

# NervGen Pharma Reports 2024 Year-End Financial Results and Provides Business Updates

- Completed enrollment in the chronic cohort and commenced enrollment in the subacute cohort of its Phase 1b/2a clinical trial for lead drug candidate, NVG-291, in spinal cord injury (SCI)
- Initiated an expanded access protocol for NVG-291 for individuals with SCI who have participated in a NervGen clinical trial and meet specific eligibility criteria
- Pipeline candidate NVG-300 showing promising activity in preclinical models of ischemic stroke and SCI

Vancouver, Canada April 3, 2025 – NervGen Pharma Corp. (TSXV: NGEN) (OTCQB: NGENF), a clinical-stage biotech company dedicated to developing neurorestorative therapeutics, today reported its financial and operational results for the full year ended December 31, 2024.

"2024 was a very productive year for NervGen as we advanced the clinical development of our lead candidate, NVG-291, in spinal cord injury and delivered on key research activities and business milestones," said Mike Kelly, President and Chief Executive Officer of NervGen Pharma. "Most notably, we completed enrollment in the chronic cohort of our Phase 1b/2a clinical study of NVG-291 for individuals with SCI and anticipate a topline data readout for this cohort in early June 2025. We also received Institutional Review Board approval for an amendment to the subacute cohort of our Phase 1b/2a clinical trial and initiated enrollment. This important proof-of-concept study is aimed at demonstrating for the first time the potential of NVG-291 in enabling repair of nervous system damage in individuals with spinal cord injury.

"Importantly, we expect that the net proceeds from our \$23 million bought deal financing completed earlier in 2024, coupled with our existing working capital and anticipated proceeds from our at-the-market equity program (ATM) will fund continued clinical development of NVG-291 along with research and development activities to support further evaluation and preclinical activities in other indications through Q3 2025," continued Mr. Kelly.

Earlier this week, NervGen also reported that the FDA informed the company that an expanded access protocol for NVG-291 may proceed. The protocol submission was in response to a request from a physician for expanded access to NVG-291 for a patient who participated in the chronic cohort of the Phase 1b/2a clinical trial.

In addition, preclinical studies of NVG-300 in ischemic stroke and SCI, initiated during 2024, showed promising initial results, suggesting further investigation is warranted. Key preclinical findings in ischemic stroke and SCI include:

- NVG-300-R, the rodent variant of NVG-300, in ischemic stroke: Preclinical data from a rat model of ischemic stroke showed rapid decrease in the ischemic lesion volume in animals treated with NVG-300-R. Significant effects of NVG-300-R also included improved performance in the functional memory and spatial recognition (Y-maze), and locomotor function (horizontal ladder) tests.
- NVG-300-R and NVG-300 in SCI: In the preclinical model of SCI caused by thoracic contusion, animals treated
  with NVG-300-R or NVG-300 showed improvement in gait quality assessed by NeuroCube®, an in vivo AI
  platform that uses computer vision combined with bioinformatics to perform objective multivariate analysis of
  gait patterns.

"The preclinical evidence of NVG-300 and NVG-300-R activity in animal models of ischemic stroke and SCI is encouraging," said Matvey Lukashev, Ph.D., Vice President of Research and Preclinical Development of NervGen Pharma. "Taken together, the results of this latest set of *in vivo* studies offer further preclinical validation of NVG-300. Preclinical validation in amyotrophic lateral sclerosis (ALS) will be paused at this time."

