

NervGen Pharma Reports Q3 2024 Financial Results and Operational Updates

- Target enrollment in the chronic cohort of our Phase 1b/2a clinical trial of NVG-291 in individuals with spinal cord injury (SCI) is approaching completion
- NVG-300 preclinical test-of-concept studies in ischemic stroke, amyotrophic lateral sclerosis (ALS) and SCI underway

Vancouver, Canada, November 14, 2024 – **NervGen Pharma Corp. (TSX-V: NGEN) (OTCQB: NGENF)**, a clinical-stage biotech company dedicated to developing neurorestorative therapeutics, reported its financial and operational results for the third quarter ended September 30, 2024.

“During the quarter we continued to benefit from our recruitment initiatives to attract study participants into our Phase 1b/2a clinical trial,” said [Mike Kelly](#), NervGen’s President & CEO. “We announced at the end of the quarter that we are approaching completion and that we will further advise when enrollment has been completed and when topline data is expected. We also advanced the preclinical test-of-concept evaluation of NVG-300 in models of ischemic stroke, ALS and SCI, and anticipate preliminary results from these studies in the first half of next year. We believe NVG-300 could add diversity to our pipeline as well as target indications and provide strategic optionality for future partnering opportunities.”

“Forecasting enrollment has been challenging given the many variables involved as well as the novel aspects of the study design and protocol of our Phase 1b/2a proof-of-concept clinical trial,” said Daniel Mikol, MD, Ph.D., NervGen’s Chief Medical Officer. “Our trial is innovative in two fundamental ways. First, it evaluates the ability of NVG-291 to enhance motor recovery through the complementary use of clinical assessments and objective electrophysiological measures of motor connectivity. Second, in order to increase the probability of success, it enrolls participants who have evidence of residual motor connectivity (electrophysiologically and functionally) which mirrors preclinical animal models of SCI. In addition, based on insights gained since initiating enrollment of the chronic cohort of this study, we have modified eligibility criteria and assessment schedule for the subacute cohort to facilitate enrollment and make participation less burdensome; this protocol amendment has been submitted to the U.S. Food and Drug Administration and is under review by the Institutional Review Board.”

Operational Highlights for Q3 2024

- We advanced the clinical development of NVG-291.
 - The initiatives and operational directives undertaken have assisted in the recruitment of our Phase 1b/2a clinical trial and we announced that target enrollment in the chronic cohort is approaching completion. Additionally, Dr. Mikol presented a clinical trial update at the 63rd International Spinal Cord Society Annual Scientific Meeting in Antwerp, Belgium. Dr. Mikol reviewed the trial design, the rationale for evaluating not just clinical outcome measures but also electrophysiological measures as biomarkers of efficacy, and he provided an update on the baseline demographic and clinical characteristics of subjects randomized. Additionally, Dr. Mikol, gave an oral presentation titled “Clinical Trials in Spinal Cord Injury ... Lost in Translation?” at the Unite 2 Fight Paralysis 19th Annual Science & Advocacy Symposium in Atlanta, Georgia.

- In addition, a protocol amendment is under review by the IRB and has been submitted to the U.S. Food and Drug Administration to modify eligibility criteria and assessment schedule for the subacute cohort to facilitate enrollment and make participation less burdensome.
- We advanced our research activities related to our drug candidates.
 - We initiated preclinical test of concept evaluation of a potential second development candidate, NVG-300, in models of ischemic stroke, ALS and SCI. In addition, we have initiated studies to further elucidate the mechanism of NVG-291 therapeutic action.
- We appointed Mr. Neil Klompas to the company's Board of Directors.
 - Mr. Klompas is an experienced life sciences and healthcare sector executive and board member. He is currently the President and Chief Executive Officer, and a member of the Board of Directors, of Augurex Life Sciences Corp. Prior to Augurex, he served as President and Chief Operating Officer and prior to that Chief Financial Officer of Zymeworks Inc. During his time with the company, he oversaw finance and operations executing the company's initial public offering on the NYSE and TSX. Prior to Zymeworks, Mr. Klompas worked with KPMG LLP as part of the Pharmaceutical, Biotech & Medical Devices M&A Transaction Services practice in Princeton, NJ, and with KPMG LLP in the life sciences assurance practice based in Vancouver. Mr. Klompas serves on the Board of HTuO Biosciences and has served as Board Chair for Ovensa Inc., and as the Chair of the Audit Committee and Special Committee of Liminal Biosciences Inc. until its acquisition in 2023. He holds a BSc in Microbiology & Immunology from the University of British Columbia and is a Chartered Professional Accountant.

Financial Highlights

- **Cash and Investments:** NervGen had cash and cash equivalents of \$21.0 million as of September 30, 2024, compared to \$11.7 million as of December 31, 2023. The net cash burn for Q3 2024 from operating activities was approximately \$5.8 million. This was offset by approximately \$0.3 million in net proceeds from financing activities related to options and warrants exercised during the quarter.
- **R&D Expenses:** Research and development expenses were \$4.4 million for the three months ended September 30, 2024, compared to \$0.8 million in the same period in 2023. The increase in the current period pertains primarily to the ongoing Phase 1b/2a clinical trial and the receipt of grant funding for the trial in excess of costs incurred in the previous period. We also incurred higher patent costs related to NVG-300 and salaries, benefits and consulting costs to support our program management, planning, and research initiatives.
- **G&A Expenses:** General and administrative expenses were \$2.8 million for the three months ended September 30, 2024, compared to \$2.6 million for the same period in 2023. The increase in the current period was primarily due to increased corporate consulting costs to support the overall growth and corporate development activities of the company as well as legal costs to support our financing initiatives. These costs were partially offset by a lower non-cash stock-based compensation expense related to option and retention security grants, and the timing of the related vesting.
- **Net Loss:** For the three months ended September 30, 2024, our net loss was \$5.2 million (\$0.07 loss per basic and diluted common share), which included \$1.7 million of non-cash expenses pertaining to amortization, stock-based compensation, unrealized foreign exchange loss, and offset by \$1.8 million non-cash gain due to the fair value adjustment of the warrant derivative. For the three

months ended September 30, 2023, net loss was \$4.3 million (\$0.07 loss per basic and diluted common share), which included \$2.8 million of non-cash expenses.

