



**ANNUAL INFORMATION FORM  
FOR THE YEAR ENDED DECEMBER 31, 2023**

[www.nervgen.com](http://www.nervgen.com)

Unless otherwise indicated, all information in the Annual Information Form is presented as at and for the year ended December 31, 2023

**October 28, 2024**

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## INTRODUCTION AND FORWARD-LOOKING STATEMENTS

The information contained in this Annual Information Form (this “AIF”) is stated as at December 31, 2023, unless otherwise indicated.

All references in this AIF to “the Company”, “NervGen”, “we”, “us”, or “our” refer to NervGen Pharma Corp. and the subsidiary through which it conducts its business, unless otherwise indicated.

All amounts are in Canadian dollars, unless otherwise indicated.

This AIF includes certain statements that are “forward-looking information” within the meaning of applicable Canadian securities legislation (collectively, the “**forward-looking statements**”). Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenue or performance, capital expenditures, financing and other information that is not historical information. These statements appear in a number of different places in this AIF and can often be identified by words such as “anticipates”, “estimates”, “projects”, “expects”, “intends”, “believes”, “plans”, “will”, “could”, “may”, or their negatives or other comparable words. Such forward-looking statements are necessarily based on estimates and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements.

Forward-looking statements in this AIF, include, but are not limited to, statements relating to:

- requirements for, and the ability to obtain, future funding on favourable terms or at all;
- business strategy;
- expected future loss and accumulated deficit levels;
- projected financial position and estimated cash burn rate;
- expectations about the timing of achieving milestones and the cost of our development programs;
- our estimates of the size and characteristics of the potential markets for our product candidates;
- observations and expectations regarding the effectiveness of our lead compound, NVG-291, and the potential benefits to patients;
- the impact of pandemics or any escalation thereof on our operations;
- plans to use and evaluate NVG-291 and other potential drug candidates in our clinical development programs;
- plans to develop additional proprietary compounds that address nervous system repair;
- expectations and intended benefits of memorandums of understanding and agreements entered into with third parties;
- expectations about the timing with respect to commencement and completion of clinical trials;
- expectations about the timing and future plans with respect to preclinical and clinical studies;

- expectations relating to the removal of the partial clinical trial hold initiated by the U.S. Food and Drug Administration (“FDA”);
- expected results of toxicology studies with respect to NVG-291 and other potential drug candidates;
- expectations about our product candidates’ safety and efficacy;
- our ability to identify and secure sources of non-dilutive funding for the development of our product candidates and technologies;
- expectations regarding our ability to arrange for the manufacturing of our product candidates and technologies;
- expectations regarding the cost, progress and successful and timely completion of the various stages of the regulatory approval process;
- expectations about the potential benefits of Fast Track designation for NVG-291 in the treatment of spinal cord injury;
- ability to secure strategic partnerships with larger pharmaceutical and biotechnology companies;
- strategy to acquire and develop new product candidates and technologies and to enhance the safety and efficacy of existing products and technologies;
- plans to market, sell and distribute our products and technologies, if approved;
- expectations regarding the acceptance of our products and technologies by the market, if approved;
- expectations regarding the use of our products and technologies in treating diseases and medical disorders;
- ability to retain and access appropriate staff, management, and expert advisers;
- expectations with respect to existing and future contractual obligations, corporate alliances and licensing transactions with third parties, and the receipt and timing of any payments to be made by the Company or to the Company in respect of such arrangements; and
- our strategy and ability with respect to the protection of our intellectual property.

Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward-looking statements included in this AIF, we have made various material assumptions, including, but not limited to:

- our ability to obtain financing on acceptable terms;
- additional sources of funding, including grants and funding from partners;

- our ability to attract and retain skilled staff;
- favourable general business and economic conditions;
- pandemics not having a material impact on our operations;
- our future research and development plans proceeding substantially as currently envisioned;
- our ability to obtain positive results from our research and development activities, including clinical trials;
- future expenditures to be incurred by us;
- research and development and operating costs;
- our ability to find partners in the pharmaceutical industry;
- the products and technology offered by our competitors;
- the impact of competition on our operations;
- our ability to identify additional product candidates;
- our ability to obtain regulatory and other approvals to commence additional clinical trials involving current and future product candidates;
- our ability to successfully out-license or sell our future products, if any, and in-license and develop new products;
- our ability to protect patents and proprietary rights; and
- expected research and development tax credits.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein under the heading “Risk Factors”. Certain risks and uncertainties that could cause such actual events or results expressed or implied by such forward-looking statements and information to differ materially from any future events or results expressed or implied by such statements and information include, but are not limited to, the risks and uncertainties related to the fact that:

- we have a limited operating history, are early in our development efforts, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability;
- since our inception, we have incurred significant net losses and expect to continue to incur significant net losses for the foreseeable future and we may never achieve or maintain profitability;
- we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts;

- raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;
- our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited;
- we are substantially dependent on the success of our lead product candidate, NVG-291, which is currently in a Phase 1b/2a clinical trial for spinal cord injury (“**SCI**”). If we are unable to complete development of, obtain approval for and commercialize NVG-291 for SCI in a timely manner, our business will be harmed;
- there are currently no FDA-approved products for the treatment of SCI;
- the regulatory approval processes of the FDA, EMA, Health Canada and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to commercialize our product candidates and generate product revenue and our business will be substantially harmed;
- preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates;
- our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. NVG-291 for SCI is currently subject to a partial clinical hold by the FDA, and we may be unable to have the hold removed which could adversely affect development of NVG-291 and our results of operations;
- the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, Health Canada or other comparable foreign regulatory authorities;
- interim, initial, top-line, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- if we fail to develop and commercialize NVG-291 for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired;
- we may expend our limited resources to pursue a particular product or indication and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success;
- changes in methods of product candidate manufacturing or formulation may result in additional costs or delay;
- if we are unable to successfully develop companion diagnostics or biomarkers that may be required for our therapeutic product candidates, or experience significant delays in doing so, we

may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates;

- if we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected;
- as an organization, we have never conducted later-stage clinical trials or submitted a new drug application, and may be unable to do so for any of our product candidates;
- we face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted;
- Fast Track, Breakthrough Therapy designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates;
- we may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity;
- even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success;
- if the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer;
- if we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be successful in commercializing our product candidates that obtain regulatory approval;
- our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities of such materials on time or at an acceptable cost;
- we rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed;
- we may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans;
- if we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations;
- we may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets;
- even if our product candidates receive regulatory approval, they will be subject to significant post marketing regulatory requirements and oversight;

- obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions;
- any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations;
- we may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations;
- our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings;
- failure to comply with laws, rules, regulations, policies, industry standards and contractual obligations relating to privacy, data protection and data security could adversely affect our business;
- if we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business;
- disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business;
- we are subject to certain U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations;
- if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business;
- our success depends on our ability to protect our intellectual property and our proprietary technologies;
- if the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected;
- intellectual property rights do not necessarily address all potential threats to our competitive advantage;

- patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time;
- others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects;
- if we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates;
- we may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad;
- we may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates;
- changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates;
- we may not be able to protect or enforce our intellectual property rights throughout the world;
- if our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected;
- if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position;
- our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others;
- the patent protection and patent prosecution for some of our product candidates may be dependent on third parties;
- we depend heavily on our executive officers, principal consultants and others, and the loss of their services would materially harm our business;
- we only have a limited number of employees to manage and operate our business;
- our future growth may depend, in part, on our ability to operate internationally, where we would be subject to additional regulatory burdens and other risks and uncertainties;
- we expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations;
- the market price of our common shares (the "**Common Shares**") may be volatile, and you could lose all or part of your investment;
- sales of a substantial number of shares of our Common Shares in the public market could cause our share price to fall;

- we do not intend to pay dividends on our Common Shares in the foreseeable future, so any returns will be limited to the value of our Common Shares;
- if securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline;
- we have broad discretion in the use of the net proceeds from any offering and may not use them effectively;
- investing in our securities is speculative, and investors could lose their entire investment;
- our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval which could result in dilution;
- the exercise of stock options and warrants could cause dilution;
- we are likely a “passive foreign investment company,” which may have adverse U.S. federal income tax consequences for U.S. shareholders;
- it may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence;
- our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition;
- cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, contract research organizations, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations; and
- we may be subject to securities litigation, which is expensive and could divert management attention.

If one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from those expressed or implied by forward-looking statements. The forward-looking statements represent our views as of the date of this AIF. While we may elect to update these forward-looking statements in the future, we have no current intention to do so except as to the extent required by applicable securities law. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements. We advise you that these cautionary remarks expressly qualify in their entirety all forward-looking statements attributable to us or persons acting on our behalf.

## CORPORATE STRUCTURE

### ***Corporate Information***

The Company was incorporated under the Business Corporations Act (British Columbia) on January 19, 2017 under the name “1104403 B.C. Ltd.”. The Company changed its name to “NervGen Pharma Corp.” on November 15, 2017.

The Company’s head office is located at 112-970 Burrard Street, Unit 1290, Vancouver, British Columbia, V6Z 2R4 and its registered and records offices are located at 1133 Melville Street, Suite 3500, The Stack, Vancouver BC V6E 4E5, Canada.

On March 15, 2019, our Common Shares began trading under the symbol “NGEN” on the TSX Venture Exchange (“**TSX-V**”). On May 3, 2019, our Common Shares began trading under the symbol “NGENF” on the over-the-counter OTCQB® Venture Market (“**OTCQB**”).

### ***Intercorporate Relationships***

The Company has two wholly owned subsidiaries: NervGen US Inc. incorporated in the State of Delaware on June 11, 2018 and NervGen Australia Pty Ltd. registered in Queensland on December 8, 2020.

The Company does not hold securities in any other corporation, partnership, trust or other corporate entity.

## GENERAL DEVELOPMENT OF THE BUSINESS

### Year ended December 31, 2021

On March 4, 2021, we provided an update regarding our NVG-291 Investigational New Drug (“**IND**”) submission, announcing that we have been cleared by the FDA to proceed with the single ascending dose portion of our Phase 1 clinical trial in females, and the multiple ascending dose portion of the trial in post-menopausal females in Australia under all of the conditions required by the FDA once we obtained final approval from the ethics review board governing the study and provide notification to the Therapeutic Goods Administration.

On March 8, 2021, we announced that the European Medicines Agency (“**EMA**”) has granted Orphan Designation for the treatment of SCI to NVG-291, which provides NervGen with multiple incentives, including improved access to scientific advice, fee reductions, and 10 years of protection from market competition in Europe from similar medicines with similar indications following the date that the drug candidate receives marketing authorization (market exclusivity).

On April 22, 2021, we announced that we have hired Daniel Mikol, MD, PhD as our Chief Medical Officer, effective May 5, 2021. Dr. Mikol joined us from Amgen where he was Executive Director and Global Therapeutic Development Head, Neurology and Nephrology. Dr. Mikol is a Board-Certified Neurologist and is overseeing our medical and clinical activities, with a primary focus on NVG-291.

On May 6, 2021, we announced that we have dosed the first subject in our Phase 1 clinical trial for NVG-291 in healthy volunteers.

On May 12, 2021, we issued 3,250,000 units of the Company at a price of \$1.55 per unit for aggregate gross proceeds of \$5,037,500 (the “**May 2021 Offering**”). Each unit is comprised of one Common Share and one-half Common Share purchase warrant of the Company. Each warrant is exercisable to acquire one Common Share at an exercise price of \$2.10 until May 12, 2023. 195,000 brokers’ warrants were also issued, exercisable to acquire one Common Share at the exercise price of C\$1.55 per Common Share, until May 12, 2023.

On August 4, 2021, we completed a financing comprised of the sale of 1,511,636 units of the Company for aggregate gross proceeds of \$2,343,036 (the “**August 2021 Private Placement**”). Each unit is comprised of one Common Share and one-half Common Share purchase warrant. Each full warrant is exercisable to acquire one Common Share at an exercise price of \$2.10 per Common Share, until August 4, 2023. 29,400 non-transferable finders’ warrants were also issued, exercisable to acquire one Common Share at the exercise price of C\$2.10 per Common Share, until August 4, 2023.

On September 10, 2021, we announced the addition of Krista McKerracher and Glenn Ives to our Board of Directors. Ms. McKerracher is a biopharmaceutical leader, Board member, and strategic advisor with 35 years’ experience in both large global pharmaceutical and small biotech companies. Mr. Ives is a senior accounting professional with strong finance experience having served as the Executive Chair of Deloitte Canada and the Chair of the Deloitte Global Risk Committee.

On September 27, 2021, we announced a partnership with Imeka Solutions Inc. (“**Imeka**”). We intend to utilize Imeka’s imaging technology as a sensitive pharmacodynamic biomarker for our lead compound, NVG-291, in our Phase 1b/2 clinical trials. Additionally, we are submitting non-dilutive grants that support combining our technologies in preclinical and clinical studies for various conditions related to central nervous system damage.

On October 18, 2021, we provided a positive update on our Phase 1 program with NVG-291 in healthy volunteers at the 14th Annual Meeting of the American Neurological Association. NervGen’s Chief Medical Officer, Dr. Daniel Mikol, presented interim blinded data from the single ascending dose (“**SAD**”)

cohort of the study that demonstrated that NVG-291 was well tolerated and had favorable pharmacokinetic properties.

On October 27, 2021, we announced the formation of a Spinal Cord Injury Clinical Advisory Board comprised of five world-class scientific and clinical researchers in the field of spinal cord injury. This Clinical Advisory Board worked closely with us on the preparations for our Phase 1b/2a clinical trial in SCI with NVG-291.

On November 12, 2021, we completed a financing comprised of the sale of 3,680,000 units of the Company for aggregate gross proceeds of \$9,200,000, including full exercise of the underwriters' over-allotment option of 480,000 units (the "**November 2021 Offering**"). Each unit is comprised of one Common Share and one-half Common Share purchase warrant. Each full warrant is exercisable to acquire one Common Share at an exercise price of \$3.20 per Common Share, until November 12, 2023. 257,600 non-transferable broker warrants were also issued, exercisable to acquire one Common Share at the exercise price of \$2.50 per Common Share, until November 12, 2023.

On November 29, 2021, we completed a private placement comprised of the sale of 892,721 units of the Company at a price of \$2.60 per unit, for aggregate gross proceeds of \$2,321,075 (the "**November 2021 Private Placement**"). Each unit is comprised of one Common Share and one-half Common Share purchase warrant. Each full warrant is exercisable to acquire one Common Share at an exercise price of \$3.20 per Common Share, until November 29, 2023.

On December 22, 2021, we received ethics board approval from HREC to proceed with the multiple ascending dose ("**MAD**") portion of our Phase 1 trial.

#### Year ended December 31, 2022

On January 10, 2022, we announced that we entered into a Memorandum of Understanding with Shirley Ryan AbilityLab with the intention of performing our first clinical trial in spinal cord injury patients. The single site clinical trial, will be a placebo-controlled trial, assessing the safety and efficacy of NVG-291 in treating acute/subacute (<3 months post-injury) and chronic (≥1 year post-injury) patients.

On March 15, 2022, we announced that we received approval from the Safety Review Committee to advance to the second cohort in the MAD portion of our Phase 1 clinical trial.

On April 3, 2022, our Chief Medical Officer, Dr. Dan Mikol, presented unblinded data from the SAD cohort of the Phase 1 clinical trial, and interim blinded data from the MAD portion of the study, at the 2022 American Academy of Neurology Annual Meeting. Dr. Mikol reported that the NVG-291 dose administered in the first MAD cohort is already above the highest corresponding dose found to be efficacious in animal models and is substantially higher than the lower effective doses where dramatic functional improvements were observed. Additionally, the day 1 and day 14 pharmacokinetic characteristics for NVG-291 at the tested dose level were very similar to each other and to those for the same dose level in the SAD portion of the Phase 1 study. A reproducible pharmacokinetic profile is a highly desirable property for any drug being developed for human use.

On April 13, 2022, we announced the appointment of Craig Thompson to our Board of Directors. Mr. Thompson brings broad leadership experience and a proven track record of successful drug development and biotech fundraising, licensing, mergers and acquisitions. Concurrently with Mr. Thompson joining the Board, Dr. Michael Abrams resigned from the Board.

On May 12, 2022, we announced that we had received approval from the Safety Review Committee to advance to the third and highest dose cohort in the MAD portion of our Phase 1 clinical trial.

On May 18, 2022, we hosted a 1-hour panel discussion at the 2022 American Spinal Cord Injury Association annual meeting held in New Orleans, Louisiana. In the translational research session, entitled “Translating Positive results with NVG-291 from Animals to Patients”, Dr. Daniel Mikol, provided an update on the Phase 1 clinical trial in healthy subjects. He also provided an overview of the Phase 1b/2a placebo-controlled clinical trial in spinal cord injury.

On July 13, 2022, we closed a non-brokered private placement of 10,150,000 units at a price of U.S.\$1.50 per unit, for aggregate gross proceeds of U.S.\$15,225,000 (\$19,783,500) (the “**July 2022 Non-Brokered Private Placement**”). Each unit consisted of one Common Share and one-half of one Common Share purchase warrant. Each whole warrant is exercisable into one Common Share at a price of U.S.\$1.75 per Common Share until July 13, 2027. The Company also paid certain finders a fee of 500,000 Common Shares at a price of U.S.\$1.50 per Common Share. In connection with the July 2022 Non-Brokered Private Placement, Adam Rogers, MD, Manager of PFP Biosciences Holdings, was appointed to NervGen’s Board of Directors.

