcoming Management Series report. Those wishing to request a meeting with NurExone Biologic can do so through the conference portal.

With these items addressed, let's begin. Lior, for those not so familiar with NurExone, can you please give our viewers an overview of your technology, development pipeline, the principal indications you are looking to address, and how large those opportunities are potentially for the company?

Lior Shaltiel: Sure. I'm happy to answer all the questions that you have. Let's start with the technology. This technology came out from two elite universities five years ago. Israel's Technion with Professor Shulamit Levenberg and Professor Daniel Offen from Tel Aviv University. The idea behind this was to show regeneration of new tissue in the spinal cord injury model. After testing several technologies, they found out that the most effective way is to use exosomes loaded with [siRNA](#).

We are working in the field of exosomes. They are tiny vesicles excreted from stem cells, and we can talk about them during our session today. They have enormous benefits for our health, and we use them for our purposes in this product. This product is exosomes loaded with siRNA to regenerate and lead to functional recovery after central nerve trauma injuries, such as spinal cord injury, optic nerve damage, facial nerve, traumatic brain injury, every part in the central nervous system that suffers from trauma can be addressed by this drug.

We have already shown three different models where ExoPTEN, our lead product, may be relevant.

Robert Sassoon: What would you say differentiates your approach to other therapeutic models targeting the same indications?

Lior Shaltiel: Let's take, for example, spinal cord injury. Spinal cord injury for years is an indication without a lot of hope. A lot of companies try to work on it in different

approaches, such as electrical stimulation via neural bypass and stem cells, which are very invasive to the injury, so in order to get the cells in, you need to open [up the patient]. It's a heroic operation. By comparison, NurExone demonstrates an advantage.

We are minimally invasive. We are cell free, so there are no cells involved. This is a product of cells, but there is no issue of proliferation. Exosomes can cross the BBB, the blood brain barrier without any modification or any engineering. They home to sites where there is inflammation of tissue after an injury, a normal biological procedure. We are using this flag of inflammation to home into this space. When the loaded exosomes are localized in the tissue, they can be active on the damaged cells and show regeneration of neurons and functional recovery.

Robert Sassoon: NurExone has demonstrated impressive functional recovery with minimally invasive administration of its lead candidate ExoPTEN across spinal cord, optic nerve, and facial nerve injuries. However, CNS injury trials have one of the highest rates of preclinical to clinical translation failure in drug development. Statistics indicate an 85% to 90% attrition rate from preclinical to clinical stages in CNS indications. What gives you confidence that the functional recovery observed in preclinical animal spinal cord injury and optical nerve damage models will translate into meaningful clinical endpoints in humans?

Lior Shaltiel: This is an excellent question, since as I answered before, a spinal cord injury is one of the toughest indications. It's a blue ocean for science to develop new innovation. In NurExone, we try to think out of the box how to give hope to those new patients with spinal cord injury in order not to spend their entire life in a wheelchair. The only way to do it is to ask if we can reverse the damage in the acute phase. Let's put aside chronic patients who have 10, 15, 20 years in a wheelchair. It's still spinal cord injury, but it's a completely different indication. We are talking about patients who have lost most of their nerves. They have a scar. This is a different indication.

We are working in the acute phase of an injury. Let's say someone was injured in a car accident and doesn't feel their legs. Maybe we have a chance to reverse the damage. Maybe we can get back some of the functions that were lost. As I said, without cells, and through a non-invasive or minimally invasive approach. My confidence, although it's a very tough indication, we could show it in a different model. We have shown it in a full transaction model, meaning cutting the spinal cord injury of a rat completely and asked if we can reconnect it in a functional way.

This is an experience of zero or one. If it works, you will see an effect. If it doesn't work and there was a good chance that it will not work, the product doesn't work.

[However, we have demonstrated that] it has worked several times, with rats that could walk again, and could improve their function after full transection. Then moving to a more physiological way, impaction, like pressing the nerves like we usually have after injury when the bone presses the nerve. Also, there we could see even better recovery, because the damage is less severe.