## **Full Year and Recent Business Highlights**

- We advanced the clinical development of NVG-291:
  - o In February 2024, we announced that we are developing plans to initiate a new study in which subjects completing the current trial who received placebo, would have the option to receive open-label NVG-291 under a separate protocol. We plan to initiate this open-label study, provided that an efficacy signal is observed in the chronic cohort, contingent upon protocol approval by the FDA as well as the study's Institutional Review Board.
  - At several scientific conferences during 2024, Daniel Mikol, M.D., Ph.D., Chief Medical Officer of NervGen Pharma, presented the trial design, the rationale for evaluating clinical outcome measures in addition to electrophysiological measures as biomarkers of efficacy, and provided an update on the baseline demographic and clinical characteristics of randomized subjects.
  - At year end, we announced the completion of enrollment in the chronic cohort of our Phase 1b/2a clinical trial of NVG-291 in individuals with SCI; topline data from the chronic cohort is expected in early June 2025. The company also received Institutional Review Board approval for an amendment to its Phase 1b/2a clinical trial protocol and initiated screening of subjects for the subacute cohort. The enrollment and dosing of the first subject in the subacute cohort was announced in early February 2025 and enrollment continues.
  - Subsequent to year-end, on March 31, 2025, we announced the initiation of an expanded access policy to allow treatment use of the investigational product NVG-291 for those individuals with SCI who have participated in NervGen clinical trials and meet specific eligibility criteria. We received a request from a physician for expanded access to NVG-291 for a subject who participated in the chronic cohort of the Phase 1b/2a clinical trial. After we submitted an expanded access protocol for NVG-291 to the FDA, the FDA informed us that the study could proceed.
- We advanced our research activities related to our drug candidates:
  - During 2024, 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 initiated studies to further elucidate the mechanism of NVG-291 therapeutic action.
- We improved our position with equity proceeds of over \$23 million and established an ATM program to fund our ongoing clinical trial:
  - On March 28, 2024, we announced the closing of the previously announced public offering, including the full exercise of the underwriters' over-allotment option for aggregate gross proceeds of \$23 million. Pursuant to the offering, the underwriters purchased, on a bought deal basis, and we issued 9,792,250 units at a price of \$2.35 per unit. Each unit was comprised of one common share and one-half of one common share purchase warrant. Each whole warrant is exercisable to acquire one common share for a period of 36 months following the closing of the offering at an exercise price of \$3.00 per warrant share. In connection with the offering, we issued an aggregate of 170,127 broker warrants and paid a cash commission of \$1.1 million to the underwriters and incurred approximately \$0.54 million in other share issue costs related to legal and listing fees.
  - On December 20, 2024, we announced the establishment of an ATM equity program that allows us to issue and sell common shares to the public from time to time through an agent at our discretion and subject to regulatory requirements. We initiated sales under the ATM in January 2025.
- During the year, we continued to add expertise to our team with the following additions and appointments:
  - o In July 2024, Mr. Neil Klompas was appointed to our 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 Chief Financial Officer, and later President and Chief Operating Officer of Zymeworks Inc. During his time with the company, he oversaw finance and operations, including leading the execution 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. He holds a BSc in Microbiology & Immunology from the University of British Columbia and is a Chartered Professional Accountant.

O During the year, we also added senior level talent to oversee our clinical operations, program management, regulatory affairs, technical operations and CMC, and corporate development.

# **Full Year 2024 Financial Highlights**

- Cash and Investments: NervGen had cash and investments of \$17.3 million as of December 31, 2024, compared to \$11.7 million as of December 31, 2023. Our cash balance was improved during the year by the net proceeds of the March 2024 bought deal financing and approximately \$1.4 million in proceeds from the exercise of stock options and warrants during the year. The net cash burn for the year ended December 31, 2024, from operating activities was approximately \$16.8 million.
- **R&D Expenses:** Research and development expenses were \$15.7 million for the year ended December 31, 2024, compared to \$8.0 million for the year ended December 31, 2023. The increase in the year ended December 31, 2024, is primarily related to clinical spend associated with a full year of Phase 1b/2a clinical trial activity, an increase in preclinical translational research, an increase in drug manufacturing costs, and an increase in headcount related spend within the R&D function. In the year ended December 31, 2023, clinical study costs were comparatively lower as we completed dosing in our Phase 1 clinical trial and we received grant funding that partially offset the costs of our Phase 1b/2a clinical trial that commenced in the second half of 2023.
- **G&A Expenses:** General and administrative expenses were \$9.2 million for the year ended December 31, 2024, compared to \$9.7 million for the year ended December 31, 2023. The decrease was primarily due to non-cash stock-based compensation expenses due to the hiring of our new President & CEO and other employees and consultants in the prior comparative period, and the timing of the related vesting.
- **Net Loss:** For the year ended December 31, 2024, net loss was \$24.0 million, or \$0.36 per basic and diluted common share. The net loss for the year included \$6.3 million of non-cash expenses pertaining to amortization, stock-based compensation, unrealized foreign exchange and the fair value adjustment of the warrant derivative. For the year ended December 31, 2023, net loss was \$22.4 million, or \$0.38 per basic and diluted common share which included \$11.3 million of non-cash expenses pertaining to amortization, stock-based compensation, unrealized foreign exchange and the fair value adjustment of the warrant derivative.