On July 28, 2022, we announced that the University of Cincinnati and Case Western Reserve University have published a pioneering preclinical study in a peer-reviewed scientific journal demonstrating that NervGen’s proprietary drug, NVG-291-R, promotes nervous system repair and significant improvement in motor function, sensory function, spatial learning, and memory in a mouse model of severe ischemic stroke, even when treatment was initiated up to 7 days after onset.

On August 3, 2022, Dr. Dan Mikol, presented unblinded data from the SAD cohort of the Phase 1 clinical trial, and interim blinded data from the MAD portion of the study, at the 2022 Alzheimer’s Association International Conference and for the first time introduced the study design for a potential Phase 1b/2a trial of NVG-291, in subjects with mild cognitive impairment or mild dementia due to Alzheimer’s disease.

On September 12, 2022, we announced the appointment of Dr. Matvey Lukashev, as our Vice President, Research and Preclinical Development. Dr. Lukashev has over 30 years of research experience in academia, industry, and non-profit biotech settings and will lead the development of NVG-291, beyond its initial formulation and core indications, and build a pipeline of additional proprietary compounds that address nervous system repair.

On September 22, 2022, we announced the appointment of our current Executive Chairman of the Board Bill Radvak as Interim Chief Executive Officer (“**CEO**”) and current Board member Dr. Adam Rogers as Interim President, replacing Paul Brennan who served as a strategic advisor to management and the Board during the transition period. The Board initiated a search for a permanent CEO.

On October 12, 2022, we announced that we have been awarded up to US\$1.5 million in US Department of Defense funding from the Military Operational Medicine Research Program to conduct preclinical studies to evaluate NVG-291 as a therapeutic that restores function following peripheral nerve injury.

On October 25, 2022, we announced that the FDA has amended the partial clinical hold to permit the inclusion of males and premenopausal females at certain dose levels in our Phase 1 clinical trial and we completed enrollment of the third and final MAD cohort of postmenopausal women.

On November 14, 2022, we announced that the FDA amendment of partial clinical hold allowed for bridging cohorts of males and premenopausal females in the Phase 1 trial to commence. Also on November 14, 2022, we announced that Glenn Ives was appointed by our Board to serve as Lead Independent Director to lead and facilitate governance oversight and deliberations of the Board during the transition period in selecting a new CEO.

On November 17, 2022, we announced that the US Patent and Trade Office has issued US Patent No. 11,497,812 B2 Compositions and Methods for Inhibiting the Activity of LAR Family Phosphatases to Case Western Reserve University. NervGen has an exclusive worldwide license to this patent and

related proprietary technology which forms the technological foundation of its NVG-291 drug development program.

Year ended December 31, 2023

On February 14, 2023, we announced that we have completed dosing of all subjects in the NVG-291 Phase 1 clinical trial and that we plan to initiate a Phase 1b/2a clinical trial of NVG-291 in individuals with spinal cord injury in Q3 2023. We also reported that, while the data from the last male and female cohorts have not yet been unblinded, there have been no serious adverse events reported in subjects receiving NVG-291.

On April 10, 2023, we announced that we had hired Mike Kelly as our President & CEO. Mr. Kelly brings three decades of pharmaceutical experience, playing instrumental roles in the creation, development and strengthening of several companies. Concurrent with Mr. Kelly's appointment, Mr. Radvak, Dr. Rogers and Mr. Ives stepped down from their positions of Interim CEO, Interim President and Lead Independent Director respectively but remained members of the Board. Mr. Radvak remained as Chairman of the Board.

Also in April 2023, our Chief Medical Officer, Dr. Dan Mikol presented the study design for our Phase 1b/2a clinical trial of NVG-291 in spinal cord injury and summarized the safety and pharmacokinetic results from the Phase 1 trial of NVG-291 in healthy volunteers at the American Spinal Injury Association 50th Annual Scientific Meeting.

On June 27, 2023, we announced that we had been awarded a grant of up to US\$3.18 million (CA\$4.22 million) from Wings for Life, a not-for-profit spinal cord injury research foundation, under the foundation's Accelerated Translational Program. The funding is to be provided in several milestone-based payments will offset a portion of the direct costs of our Phase 1b/2a proof-of-concept clinical trial for NVG-291, in individuals with SCI. Additionally, the FDA completed their review of our clinical trial protocol and determined that the study may proceed. Then on August 8, 2023, we announced that we received Institutional Review Board approval for this study, and recruitment was initiated.

On September 25, 2023, we announced that the first subject was dosed in our Phase 1b/2a proof-of-concept clinical trial protocol of NVG-291, in individuals with SCI.

On October 17, 2023, 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 will provide 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.

On October 23, 2023, 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 also provides eligibility for both Priority Review, which can shorten the New Drug Application (NDA) review process, and for Accelerated Approval, which can allow for an earlier or faster approval based on a surrogate or intermediate clinical endpoint.

Subsequent to December 31, 2023

On February 15, 2024, we provided an update on the timing for enrollment and delivery of the data readout of the chronic cohort in the Company's Phase 1b/2a proof-of-concept, double blind, randomized placebo-controlled clinical trial for our proprietary investigational lead compound, NVG-291, in

individuals with SCI. Additionally, 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 NVG-291 under a separate open-label 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.

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 to the Company of \$23,011,788 (the "**March 2024 Offering**"). The March 2024 Offering was made pursuant to an underwriting agreement entered into with a syndicate of underwriters led by Stifel Canada and including Canaccord Genuity Corp. and PI Financial Corp. Pursuant to the March 2024 Offering, the underwriters purchased, on a "bought deal" basis, and the Company issued 9,792,250 units at a price of \$2.35 per unit including the full exercise of the underwriters' over-allotment option. 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 March 2024 Offering at an exercise price of \$3.00 per warrant share. In connection with the March 2024 Offering, we issued an aggregate of 170,127 broker warrants to the underwriters. Each broker warrant is exercisable to acquire one Common Share at the exercise price of \$2.35 per Common Share for a period of 24 months from the closing date of the March 2024 Offering. The Company also paid a cash commission of \$1,090,152 to the underwriters and incurred approximately \$540,000 in other share issue costs related to legal and listing fees.

On May 20 and 21, 2024, Dr. Dan 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 provided an update on the baseline demographic and clinical characteristics of initial subjects randomized in the ongoing Phase 1b/2a clinical trial, which evaluates MEPs and other electrophysiological measures in target muscle groups as biomarkers of efficacy in addition to clinical assessments to monitor motor recovery.

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, our 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.

On June 25, 2024, we announced our plans to initiate a preclinical test of concept evaluation of our next pipeline candidate, NVG-300, in models of ischemic stroke, amyotrophic lateral sclerosis ("**ALS**") and spinal cord injury. 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 in 2022. NVG-300's 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.

On July 22, 2024, we announced the appointment of Neil Klompas to the Board. Mr. Klompas is a seasoned pharmaceutical executive with extensive experience in high-growth companies.

On September 30, 2024, we announced that target enrollment in the chronic cohort of our Phase 1b/2a clinical trial of NVG-291 in individuals with SCI is approaching completion.

## ***Significant Acquisitions and Dispositions***

Except as set forth herein, the Company has not completed any significant acquisitions for which disclosure would be required under Part 8 of National Instrument 51-102 as at the date hereof.

## **NARRATIVE DESCRIPTION OF THE BUSINESS**

### ***Overview of the Company***

Nervous system damage affects millions of people resulting in significant healthcare costs and symptoms ranging from loss of sensation to paralysis. Nervous system damage can occur from an acute physical trauma (e.g. spinal cord injury, traumatic brain injury), from chronic neurodegenerative diseases, such as multiple sclerosis, Alzheimer's disease, amyotrophic lateral sclerosis and Parkinson's disease, and from other conditions that result in brain, spinal cord or peripheral nerve damage, such as stroke, cancer, infectious diseases, diabetes and autoimmune disease. Following nervous system damage, the body responds with natural protective mechanisms, some of which prevent or inhibit neurorepair. There are currently no approved drugs available to repair damage to the nervous system to enable an individual to regain key bodily functions<sup>1</sup> or regain cognitive function<sup>2</sup>, which together affect millions of people and cost billions of healthcare dollars.

NervGen is a clinical stage biotech company dedicated to developing innovative treatments which may enable the nervous system to repair itself following damage, whether due to injury or disease. Our principal business activity is the discovery, development and commercialization of pharmaceutical products for the treatment of nervous system damage, with our initial focus on SCI. We are also utilizing our intellectual property and know-how to develop our products for other related medical conditions. We may seek Orphan Drug Designation, Fast Track Designation and/or Breakthrough Therapy Designation with the FDA when, and if applicable, should our research indicate that such an application may assist in the development of our drug candidates.

The Company currently has no commercial products or services and no operating revenues. The process of developing a drug and receiving the necessary regulatory approvals to sell a drug typically takes years and no near-term revenues from product sales or services are expected.

### ***Spinal Cord Injury***

SCI disrupts signals normally transmitted between the brain and the body that results in a loss of motor function, such as mobility, feeling, and/or autonomic function (for example, bladder control) in the parts of the body below the level of the injury. Injury can occur at any level of the spinal cord and can be complete injury, with a total loss of sensation and muscle function, or incomplete, meaning some signals are able to travel past the injured area of the spinal cord.

In the majority of cases, the damage results from physical trauma, such as falls, car accidents, sports or other injuries, but SCI can also result from non-traumatic causes, such as infections, surgical complications, insufficient blood flow, tumours or disease (e.g. stroke, demyelinating disease, etc.). The spinal cord does not have to be completely severed for a loss of function to occur. In fact, in most people with SCI, some areas of the spinal cord remain intact ("**tissue bridges**"). There are no approved pharmacologic therapies that enable repair following SCI.

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<sup>1</sup> Sami, Selzer and Li. Advances in the Signaling Pathways Downstream of Glial-Scar Axon Growth Inhibitors. *Frontiers in Cellular Neuroscience* **14**, doi:10.3389/fncel.2020.00174 (2020).

<sup>2</sup> Hsu, Lane and Lin. Medications Used for Cognitive Enhancement in Patients With Schizophrenia, Bipolar Disorder, Alzheimer's Disease, and Parkinson's Disease. *Frontiers in Psychiatry* **9**, doi:10/gdcwhj (2018).

According to data retrieved from the National Spinal Cord Injury Statistical Center<sup>3</sup>

- approximately 302,000 Americans are spinal cord injured;
- approximately 18,000 new injuries occur each year;
- the average lifetime costs for SCI patients, if the age of injury is 25, are US\$2.0 million to US\$5.8 million, depending on severity of the injury; and
- the average annual direct cost of SCI patients after the first year range from approximately US\$52,000 to US\$228,000, depending on severity of the injury.

### ***The Company's Lead Compound and License***

#### ***License Overview***

On June 25, 2018, NervGen entered into a licensing agreement with Case Western Reserve University (“CWRU”) granting a license (the “**License**”) to the Company to use certain licensed technology (the “**Technology**”). The License allows the Company to research, develop and commercialize a patented technology with therapeutic potential for SCI and other conditions associated with nerve damage. The License provides NervGen with an exclusive worldwide right to use the Technology relating to leukocyte-common antigen related (“**LAR**”) family function blocking peptides in diseases and injuries and applications thereof to research, develop, make, have made, use, dispose and import licensed products for all applications. The License also grants NervGen the right to use, develop and commercialize the Technology for all diseases and medical conditions including, but not limited to, SCI, peripheral nerve injury, MS, AD, stroke and acute myocardial ischemia. Included in the License is U.S. Patent 9,937,242 entitled “Compositions and Methods for Inhibiting the Activity of LAR Family Phosphatases” issued by the United States Patent and Trademark Office, as well as its equivalent in other jurisdictions around the world. This patent and its equivalents in other global jurisdictions, is central to our development and commercialization of the Technology. The License also includes other patents and patent applications encompassing claims related to the use of the licensed technology in various diseases such as MS, AD, stroke and acute myocardial ischemia.

#### ***Key License Terms***

Following execution of the licensing agreement, CWRU was issued 439,000 Common Shares valued at \$87,800 and paid \$32,920 (US\$25,000). An additional 162,659 Common Shares valued at \$81,330 were issued to CWRU on September 13, 2018. Pursuant to the licensing agreement, CWRU had a pre-emptive right to maintain its percentage ownership and participate in any further financings on the same terms as other investors until the Company completed its IPO.

The License has a term which expires on the latest to occur of the expiration date of the last-to-expire valid claim of any related patent, the end of the last-to-expire market exclusivity period for any licensed product or June 25, 2038.

The Company is required to meet certain milestones under the License and has the option to extend the date of any such milestone obligation for up to two periods of six months each upon the payment of certain prescribed fees. Should we elect not to extend the obligation or fail to meet the extended obligation date, then CWRU has the right to either terminate the License or convert the License into a non-exclusive license. The License includes a multi-step dispute resolution process, including right to

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<sup>3</sup> National Spinal Cord Injury Statistical Center. “Traumatic Spinal Cord Injury Facts and Figures at a Glance.” *Birmingham, AL: University of Alabama at Birmingham, 2023.*

arbitration to be conducted in Chicago, Illinois in accordance with the then current Licensing Agreement Rules of the American Arbitration Association.

We are required to give a right of first preference to CWRU in respect of any clinical studies arising from any licensed products under the License.

If the License is terminated prior to a change of control of the Company, then, from the date of termination until such date of a change of control, CWRU will be granted an internal, fully paid up, perpetual, non-exclusive license to use any patents forming part of the licensed Technology for research or educational purposes.

## The Technology

NVG-291 technology is licensed from CWRU and based on academic studies that demonstrated the preclinical efficacy of NVG-291-R, the rodent prototype of NVG-291, in animal models of SCI. These studies implicated several potential molecular and cellular mechanisms by which NVG-291-R promotes neurorepair and functional improvement in both central and peripheral nervous system injury models. The implicated mechanisms include the promotion of neuronal sprouting, or plasticity<sup>4 5 6 7 8 9 10</sup>, remyelination<sup>11 12 13 14 15 16 17</sup>, and promotion of a non-inflammatory phenotype in the microglial cells<sup>18 19 20 21</sup>.

## NVG-291

Our lead molecule NVG-291 is a humanized analog of NVG-291-R. NVG-291 is a 35 amino acid-long synthetic peptide composed of the cell-penetrating transactivator of transcription<sup>22</sup> sequence fused to a sequence derived from the wedge domain of PTPRS (“PTP $\sigma$ ”).

NVG-291 is currently being evaluated in clinical trials as a once-daily subcutaneous injection; the duration of treatment will depend upon the condition being treated.

## Spinal Cord Injury

The robust preclinical efficacy consistently observed in independently conducted studies across a range of animal SCI models, as well as the potential for a good safety profile, and the opportunity to treat a severely debilitating and life-threatening medical condition of high unmet need with effective

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<sup>4</sup> Ham, Farrag, Soltisz, Lakes, Allen and Leipzig. Automated Gait Analysis Detects Improvements after Intracellular  $\sigma$  Peptide Administration in a Rat Hemisection Model of Spinal Cord Injury. *Ann Biomed Eng* **47**, 744-753, doi:10/gftgtz (2019).

<sup>5</sup> Lang, Cregg, DePaul, Tran, Xu, Dyck, Madalena, Brown, Weng, Li, Karimi-Abdolrezaee, Busch, Shen and Silver. Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury. *Nature* **518**, 404-408, doi:10/gfkk8 (2015).

<sup>6</sup> Rink, Arnold, Wöhler, Bendella, Meyer, Manthou, Papamitsou, Sarikcioglu and Angelov. Recovery after spinal cord injury by modulation of the proteoglycan receptor PTP $\sigma$ . *Exp Neurol* **309**, 148-159, doi:10/gfdh8f (2018).

<sup>7</sup> Tran, Sundar, Yu, Lang and Silver. Modulation of Receptor Protein Tyrosine Phosphatase Sigma Increases Chondroitin Sulfate Proteoglycan Degradation through Cathepsin B Secretion to Enhance Axon Outgrowth. *The Journal of Neuroscience* **38**, 5399-5414, doi:10/gdrsh2 (2018).

<sup>8</sup> Luo, Wang, Zhang, You, Bedolla, Okwubido-Williams, Huang, Silver and Luo. Inhibition of CSPG receptor PTP $\sigma$  promotes migration of newly born neuroblasts, axonal sprouting, and recovery from stroke. *Cell Reports* **40**, 111137, doi:10/gqkdqz (2022).

<sup>9</sup> Yao, Fang, Li, Ng, Liu, Leung, Song, Zhang and Chang. Modulation of the proteoglycan receptor PTP $\sigma$  promotes white matter integrity and functional recovery after intracerebral hemorrhage stroke in mice. *J Neuroinflammation* **19**, 207, doi:10/gqr8hg (2022).

<sup>10</sup> Milton, Silver, Kwok, McClellan, Warren and Silver. Recovery of forearm and fine digit function after chronic spinal cord injury by simultaneous blockade of inhibitory matrix CSPG production and the receptor PTP $\sigma$ . doi:10.1101/2022.08.01.502398 (2022).

<sup>11</sup> Dyck, Kataria, Akbari-Kelachayeh, Silver and Karimi-Abdolrezaee. LAR and PTP $\sigma$  receptors are negative regulators of oligodendrogenesis and oligodendrocyte integrity in spinal cord injury. *Glia* **67**, 125-145, doi:10/gfkmbt (2018).

