

# NervGen Pharma Reports Q3 2023 Financial Results and Operational Updates

- Phase 1a/2b clinical trial of NVG-291 underway with dosing of individuals with spinal cord injury; results from chronic cohort expected in mid-2024
- Fast Track designation granted by U.S. Food and Drug Administration (FDA) for NVG-291 in spinal cord injury
- Seasoned financial industry executive, John Ruffolo, appointed to Board

Vancouver, British Columbia--(Newsfile Corp. - November 9, 2023) - **NervGen Pharma Corp. (TSXV: NGEN) (OTCQX: NGENF)** ("NervGen" or the "Company"), a clinical stage biotech company dedicated to developing innovative solutions for the treatment of nervous system damage, today reported its financial and operational results for the third quarter ended September 30, 2023.

"We've made great progress recently starting with the dosing of subjects in our landmark Phase 1a/2b clinical study of NVG-291 for individuals with spinal cord injury, followed by receiving Fast Track designation from the FDA for NVG-291 in spinal cord injury," said [Mike Kelly](#), NervGen's President & CEO. "Additionally, we are very fortunate to have John Ruffolo join our Board. John brings substantial expertise in the finance and capital arena along with his personal experience and passion to advance therapies in spinal cord injury and we look forward to benefiting from his substantial expertise."

"The FDA's decision to grant Fast Track designation for NVG-291 is a big step forward for our development program and it underscores the significance and severity of the unmet medical need that exists for individuals living with spinal cord injury and their caregivers," continued Mr. Kelly. "Our clinical trial is an important proof-of-concept study aimed at demonstrating the potential NVG-291 may have in enabling repair of nervous system damage in individuals with spinal cord injury, which has never been achieved before."

## Operational Highlights for Q3 2023

- We advanced the clinical development of NVG-291.
  - In August, we received Institutional Review Board approval of our landmark Phase 1b/2a proof-of-concept clinical trial of NVG-291, in individuals with spinal cord injury (SCI) and in September we announced that the first subject was dosed in this trial.
  - Subsequent to the quarter-end, we announced that the FDA has granted Fast Track designation for NVG-291 in individuals with spinal cord injury. FDA's Fast Track program is designed to facilitate the development of drugs intended to treat serious conditions and fill unmet medical needs as part of the FDA's goal to get important new drugs to patients earlier. Fast Track designation also provides eligibility for both Priority Review, which can shorten the New Drug Application review process, and for Accelerated Approval, which can allow for an earlier or faster approval based on a surrogate or intermediate clinical endpoint.
- We expanded the expertise of our Board with the following addition.
  - Subsequent to the quarter-end, we announced the appointment of John Ruffolo, Founder and Managing Partner of Maverix Private Equity, to the Company's Board of Directors. Mr. Ruffolo previously founded OMERS Ventures, the venture capital arm of the large Ontario pension fund, and championed Canada's technology industry as a co-founder of the Council of Canadian Innovators. Mr. Ruffolo brings substantial expertise in finance and developing leading-edge technologies to our Board, and he also brings the very unfortunate experience of surviving a tragic accident, which resulted in severe injuries including a spinal cord injury.
- We improved our cash position with equity proceeds and grant funding to support our ongoing clinical and preclinical activities.

- During the nine months ended September 30, 2023, we received \$767,211 from the exercise of stock options and Common Share Purchase Warrants.
- On June 27, 2023, we announced that we had been [awarded a grant of up to US\\$3.18 million from Wings for Life](#), a not-for-profit spinal cord injury research foundation, under the foundation's Accelerated Translational Program. The funding is being provided in several milestone-based payments and will offset a portion of the direct costs of our Phase 1b/2a proof-of-concept clinical trial for NVG-291. As at September 30, 2023, we have achieved three of the five milestones in the grant, and received US\$1.92 million.

## Financial Highlights

- **Cash and Investments:** NervGen had cash and investments of \$14.8 million as of September 30, 2023, compared to \$22.5 million as of December 31, 2022. The net cash burn for Q3 2023 from operating and investing activities was approximately \$1.6 million. This was offset by approximately \$0.1 million in proceeds from the exercise of options and warrants during the quarter.
- **R&D Expenses:** Research and development expenses net of grant funding received were \$0.8 million for the three months ended September 30, 2023, compared to \$3.2 million in the same period in 2022. The decrease in Q3 2023 was primarily due to the receipt of grant funding from Wings for Life which offset the startup costs for our Phase 1b/2a proof-of-concept clinical trial, chemistry, manufacturing and control work pertaining to the manufacture of NVG-291 required for chronic toxicology studies and clinical trials conducted in the previous period, as well as a decrease in clinical and regulatory costs as we completed our Phase 1 clinical study.
- **G&A Expenses:** General and administrative expenses were \$2.6 million for the three months ended September 30, 2023, compared to \$1.7 million for the same period in 2022. The increase in Q3 2023 was primarily due to non-cash stock-based compensation expense related to option and retention security grants to our new President & CEO, other employees and consultants, and the timing of the related vesting, partially offset by a decrease in employee salaries related to severance payments to our previous President & CEO in the prior period.
- **Net Loss:** For the three months ended September 30, 2023, net loss, which included \$2.8 million of non-cash expenses, was \$4.3 million, or \$0.07 per basic and diluted common share. For the three months ended September 30, 2022, net loss, which included \$1.2 million of non-cash expenses, was \$3.5 million, or \$0.06 per basic and diluted common share.

## 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 $\sigma$ ). NVG-291-R, a rodent analog of NVG-291, has been shown to promote nervous system repair and functional recovery in preclinical models of spinal cord injury (acute and chronic intervention), peripheral nerve injury, multiple sclerosis and stroke, through enhanced plasticity, axonal regeneration, and remyelination. NervGen has initiated a Phase 1b/2a placebo-controlled proof-of-concept trial (NCT05965700) to 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 (10-49 days post-injury), given demonstrated efficacy in preclinical models of both chronic and acute spinal cord injury. Initial results for the chronic cohort are expected in mid-2024.

## About NervGen

NervGen (TSXV: NGEN) (OTCQX: NGENF) is a clinical stage biotech company dedicated to developing innovative treatments that enable the nervous system to repair itself following damage, whether due to injury or disease. NervGen's lead drug candidate, NVG-291, is to be evaluated in a Phase 1b/2a clinical trial. The Company's initial target indication is spinal cord injury. For more information, go to [www.nervgen.com](http://www.nervgen.com) and follow NervGen on [Twitter](#), [LinkedIn](#), and [Facebook](#) 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. 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, timing, rate of subject recruitment and study design of the clinical development of NVG-291 including the planned single site Phase 1b/2a clinical trial in SCI; the expected benefit of Fast Track designation and its potential impact for the timeline for approval of NVG-291; the expected contributions of our new Board member; the expected contribution of grant funding to our clinical trial costs; our initial target indication of spinal cord injury; the belief that modulating the activity of PTP $\sigma$  is a promising target for reducing the clinical effects of nervous system damage through multiple mechanisms; and the creation of innovative treatments that enable the nervous system to repair itself following damage, whether due to injury 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 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 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, Short Form Base Shelf Prospectus, 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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