The company also announces that it has engaged Sam Brown Healthcare Communications, a Blue Matter Company (Sam Brown), a leading integrated communications and public relations agency focused on corporate, clinical and commercial communications for the life sciences industry. Sam Brown will provide media and public relations and related services for the company and is engaged for an initial period of nine months that will continue thereafter on a month-to-month basis unless terminated by either party with 30 days' notice. It is expected that the cash compensation that is paid in the first twelve months will not exceed US\$46,000 per month. Sam Brown has no other indirect or direct interest in the company. The appointment of Sam Brown as a public relations consultant to NervGen is subject to regulatory acceptance of applicable filings with the TSX Venture Exchange.

#### About Phase 1b/2a Trial

The double-blind, placebo-controlled proof-of-concept Phase 1b/2a clinical trial (NCT05965700) evaluates the safety and efficacy of NVG-291 in two separate cohorts of individuals with cervical spinal cord injury: chronic (1-10 years postinjury) and subacute (20-90 days post-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 and strength, 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. More information about participation in the subacute study is available at <a href="https://www.connectscistudy.com">www.connectscistudy.com</a>.

#### **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, dementia, and peripheral nervous system injury. NVG-291 has received Fast Track designation in spinal cord injury from the FDA.

## **About NVG-300**

The discovery of NVG-300, a new biological molecule, is the result of a research effort initiated by NervGen in 2022, leveraging NervGen's extensive internal expertise and the evolving scientific understanding of the mechanisms involved in nervous system repair. NVG-300 is the first of what NervGen believes will be a pipeline of new molecules addressing high unmet need neurologic indications. NVG-300 product and process development have progressed to successfully establish manufacturability and feasibility of high concentration liquid formulation to enable self-administration of the product in a prefilled syringe format. NVG-300 will be developed under the Biologics License Application regulatory framework that provides 12 years of market exclusivity post-approval, and its composition of matter intellectual property protection is expected to extend beyond 2040.

## **About Ischemic Stroke**

Stroke is the leading cause of death and severe disability worldwide, significantly diminishing the quality of life for many affected individuals. Globally, nearly 17 million people experience a stroke each year, with over two million cases annually in the United States, Europe, and Japan combined. The most prevalent type of stroke, ischemic stroke, occurs when a blockage in the brain's blood flow deprives it of oxygen and nutrients, often leading to long-term or permanent neurological damage. Unfortunately, treatment options for ischemic stroke are limited. Current therapies, such as the administration of the clot-dissolving agent tissue plasminogen activator or surgical clot removal, must generally be performed within a few hours of stroke onset.

## **About Sam Brown Healthcare Communications**

A Blue Matter company, Sam Brown Healthcare Communications is a leading corporate, clinical, and commercial communications agency for the life sciences industry. Sam Brown provides broad strategic communications services to a wide range of biotechnology, biopharmaceutical and venture capital companies whose cutting-edge science and innovation impact human health. For more information, visit <a href="https://www.sambrown.com">www.sambrown.com</a>.

#### **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 and spinal cord injury. For more information, visit <a href="www.nervgen.com">www.nervgen.com</a> and follow NervGen on <a href="mailto:X, LinkedIn">X, LinkedIn</a>, and <a href="facebook">Facebook</a> for the latest news on the company.

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## **Cautionary Note Regarding Forward-Looking Statements**

This news release may contain "forward-looking information" and "forward-looking statements" within the meaning of applicable Canadian and United States securities legislation (collectively, "forward-looking statements"). Such forwardlooking 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 forwardlooking statements. Forward-looking statements include, without limitation, statements relating to: the objectives, planned clinical endpoints, timing, expected rate of enrollment, and timing of data readout and study design of our Phase 1b/2a clinical trial of NVG-291 in individuals with spinal cord injury; the potential access to NVG-291 through the company's expanded access policy; our belief that the net proceeds from our bought deal financing, along with our current working capital and anticipated proceeds from our ATM program is sufficient to fund our planned research and development activities through Q3 2025; the development plans, timelines, expected benefits, and prospective target indications for NVG-300; the expected contributions from the added senior level talent and engagement of Sam Brown; the expected compensation payable to Sam Brown in the next twelve months; 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 most recently filed prospectus supplement, short form base shelf prospectus, annual information form, financial statements and management discussion and analysis all of which can be found on NervGen's profile on SEDAR+ at www.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.