<sup>12</sup> Li, Wong, Li, Ruven, He, Wu, Lang, Silver and Wu. Enhanced regeneration and functional recovery after spinal root avulsion by manipulation of the proteoglycan receptor PTP $\sigma$ . *Scientific Reports* **5**, 1-14, doi:10/gfkk9 (2015).

<sup>13</sup> Luo, Tran, Xin, Sanapala, Lang, Silver and Yang. Modulation of proteoglycan receptor PTP $\sigma$  enhances MMP-2 activity to promote recovery from multiple sclerosis. *Nature Communications* **9**, 1-16, doi:10/gfb3xm (2018).

<sup>14</sup> Niknam, Raoufy, Fathollahi and Javan. Modulating proteoglycan receptor PTP $\sigma$  using intracellular sigma peptide improves remyelination and functional recovery in mice with demyelinated optic chiasm. *Molecular and Cellular Neuroscience* **99**, 103391, doi:10/gf4mn6 (2019).

<sup>15</sup> Yao, Sun, Yuan, Li, Li, Tang, Leung and Wu. Targeting proteoglycan receptor PTP $\sigma$  restores sensory function after spinal cord dorsal root injury by activation of Erks/CREB signaling pathway. *Neuropharmacology* **144**, 208-218, doi:10/gfkkw7 (2019).

<sup>16</sup> Yao, Fang, Tao, Feng, Wei, Gao, Xin, Li and Du. Modulation of proteoglycan receptor regulates RhoA/CRMP2 pathways and promotes axonal myelination. *Neuroscience Letters* **760**, 136079, doi:10/gksprh (2021).

<sup>17</sup> Yao, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes white matter integrity and functional recovery after intracerebral hemorrhage stroke in mice," (2022); Yao, et al., "Modulation of proteoglycan receptor regulates RhoA/CRMP2 pathways and promotes axonal myelination," (2021).

<sup>18</sup> Luo, et al., "Modulation of proteoglycan receptor PTP $\sigma$  enhances MMP-2 activity to promote recovery from multiple sclerosis," (2018).

<sup>19</sup> Niknam, et al., "Modulating proteoglycan receptor PTP $\sigma$  using intracellular sigma peptide improves remyelination and functional recovery in mice with demyelinated optic chiasm," (2019).

<sup>20</sup> Dyck, Kataria, Alizadeh, Santhosh, Lang, Silver and Karimi-Abdolrezaee. Perturbing chondroitin sulfate proteoglycan signaling through LAR and PTP $\sigma$  receptors promotes a beneficial inflammatory response following spinal cord injury. *J Neuroinflammation* **15**, 90, doi:10/gfv9pp (2018).

<sup>21</sup> Yao, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes white matter integrity and functional recovery after intracerebral hemorrhage stroke in mice," (2022).

<sup>22</sup> Lang. THE ROLE OF PTP $\sigma$  IN REGENERATION FAILURE FOLLOWING SPINAL CORD INJURY. [https://etd.ohiolink.edu/etd.send\\_file?accession=case1417619755&disposition=inline](https://etd.ohiolink.edu/etd.send_file?accession=case1417619755&disposition=inline), 212 (2015).

pharmacologic treatment options, provide the basis for our plans to focus our early efforts on SCI. Notable NVG-291-R effects observed in the preclinical SCI studies include:

- Enhanced recovery of motor function with a significant percentage of injured animals achieving nearly complete recovery<sup>23 24</sup>;
  - NVG-291-R produced lasting improvement in locomotion after a finite period of daily injections followed by a treatment-free observation period. This therapeutic effect of NVG-291-R was maintained with an apparent trend toward further improvement after cessation of the dosing<sup>25 26 27 28</sup>;
- NVG-291-R also produced lasting improvement in bladder functions after a finite period of daily injections<sup>29 30</sup>;
  - all spinal cord injured animals experienced partial to near complete recovery of bladder function at the top dose tested<sup>31</sup>;
- The positive effects of NVG-291-R were observed when NVG-291-R treatment was initiated acutely (24 hours)<sup>32 33</sup> or chronically (3 months)<sup>34</sup> following injury in the rat SCI model; and
- Similar positive results have been reported in multiple studies conducted independently by several laboratories' SCI studies<sup>35 36 37 38 39 40</sup>.

### **Other Diseases**

The potential therapeutic utility of NVG-291 in medical conditions other than SCI was assessed in preclinical models of ischemic<sup>41 42</sup> and hemorrhagic<sup>43</sup> stroke, MS<sup>44</sup>, peripheral nerve injury<sup>45 46 47 48</sup>,

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<sup>23</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>24</sup> Rink, et al., "Recovery after spinal cord injury by modulation of the proteoglycan receptor PTP $\sigma$ ," (2018).

<sup>25</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>26</sup> Rink, et al., "Recovery after spinal cord injury by modulation of the proteoglycan receptor PTP $\sigma$ ," (2018).

<sup>27</sup> Ham, et al., "Automated Gait Analysis Detects Improvements after Intracellular  $\sigma$  Peptide Administration in a Rat Hemisection Model of Spinal Cord Injury," (2019).

<sup>28</sup> Milton, et al., "Recovery of forearm and fine digit function after chronic spinal cord injury by simultaneous blockade of inhibitory matrix CSPG production and the receptor PTP $\sigma$ ," (2022).

<sup>29</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>30</sup> Rink, et al., "Recovery after spinal cord injury by modulation of the proteoglycan receptor PTP $\sigma$ ," (2018).

<sup>31</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>32</sup> Rink, et al., "Recovery after spinal cord injury by modulation of the proteoglycan receptor PTP $\sigma$ ," (2018).

<sup>33</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>34</sup> Milton, Kwok, McClellan, Saber, Lathia, Warren, Silver and Silver. Recovery of forearm and fine digit function after chronic spinal cord injury by simultaneous blockade of inhibitory matrix CSPG production and the receptor PTP $\sigma$ . *J Neurotrauma*, doi:10.1089/neu.2023.0117 (2023).

<sup>35</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>36</sup> Rink, et al., "Recovery after spinal cord injury by modulation of the proteoglycan receptor PTP $\sigma$ ," (2018).

<sup>37</sup> Ham, Pukale, Hamrangsekachae and Leipzig. Subcutaneous priming of protein-functionalized chitosan scaffolds improves function following spinal cord injury. *Materials Science and Engineering: C* **110**, 110656, doi:10/ggmbpz (2020).

<sup>38</sup> Ham, et al., "Automated Gait Analysis Detects Improvements after Intracellular  $\sigma$  Peptide Administration in a Rat Hemisection Model of Spinal Cord Injury," (2019).

<sup>39</sup> Milton, et al., "Recovery of forearm and fine digit function after chronic spinal cord injury by simultaneous blockade of inhibitory matrix CSPG production and the receptor PTP $\sigma$ ," (2022).

<sup>40</sup> Wang, Feng, Liu, Xie, Zhou, Zhao, Xiao and Yang. Inhibition of CSPG-PTP $\sigma$  Activates Autophagy Flux and Lysosome Fusion, Aids Axon and Synaptic Reorganization in Spinal Cord Injury. *Molecular Neurobiology*, doi:10.1007/s12035-024-04304-3 (2024).

<sup>41</sup> Luo, et al., "Inhibition of CSPG receptor PTP $\sigma$  promotes migration of newly born neuroblasts, axonal sprouting, and recovery from stroke," (2022).

<sup>42</sup> Wang, Li, Diao and Chen. Inhibition of the proteoglycan receptor PTP $\sigma$  promotes functional recovery on a rodent model of preterm hypoxic-ischemic brain injury. *Exp Neurol*, 114564, doi:10.1016/j.expneurol.2023.114564 (2023).

<sup>43</sup> Yao, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes white matter integrity and functional recovery after intracerebral hemorrhage stroke in mice," (2022).

<sup>44</sup> Luo, et al., "Modulation of proteoglycan receptor PTP $\sigma$  enhances MMP-2 activity to promote recovery from multiple sclerosis," (2018).

<sup>45</sup> Li, et al., "Enhanced regeneration and functional recovery after spinal root avulsion by manipulation of the proteoglycan receptor PTP $\sigma$ ," (2015).

<sup>46</sup> Yao, et al., "Targeting proteoglycan receptor PTP $\sigma$  restores sensory function after spinal cord dorsal root injury by activation of Erks/CREB signaling pathway," (2019).

<sup>47</sup> Lv and Wu. ISP and PAP4 peptides promote motor functional recovery after peripheral nerve injury. *Neural Regeneration Research* **16**, 1598, doi:10/ghsqgh (2021).

<sup>48</sup> Yao, et al., "Modulation of proteoglycan receptor regulates RhoA/CRMP2 pathways and promotes axonal myelination," (2021).

cardiac ischemia<sup>49 50 51</sup> and demyelination<sup>52 53</sup>, including optic neuritis<sup>54</sup>. In vitro studies have shown that NVG-291-R treatment could rescue cell organelle recycling (autophagy)<sup>55</sup> and influence synapse development<sup>56 57</sup>.

### ***Translating the Technology from In Vitro to In Vivo***

NVG-291 has been shown to alleviate the inhibitory effects of chondroitin sulfate proteoglycans (“**CSPGs**”) on axonal growth in cell cultures of rodent and human neurons with effectiveness similar to that of the rodent version NVG-291-R<sup>58 59</sup>. Preclinical contusion and compression models of SCI in the rat are broadly viewed as preclinical mimics of the human response to injury<sup>60</sup> and thus offer an appropriate model to test the efficacy of our technology.

### ***Clinical Development***

In 2023, we completed dosing in a Phase 1 placebo-controlled clinical trial of NVG-291 in Australia that enrolled 70 healthy adult male and female participants. The single ascending dose (“**SAD**”) portion of the study evaluated 37 female subjects across 6 dose cohorts, while the multiple ascending dose (“**MAD**”) portion of the study, evaluated 33 male and female subjects across 4 dose levels. NVG-291 was well tolerated overall in the Phase 1 clinical study. A maximally tolerated dose was not reached, all adverse events were mild or moderate, and there were no serious adverse events reported in subjects receiving NVG-291. Injection site related adverse events were the only type of adverse event increased in subjects receiving NVG-291 compared to placebo. There was no effect of NVG-291 on vital signs, electrocardiograms, laboratory studies or other clinical parameters measured in the healthy participants in this study.

In September 2023, we initiated dosing in our double blind, placebo-controlled proof-of-concept Phase 1b/2a clinical trial (NCT05965700) that will evaluate the safety and efficacy of NVG-291 in two separate cohorts of individuals with cervical SCI: 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 SCI. The trial is designed to evaluate 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

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<sup>49</sup> Gardner, Wang, Lang, Cregg, Dunbar, Woodward, Silver, Ripplinger and Habecker. Targeting protein tyrosine phosphatase  $\sigma$  after myocardial infarction restores cardiac sympathetic innervation and prevents arrhythmias. *Nature communications* **6**, 6235, doi:10/gfkk7 (2015).

<sup>50</sup> Johnsen, Olivas, Lang, Silver and Habecker. Disrupting protein tyrosine phosphatase  $\sigma$  does not prevent sympathetic axonal dieback following myocardial infarction. *Experimental Neurology* **276**, 1-4, doi:10/f78b35 (2016).

<sup>51</sup> Sedaghat, Gardner, Kabir, Ghafoori, Habecker and Tereshchenko. Correlation between the High-Frequency Content of the QRS on Murine Surface Electrocardiogram and the Sympathetic Nerves Density in Left Ventricle after Myocardial Infarction: Experimental Study. *Journal of electrocardiology* **50**, 323-331, doi:10/f98r7w (2017).

<sup>52</sup> Luo, et al., "Modulation of proteoglycan receptor PTP $\sigma$  enhances MMP-2 activity to promote recovery from multiple sclerosis," (2018).

<sup>53</sup> Yao, et al., "Modulation of proteoglycan receptor regulates RhoA/CRMP2 pathways and promotes axonal myelination," (2021).

<sup>54</sup> Niknam, et al., "Modulating proteoglycan receptor PTP $\sigma$  using intracellular sigma peptide improves remyelination and functional recovery in mice with demyelinated optic chiasm," (2019).

<sup>55</sup> Sakamoto, Ozaki, Ko, Tsai, Gong, Morozumi, Ishikawa, Uchimura, Nadanaka, Kitagawa, Zulueta, Bandaru, Tamura, Hung and Kadomatsu. Glycan sulfation patterns define autophagy flux at axon tip via PTPR $\sigma$ -cortactin axis. *Nature Chemical Biology* **15**, 699-709, doi:10/gf2g9b (2019).

<sup>56</sup> Farhy-Tselnicker, van Casteren, Lee, Chang, Aricescu and Allen. Astrocyte-Secreted Glypican 4 Regulates Release of Neuronal Pentraxin 1 from Axons to Induce Functional Synapse Formation. *Neuron* **96**, 428-445.e413, doi:10/gcf2dm (2017).

<sup>57</sup> Hosseini, Alizadeh, Shahsavani, Chopek, Ahlfors and Karimi-Abdolrezaee. Suppressing CSPG/LAR/PTP $\sigma$  Axis Facilitates Neuronal Replacement and Synaptogenesis by Human Neural Precursor Grafts and Improves Recovery after Spinal Cord Injury. *The Journal of Neuroscience* **42**, 3096-3121, doi:10.1523/JNEUROSCI.2177-21.2022 (2022).

<sup>58</sup> Lang, et al., "Modulation of the proteoglycan receptor PTP $\sigma$  promotes recovery after spinal cord injury," (2015).

<sup>59</sup> Lang, "THE ROLE OF PTP $\sigma$  IN REGENERATION FAILURE FOLLOWING SPINAL CORD INJURY," (2015).

<sup>60</sup> Sharif-Alhoseini, Khormali, Rezaei, Safdarian, Hajjghadery, Khalatbari, Safdarian, Meknatkhah, Rezvan, Chalangari, Derakhshan and Rahimi-Movaghar. Animal models of spinal cord injury: a systematic review. *Spinal Cord* **55**, 714-721, doi:10/f9mpr3 (2017).

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 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.

In October 2023, NVG-291 received Fast Track designation from the FDA for NVG-291 in individuals with SCI. 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 also provides potential eligibility for both Priority Review, which can shorten the New Drug Application ("**NDA**") review process, and potential for Accelerated Approval, which can allow for an earlier or faster approval based on a surrogate or intermediate clinical endpoint.

NVG-291 has qualified for Orphan Designation in the European Union ("**EU**") and we believe that it may qualify for FDA Fast Track and Breakthrough designation status for certain indications which could reduce regulatory time to approval and provide for preferential support through clinical development<sup>61</sup>. In the EU, Orphan Designation provides recipients with multiple incentives, including improved access to scientific advice, fee reductions, and 10 years of protection from market competition in Europe from similar medicines with similar indications following the date that the drug candidate receives marketing authorization.

The planned timing of clinical trials for other indications is being evaluated by management. We believe SCI represents a significant commercial opportunity due to the dramatic impact on quality of life and the high-cost burden to the healthcare system, as well as the current absence of pharmacologic therapies in the market that promote neurorepair.

Initiation of future clinical trials is subject to additional funding. The duration and cost of a clinical trial can range significantly depending on a variety of factors, including the rate of enrollment, the number of sites, the country in which the trial is conducted and the complexity of the trial.

Our clinical and other required preclinical studies will be conducted using one or more contract research organizations ("**CRO**"), which are companies that provide outsource support to the pharmaceutical industry in the form of contracted research services.

NVG-291 is being manufactured using well-established peptide synthesis procedures by an experienced contract manufacturing organization ("**CMO**") and we are in the process of establishing a secondary source for manufacturing. NVG-291 is a linear peptide comprised of common amino acids and has been produced previously in small quantities for research studies. Materials to be used in clinical trials are being manufactured by an CMO under Current Good Manufacturing Practices ("**cGMP**") regulations enforced by the FDA. Several research and clinical batches of NVG-291 have been successfully manufactured.

### ***Future Plans***

We plan to work in cooperation with other parties, including academic institutions, contract laboratories and not-for-profit foundations, to conduct additional research to further the development of NVG-291 and other potential drug candidates and continue the advancement of the licensed technology.

NervGen also seeks to identify new compounds for treatment of neurologic conditions beyond SCI. In Q3 2024, we initiated preclinical test of concept evaluation of our next pipeline candidate, NVG-300, in models of ischemic stroke, ALS, and spinal cord injury. In addition, we have initiated translational studies to further elucidate the mechanism of NVG-291 therapeutic action. We believe these indications

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<sup>61</sup> US Food & Drug Administration. Expedited Programs for Serious Conditions — Drugs and Biologics. (2020).

represent significant commercial opportunities: ALS, stroke, AD and MS due to the limited pharmacologic therapies in the market that promote neurorepair in these diseases.

In 2020, we engaged Michael Davis, MD, FACS, FRCS (Hon.), Colonel (Ret.), formerly Director of the U.S. Combat Casualty Care Research Program, to help us identify, prioritize and secure sources of non-dilutive funding for developing NVG-291, for treating not only our priority indication of SCI but to also bring an emphasis to finding support for important non-core indications including traumatic brain injury, peripheral nerve injury and other conditions that result in nervous system damage.

Additional areas of focus for the Company include strategically building the intellectual property portfolio, and developing business partnerships with potential sublicensees, marketing partners and strategic partners.