About the NVG-291 Phase 1b/2a Trial

The double-blind, placebo-controlled proof-of-concept Phase 1b/2a clinical trial (NCT05965700) will evaluate the safety and efficacy of NVG-291 in two separate cohorts of individuals with cervical spinal cord injury: chronic (1-10 years post-injury) and subacute (those who are closer to their time of injury), given demonstrated efficacy in preclinical models of both chronic and acute spinal cord injury. The trial is designed to evaluate the efficacy of a fixed dose of NVG-291 using multiple clinical outcome measures as well as objective electrophysiological and MRI imaging measures and blood biomarkers that together will provide comprehensive information about the extent of recovery of function, with a focus on improvements in motor function. Specifically, the primary objective is to assess the change in corticospinal connectivity of defined upper and lower extremity muscle groups following treatment based on changes in motor-evoked potential amplitudes. Secondary objectives are to evaluate changes in a number of clinical outcome assessments focusing on motor function, upper extremity dexterity and grasping and mobility, as well as changes in additional electrophysiological measurements. The cohorts will be comprised of approximately 20 subjects each and will be evaluated independently as the data becomes available. The trial is being partially funded by a [grant from Wings for Life](#), which is being provided in several milestone-based payments and will offset a portion of the direct costs of this clinical trial.

About NervGen

NervGen (TSXV: NGEN, OTCQB: NGENF) is a clinical-stage biotech company dedicated to developing innovative treatments to promote nervous system repair in settings of neurotrauma and neurologic disease. The company is testing the clinical efficacy of its lead molecule, NVG-291, in a Phase 1b/2a clinical trial in spinal cord injury and has initiated preclinical evaluation of a new development candidate, NVG-300, in models of ischemic stroke, amyotrophic lateral sclerosis (ALS) and spinal cord injury. For more information, visit www.nervgen.com and follow NervGen on [X](#), [LinkedIn](#), and [Facebook](#) for the latest news on the company.

About NVG-291

NervGen holds exclusive worldwide rights to NVG-291, a first-in-class therapeutic peptide targeting nervous system repair. NVG-291's technology was licensed from Case Western Reserve University and is based on academic studies demonstrating the preclinical efficacy of NVG-291-R, the rodent prototype of NVG-291, in animal models of spinal cord injury. Effects of NVG-291-R reported in multiple independent academic studies include the promotion of neuroplasticity, remyelination, anti-inflammatory polarization of microglia, and functional improvement in preclinical models of spinal cord injury, stroke, and peripheral nervous system injury. NVG-291 has received Fast Track designation in spinal cord injury from the U.S. Food and Drug Administration.

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This news release may contain “forward-looking information” and “forward-looking statements” within the meaning of applicable Canadian and United States securities legislation. Such forward-looking statements and information herein include but are not limited to, the company’s current and future plans, expectations and intentions, results, levels of activity, performance, goals or achievements, or any other future events or developments constitute forward-looking statements, and the words “may”, “will”, “would”, “should”, “could”, “expect”, “plan”, “intend”, “trend”, “indication”, “anticipate”, “believe”, “estimate”, “predict”, “likely” or “potential”, or the negative or other variations of these words or other comparable words or phrases, are intended to identify forward-looking statements. Forward-looking statements include, without limitation, statements relating to: the objectives, planned clinical endpoints, timing, expected rate of enrollment and data readout and study design of our Phase 1b/2a clinical trial of NVG-291 in individuals with spinal cord injury; the development plans, timelines, expected benefits, and prospective target indications for NVG-300; the objective of further studies of NVG-291; the receipt of the milestone-based grant payments; and the creation of neurorestorative therapeutics to promote nervous system repair in settings of neurotrauma and neurologic disease.

Forward-looking statements are based on estimates and assumptions made by the company in light of management’s experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate and reasonable in the circumstances. In making forward-looking statements, we have relied on various assumptions, including, but not limited to: our ability to obtain future funding on favourable terms or at all; the accuracy of our financial projections; obtaining positive results in our clinical and other trials; our ability to obtain necessary regulatory approvals; our ability to arrange for the manufacturing of our product candidates and technologies; and general business, market and economic conditions.

Many factors could cause our actual results, level of activity, performance or achievements or future events or developments to differ materially from those expressed or implied by the forward-looking statements, including without limitation, a lack of revenue, insufficient funding, reliance upon key personnel, the uncertainty of the clinical development process, competition, and other factors set forth in the "Risk Factors" section of the company’s Annual Information Form, Preliminary Short Form Base Shelf Prospectus, financial statements and Management Discussion and Analysis which can be found on SEDARplus.ca. All clinical development plans are subject to additional funding.

Readers should not place undue reliance on forward-looking statements made in this news release. Furthermore, unless otherwise stated, the forward-looking statements contained in this news release are made as of the date of this news release, and we have no intention and undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. The forward-looking statements contained in this news release are expressly qualified by this cautionary statement.