Moving to another completely different indication like optic nerve damage. What happens in glaucoma is that when the pressure in the eyes goes up, the optic nerve is damaged. We reversed that after 18 days damage of an optic nerve, showing rats with a normal ERG, normal electrical retinographic activity of the optic nerve, like a normal eye. We have also the results in facial nerves. The accumulation of our results over time gives me confidence that we may target a very universal approach to that type of acute spinal cord injury or traumatic CNS injuries.

Robert Sassoon: Very interesting. NurExone is now at an important inflection point as it transitions from preclinical development, which you've just described, to human trials. Can you walk us through the key milestones achieved to date that have enabled this transition? What critical steps remain before you are ready to submit an IND? What is the anticipated timeline for an IND submission and the initiation of the Phase 1/2a clinical trials of spinal cord injury and glaucoma.

Lior Shaltiel: ExoPTEN is a complex product. We are talking about drug substances of naive exosomes, and the drug substance of the siRNA that we combine together. Each of them needs to be well characterized. Let's speak about the exosomes. With the exosome part, we are quite advanced. Last year we secured a master cell bank that allows us to produce more than 100,000 batches in very conservative way. We can even increase it more. We have enough cell sources, which are fully characterized, FDA approved, and also at a GMP level, so we can produce the clinical material tomorrow.

About the siRNA, we're also very advanced in several levels. The sequence is patented. The loading mechanism is patented. We also have results that show together with the exosomes that we are functionally active in the rats. This is the preclinical work, and we are continuing to prepare the toxicity report, the last thing that matters in our in vivo study.

In parallel, we have worked with the regulatory agencies, FDA and EMA to secure orphan drug designation for acute spinal cord injury in the US and Europe. We passed the pre-IND meeting at the end of 2023 showing the FDA our results. We are also going to have another follow-up meeting this year, probably type C meeting to update the agency with

more of our results because we are moving from internal nasal administration through the nose, our first proof of concept to intrathecal administration [injection] just to get the product as fast as possible into clinic. I'm anticipating having a ready product by the end of 2026.

Submission of the IND will be around that time or beginning of 2027 and in 2027 to start recruiting the patients.

Meanwhile, there is a lot of demand that NurExone has for having first in humans in a compassionate use approach. This is something that I'm also open-minded to have in order to gain some early information on drug safety and how effective it is across different indications.

Robert Sassoon: Great. Thank you for that. Acute spinal cord injury is well known to present significant enrollment challenges given the narrow post-injury dosing window and the need to treat patients in emergency care settings. Can you explain why ExoPTEN may be better positioned than many other experimental approaches in this regard, including how its minimally invasive administration and potential treatment window could support smoother trial enrollment and real-world clinical use?

Lior Shaltiel: Those are questions that are relevant to who exactly is going to use this drug. This drug, as you mentioned, will be used in the first few days after the injury. In this case, there are several decision makers that will be involved in determining whether the patient will get the drug, including the neurosurgeons, the orthopedists, the trauma centers or trauma center specialists that are working with the patient just after admission into the hospital. There is also a part of the rehabilitation. The post-trauma patient needs to move to rehabilitation.

In this case, the idea is to treat the patient up to 72 hours from the injury, and this is a quite large window, okay? If you compare AbbVie (NYSE: ABBV) with the antibody that they use also for spinal cord injury, one of the, I would say, the operational failure is that they start to administer the drug in the clinical setting 24 hours after the injury. This is very tough operationally to ask the hospital to start the procedure, getting the consent from the family because the patient usually is full of morphine. He doesn't feel anything. It's a very critical condition. We have a bit of a larger window to start, and we can administer two to four injections up to the first two weeks from the injury. This is the therapeutic window of acute spinal cord injury.

Based on what we see in rats, this will be enough to reverse some of the functions, including mobility in humans. My hope is that we will be able to translate it into humans in clinical trials. The results are very encouraging. We see a large percentage of rats that recover, including motorically, sensorially, and also quality of life. For example, one of the conditions that humans suffer from after injury is 'phantom' pain (a chronic, neuropathic pain sensation felt in a body part that is no longer there, typically following amputation or severe injury, resulting from misfiring nerves or brain reorganization). We cannot, of course, ask the rats if they feel any pain, but what we see is that in the control group, they start to gnaw at their legs, meaning, they

don't feel or they feel very painful, so they start to eat themselves. We didn't see this behavior in the group of rats that received ExoPTEN. This is very encouraging, and I really hope that we will be able to translate those results to humans.