### ***Trends and Uncertainties***

There are significant uncertainties regarding the regulatory approval, reimbursement and prices of future drugs, and the availability of financing for the purposes of pharmaceutical development. In addition, there is significant uncertainty in the Canadian-U.S. foreign exchange rate which presents a risk in that we have historically raised the majority of our funds in Canadian dollars and expect to be spending the funds largely in U.S. dollars. Apart from those risks, and the risk factors noted under the heading “Risk Factors”, we are not aware of any other trends, commitments, events or uncertainties that would have a material adverse effect on our business, financial condition or results of operations.

### ***Competitive Conditions***

#### Spinal Cord Injury

As reported by organizations searching for cures for paralysis, such as the Rick Hansen Institute or the United States National Institute of Health and the National Institute of Neurological Disorders and Stroke, there are no approved pharmacologic therapies that have been demonstrated to sustainably improve function following a SCI<sup>62</sup>. The current approach to treating SCI focuses on preventing further injury acutely, followed by rehabilitation and empowering SCI patients to live with injury as actively and productively as possible. Although there are no approved drugs available to repair damage and allow an individual to regain key bodily functions, such as movement, bladder control, bowel control and sexual function, many companies are investigating treatments for SCI and other types of nervous system damage.

The Company categorizes therapies currently under development as neuroprotective drugs, cellular therapies, or neuroreparative drugs.

- Neuroprotective drugs<sup>63</sup>: attempt to intervene very soon after the acute injury in order to protect the injured neurons. Neuroprotective drugs must be used acutely and otherwise do not actively promote the restoration of connectivity and so are generally not considered competitive although in many cases could be complementary to NVG-291.
- Cellular therapies: the use of transplanted cellular therapies (such as stem cells and Schwann cells) has generated interest for their potential to promote neuro-regeneration and restoration of function in both chronic and acute SCI. However, cost, manufacturing and regulatory hurdles along with safety concerns make the clinical translation of this technology extremely challenging. Current clinical trials in this area are largely focused on evaluating safety and clinical feasibility

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<sup>62</sup> National Institute of Neurological Disorders and Stroke. Spinal Cord Injury Information Page. (2019).

<sup>63</sup> UIndreaj, Badner and Fehlings. Promising neuroprotective strategies for traumatic spinal cord injury with a focus on the differential effects among anatomical levels of injury. *F1000Res* 6, 1907, doi:10/ggs96q (2017).

of this technology<sup>64,65</sup>.

- Neuroreparative drugs (such as NVG-291): act to restore lost nervous system function by promoting sprouting/regeneration of damaged axons and/or by promoting remyelination of demyelinated axons. We believe these biological mechanisms offer the greatest potential to improve function after SCI and this approach could be used in combination with cellular therapies or neuroprotective drugs, if approved alongside NVG-291 in the future.

Companies known to be working on reparative or regenerative pharmacological drugs to treat SCI that are currently in clinical development include Eusol Biotech Co (ES-135), Nordic Life Sciences (Spinalon), ReNeTx (AXER-204), AbbVie (elezanumab), University of Zurich (NG-101), Pharmazz (sovateltide) and Mitsubishi Tanabe (MT-3921). Currently, to our knowledge there has been no published data from randomized controlled clinical trials demonstrating efficacy in restoring function in SCI for any of the therapies listed above.

We are aware of potential non-pharmacological therapies being researched and developed for SCI, such as electrical stimulation using either non-invasive or implanted medical devices. However, we are not aware of any large-scale controlled clinical trials having been completed. We also believe that drug and device companies are fundamentally different businesses with different risk profiles, commercial propositions, and potential for reimbursement.

Management, with its advisors, has periodically reviewed technologies that could potentially be competitive or complementary to NVG-291 and considering various factors we believe are of greatest importance in the marketplace. These factors include strength and consistency of effect, the window of time after injury during which the drug is effective, and the degree of invasiveness associated with the drug's administration. Based on our studies to date, we believe that the potential utility of NVG-291 used weeks, months and even years after initial SCI could offer advantages over the neuroprotective investigational drugs that require administration within ~48 hours or earlier after injury often in a surgical setting. Based on this information, we believe NervGen's neuroreparative technology, if successfully developed and commercialized, has the potential to provide a highly competitive therapeutic solution for SCI and potentially other forms of nervous system damage.

On an ongoing basis, we use multiple sources, including dialogue with key opinion leaders ("KOLs"), and databases and web searches, to survey the landscape for drug therapies for SCI. The ongoing surveys confirm that drugs currently marketed for SCI are used for alleviating symptoms such as pain, spasm and inflammation.

Competitors in this industry are also competing for available investment funds, recruitment of qualified personnel, facilities and equipment. As noted, some of our competitors are much larger companies with significantly greater resources (see "Risk Factors").

### **Government Regulation**

The Company's operations and activities in Canada, the U.S. and Australia are subject to various federal, provincial, state and local laws and regulations which govern pharmaceutical development, exports, taxes, labour standards, occupational health, waste disposal, protection of the environment, safety, hazardous substances and other matters.

The majority of development activities in the next two years will occur in government certified contract organization facilities. In addition, we believe that we are, and will continue to be, in compliance in all

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<sup>64</sup> Donnelly, Lamanna and Boulis. Stem cell therapy for the spinal cord. *Stem Cell Research & Therapy* 3, 24, doi:10/ggsp7d (2012).

<sup>65</sup> Aboody, Capela, Niazi, Stern and Temple. Translating stem cell studies to the clinic for CNS repair: current state of the art and the need for a Rosetta stone. *Neuron* 70, 597-613, doi:10/dq6926 (2011).

material respects with applicable statutes and the regulations passed, and related to our operations, in Canada, the U.S. and Australia. To our knowledge, there are no current orders or directions relating to the Company with respect to the foregoing laws and regulations.

### ***Clinical Trials***

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices (“**GCP**”), which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site’s institutional review board (“**IRB**”) or ethics committee, before the trials may be initiated, and the IRB or ethics committee must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1: the drug is introduced into healthy human subjects or with patients having a condition/disease of interest. These studies are designed to evaluate safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses.
- Phase 2: the drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.
- Phase 3: the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational new drug product, and to provide an adequate basis for physician labeling.
- Phase 4: the drug may be further evaluated in post-approval studies typically referred to as Phase 4 clinical trials.

Clinical trial sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator’s brochure, or any findings from other studies or animal testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB or ethics committee, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated checkpoints based on access to certain data from the trial.

The clinical trial process can take years to complete, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Results from one trial are not necessarily predictive of results from later trials.

## ***Submission of an NDA or BLA to the FDA***

Assuming successful completion of all required preclinical studies and clinical testing in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee. Applications for orphan drug products are exempted from the NDA and BLA application user fee, unless the application includes an indication for other than a rare disease or condition.

An NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data comes from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product and may also come from a number of alternative sources, including trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational new drug product to the satisfaction of the FDA.

Once an NDA or BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA's requests for additional information or clarification.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an NDA or BLA for a novel drug (in which no active ingredient has been approved in any other application) to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

## ***The FDA's Decision on an NDA or BLA***

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA will issue either an approval letter or a complete response letter ("**Complete Response Letter**"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. In order to satisfy deficiencies identified in a Complete Response Letter, additional clinical data and/or additional Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing may be required for the product candidate. Even if such additional information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA could also approve the NDA or BLA with a risk evaluation and mitigation strategy, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a

commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

### ***Patent Term Restoration***

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the *Drug Price Competition and Patent Term Restoration Act* of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a NDA or BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

### ***Environmental Regulation***

The Company's policy is to conduct its business in a way that safeguards public health and the environment. We believe that our operations are conducted in material compliance with applicable environmental laws and regulations. Since most of our development activities are outsourced, we believe our exposure to environmental risk is low.

### ***Specialized Skill and Knowledge***

We have extensive knowledge in scientific research, clinical development and commercialization of drugs and therapies in the areas of neurology, pain, inflammation and regenerative medicine. By enlisting the support of experienced preclinical, clinical trial, regulatory and legal consultants, we are able to use expert knowledge to assist in the successful development of our products and the protection of our intellectual property. We continually evaluate our internal resources and may add talented senior professionals to our team as needed to support growth.

### ***Employees and Consultants***

As at December 31, 2023, NervGen had eleven full-time employees, one part-time employee and four part-time consultants, including four holding MD and/or PhD degrees, and a number of other employees holding master's degrees or CPA designations.

Our employees are not governed by a collective bargaining agreement. We depend on certain key members of our management and scientific staff and the loss of services of one or more of these persons could adversely affect the Company.

We also use consultants and outside contractors to carry on many of our activities, including preclinical testing and validation, formulation, assay development, manufacturing, clinical and regulatory affairs, toxicology and clinical trials.

**Facilities**

NervGen entered into a lease agreement for a head office in Vancouver, British Columbia, for 3.83 years, effective May 1, 2022. In 2024, we entered into a sub-sublease pursuant to which we have agreed to sub-sublease our head office for a term of one (1) year, nine (9) months less two (2) days, commencing on June 1, 2024, and expiring on February 26, 2026 (the remaining term of our sublease). The sub-subtenant will pay base rent plus property taxes and operating expenses, equal to the amount owed by the Company under the sublease. The nature of the space is immaterial to our operations as operating activities related to the NVG-291 program are primarily outsourced to contractors.

**Legal Proceedings**

To our knowledge, there have not been any legal or arbitration proceedings, including those relating to bankruptcy, receivership or similar proceedings, those involving any third party, and governmental proceedings pending or known to be contemplated, which may have, or have had in the recent past, significant effect on our financial position or profitability.

To our knowledge, there have been no material proceedings in which any director, any member of senior management, or any of our affiliates is either a party adverse to NervGen or any of our subsidiaries or has a material interest adverse to NervGen or any of our subsidiaries.

## RISK FACTORS

An investment in the Common Shares involves a high degree of risk and should be considered speculative. An investment in the Common Shares should only be undertaken by those persons who can afford the total loss of their investment. Investors should carefully consider the risks and uncertainties set forth below, as well as other information described elsewhere in this AIF. The risks and uncertainties below are not the only ones faced. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed, and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our Common Shares could decline.

### **Risks Related to Our Financial Position, Need for Additional Capital and Limited Operating History**

***We have a limited operating history, are early in our development efforts, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.***

We are a clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue from product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. In October 2023, we initiated a Phase 1b/2a trial evaluating NVG-291 in individuals with spinal cord injury, or SCI, which is the most advanced product candidate in clinical development. To date, we have devoted substantially all of our resources and efforts to developing our product candidates, building our intellectual property portfolio, business planning, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully initiate or complete any pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage pharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

***Since our inception, we have incurred significant net losses and expect to continue to incur significant net losses for the foreseeable future and we may never achieve or maintain profitability.***

We have incurred significant net losses since our inception and have financed our operations principally through equity financings. Our net loss was C\$10.2 million and C\$9.5 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of C\$88.3 million. Given that our lead product candidate, NVG-291 for the treatment of SCI, is in a Phase 1b/2a clinical trial, and our other programs are in preclinical or discovery stages, we expect that it will be several years, if ever, before we receive approval to commercialize a product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-

period comparison of our results of operations may not be a good indication of our future performance, particularly since we expect our expenses to increase if and when our product candidates progress through clinical development as product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. We expect such net losses to increase substantially as we continue our research and development of, and seek regulatory approvals for, our lead product candidates and any other current or future product candidates. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and, following the completion of any offering, the performance of our share price.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.***

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our lead product candidates and advance our other programs. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, the FDA, the European Medicines Agency, the EMA, Health Canada, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote NVG-291 for SCI or any other indication, or any other product candidate we are developing, before we receive marketing approval from the FDA or other comparable regulatory authority.

As of June 30, 2024, we had C\$26.6 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date of this AIF. We will need to raise additional capital to complete the development and commercialization of our products. Our estimate as to how long we expect our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be inaccurate, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future capital requirements, both short- and long-term, will depend on a variety of factors, including, but not limited to:

- the scope, timing, costs, rate of progress, and results of our discovery research, results from our preclinical studies including toxicology, and results of our clinical trials including later stage clinical trials;
- the number and scope of preclinical studies and clinical trials that we pursue;
- the cost, timing, and outcome of seeking and obtaining approvals by the FDA, EMA, Health Canada and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- our ability to establish licensing or collaboration agreements or other strategic agreements;
- the achievement of milestones or other developments that result in obligations under any collaboration agreements we may enter into in the future;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements we have entered into and may enter into in the future;
- the cost of establishing, maintaining, expanding, enforcing, and defending the scope of our intellectual property portfolio;
- the cost of acquiring, licensing, or investing in additional businesses, products, product candidates, and technologies that we may identify;
- the cost of manufacturing or to have manufactured and our ability to manufacture sufficient, reliable, timely, and affordable supply of materials in accordance with current good manufacturing practices, or cGMP, that can be used in clinical trials and potential commercial sales;
- the cost of commercializing product candidates, if approved, whether alone or in collaboration with others;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of building or contracting sales, marketing, and or distribution capabilities, systems, and internal infrastructure if or when we obtain regulatory approvals for a product candidate;
- the impact of competitors' product candidates and technological advances and other market developments;
- the expenses needed to attract and retain skilled personnel; and
- the size of the markets and degree of market acceptance of any product candidates in territories in which we receive regulatory approval, including product pricing, product coverage, and the adequacy of reimbursement by third-party payors.

A change in the outcome of any of these factors or underlying variables with respect to the development of a product candidate or future product candidate could significantly change the costs and timing associated with the development of that product candidate. Our business plans may change in the future and we will continue to require additional capital to meet the needs of our operating expenses. If we are

unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include rights or preferences that adversely affect your rights as a Common Shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.***

We have net operating loss carryforwards in Canada, the United States and internationally which could expire unused and become unavailable to offset future income tax liabilities. The rules dealing with Canadian and U.S. federal, provincial, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Canada Revenue Agency, Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws, or changes in interpretations of existing laws (which changes may have retroactive application), including with respect to net operating losses and tax credits, could adversely affect us or holders of our Common Shares. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

## **Risks Related to the Discovery, Development and Commercialization of Our Product Candidates**

***We are substantially dependent on the success of our lead product candidate, NVG-291, which is currently in a Phase 1b/2a clinical trial for SCI. If we are unable to complete development of, obtain approval for and commercialize NVG-291 for SCI in a timely manner, our business will be harmed.***

Our future success is dependent on our ability to timely complete clinical trials, the results of those trials, the results of all preclinical studies which include toxicology, our ability to manufacture product using third party partnerships and our ability to obtain marketing approval for and successfully commercialize NVG-291 for SCI, our lead product candidate. We have invested, and continue to invest, significant efforts and financial resources in the research and development of NVG-291 for SCI as well as potential other indications. We are currently conducting a Phase 1b/2a trial that aims to demonstrate the efficacy, safety, and tolerability of NVG-291 for SCI. NVG-291 will require additional clinical development and evaluation of clinical results from those trials, preclinical studies including toxicology and manufacturing

activities, regulatory submission, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from product sales. In addition, because our lead product candidate is our most advanced product candidate, if NVG-291 for SCI encounters safety or efficacy problems, manufacturing or supply interruptions, developmental delays, regulatory issues, or other problems, our development plans and business related to other indications for NVG-291 could be significantly harmed. We are not permitted to market or promote NVG-291 for SCI or any indication, or any other product candidate we are developing, before we receive marketing approval from the FDA and comparable non-U.S. regulatory authorities, and we may never receive such marketing approvals.

Our ability to generate revenue and achieve profitability depends significantly on several factors, including but not limited to the following:

- successful outcomes of and timely completion of nonclinical and clinical development of our product candidates and any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of nonclinical study or clinical trial delays due to any public health emergencies or other causes;
- our ability to remove or mitigate the impact of the partial clinical hold imposed by the FDA;
- the initiation and successful recruitment of subjects and completion of additional clinical trials on a timely basis;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and other countries, of our product candidates and any future product candidates;
- the frequency and severity of adverse events in the clinical trials;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, the EMA, Health Canada or any comparable foreign regulatory authority for marketing approval;
- developing complete regulatory submissions, including information related to the preclinical, clinical, and CMC development of any product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- completing any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale and meet other cGMP requirements;
- establishing and maintaining commercially viable supply, manufacturing, and distribution relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;

- a continued acceptable safety profile following any marketing approval of our product candidates and compliance with any post-market safety-related requirements;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and other countries;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining key personnel, including research and development personnel, quality and regulatory personnel, manufacturing and technical operations personnel and future commercial personnel.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the development, manufacturing, marketing, distribution, and sales efforts of any future collaborator. We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability.

***There are currently no FDA-approved products for the treatment of SCI.***

There is currently no FDA-approved therapeutic for the treatment of SCI. We have not received regulatory approval for NVG-291, and cannot be certain that our approach will lead to the development of an approvable or marketable product, alone or in combination with other therapies. We may not succeed in demonstrating the safety and efficacy of NVG-291 in our ongoing clinical trials or in larger-scale clinical trials.

