

NervGen Pharma Reports Q2 2024 Financial Results and Operational Updates

- Targeting to complete enrollment in the Phase 1b/2a chronic cohort in Q3 2024
- Protocol being amended to enhance enrollment and lessen burden on participants in the subacute cohort
- NVG-300 advanced into preclinical proof-of-concept studies in ischemic stroke, amyotrophic lateral sclerosis (ALS) and spinal cord injury (SCI)

Vancouver, British Columbia--(Newsfile Corp. - August 22, 2024) - **NervGen Pharma Corp. (TSXV: NGEN) (OTCQB: NGENF)**, a clinical-stage biotech company dedicated to developing innovative solutions for the treatment of nervous system damage, reported its financial and operational results for the second quarter ended June 30, 2024.

"During the quarter we implemented a communication plan to expand awareness of our Phase 1b/2a clinical trial nationwide. We announced to the SCI community that we will cover the cost of travel and accommodation for participants during the 16-week trial," said [Mike Kelly](#), NervGen's President & CEO. "These initiatives are increasing the number of potential candidates inquiring about the study as we strive to complete enrollment in the chronic cohort and begin enrollment in the subacute cohort. In addition, we announced a new drug candidate during the quarter, [NVG-300](#). This new molecule, discovered internally at NervGen, will initially be evaluated in efficacy studies in preclinical models including the additional indications of ischemic stroke and ALS. We expect NVG-300 to add diversity to our pipeline and provide strategic optionality for future partnering opportunities."

"Our Phase 1b/2a, proof-of-concept clinical trial is innovative in two fundamental ways," said Daniel Mikol, MD, Ph.D., NervGen's Chief Medical Officer. "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 testing requirements for the subacute cohort to facilitate enrollment and make participation less burdensome and we have submitted a protocol amendment to the Institutional Review Board and the U.S. Food and Drug Administration."

Operational Highlights for Q2 2024

- We advanced the clinical development of NVG-291.
 - The initiatives and operational directives undertaken during the quarter have assisted in recruitment of our Phase 1b/2a clinical trial and we are targeting to complete enrollment of the chronic cohort by the end of Q3 2024. Additionally, Dr. Mikol [presented two posters](#) at the American Spinal Injury Association (ASIA) 51st Annual Scientific Meeting. Dr. Mikol presented preclinical and clinical data supporting an association between improvements in motor evoked potentials (MEPs) and functional/clinical motor recovery after SCI, proposing that MEPs might be used as an efficacy biomarker in SCI proof-of-concept trials. He also presented the study design and provided an update on the baseline demographic and clinical characteristics of initial subjects randomized in the ongoing Phase 1b/2a clinical trial. In addition, a protocol amendment was submitted to the Institutional Review Board and the U.S. Food and Drug Administration to modify eligibility criteria and testing requirements for the subacute cohort to facilitate enrollment and make participation less burdensome.
- We added to our pipeline of drug candidates.
 - We announced our plans to initiate preclinical evaluation of a potential second drug

candidate, NVG-300, in models of ischemic stroke, ALS and SCI. Pending successful preclinical validation and formulation development, NVG-300 may be developed under the Biologics License Application regulatory framework providing 12 years of market exclusivity post-approval. NVG-300's composition of matter intellectual property protection is expected to extend beyond 2040. The discovery of NVG-300 is the result of a research effort initiated by NervGen in 2022. NVG-300's product and process development have progressed to successfully establish the manufacturability and feasibility of high-concentration liquid formulation to enable self-administration of the product in a prefilled syringe format.

- We held our Annual General Meeting and added additional pharmaceutical experience to our Board of Directors.
 - We held our Annual General Meeting on June 4, 2024. All resolutions submitted for approval were passed by shareholders including the election of directors, appointment of auditors and certain amendments to our existing stock option plan including an increase in the number of shares reserved for issuance. Bill Radvak, NervGen's former Executive Chairman did not stand for reelection. Subsequent to the meeting, Glenn Ives was appointed as the new Chair of the Board and John Ruffolo as Audit Committee Chair. In addition, Neil Klompas, a seasoned pharmaceutical executive with extensive experience in high-growth companies joined our Board subsequent to the end of the quarter.

Financial Highlights

- **Cash and Investments:** NervGen had cash and cash equivalents of \$26.6 million as of June 30, 2024, compared to \$11.7 million as of December 31, 2023. The net cash burn for Q2 2024 from operating activities was approximately \$4.2 million. This was offset by approximately \$0.1 million in net proceeds from financing activities during the quarter.
- **R&D Expenses:** Research and development expenses were \$3.8 million for the three months ended June 30, 2024, compared to \$1.5 million in the same period in 2023. The increase in the current period pertain 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 quarter. A decrease in preclinical study costs in the quarter compared to costs spent last year to enable us to expand our clinical trials was offset by 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 \$2.2 million for the three months ended June 30, 2024, compared to \$3.3 million for the same period in 2023. The decrease in the current period was primarily due to non-cash stock-based compensation expense related to option and retention security grants, and the timing of the related vesting. Investor and public relations pertaining to federal and state government relations, public affairs, strategic communications, and other consulting services were also reduced from the prior period.
- **Net Loss:** For the three months ended June 30, 2024, our net loss was \$7.8 million (\$0.11 loss per basic and diluted common share), which included \$3.2 million of non-cash expenses pertaining to amortization, stock-based compensation and a \$2.2 million non-cash loss due to the fair value adjustment of the warrant derivative, and offset by a \$0.3 million unrealized foreign exchange gain on cash. For the three months ended June 30, 2023, net loss was \$4.8 million (\$0.08 loss per basic and diluted common share), which included \$2.3 million of non-cash expenses.

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

The double-blind, placebo-controlled proof-of-concept trial (NCT05965700) will evaluate the efficacy of NVG-291 in two separate cohorts of individuals with cervical spinal cord injury: chronic (1-10 years post-injury) and subacute (those with a more recent 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. Each cohort 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 that 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 enable nervous system repair in the settings of traumatic injury and disease. NervGen's lead drug candidate, NVG-291, is being evaluated in a Phase 1b/2a clinical trial in the company's initial target indication, spinal cord injury. The company 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 mechanisms that interfere with nervous system repair. NVG-291 is derived from the intracellular wedge domain of the receptor type protein tyrosine phosphatase sigma (PTP σ). NVG-291-R, a rodent analog of NVG-291, has been shown to promote nervous system repair and functional recovery in animal models of spinal cord injury (acute and chronic intervention), peripheral nerve injury, multiple sclerosis and stroke, through enhanced plasticity, axonal regeneration, and remyelination. 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, study design, planned clinical endpoints, timing, expected rate of enrollment and data readout of our Phase 1b/2a clinical trial in individuals with spinal cord injury; the expected benefits of our proposed protocol amendments and initiatives; the development plans, timelines and expected benefits from NVG-300; the receipt of the milestone-based grant payments; the belief that targeting mechanisms that interfere with nervous system repair is a promising target for reducing the clinical effects of nervous system damage through multiple mechanisms; and the creation of innovative treatments of nervous system damage due to trauma or 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, the Company has relied on various assumptions, including, but not limited to: the Company's ability to manage the effects of pandemics such as COVID-19; the accuracy of the Company's financial projections; the Company obtaining positive results in its clinical and other trials; the Company obtaining necessary regulatory approvals; 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, the impact of pandemics such as COVID-19, 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, Prospectus Supplement, financial statements and Management Discussion and Analysis which can be found on [SEDARplus.ca](https://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.



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