Robert Sassoon: Right. One of the key differentiators for NurExone is that it has a US-based master cell bank, which is now owned by your US subsidiary, Exo-TOP. What is your strategy for scalable, reproducible bio manufacturing, and how close are you to commencing GMP clinical production and commercial scale up?

Lior Shaltiel: Okay. This question is exactly the point of our [Press Release](#) released a few days ago about our LOI with a Florida-based clinical stage company called [BioXTek](#). The idea is to produce and commercialize naive exosomes. Naive exosomes, again, I want to remind us and the audience that this is the drug substance of ExoPTEN. We have naive exosomes. The naive exosome will be produced in the US, and the overcapacity of production can be commercialized for other therapies.

Florida, in this case, is a very unique state, one of the first in the US that allows a treatment of cell therapy, and it's defined for three different indications: Pain management, wound healing, and orthopedics. Our exosomes can be a good answer for the increased demand in the market for a solution in the field, and this will enable NurExone and Exo-TOP, our fully owned US subsidiary, to gain revenue even before getting into the first in human trials.

Robert Sassoon: Right. You mentioned your LOI with BioXTek, both in terms of supporting ExoPTEN's future therapeutic and clinical development and potentially expanding NurExone's commercialization capabilities. Can you add some color on what opportunities you see for these exosomes?

Lior Shaltiel: The exosomes can be for different indications. As I said, in Florida specifically is for pain, orthopedics, and wound healing. You can get it in their direction of longevity. This is a very interesting topic, but needs to be, of course, based on getting more scientific-based results. By having NurExone's exosomes, we can provide the market with the highest quality of exosomes. Those exosomes will be GMP-grade. It's not exosomes that you produce in two dimensions or without any control. Those will be of the highest standards that the market can have, because it must be in the standard of FDA in order for us to produce ExoPTEN. We have this approach. We can also have a cosmetic or aesthetic approach. This is also an interesting field.

Then we can talk about having the IP portfolio of NurExone. We have five families of patents covering production to loading and what we load into the exosomes in a collaboration mode. By that, we can produce more and more new drugs for different indications because, again, the modification step of turning naive exosomes into ExoPTEN is post-production.

We first produce naive exosomes, and then on top of that, we modify it with siRNA. Then, it starts to be like a Lego [set]. You can build each product that you want to have based on your request. This can be a potential licensing and partnership in the therapeutic field.

Robert Sassoon: You've emphasized that US-based manufacturing of bone marrow derived naive exosomes is an important strategic priority. Obviously, the LOI was recently announced as part of that. How do you see that initiative de-risking the business in both the near term and the long term?

Lior Shaltiel: Your question is how this LOI will change the business?

Robert Sassoon: Well, yes. I mean, just the strategy in general is that you've always focused on manufacturing exosomes, naive exosomes. This LOI is a stepping stone toward that goal. How does this initiative de-risk your business both on the therapeutic side and the commercial side?

Lior Shaltiel: That allows NurExone to produce faster in order to get our final product to a toxicity [report]. IND submission can be faster in this case because, again, the naive exosomes are our drug substances. De-risking the time to become a clinical stage company. On the other hand, producing a potential revenue stream for the company by selling the extra supply that we have of naive exosomes. The comparison here is that because of our Orphan Drug Designation, we [only] need nine to 30 patients in a Phase 1 and Phase 1/2a trial in total, so it's like asking for a glass of milk when we have the bought the whole cow shed [meaning that NurExone's internal exosome needs are a fraction of the supply it can produce]. All the cows produce milk, and we can actually, by that de-risk the company and be less dependent on future fundraising because we can with Exo-TOP produce revenue by selling those naive exosomes [to third parties].