***The regulatory approval processes of the FDA, EMA, Health Canada and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to commercialize our product candidates and generate product revenue and our business will be substantially harmed.***

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many non-U.S. jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming,

uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable non-U.S. regulatory agency for marketing approval;
- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may not accept data generated from our preclinical studies and/or clinical trial sites, or may require that we conduct additional non-clinical or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative of the real-world population to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not approve the formulation, labeling or specifications of any of our current or future product candidates;
- the data collected from manufacturing and testing, preclinical studies, or clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA, Health Canada or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- if an advisory committee is needed to review our marketing application submitted to the FDA, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend

a conditional approval or additional non-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- contract research organizations, or CROs, that we retain to conduct our non-clinical or clinical studies may take actions outside of our control that materially adversely impact our business operations or clinical development plans;
- the FDA or the applicable non-U.S. regulatory agency may be delayed in their review processes due to staffing shortages or other restrictions or government policies that may impact its resources and operations; and
- the approval policies or regulations of the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects. Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement, and we have had limited interactions with foreign regulatory authorities. The foreign regulatory approval process varies among countries and may include all of the risks associated with obtaining FDA approval described above as well as risks attributable to the satisfaction of local regulations in non-U.S. jurisdictions. We may not obtain regulatory approvals in any jurisdiction on a timely basis, if at all. We may not be able to file for regulatory approvals, and, even if we file, we may not receive the necessary approvals to commercialize our products in any market, which will prevent us from marketing our products internationally and have an adverse effect on our business and financial condition. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

***Preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates.***

Before obtaining marketing approval from the FDA, EMA, Health Canada or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We do not know whether our future clinical trials will begin on time or enroll subjects on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable non-U.S. regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to adhere to the clinical trial protocol or return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable non-U.S. regulatory authorities to temporarily or permanently shut down or

voluntarily shutting down or reducing capacity due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

- any changes to our manufacturing process that may be necessary or desired or additional manufacturing work required to support the stability of product candidates or verify or validate manufacturing processes;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- company employees or third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Disruptions caused by public health emergencies may also increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable non-U.S. regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, unfavorable inspection of the clinical trial operations or trial site resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects or failure to demonstrate a benefit from using a drug. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, comparable non-U.S. regulatory authorities, or other government. The FDA or comparable non-U.S. regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable non-U.S. regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable non-U.S. regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. NVG-291 for SCI is currently subject to a partial clinical hold by the FDA, and we may be unable to have the hold removed which could adversely affect development of NVG-291 and our results of operations.***

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us, an IRB, a Data Safety Monitoring Board, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable non-U.S. regulatory authorities. For example, a partial clinical hold was placed on NVG-291 by the FDA in March 2020 when adverse dose-dependent reproductive organ toxicity results were observed in initial 7-day and 28-day preclinical animal toxicology studies. Under the partial clinical hold, we were permitted to enroll postmenopausal females in the single ascending dose and multiple ascending dose portions of the study, respectively. After we completed the preclinical studies requested by the FDA, in October 2022, the FDA amended the partial clinical hold to permit the inclusion of males and premenopausal females at certain dose levels in our Phase 1 clinical trial of NVG-291. The additional preclinical safety studies requested by the FDA will further investigate the preclinical safety margin of NVG-291, testing exposures of NVG-291 higher than those tested in the follow-up preclinical safety studies and for longer durations to enable chronic dosing greater than 3 months. These 6-month chronic toxicity preclinical studies are required to gain marketing approval but could result in unexpected negative results which could impact our ability to dose for longer durations or at higher dose levels deemed necessary for efficacy. Pending successful completion of these preclinical safety studies and provision of available data from the Phase 1 and ongoing Phase 1b/2a studies to the FDA, we intend to seek full removal of the partial clinical hold, though we may not be successful in these efforts. If we are unsuccessful in removing the partial hold and we later determine that the permitted dose levels are insufficient to show clinical efficacy of NVG-291 for SCI, our development of NVG-291 may be adversely affected.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Subjects in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. In addition, if our product candidates are used in combination with other therapies, our product candidates may

exacerbate adverse events associated with the therapy. Subjects treated with our product candidates may also be undergoing other treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, subjects may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, Health Canada, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product candidate from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

***The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, Health Canada or other comparable foreign regulatory authorities.***

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, including NVG-291, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. We do not know whether NVG-291 or our potential future product candidates will perform in current or future clinical trials as in preclinical studies or early clinical studies. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, Health Canada and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the study populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Subjects treated with our product candidates may also be undergoing other treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a given individual, and from subject to subject and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Most product candidates that begin clinical trials are never

approved by regulatory authorities for commercialization. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful.

***Interim, initial, top-line, and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available or as subjects from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Common Shares after any offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, including our interpretation of biomarker measures or exploratory data, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates, may be harmed, which could harm our business, operating results, prospects or financial condition.

***If we fail to develop and commercialize NVG-291 for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.***

Although the development and commercialization of NVG-291 for the treatment of SCI is our primary focus, as part of our longer-term growth strategy, we are also conducting preclinical test of concept evaluation of NVG-300-R in animal models of stroke and amyotrophic lateral sclerosis. We intend to evaluate internal opportunities potentially provided by NVG-291, NVG-300 or other potential product candidates, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable non-U.S. regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval

by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth and achieving our strategic objectives may be impaired.

***We may expend our limited resources to pursue a particular product or indication and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.***

We have limited financial and managerial resources. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued. As a result, we may forgo or delay pursuit of other opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield, minimize costs and achieve consistent quality and results. For example, the manufacturing process used to produce clinical supplies for our clinical trials may be different from that used in prior or future trials, and we may use a different supplier or contract manufacturer for commercial supplies after regulatory approval. There can be no assurance that such changes will achieve the intended objectives. These changes and any future changes we may make to any product candidates may also cause such candidates to perform differently and affect the results of future clinical trials conducted with the modified materials. Such changes or related unfavorable clinical trial results could delay initiation or completion of additional clinical trials, require the conduct of comparability bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential marketing approval and jeopardize our ability to commercialize the affected product candidates, if approved, and generate revenue. There can be no assurance that FDA, EMA, Health Canada, or comparable regulatory authorities will accept our conclusions that any such changes did not have an adverse effect on the product candidate or that such changes may negatively impact the interpretation of the study data.

***If we are unable to successfully develop companion diagnostics or biomarkers that may be required for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates.***

We may develop companion diagnostics or biomarkers for our therapeutic product candidates. It is expected that, at least in some cases, regulatory authorities may require the development and regulatory approval of a companion diagnostic or biomarkers as a condition to approving a therapeutic product candidate. We have limited experience and capabilities in developing or commercializing diagnostics or biomarkers and plan to rely in large part on third parties to perform these functions. We do not currently

have any agreement in place with any third party to develop or commercialize companion diagnostics or biomarkers for any of our therapeutic product candidates.

Companion diagnostics or biomarkers are subject to regulation by the FDA, EMA, Health Canada and comparable foreign regulatory authorities and may require separate regulatory approval or clearance prior to commercialization. If we, or any third parties that we engage to assist, are unable to successfully develop companion diagnostics or biomarkers for our therapeutic product candidates, or experience delays in doing so, our business may be substantially harmed.

***If we experience delays or difficulties in the enrollment and/or retention of subjects in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Subject enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. In particular, for our trials in SCI, participants are difficult to enroll given the nature of their injuries and the need to travel for treatment. In the past we have encountered enrollment delays and may experience additional delays in the future. As such, we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials to such trial's conclusion as required by the FDA, EMA, Health Canada or other comparable foreign regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible subjects or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Subject enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and subjects who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Subject enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- the ability to enroll subjects quickly after SCI for our subacute study population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- subject eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor subjects adequately during and after treatment;

- proximity and availability of clinical trial sites for potentially interested study participants;
- continued enrollment of prospective subjects by clinical trial sites; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials.

***As an organization, we have never conducted later-stage clinical trials or submitted a new drug application, and may be unable to do so for any of our product candidates.***

We are early in our development efforts for our product candidates, and we will need to successfully complete pivotal clinical trials in order to seek approval from the FDA or other non-U.S. regulatory authority to market NVG-291 or any future product candidates we may develop. Carrying out clinical trials and the submission of new drug applications, or NDAs, is complicated. As an organization, we have not conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting, and prosecuting regulatory filings and have not previously submitted an NDA or other applicable non-U.S. regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. In addition, we may need to enter into arrangements with collaborators or others to conduct, or assist us in conducting, such clinical trials and we may not be successful in entering into arrangements with third parties to conduct, or assist us with conducting such clinical trials, or may be unable to do so on terms that are favorable to us. If we engage such third parties, our product revenues and our profitability, if any, could be lower than if we were to clinically develop product candidates ourselves, we may have little control over such third parties and any of them may fail to devote the necessary resources and attention to conduct such clinical trials effectively. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

***We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.***

The biotechnology and pharmaceutical industries are characterized by rapidly evolution of technologies, fierce competition and strong defense of intellectual property. Our competitors are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

There are currently no approved pharmaceutical products that enable sustained improvements in function for people with SCI. There are a number of mobility assistance and neuro stimulation devices in development or approved to improve quality of life for individuals living with SCI.

There are a significant number of approved therapies for multiple sclerosis (MS) and fewer approved for stroke, but they all target the immune system in one way or another (immunomodulatory or immunosuppressive). There are several treatments approved for stroke, which are either preventive (antiplatelet or anticoagulant) or require acute intervention and are focused on early revascularization (e.g. tissue plasminogen activator). There are no approved therapies that promote neural repair (e.g. remyelination, plasticity) for either MS or stroke.

Currently, there are three FDA-approved ALS therapies, Riluzole, Radicava (available as IV and oral formulations) and Tofersen, that have demonstrated modest improvements in survival or ALS function, respectively. Riluzole, approved by the FDA in 1995, extends the time to death or ventilation by several months; however, it has not been shown to improve the daily functioning of ALS patients. Radicava (Edaravone) is a free radical scavenger approved by FDA in May 2017 based on a single Phase 3 study carried out in Japan. Edaravone oral formulation (Radicava ORS) was approved in 2022. Relyvrio demonstrated slowing of disease progression versus placebo and in a post hoc exploratory analysis, a longer median survival was observed in participants originally randomized to Relyvrio. Relyvrio was approved based on the results of a Phase 2 trial but has subsequently been removed from the market by the manufacturer based on the negative results of a Phase 3 trial. Tofersen, which targets a familial genetic form of ALS (super oxide dismutase 1 gene mutations, or SOD1), responsible for a small percentage of ALS cases, is an intrathecally administered drug approved in 2023 for patients with ALS caused by SOD1 mutations. There are no approved therapies shown to promote neural repair in ALS.

There are several clinical trials underway evaluating experimental treatments for SCI, ALS, stroke and MS.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge. Competitors, independently or through collaboration, are developing products that potentially directly compete with our current or future product candidates and which may either be a longer lasting or a more efficacious treatment or receive FDA or other applicable regulatory approval more rapidly than our current or future product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

***Fast Track, Breakthrough Therapy designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates.***

We may seek Fast Track or Breakthrough Therapy designation from the FDA for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with such designations. The FDA's Fast Track and Breakthrough Therapy designation programs are intended to expedite the development of certain qualifying product candidates intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA Fast Track designation.

A product candidate may be designated as a breakthrough therapy if it is intended, alone or in combination with one or more other drugs or biologics to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

We have received Fast Track designation for NVG-291 in individuals with SCI. While we may seek Fast Track or Breakthrough Therapy designation for some or all of our product candidates, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track or Breakthrough Therapy designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular time frame. In addition, the FDA may withdraw Fast Track, Breakthrough Therapy, or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track and/or Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures.

***We may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.***

As part of our business strategy, we may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs and biologics that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating

conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs and biologics intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug or biologic in Europe would be sufficient to justify the necessary investment in developing the drug or biologic. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug or biologic is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency, or EMA, or the FDA from approving another marketing application for the same drug and for the same indication during the period of exclusivity, except in limited circumstances. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect such product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug or biologic is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designation, there is no guarantee that we will enjoy the benefits of that designation.

***Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including, but not limited to:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;

- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any one or more of our product candidates are approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

***If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.***

Our estimates of the potential market opportunity for NVG-291 for the treatment of SCI as well as any other product candidates include several key assumptions based on our industry knowledge, industry publications and third-party research reports. There can be no assurance that any of these assumptions are, or will remain, accurate. If the actual market for NVG-291 for SCI or other indications, or for any other product candidate we may develop, is smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

***If we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be successful in commercializing our product candidates that obtain regulatory approval.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we obtain marketing approval, and for which we decide to independently commercialize, we will need to establish a sales and marketing organization or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is

delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, could be lower than if we were to market, sell and distribute any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

### **Risks Related to Our Dependence on Third Parties**

***Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities of such materials on time or at an acceptable cost.***

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for the development, manufacture and supply of the active pharmaceutical ingredients, or APIs, in our product candidates. We have not made large scale up batches required for commercialization and NVG-291 is a large peptide that requires specialists in manufacturing and development of which we outsource. Our current strategy is to continue to outsource all manufacturing of our product candidates to third parties.

We currently engage third-party manufacturers to provide the APIs of NVG-291 and for the final drug product formulation of NVG-291 that is being used in our clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture NVG-291, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do

so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of NVG-291, and the costs of manufacturing could be prohibitive.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA, EMA, Health Canada and other foreign regulatory authorities.

If NVG-291 for SCI or potential additional indications or any other product candidate is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA and corresponding non-U.S. regulators. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable non-

U.S. regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA, Health Canada and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA, EMA, Health Canada and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding non-U.S. regulators also inspect these facilities to confirm compliance with cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA, Health Canada and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

***We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.***

We have relied upon and plan to continue to rely on third parties, such as CROs, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Moreover, the FDA requires us to comply with GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including

clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

***We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, EMA, Health Canada or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

***If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.***

We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

***We may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets.***

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they may have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

#### **Risks Related to Legal and Regulatory Compliance Matters**

***Even if our product candidates receive regulatory approval, they will be subject to significant post marketing regulatory requirements and oversight.***

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or non-U.S. regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, failure to comply with FDA, EMA, Health Canada and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or maintain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including the FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue, could require us to expend significant time and resources in response and could generate negative publicity.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA, EMA or Health Canada grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the product candidate based on their own review of its clinical development, manufacturing, marketing and promotion and reimbursement. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We have conducted and may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA, Health Canada or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from clinical trials outside the U.S. are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means, if the FDA deems it necessary. Additionally, the FDA's clinical trial requirements, including the adequacy of the study population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, Health Canada or any applicable foreign regulatory authority will accept data from trials conducted outside of their applicable jurisdiction. If the FDA, EMA, Health Canada or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

***Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.***

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product

candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; and cost-effectiveness data.

Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products reimbursed by certain federal healthcare programs are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. In addition, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately where coverage is available, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement

rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.***

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or maintain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, the “ACA”), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services Secretary, the HHS Secretary, as a condition for states to receive federal matching funds for the manufacturer’s outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care organizations. The ACA also established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. In December 2020, the CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business.

There has been increasing legislative and enforcement interest in the United States aimed at increasing transparency of drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs. In particular, in August 2022, Congress passed the Inflation Reduction Act, or IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including

certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Further, uncertainties created by the IRA and other cost containment measures may negatively impact potential investments, company valuation, royalty-based earnings, mergers and acquisitions in our industry.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status are attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our ability to develop current or future product candidates we may develop may be at risk and could be delayed, undermined or subject to protracted litigation. Finally, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as FDA acted within its statutory authority under the Administrative Procedure Act (the "APA"). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services that

we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

***Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.***

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and non-U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims, including the civil False Claims Act, the FCA, that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;
- the Federal Health Insurance Portability and Accountability Act of 1996, HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, also known as the CMS Open Payments, and its implementing regulations, which require manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-

physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and non-U.S. laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical and/or medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages,

finances, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs, as such laws and regulations may also become more complex over time. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Failure to comply with laws, rules, regulations, policies, industry standards and contractual obligations relating to privacy, data protection and data security could adversely affect our business.***

We collect, maintain and otherwise process a large quantity of data relating to our employees and in connection with our clinical trials, and we face risks inherent in both handling large volumes of data and in protecting the security of such data. Our data processing activities subject us to numerous laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other actual and asserted obligations relating to privacy, data protection and data security. Our actual or perceived failure to comply with any such actual or alleged obligations could result in enforcement actions and other claims, demands and proceedings that may negatively impact our revenue, as well as expose ourselves to criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings. In Canada, where we are headquartered, federal and provincial legislation impose strict requirements for the processing of personal data of individuals, with substantial penalties for noncompliance. In the United States, both federal and various state governments have adopted, or are considering, laws, guidelines or rules for the collection, distribution, use and storage of information collected from or about individuals. Many of the state laws differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, the CCPA, which went into effect on January 1, 2020 and was amended by the California Privacy Rights Act of 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. Although the CCPA exempts some data

processed in the context of clinical trials and exempts protected health information, as defined by HIPAA, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws have been enacted in several other states, such as Virginia, Connecticut, Colorado, Utah, Iowa, Indiana, Montana, Tennessee, Florida, Oregon, Delaware, Texas and New Jersey, and proposed in other states and at the federal level. In addition to these consumer privacy laws, in April 2023, the state of Washington enacted the My Health My Data Act, which went into effect in March 2024. This new law imposes strict requirements on the collection, use and processing of health-related information that is not subject to HIPAA, and provides for a private right of action. The Washington law adds additional complexity to our existing compliance obligations and may increase our potential liability relating to our collection and processing of health-related information.

Outside of the United States, certain foreign jurisdictions, including the European Economic Area, EEA, and the United Kingdom have laws and regulations which are more restrictive in certain respects than those in the United States. For instance, the collection and use of personal data, including health data, in the EEA is governed by the General Data Protection Regulation, in the UK by the UK General Data Protection Regulation, (collectively “**GDPR**”). The GDPR, and national implementing legislation in EEA member states and the United Kingdom, impose a strict data protection compliance regime which tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Actual or alleged failure to comply with the GDPR may result in regulatory inquiries and other proceedings by regulatory authorities and, in certain cases, private individuals and may result in substantial fines and other administrative penalties, restrictions upon our data processing activities and other liabilities. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to address the GDPR’s requirements. We may incur liabilities, expenses, costs, and other operational losses under the GDPR and local laws of nations included within the EEA, the UK, and other regions in connection with any measures we take to comply with them. Working to comply with the GDPR and other laws and regulations to which we are subject in the EEA, UK, and other regions outside the United States relating to privacy, data protection and data security will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our activities in those regions, and our business could be adversely affected.

Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals’ privacy rights, failed to comply with laws, regulations, contractual obligations or other actual or asserted obligations relating to privacy, data protection or data security, even if resolved in our favor, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties to perform laboratory work and for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any

resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***We are subject to certain U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, (collectively, the "**Trade Laws**"), prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We currently engage third parties for clinical trials and research and development activities and have obtained, or intend to obtain, necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

## Risks Related to Our Intellectual Property

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.***

We are developing NVG-291 pursuant to the license agreement with Case Western Reserve University, or Case Western and may develop other early stage preclinical or discovery drug candidates. We are subject to a number of risks associated with our agreement with Case Western, including the risk that Case Western may terminate the license agreement upon the occurrence of certain specified events. The license agreement requires, among other things, that we make certain payments and use reasonable commercial efforts to meet certain business, preclinical, clinical and regulatory milestones. If we fail to comply with any of these obligations or otherwise breach this or similar agreements, the licensor may have the right to terminate the license in whole. Loss of our rights to the licensed intellectual property from Case Western or any similar license granted to us in the future, or the exclusivity rights provided therein, can harm our financial condition and operating results.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors

would have the freedom to seek regulatory approval of, and to market, products identical to ours including upon expiration of any applicable regulatory exclusivity. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

***Our success depends on our ability to protect our intellectual property and our proprietary technologies.***

Our commercial success depends in part on our ability to obtain and maintain patent and other intellectual property protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others, and maintain trade secret protection of technologies.

We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies, and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

We currently own or in-license issued and pending patents directed to the composition of the product candidates that we have thus far developed. Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to their method of use or production process. However, we cannot be certain that any claims in our patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in countries outside the U.S., or that, if issued, the claims in any such patents, if challenged, will be adjudicated to be not invalid and enforceable by courts and administrative bodies in the U.S. or other countries. Further, if issued, any composition of matter patents covering our product candidates may expire at such a date that competitors may not be prevented from developing, making and marketing a product identical to our product candidates after expiration of any applicable regulatory exclusivities. Method of use patents protect the use of a product for the specified method or indication. This type of patent does not prevent a competitor from making and marketing a product identical to our product candidate for an indication that is outside the scope of the patented methods of use. Moreover, even if competitors do not actively promote their product for indications covered by our patents, clinicians may prescribe these competitor products “off-label” for uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. To establish our proprietary position, we own and have in-licensed certain intellectual property rights, and we and our licensors have filed and may file provisional and non-provisional patent applications in the U.S. or abroad relating to our product candidates and certain technologies that are important to our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our future licensors’ proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual

property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding patent applications and patent applications in certain non-U.S. territories, or those of our future licensors, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in other countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom may have substantially greater resources than we do and many of whom may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and other governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing non-U.S. competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.***

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review and *inter partes* review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our future licensors may become subject to post-grant challenge proceedings, such as oppositions in a patent office outside of the U.S., that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;

- we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

***Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.***

A third party or former employee or collaborator may claim an inventorship or ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third-parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Further, regardless of the outcome, if we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidate without infringing the intellectual property and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates, including patent infringement lawsuits in the US or abroad, as well as interference, derivation, *inter partes* review, and post-grant proceedings before the USPTO and opposition or other proceedings before corresponding patent offices outside of the U.S. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims

of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.***

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include patent ineligibility, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, indefiniteness, and/or

obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution with intent to deceive the USPTO.

Our patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review or *inter partes* review, derivation proceedings, and equivalent proceedings in other jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to

as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

***Changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other non-U.S. legislative bodies may pass patent reform legislation that is unfavorable to us.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application would be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent

application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included several significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned and in-licensed patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

U.S. law relating to the patentability of certain inventions in the life sciences is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future. The U.S. Supreme Court and federal courts have ruled on several patent cases in recent years that impact the scope of patentability of certain inventions or discoveries related to the life sciences, including both narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products, and could jeopardize or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable our patent rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For example, the U.S. Supreme Court recently held in *Amgen v. Sanofi* (2023) that a functionally claimed overly broad genus claim without sufficient data support was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Additionally, other decisions in prior years found that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a “sufficient” additional feature is uncertain. Depending on future actions and/or decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

In 2012, the European Union Patent Package, the EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC’s existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and

requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

***We may not be able to protect or enforce our intellectual property rights throughout the world.***

Although we have pending patent applications in the United States and other countries, filing, prosecuting and defending patents and trademarks on all of our planned products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing our patented products in and into other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our future licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or our future licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our future licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo-political actions in the United States and in other countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.***

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market.

Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions assignment agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

***Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others.***

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent

applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

***The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.***

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

### **Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business**

***We depend heavily on our executive officers, principal consultants and others, and the loss of their services would materially harm our business.***

Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, principal consultants and others, including our President and Chief Executive Officer, our Chief Medical Officer, and our Chief Financial Officer. We have entered into

employment agreements with each of the key members of our executive, scientific and operating staff, but they may terminate their employment with us at any time. The loss of their services might impede the achievement of our discovery research, preclinical development, manufacturing and technical operations and commercialization objectives.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific, regulatory, financial and clinical advisors, to assist us in formulating our research and development and commercialization strategy and capitalization plans. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

***We only have a limited number of employees to manage and operate our business.***

As of June 30, 2024, we had 12 full-time employees. Our focus on the development of NVG-291 for SCI and the future development of NVG-300 requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop NVG-291 for SCI or any other indication or to develop NVG-300 or other exploratory drug candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

***Our future growth may depend, in part, on our ability to operate internationally, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize our programs in international markets for which we may rely on collaboration with third parties. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure to obtain regulatory approvals for the sale or use of our product candidates in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes or self-pay systems;

- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if we or our collaborators do not execute successfully;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, including the military conflict between Russia and Ukraine and the war between Israel and Hamas, public health emergencies, including pandemics, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities.

Any of these risks, if encountered, could have a material adverse effect on our financial condition, results of operations and cash flows.

***We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

### **Risks Related to Ownership of Our Securities**

***The market price of our Common Shares may be volatile, and you could lose all or part of your investment.***

The trading price of our Common Shares is likely to continue to be volatile and could be subject to fluctuations in response to various factors, some of which are beyond our control. These fluctuations could cause you to lose all or part of your investment in our Common Shares since you might be unable to sell your shares at or above the price you paid. In addition to the factors discussed in this “Risk

Factors” section and elsewhere in this AIF, factors that could cause fluctuations in the trading price of our Common Shares include the following:

- the timing and results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States, Canada and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the public’s reaction to our press releases, other public announcements and filings;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our Common Shares by us, our insiders or our other shareholders;
- the impact of any natural disasters or public health emergencies, including pandemics;
- general economic, political, industry and market conditions including the impact of increasing inflation;
- rumors and market speculation involving us or other companies in our industry;
- litigation involving us, our industry or both;
- expiration of market stand-off or lock-up agreements; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have an adverse impact on the market price of our Common Shares.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company’s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management’s attention and resources.

***Sales of a substantial number of shares of our Common Shares in the public market could cause our share price to fall.***

Sales of a substantial number of shares of our Common Shares in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Shares and could impair our ability to raise capital through the sale of additional equity securities. In the future, we may issue additional Common Shares or other equity or debt securities convertible into Common Shares in connection with a financing, acquisition, litigation settlement, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause our share price to decline.

***We do not intend to pay dividends on our Common Shares in the foreseeable future, so any returns will be limited to the value of our Common Shares.***

We have never declared or paid any cash dividends on our Common Shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to any appreciation in the value of their shares.

***If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline.***

The trading market for our Common Shares will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more securities analysts initiate research with an unfavorable rating or downgrade our Common Shares, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our Common Shares price would likely decline. If few securities analysts commence coverage of us, or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets and demand for our securities could decrease, which in turn could cause the price and trading volume of our Common Shares to decline.

***We have broad discretion in the use of the net proceeds from any offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from any offering, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from any offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these proceeds effectively could adversely affect our business, financial condition and results of operations. Pending their use, we may invest our net proceeds in a manner that does not produce income or that loses value. Our investments may not yield a favorable return to our investors and may negatively impact the price of our Common Shares.

***Investing in our securities is speculative, and investors could lose their entire investment.***

An investment in our securities is speculative and may result in the loss of an investor's entire investment. Only potential investors who are experienced in high-risk investments and who can afford to lose their entire investment should consider an investment in our securities.

***Our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval which could result in dilution.***

Our notice of articles and articles permit us to issue an unlimited number of Common Shares. We anticipate that we will, from time to time, issue additional Common Shares in the future. Subject to the requirements of the TSX Venture Exchange, we will not be required to obtain the approval of shareholders for the issuance of additional Common Shares. Any further issuances of Common Shares will result in immediate dilution to existing shareholders and may have an adverse effect on the value of their shareholdings.

***The exercise of stock options and warrants could cause dilution.***

The exercise of stock options, outstanding warrants and the subsequent resale of such Common Shares in the public market, could adversely affect the prevailing market price of the Common Shares and our ability to raise equity capital in the future at a time and price which it deems appropriate. We may also enter into commitments in the future which would require the issuance of additional Common Shares and we expect to grant additional stock options. Any Common Share issuances from treasury will result in immediate dilution to existing shareholders.

***We are likely a "passive foreign investment company," which may have adverse U.S. federal income tax consequences for U.S. shareholders.***

U.S. investors should be aware that we believe we would be classified as a passive foreign investment company, or PFIC, during the tax year ended December 31, 2023, and based on current business plans and financial expectations, we expect that we could be a PFIC in future tax years. If we are a PFIC for any year during a U.S. shareholder's holding period of the Common Shares, then such U.S. shareholder will generally be required to treat any gain realized upon a disposition of the Common Shares, or any so-called "excess distribution" received on the Common Shares, as ordinary income, and to pay an interest charge on a portion of such gain or distributions, unless the shareholder makes a timely and effective "qualified electing fund" election, QEF Election, or a "mark-to-market" election with respect to the Common Shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of the Company's net capital gain and ordinary earnings for any year in which the Company is a PFIC, whether or not the Company distributes any amounts to its shareholders. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the Common Shares over the shareholder's adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the Common Shares.

***It may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.***

We are a corporation existing under the laws of the Province of British Columbia, Canada. Several of our directors and officers, and several of the experts are residents of Canada, and all or a substantial portion of their assets, and a substantial portion of the Company's assets, are located outside the U.S. Consequently, although we have appointed an agent for service of process in the U.S., it may be difficult for holders of our securities who reside in the U.S. to effect service within the U.S. upon those directors and officers, and the experts who are not residents of the U.S. It may also be difficult for holders of our

securities who reside in the U.S. to realize in the U.S. upon judgments of courts of the U.S. predicated upon our civil liability and the civil liability of our directors, officers and experts under the U.S. federal securities laws. Investors should not assume that Canadian courts would (i) enforce judgments of U.S. courts obtained in actions against the Company or such directors, officers or experts predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or “blue sky” laws of any state or jurisdiction of the U.S. or (ii) enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the U.S. federal securities laws or any securities or “blue sky” laws of any state or jurisdiction of the U.S.. In addition, the protections afforded by Canadian securities laws may not be available to investors in the U.S.

## **General Risks**

***Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.***

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA, Health Canada or other regulatory authority investigation of the safety and effectiveness of our product candidates, our manufacturing processes and facilities or our marketing programs. FDA, EMA, Health Canada or other regulatory authority investigations could potentially lead to a recall of our product candidates or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, injury to our reputation, costs to defend the related litigation, a diversion of management’s time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

***Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, contract research organizations, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.***

We, our collaborators, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators’, our CROs’, third-party logistics providers’, distributors’ and other contractors’ and consultants’ systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S., Canadian and international privacy, data protection

and other laws, and subject us to litigation and governmental investigations and proceedings by federal, state, provincial and local regulatory entities in the United States and Canada and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that maybe imposed; and could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our Common Shares may be volatile and, in the past, companies that have experienced volatility in the market price of their share have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years and we may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

## **DIVIDENDS**

There are no restrictions in the Company's articles preventing us from paying dividends. We have not declared or paid any dividends since our incorporation. The directors of the Company anticipate that we will retain all future earnings and other cash resources for the future operation and development of our business, and accordingly, do not intend to declare or pay any cash dividends in the foreseeable future. Payment of any future dividends will be at the discretion of the Board of the Directors after taking into account many factors, including the Company's operating results, financial condition and current and anticipated cash assets.

## **SHARE CAPITAL**

### ***Common Shares***

The authorized share capital of the Company consists of an unlimited number of Common Shares of which 70,273,149 Common Shares are issued and outstanding as fully paid and non-assessable as at the date hereof.

Each Common Share carries one vote at all meetings of shareholders, is entitled to receive dividends as and when declared by the directors and is entitled to a pro-rata share of the remaining property and assets of the Company distributable to the holders of the Common Shares upon any liquidation, dissolution or winding up of the Company.

### ***Stock Options***

The Company has a share option plan which authorizes the Company to grant up to 13,985,529 options to acquire Common Shares to directors, officers, employees and consultants of the Company or any of its subsidiaries. The exercise price of options granted under the plan must be greater than or equal to the fair market value of the Common Shares on the date the option is granted. The options are generally exercisable for three to ten years from the date of grant. As at the date hereof, there were options exercisable for 11,577,700 Common Shares outstanding.

## **Retention Securities**

In connection with the appointment of Michael Kelly as President and CEO on April 10, 2023, we granted 590,000 retention securities (the “**Retention Securities**”) to Mr. Kelly, each exercisable into one Common Share at a price of \$1.78 per share for a period of 10 years and that vest equally every month over a three-year period. The Retention Securities were granted outside of the Company’s stock option plan, as an inducement grant to Mr. Kelly becoming the President and CEO of the Company pursuant to Section 6.4 of TSX-V Policy 4.4 – *Security Based Compensation* (“**Policy 4.4**”).

## **Warrants**

As of the date of this AIF, there were 10,118,750 warrants outstanding (the “**Warrants**”) with a weighted average exercise price of \$2.67 and expiry dates ranging from March 28, 2026 to July 13, 2027. The 5,043,750 outstanding Warrants issued pursuant to the March 2024 Offering are governed by a warrant indenture (the “**Warrant Indenture**”) entered into between the Company and Computershare Trust Company of Canada, dated March 28, 2024. The 5,075,000 outstanding Warrants issued pursuant to the July 2022 Non-Brokered Private Placement are exercisable in U.S. dollars. The warrant certificates representing the Warrants include customary adjustment provisions relating to the number of securities issuable and the exercise price per security in the event of material transactions or capital reorganization events that would affect the Common Shares (such as a subdivision or consolidation of the Common Shares, the issuance of other securities convertible into Common Shares or payment of an in-kind dividend or distribution) or would be a fundamental change to the Company (including a reclassification of Common Shares or completion of a material corporate transaction).

## **MARKET FOR SECURITIES**

### **Trading Price and Volume**

Our Common Shares are listed on the TSX-V under the trading symbol NGEN and the OTCQB under the trading symbol NGENF. The following table sets forth, for the calendar periods indicated, the high and low trading prices and composite volume of trading of our Common Shares as reported on the TSX-V and OTCQB respectively.