Robert Sassoon: Okay. Moving on, you mentioned funding. Historically, NurExone's capital raises have consisted primarily of small non-brokered private placements and accelerated warrant conversions. That's enabled you to raise capital as needed. However, with an IND filing, GMP facility build-out at Exo-TOP and a Phase 1 trial initiation, all competing for resources against the burn rate that currently exceeds your current cash position, what is your financial strategy to fund operations through to a meaningful clinical readout? What specific de-risking milestones do you believe would unlock the scale of institutional capital required to execute that plan without continued reliance on dilutive microcap financing?

Lior Shaltiel: That's an excellent question, because we are actually exactly at the junction where I anticipate we should be, when a startup turns to become a mid-sized pharmaceutical. In this case, those initial investors, with whom we have a very strong connection, are loyal to the company. You can see it with the exercise of warrants

that we had in November 2025. We had 100% exercise of warrants. It's double acceleration of warrants, and this injected CAD\$3.2 million to the company.

Our current investors so far are very loyal, and we are now in the transition to becoming a US-based company, meaning listed in the US. This is the main market. It will bring us new investment opportunities. Second, when [our share price] gets higher than the usual \$1, \$1.50, you are attracting more institutional [investors]. This is part of the evolution of any company in the field. Unfortunately, some companies couldn't get into this advanced situation because of the micro economy. This is a very challenging situation [for microcaps], I would say, even in the last five years to now.

We could see some changes coming. I think the IPO numbers are going up again, and biotech is attracting more attention. But in the end, we as a company need to show how NurExone is different than the rest of biotech. I think we can bring here, first of all, technology that is very cutting edge. Second, a new mechanism to finance the company, and we did this quite successfully over the years.

Last year, we also were announced as part of the best 50 companies of the Toronto Stock Exchange Venture. This is just two years after we became public. We have been now public for four years. We got mature at the TSXV, and now we need to move to the US market where we can also be able to finance the significant amount for securing our future clinical studies.

Robert Sassoon: Good. We wish you the best of luck there. Now the final question, I guess it's connected. What do you believe investors are still under appreciating most about NurExone story today?

Lior Shaltiel: I see it all the time when I meet investors, is there a wow effect? It is hard for them to understand the magic that we bring. A lot of people think that it's really science fiction, and it takes time to convince us that what we see is true. When, I would say, smart investors in the field getting into our visual data room and see the results, they understand, okay, you have something, and you have something big, and we would like to be part of it.

There is a lot of skepticism if what we see is correct, but when you dig into the data, you are convinced more and more. Of course, there is always risk in biotech, but I think besides the strong IP that we have, some of it is by the way granted in the US, I think we also bring to the table a very experienced team and management team that could execute in one of the hardest times in biotech and get the company NurExone from zero to 21 employees. We raised so far more than \$20 million. I don't think there are many preclinical companies that could raise that amount of money and receive support from so many investors.

Robert Sassoon: Well, thank you, Dr. Lior Shaltiel for spending time with us and engaging in a very informative discussion. We wish you the best of luck going forward, and we're definitely going to continue to monitor you.

Lior Shaltiel: Thank you so much.

Robert Sassoon: Thank you to all who joined and contributed to this fireside chat. You can find current and future research and insights at www.watertowerresearch.com. If you have additional questions or would like to request a meeting with management, please indicate that through the conference portal, and we will attempt to accommodate requests.

ABOUT THE ANALYST



Robert Sassoon

Managing Director – Healthcare, Emerging Growth & Special Situations, Neurosciences

Robert Sassoon has been an equity analyst for more than three decades, focusing primarily on global special situations. During his career, Robert has worked for several sell-side institutions in London, Hong Kong, and New York, including Credit Suisse, NatWest Capital Markets, and Societe Generale. In 2017, Robert founded AlphaSituations, an independent idea-generating event driven/special situations investment research service, which produced comprehensive research on early stage/emerging publicly traded and privately owned companies with the goal of telling an underappreciated or unknown story to relevant investors.

Robert has developed a uniquely broad and deep knowledge base in multiple industries from a global perspective and has achieved top five rankings in various analyst surveys, including the Extel and Greenwich surveys. Robert holds an MSc in Economics from the London School of Economics and Political Science, and has held FINRA licenses Series 7, 63, 86, 87, and 24.

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