#### **TSX-V**

| <b>Month</b>   | <b>Monthly High Price<br/>(C\$)</b> | <b>Monthly Low Price<br/>(C\$)</b> | <b>Monthly<br/>Volume</b> |
|----------------|-------------------------------------|------------------------------------|---------------------------|
| January 2023   | 2.21                                | 1.63                               | 454,195                   |
| February 2023  | 2.27                                | 1.82                               | 547,017                   |
| March 2023     | 1.92                                | 1.51                               | 423,818                   |
| April 2023     | 1.94                                | 1.50                               | 444,847                   |
| May 2023       | 1.85                                | 1.50                               | 485,178                   |
| June 2023      | 1.76                                | 1.60                               | 269,111                   |
| July 2023      | 1.75                                | 1.60                               | 239,218                   |
| August 2023    | 2.15                                | 1.63                               | 575,366                   |
| September 2023 | 2.16                                | 1.90                               | 405,390                   |
| October 2023   | 2.05                                | 1.72                               | 506,984                   |
| November 2023  | 2.07                                | 1.70                               | 882,992                   |
| December 2023  | 3.33                                | 1.58                               | 1,005,430                 |

**OTCQB**

| <b>Month</b>   | <b>Monthly High Price<br/>(US\$)</b> | <b>Monthly Low Price<br/>(US\$)</b> | <b>Monthly<br/>Volume</b> |
|----------------|--------------------------------------|-------------------------------------|---------------------------|
| January 2023   | 1.66                                 | 1.20                                | 766,219                   |
| February 2023  | 1.75                                 | 1.36                                | 769,948                   |
| March 2023     | 1.49                                 | 1.10                                | 527,850                   |
| April 2023     | 1.45                                 | 1.10                                | 580,648                   |
| May 2023       | 1.33                                 | 1.10                                | 499,298                   |
| June 2023      | 1.31                                 | 1.21                                | 441,228                   |
| July 2023      | 1.33                                 | 1.22                                | 294,337                   |
| August 2023    | 1.60                                 | 1.21                                | 646,041                   |
| September 2023 | 1.68                                 | 1.40                                | 549,963                   |
| October 2023   | 1.50                                 | 1.20                                | 533,670                   |
| November 2023  | 1.50                                 | 1.25                                | 1,124,497                 |
| December 2023  | 2.51                                 | 1.16                                | 1,602,535                 |

***Prior Sales***

The Company has issued the following Common Shares, or securities that are convertible or exchangeable into Common Shares, during the year ended December 31, 2023:

| <b>Date of Issue</b> | <b>Security</b>      | <b>Number</b> | <b>Exercise Price</b> |
|----------------------|----------------------|---------------|-----------------------|
| February 22, 2023    | Stock Options        | 543,000       | \$1.94                |
| February 24, 2023    | Stock Options        | 35,000        | \$1.97                |
| April 10, 2023       | Retention Securities | 590,000       | \$1.78                |
| April 10, 2023       | Stock Options        | 2,862,000     | \$1.78                |
| May 23, 2023         | Stock Options        | 400,000       | \$1.61                |
| June 1, 2023         | Stock Options        | 100,000       | \$1.70                |
| August 23, 2023      | Stock Options        | 200,000       | \$1.89                |
| September 6, 2023    | Stock Options        | 200,000       | \$1.97                |
| October 16, 2023     | Stock Options        | 150,000       | \$1.75                |

**BOARD OF DIRECTORS AND MANAGEMENT**

The following are the names and municipalities of residence of each of the directors and officers of the Company, the positions and offices held with the Company, their respective principal occupations within the five preceding years and the number and percentage of Common Shares beneficially held by each of them as of the date hereof. Each director will hold office until the Company's next annual meeting of the shareholders, unless his or her office is earlier vacated in accordance with the Business Corporations Act (British Columbia) or the Articles of the Company.

| <b>Name, State/ Province and Country of Residence</b>            | <b>Positions with the Company and, if Director, Date First Elected</b> | <b>Principal Occupation(s) for Past 5 Years</b>   | <b>Number and Percentage of Common Shares Owned</b> |
|--|--|---|---|
| <b>J. Craig Thompson</b><br>California, USA                      | Director<br>April 13, 2022   | CEO, Cerevance since April 2022, President and CEO, Neurana Pharmaceuticals from June 2018 to April 2022; President and CEO, Anthera Pharmaceuticals from January 2016 to June 2018.  | -<br>(0.00%)  |
| <b>Krista L. McKerracher</b><br>Florida, USA                     | Director<br>September 9, 2021  | Founder, FIG Advisory LLC from September 2017; VP, Head of Hemoglobinopathy Programs at CRISPR Therapeutics from November 2017 to October 2019; Vice President & Global Program Franchise Head, Novartis Oncology from February 2008 to July 2017.  | 7,758<br>(0.01%)                                    |
| <b>Glenn A. Ives</b><br>British Columbia, Canada                 | Director and Chair of Board<br>September 9, 2021                       | Director and Chair of Audit Committee, Kinross Gold Corporation and Director of Wheaton Precious Metals Corp. from May, 2020; Partner, Deloitte LLP (Canada) from 2000 to March 2020 and Chair from 2010 to 2018; Director, Deloitte Global from 2010 to 2018 and Chair of Risk Committee 2012 to 2018.                   | 58,511 <sup>2</sup><br>(0.08%)                      |
| <b>Harold M. Punnett<sup>1</sup></b><br>British Columbia, Canada | Director<br>January 19, 2017   | Retired since March, 2024, Previously self-employed dentist and sole owner of Dr. Harold Punnett, Inc.  | 1,125,532<br>(1.60%)                                |
| <b>Randall E. Kaye</b><br>New York, USA                          | Director<br>October 26, 2020   | Chief Medical Officer of Longboard Pharmaceuticals from March 2022; Chief Medical Officer of Neurana Pharmaceutical from September 2019 to March 2022; Chief Medical Officer of Click Therapeutics from September 2018 to September 2019; Chief Scientific Officer of SSI Strategy from September 2014 to September 2018. | 10,000<br>(0.01%)                                   |
| <b>Brian E. Bayley<sup>1</sup></b><br>British Columbia, Canada   | Director<br>May 16, 2018   | President of Earlston Management Corp., a private management company; and Executive Chairman of Earlston Investments Corp.  | 400,000<br>(0.57%)                                  |
| <b>Adam H. Rogers</b><br>Massachusetts, USA                      | Director<br>July 13, 2022  | Principal of PFP Biosciences Holdings from 2022; Interim President of NervGen from September 2022 to April 2023; Founder (2010) and CEO of Hemera Biosciences from November 2017 to December 2020; Assistant Professor of Ophthalmology of New England Eye Center from July 2000 to June 2020.                            | 12,889,149 <sup>3</sup><br>(18.35%)                 |
| <b>Gianni (John) Ruffolo<sup>1</sup></b><br>Ontario, Canada      | Director<br>October 13, 2023   | Founder & Managing Partner of Maverix Private Equity from January 2019; Chief Executive Officer of OMERS Ventures from January 2011 to December 2018.   | 70,407<br>(0.10%)                                   |
| <b>Michael Kelly</b><br>Pennsylvania, USA                        | President & CEO, Director<br>April 10, 2023                            | President and CEO of NervGen since April 2023; Advisor of MK Advisory LLC from October 2019 to December 2022; President, US Operations of Adapt Pharma Inc. from March 2016 to June 2019.   | 143,957<br>(0.20%)                                  |
| <b>Neil A. Klompas</b><br>British Columbia, Canada               | Director<br>July 22, 2024  | President and CEO of Augurex Life Sciences Corp. since August 2024; President and Chief Operating Officer of Zymeworks Inc. from February 2022 to June 2023, Chief Financial Officer & Executive VP, Business   | -<br>(0.00%)  |

|   |   |   |                    |
|---|---|---|--------------------|
|   |   | Operations of Zymeworks Inc. from September 2019 to February 2022, Chief Financial Officer of Zymeworks Inc. from March 2007 to September 2019.   |                    |
| <b>William J. Adams</b><br>British Columbia, Canada | Chief Financial Officer,<br>Corporate Secretary | Chief Financial Officer, Corporate Secretary of NervGen from February 2020;<br>Chief Corporate Officer, Chief Financial Officer of Anandia Laboratories Inc. from September 2017 to February 2020;<br>Chief Financial Officer, Corporate Secretary of Response Biomedical Corp. from June 2012 to April 2017. | 155,820<br>(0.22%) |
| <b>Daniel D. Mikol</b><br>California, USA           | Chief Medical Officer                           | Chief Medical Officer of NervGen from May 2021;<br>Executive Medical Director of Amgen Inc. from September 2015 to May 2021.  | -<br>(0.00%)       |

Notes:

- (1) Member of the Company's Audit Committee.
- (2) All Common Shares are held through Mr. Ives private company, Glenn Antony Ives Professional Corporation.
- (3) Includes 10,000,000 Common Shares held by PFP Biosciences Holdings LLC for which Dr. Rogers serves as Managing Member and 2,879,149 Common Shares held by an affiliate of PFP Biosciences Holdings LLC.

### ***Biographies of Executive Officers and Directors***

**J. Craig Thompson** – Mr. Thompson joined Cerevance as CEO and as a member of the Board in April 2022. Prior to Cerevance Mr. Thompson was at Neurana Pharmaceuticals as President & CEO and as a member of the board of directors from June 2018 to April 2022. Prior to Neurana, Mr. Thompson was President & CEO of Anthera Pharmaceuticals, Inc. His previous biotech experience includes Chief Operating Officer for Tetrphase Pharmaceuticals, Inc. and Chief Commercial Officer for Trius Therapeutics, Inc. where he was involved in the \$700M+ acquisition of Trius Therapeutics, Inc. by Cubist Pharmaceuticals, Inc., as well as a partnership with Bayer Pharma AG. Prior to Trius Therapeutics Inc., Mr. Thompson served in various global and U.S. roles at Pfizer Inc., including Therapeutic Group Leader of Allergy, Respiratory, Pulmonary Vascular Disease and Inflammation; and ultimately served as Vice President of Marketing for Pfizer's Specialty Care Business Unit. Previous to Pfizer Inc., Mr. Thompson served in positions of increasing responsibility at Merck & Co., Inc., including the European partnership with Schering Plough.

Mr. Thompson holds a Bachelor's degree in Commerce from McMaster University and an MBA from the University of Notre Dame.

**Krista L. McKerracher** – Ms. McKerracher is a biopharmaceutical leader, Board member, and strategic advisor with over 35 years' experience in both large global pharmaceutical and small biotech companies. Her last corporate role was VP, Head of Hemoglobinopathy Programs at CRISPR Therapeutics where she and her team took the first CRISPR gene-edited product into the clinic. Prior to CRISPR Therapeutics she was VP & Global Program Franchise Head at Novartis where she led a global cross-functional development team. She also held series of commercial roles over 14 years at the Johnson & Johnson family of companies. Ms. McKerracher is currently Founder of FIG Advisory LLC focused on advising early stage companies on strategy and business development. Additionally, she serves on Advisory Boards to Cureleads and BioAxone Biosciences and is a mentor at Springboard, an incubator for female led healthcare and technology companies.

Ms. McKerracher holds a BSc in Applied Health Studies from the University of Waterloo and an MBA from the Schulich School of Business at York University.

**Glenn A. Ives** – Mr. Ives is a Director and the Audit Committee Chair of Kinross Gold Corporation and a Director of Wheaton Precious Metals Corp. Mr. Ives retired as a Canadian partner of Deloitte LLP on March 31, 2020. He served as the Executive Chair of Deloitte Canada from 2010 and 2018, a director of Deloitte Global from 2010 to 2018 and Chair of the Deloitte Global Risk Committee from 2012 to 2018. Mr. Ives has extensive corporate governance experience with non-profit organizations including serving as Chair of St. Paul's Foundation (Vancouver) and a director of the Princess Margaret Cancer Foundation from 2010 to 2019 and Chairman from 2016 to 2018.

Mr. Ives holds a Bachelor of Mathematics degree (honors) from the University of Waterloo, graduating on the Dean's Honor List. He is a Fellow of the Chartered Professional Accountants of British Columbia, a member of the Chartered Professional Accountants of Ontario and was the Ontario Gold medalist for the Uniform Final Exams in 1984. Mr. Ives is also a member of the Institute of Corporate Directors and the National Association of Corporate Directors.

**Harold M. Punnett** – Dr. Punnett is a retired member of the Canadian Dental Association, College of Dental Surgeons of British Columbia, and the British Columbia Dental Association. Dr. Punnett is an experienced angel investor and has previously acted as a director of two public issuers. A co-founder and current Board member of NervGen, he has a passion for helping those with spinal cord injuries and nerve related challenges.

Dr. Punnett holds a Doctor of Dental Medicine degree from the University of British Columbia.

**Randall E. Kaye** – Dr. Kaye is currently Chief Medical Officer at Longboard Pharmaceuticals in San Diego, California. Prior to Longboard, Dr. Kaye served as Chief Medical Officer at Neurana Pharmaceuticals, Click Therapeutics, Axsome Therapeutics and Avanir Pharmaceuticals. Earlier in his career, Dr. Kaye held leadership positions at Scios Inc., InterMune and Pfizer Inc.

Dr. Kaye earned an MD, MPH, and BS at George Washington University. He was a Research Fellow at Harvard Medical School.

**Brian E. Bayley** – Mr. Bayley serves as the President and a director of Earlston Management Corp. (a private management company) and Executive Chairman of Earlston Investments Corp. (a private merchant bank). Previously, Mr. Bayley was a director and Resource Lending Advisor for Sprott Resource Lending Corp. (formerly Quest Capital Corp.), a Toronto Stock Exchange and NYSE American listed resource lending corporation. He has held active senior management positions in both private and public natural resource companies and has over 30 years of public issuer experience, both as an officer and a director.

Mr. Bayley holds an MBA from Queen's University. He is also a director and officer of several other public companies.

**Adam H. Rogers** – Dr. Rogers was the interim President of NervGen Pharma Corp from September 2022 to April 2023 and is a Principal of Boston based PFP Biosciences Holdings and a board-certified ophthalmologist specializing in diseases and surgery of the retina and vitreous. Dr. Rogers co-founded Hemera Biosciences in 2010, a clinical stage gene therapy biotech company targeting dry age-related macular degeneration. He assumed the role of CEO in 2017 and oversaw all aspects of the company until the Hemera assets were acquired in December 2020 by Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson. From 2001 to 2020 he served as an Assistant Professor of Ophthalmology at the New England Eye Center of Tufts Medical Center (Boston, MA). Dr. Rogers has published 27 articles in peer reviewed journals and co-authored two textbooks and numerous chapters in major ophthalmic textbooks. Since 2007 he has served on the board of One Family Inc., an organization whose mission is to end homelessness in Massachusetts. He is a member of the Emory University Board of Trustees.

Dr. Rogers has a MD from Emory College and Emory University School of Medicine.

**Gianni (John) Ruffolo** – Mr. Ruffolo is the Founder and Managing Partner of Maverix Private Equity (“Maverix”), a private equity firm focused on innovation-enabled growth and disruption investment strategies. Mr. Ruffolo chairs the Investment Committee, guides the strategy of the firm, is deeply involved with fundraising and sourcing and leading investment opportunities, particularly within the technology and life sciences industries.

Mr. Ruffolo is also the Founder of OMERS Ventures and Co-Founder and Vice Chair of the Council of Canadian Innovators. As an active board member in the profit and not-for-profit sectors, Mr. Ruffolo currently works with many leading innovative organizations collaborating with organizations like KODE Labs, Viral Nation, CIBC Foundation, OneEleven, Federal Government's Global Hypergrowth Project, Rick Hansen Foundation, TIFF – Toronto International Film Festival, Schulich School of Business's Dean's Global Council, and the Caldwell's Top 40 Under 40.

Mr. Ruffolo holds a BBA, Accounting degree from York University. He is a Fellow of the Chartered Professional Accountants of Ontario.

**Michael Kelly** – Mr. Kelly brings three decades of pharmaceutical experience playing instrumental roles in the creation, development and strengthening of several companies to his role as President & CEO of NervGen. Most recently, Mr. Kelly served as President of U.S. Operations for Adapt Pharma, Inc., from March 2016 to June 2019, and played a key leadership role in the development and commercialization of NARCAN (naloxone HCl) Nasal Spray in the US and Canada and in the eventual sale to Emergent BioSolutions for US\$735 million. Prior to his tenure at Adapt Pharma, Inc., Mr. Kelly served as the Chief Executive Officer and a Director of Covis Pharmaceuticals, Inc., where, along with its European affiliate, grew and sold the company assets for US\$1.2 Billion. Mr. Kelly was also a member of the founding management team of Azur Pharma Limited, a specialty pharmaceutical company, and later, following a strategic merger, served as the Senior Vice President of Sales and Marketing for Jazz Pharmaceuticals Inc. Mr. Kelly has also held various commercial and medical roles at Guilford Pharmaceuticals Inc., ViroPharma Incorporated and TAP Pharmaceuticals Inc and has been a Director of ARS Pharmaceuticals Inc. since May 2019.

Mr. Kelly holds a Bachelor of Science in business administration from The College of New Jersey and a Master of Business Administration from Rider University.

**Neil A. Klompas** – 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.

Mr. Klompas holds BSc in Microbiology & Immunology from the University of British Columbia and is a Chartered Professional Accountant, CA.

**William J. Adams** – Mr. Adams has over 25 years of strategic financial management experience that includes mergers and acquisitions, operations and capital markets in both Canada and the U.S., as well as corporate and operational finance having held a number of executive positions with high-growth technology and life sciences companies, including Chief Financial Officer roles at Anandia Laboratories Inc., Response Biomedical Corp., CellFor Inc., and AnorMED Inc. He had a leading role in the sale of AnorMED to Genzyme for \$580 million and was instrumental in the sale of Anandia in 2018 for \$118 million. Mr. Adams has been responsible for completing over \$250 million in public and private equity

financing, including listing on the TSX and NASDAQ, and over \$750 million in mergers and acquisitions and technology licensing transactions.

Mr. Adams is a Chartered Professional Accountant, CA and holds a Bachelor of Commerce from the University of British Columbia.

**Daniel D. Mikol** – Dr. Mikol has over 25 years of experience in the pharmaceutical industry and as a practicing neurologist conducting clinical research. For 12 years, he was an active clinician and clinical researcher in the Department of Neurology at the University of Michigan, specializing in the treatment of multiple sclerosis, where he rose to the level of Associate Professor. For the past 13 years, Dr. Mikol has had leadership roles in industry working in neuroscience clinical development. Prior to joining NervGen, Dr. Mikol was at Amgen, where he served as the Head of clinical development in the neuroscience and nephrology therapeutic areas, as well as Head of the molecular genetics team across therapeutic areas. He was instrumental in the approval of Aimovig for migraine prevention in 2018. Prior to Amgen, Dr. Mikol was the development lead for Tysabri at Biogen and supported the Japan approval of Tysabri for relapsing multiple sclerosis in 2014. Prior to that, Dr. Mikol had senior clinical development and medical affairs roles in neuroscience at Novartis and EMD Serono.

Dr. Mikol was educated at the University of Chicago for both his MD and PhD, and was a Fulbright Scholar, Immunological Research, Ludwig Maximilian University of Munich, Germany. He held a staff physician role treating patients for 12 years at The University of Michigan, Department of Neurology.

### ***Shareholdings of Directors and Executive Officers***

As at the date hereof, the directors and executive officers of the Company as a group beneficially own, directly or indirectly, or exercise control or direction over 14,861,134 or approximately 21.2% of the number of issued and outstanding Common Shares.

## **CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS**

### ***Cease Trade Orders***

To the knowledge of the Company, no director or executive officer of the Company is, or within the ten years prior to the date hereof has been, a director, chief executive officer, or chief financial officer, of any company (including the Company) that was subject to (a) a cease trade order; (b) an order similar to a cease trade order; or (c) an order that denied the relevant company access to any exemption under securities laws, that was in effect for a period of more than thirty consecutive days, issued while that person was acting in such capacity or issued thereafter but resulted from an event that occurred while that person was acting in such capacity.

### ***Bankruptcies***

To the knowledge of the Company, no director or executive officer or shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company is, or within the ten years prior to the date hereof has been, a director or executive officer of any company (including the Company) that, while that person was acting in such capacity or within a year of that person ceasing to act in such capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets.

To the knowledge of the Company, no director or executive officer or shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company has, within the ten years prior to the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement, or

compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold that person's assets.

### ***Penalties and Sanctions***

No director or executive officer of the Company, or a shareholder holding a sufficient number of securities of NervGen to affect materially the control of the Company has been subject to (a) any penalties or sanctions imposed by a court relating to securities laws or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

All of the above disclosure also applies to any personal holding companies of any of the persons referred to above.

## **CONFLICTS OF INTEREST**

NervGen's directors are required by law to act honestly and in good faith with a view to the best interests of the Company and to disclose any interests that they may have in any project or opportunity of the Company. If a conflict of interest arises at a meeting of the Board, any director in a conflict must disclose his interest and abstain from voting on such matter. To the best of our knowledge, and other than as disclosed in the following paragraph, there are no known existing or potential conflicts of interest among the Company or its subsidiaries, its directors and officers or other members of management or of any proposed promoter, director, officer or other member of management as a result of their outside business interests.

Some of NervGen's directors and officers serve as directors and officers of other private and public companies (including pharma development companies). Additionally, some of NervGen's directors and officers are engaged and will continue to be engaged in the search for additional business opportunities on behalf of other corporations (including pharma development companies), and situations may arise where these directors and officers may be serving another corporation with interests that are in direct competition with the Company. In the event of any conflicts of interest, such conflicts must be disclosed to the Company and dealt with in accordance with the provisions of the Business Corporations Act (British Columbia).

## **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

There are no existing or contemplated material legal proceedings to which NervGen or a subsidiary of NervGen is a party or of which any of their respective property is the subject matter and no such proceedings known to NervGen is contemplated. NervGen has not had any material penalties or sanctions imposed against it by any legal or regulatory authorities.

## **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Except as otherwise set out herein, there are no material interests, direct or indirect, of any director, executive officer, person who beneficially owns, or controls or directs, directly or indirectly, more than 10% of the outstanding Common Shares, or any known associates or affiliates of such persons, in any transaction within the last three completed financial years or during the current financial year which has materially affected or is reasonably expected to materially affect the Company.

On July 13, 2022, we closed a non-brokered private placement of 10,150,000 units of the Company at a price of US\$1.50 per unit, for aggregate gross proceeds of US\$15,225,000. In connection with the private placement, PFP Biosciences Holdings, acquired 17% of the outstanding Common Shares. An affiliate of PFP Bioscience Holdings purchased an additional 2,879,149 units in the March 2024 Offering

and currently, together these entities hold 18.3% of the outstanding Common Shares. Adam Rogers, MD, serves as Managing Member of PFP Biosciences Holdings.

### **TRANSFER AGENT**

The registrar and transfer agent for the Common Shares is Computershare Investor Services Inc. in Vancouver, British Columbia. The Company and Computershare Investor Services Inc. have entered into an agreement dated September 16, 2018, known as the Transfer Agent, Registrar and Dividend Disbursing Agent Agreement, governing their respective rights and duties pertaining to this relationship.

### **MATERIAL CONTRACTS**

The Company is not party to any material contract that was entered into either (1) in the last completed fiscal year, or (2) before the most recently completed fiscal year but that is still in effect as of the date hereof, except for contracts entered into in the ordinary course of business and as set out below.

1. The License for the Technology (see “Narrative Description of the Business – The Company’s Lead Compound and License – License Overview”); and
2. The Warrant Indenture governing the terms of the Warrants issued pursuant to the March 2024 Offering (see “Share Capital – Warrants”).

### **INTEREST OF EXPERTS**

The Company’s auditor, KPMG LLP, has audited the Company’s financial statements for the years ended December 31, 2023 and 2022. KPMG LLP has confirmed that they are independent from the Company within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation and regulations.

### **ADDITIONAL INFORMATION**

Additional information about us may be found under our profile on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca). Additional information, including directors’ and officers’ remuneration and indebtedness, principal holders of our securities, options to purchase securities and securities authorized for issuance under equity compensation plans, is contained in our Management Information Circular for our most recent annual meeting of shareholders. Additional information may also be found in our audited financial statements and related management’s discussion and analysis for our most recently completed financial year.

## SCHEDULE A

### AUDIT COMMITTEE INFORMATION

**a) Audit Committee Charter**

See Appendix 1 attached hereto.

**b) Composition of the Audit Committee**

The Audit Committee consists of three directors – John Ruffolo (Chair), Brian E. Bayley and Dr. Harold M. Punnett. All members of the Audit Committee are considered to be independent and financially literate within the meaning of National Instrument 52-110 – Audit Committees.

**c) Relevant Education and Experience**

The relevant education and experience of each member of the Audit Committee is provided above, under the heading “Directors and Officers”. All of the Audit Committee members are independent of management of the Company as required by the TSX and each member is financially literate in that each has the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company’s financial statements. Each individual has experience managing a company at senior roles and, in those roles, reviewing financial statements and reports.

**d) Audit Committee Oversight**

At no time since the commencement of the Company’s most recently completed financial period was a recommendation made of the Audit Committee to nominate or compensate an external auditor not adopted by the Board of Directors.

**e) Reliance on Certain Exemptions**

At no time since the commencement of the Company’s most recently completed financial period has the Corporation relied on the following exemptions under NI 52-110: section 2.4 (*De Minimis Non-Audit Services*), subsection 6.1.1(4) (*Circumstances Affecting the Business or Operations of the Venture Issuer*), subsection 6.1.1(5) (*Events Outside Control of Member*), subsection 6.1.1(6) (*Death, Incapacity or Resignation*) or in whole or in part, granted under Part 8 of NI 52-110 (Exemptions).

**f) Pre-Approval Policies and Procedures**

The Audit Committee has adopted specific policies and procedures for the engagement of non-audit services, as described in the Audit Committee Charter attached hereto as Appendix 1 to this Schedule A.

**g) External Auditor Service Fees**

| <b><u>Financial Period Ending</u></b> | <b><u>Audit Fees</u></b> <sup>(1)</sup> | <b><u>Audit Related Fees</u></b> | <b><u>Tax Fees</u></b> | <b><u>All Other Fees</u></b> |
|---------------------------------------|---|----------------------------------|------------------------|------------------------------|
| December 31, 2022                     | \$308,603                               | Nil                              | \$5,400                | Nil                          |
| December 31, 2023                     | \$251,265                               | Nil                              | \$119,673              | Nil                          |

Notes: (1) Effective November 15, 2022, KPMG LLP was appointed and Davidson & Company LLP resigned as auditor of the Company.

“Audit Fees” refers to the aggregate fees billed by the Company’s external auditors for audit services including interim reviews. “Audit Related Fees” refers to aggregate fees billed for assurance and related services by our external auditors that are reasonably related to the performance of the audit or review of our financial statements and not reported under Audit Fees. “Tax Fees” includes fees for professional services rendered by our external auditors for tax compliance, tax advice and tax planning. “All Other Fees” includes all fees billed by our external auditors for services not covered in the other three categories.

## APPENDIX 1

### AUDIT COMMITTEE CHARTER

Effective September 26, 2018 and revised on February 23, 2022, the Board adopted the following as the Audit Committee's Charter.

#### Purpose

The Audit Committee (the "**Audit Committee**") assists the Board of Directors (the "**Board**") of NervGen Pharma Corp. ("**NervGen**" or the "**Company**") in fulfilling its oversight responsibilities in relation to the following:

- i. the integrity of the Company's financial statements;
- ii. the Company's compliance with legal and regulatory requirements;
- iii. the qualifications, independence and performance of the Company's independent auditors engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company (the "**External Auditors**");
- iv. the performance of the Company's internal audit function; and
- v. the preparation of the report required by applicable securities regulators to be included in the Company's annual proxy statement.

#### Composition and Process

The Audit Committee shall be composed of a minimum of three members of the Board of Directors, each of whom are independent. An independent director, as defined in National Instrument 52-110 - *Audit Committees* ("**NI 52-110**"), is a director who has no direct or indirect material relationship which could, in the view of the Company's Board of Directors, be reasonably expected to interfere with the exercise of a member's independent judgment or as otherwise determined to be independent in accordance with NI 52-110 or other applicable laws, regulations, rules and guidelines. The Board may remove members of the Audit Committee at any time, with or without cause.

- (a) Members shall serve one-year terms and may serve consecutive terms, which are encouraged to ensure continuity of experience. Resignation or removal of a Director from the Board, for whatever reason, shall automatically constitute resignation or removal, as applicable, from the Audit Committee. Vacancies, for whatever reason, may be filled only by the Board.
- (b) The chairperson (the "**Chair**") shall be designated by the Board; provided, that if the Board does not so designate a Chair, the Audit Committee shall choose one of its members to be its Chair by majority vote.
- (c) All members of the Audit Committee shall be financially literate. Financial literacy is the ability to read and understand a balance sheet, income statement and cash flow statement that present a breadth and level of complexity comparable to the Company's financial statements. At least one member of the Audit Committee shall have past employment experience in finance or accounting, requisite professional certification in accounting, or comparable experience or background that results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities. One or more members of the Audit Committee

may qualify as an “audit committee financial expert” under the rules promulgated by applicable securities regulations.

- (d) A member of the Audit Committee may not, other than as a member of the Audit Committee, the Board or any other committee established by the Board, receive directly or indirectly any consulting, advisory or other compensatory fee from the Company.
- (e) The Chairperson shall, in consultation with management and the external auditor and internal auditor (if any), establish the agenda for the meetings and ensure that properly prepared agenda materials are circulated to the members with sufficient time for study prior to the meeting. The external auditor will also receive notice of all meetings of the Audit Committee. The Audit Committee may employ a list of prepared questions and considerations as a portion of its review and assessment process.
- (f) The Audit Committee shall meet as often as it deems appropriate, but no less frequently than quarterly. A quorum at meetings of the Audit Committee shall be a majority of its members. The Audit Committee may hold its meetings, and members of the Audit Committee may attend meetings, by telephone conference or other electronic means if this is deemed appropriate. In lieu of a meeting, the Audit Committee may act by unanimous written consent in accordance with the Company’s articles of incorporation.
- (g) The minutes of the Audit Committee meetings shall accurately record the decisions reached and shall be distributed to Audit Committee members with copies to the Board of Directors, the Chief Executive Officer, the Chief Financial Officer and the external auditor.
- (h) The Audit Committee reviews, prior to their presentation to the Board of Directors and their release, all material financial information required by securities legislation and policies.
- (i) The Audit Committee enquires about potential claims, assessments and other contingent liabilities.
- (j) The Audit Committee periodically reviews with management, depreciation and amortization policies, loss provisions and other accounting policies for appropriateness and consistency.
- (k) The Audit Committee shall review and reassess the adequacy of this Charter annually and recommend to the Board any amendments or modifications it deems appropriate.

#### Authority

- (l) Appointed by the Board of Directors pursuant to the provisions of the *Business Corporations Act* (British Columbia) and the by-laws of the Company.
- (m) Primary responsibility for the Company’s financial reporting, accounting systems and internal controls is vested in senior management and is overseen by the Board of Directors. The Audit Committee is a standing committee of the Board of Directors established to assist it in fulfilling its responsibilities in this regard. The Audit Committee shall have responsibility for overseeing management reporting on internal controls. While it is management’s responsibility to design and implement an effective system of internal control, it is the responsibility of the Audit Committee to ensure that management has done so.
- (n) In fulfilling its responsibilities, the Audit Committee shall have unrestricted access to the Company’s personnel and documents and will be provided with the resources necessary to carry out its responsibilities.

- (o) The Audit Committee shall have direct communication channels with the internal auditor (if any) and the external auditor to discuss and review specific issues, as appropriate.
- (p) The Audit Committee shall have the authority to engage independent counsel and other advisors as it determines necessary to carry out its duties.
- (q) The Audit Committee shall establish the compensation to be paid to any advisors employed by the Audit Committee and such compensation shall be paid by the Company as directed by the Audit Committee.

#### Relationship with External Auditors

- (r) The Audit Committee shall be directly responsible for appointing, retaining and terminating, and for determining the compensation, of the Company's External Auditors. The Audit Committee may consult with management in fulfilling these duties, but may not delegate these responsibilities to management.
- (s) An external auditor must report directly to the Audit Committee.
- (t) The Audit Committee is directly responsible for overseeing the work of the external auditor including the review and approval of the scope and staffing of the external auditor annual audit plan and the resolution of disagreements between management and the external auditor regarding financial reporting.
- (u) The Audit Committee shall implement structures and procedures to ensure that it meets with the external auditor as frequently as it deems necessary and at least annually in the absence of management.
- (v) At least annually, and before the external auditors issue their report on the annual financial statements, the Audit Committee shall obtain from the external auditors a formal written statement describing all relationships between the external auditors and the Company; discuss with the external auditors any disclosed relationships or services that may affect the objectivity and independence of the external auditors; and obtain written confirmation from the external auditors that they are objective and independent within the meaning of the applicable Rules of Professional Conduct/Code of Ethics adopted by the provincial institute or order of chartered accountants to which the external auditors belong and other Applicable Requirements. The Audit Committee shall take appropriate action to oversee the independence of the external auditors.

#### Accounting Systems, Internal Controls and Procedures

- (w) Obtain reasonable assurance from discussions with and/or reports from management, and reports from external auditors that accounting systems are reliable and that the prescribed internal controls are operating effectively for the Company and its subsidiaries and affiliates.
- (x) The Audit Committee shall review to ensure to its satisfaction that adequate procedures are in place for the review of the Company's disclosure of financial information extracted or derived from the Company's financial statements and will periodically assess the adequacy of those procedures.
- (y) Direct the external auditor's examinations to particular areas.
- (z) Review control weaknesses identified by the external auditor, together with management's response.

- (aa) Review with the external auditor its view of the qualifications and performance of the key financial and accounting executives.
- (bb) In order to preserve the independence of the external auditor the Audit Committee will:
  - (i) recommend to the Board of Directors the external auditor to be nominated; and
  - (ii) recommend to the Board of Directors the compensation of the external auditor's engagement;
- (cc) The Audit Committee shall review and pre-approve any engagements for non-audit services to be provided by the external auditor or its affiliates, together with estimated fees, and consider the impact on the independence of the external auditor.
- (dd) Review with management and with the external auditor any proposed changes in major accounting policies, the presentation and impact of significant risks and uncertainties, and key estimates and judgments of management that may be material to financial reporting.
- (ee) The Audit Committee shall review and approve the Company's hiring policies regarding partners, employees and former partners and employees of the present and most recent former external auditor of the Company.
- (ff) The Audit Committee shall establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.
- (gg) The Audit Committee shall on an annual basis, prior to public disclosure of its annual financial statements, ensure that the external auditor has entered into a participation agreement and has not had its participant status terminated, or, if its participant status was terminated, has been reinstated in accordance with the Canadian Public Accountability Board ("**CPAB**") and Public Company Accounting Oversight Board ("**PCAOB**") bylaws and is in compliance with any restriction or sanction imposed by the CPAB or PCAOB.

#### Statutory and Regulatory Responsibilities

- (hh) Annual Financial Information - review the annual audited financial statements and related management's discussion and analysis ("**MD&A**"), including any letter to shareholders and related press releases, and recommend their approval to the Board of Directors, after discussing matters such as the selection of accounting policies (and changes thereto), major accounting judgments, accruals and estimates with management and the external auditor.
- (ii) Annual Report - review the management MD&A section and all other relevant sections of the annual report, if prepared, to ensure consistency of all financial information included in the annual report.
- (jj) Interim Financial Statements - review the quarterly interim financial statements and related MD&A, including any letter to shareholders and related press releases and recommend their approval to the Board of Directors.
- (kk) Earnings Guidance/Forecasts - review forecasted financial information and forward-looking statements.

- (ll) Review the Company's financial statements, MD&A, prospectuses or other securities offering document, earnings press releases and any other publicly disseminated material financial disclosure before the Company publicly discloses such information.

#### Reporting

- (mm) Report, through the Chairperson of the Audit Committee, to the Board of Directors following each meeting on the major discussions and decisions made by the Audit Committee.
- (nn) Report annually to the Board of Directors on the Audit Committee's responsibilities and how it has discharged them.
- (oo) Review the Audit Committee's Charter annually and recommend the approval of any proposed amendments to the Board of Directors.

#### Other Responsibilities

- (pp) Investigating fraud, illegal acts or conflicts of interest.
- (qq) Discussing selected issues with corporate counsel or the external auditor or management.