

**Corporate Presentation** 

**JULY 2023** 

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## NervGen Highlights

Developing therapies to **revolutionize treatment** for a broad range of therapeutic indications

NVG-291, a first-in-class drug candidate under development with potential to repair nervous system damage

Demonstrated functional improvement in six different models of nervous system damage

Targeting indications of high unmet medical need beginning with spinal cord injury (SCI)

Proof of concept (Phase 1b/2a) spinal cord injury clinical trial enrolling in 2023 with results expected in 2024



### Leadership



companies.

Mike Kelly, MBA, BSBA
Chief Executive Officer
Mike brings three decades of pharmaceutical industry experience in creation, development and strengthening of both private and public



Bill Adams, CPA, CA

Chief Financial Officer
Bill has over 25 years of strategic financial management experience that includes mergers and acquisitions, operations and capital markets in Canada and the US.



Chief Medical Officer

Dan has over 25 years of experience in the pharmaceutical industry and as a practicing physician conducting clinical research in the field of neurology.

Dan Mikol, MD, PhD



Matvey Lukashev, PhD

VP, Research & Preclinical Devt.

Matvey has over 30 years of experience in academia, industry and biotech settings focused on translational research and drug discovery.



VP, Program Management
Nana has over 20 years experience
managing biopharma product
development programs from
preclinical stage to Phase 3 across
a range of therapeutic areas.

Nana Collett, MS, MBA

































## History of NervGen Technology

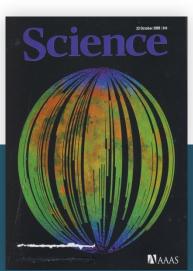
#### 1990s

Dr. Silver discovered that glial scars contains chondroitin sulfate proteoglycans (CSPG), a group of molecules known to inhibit cellular events central to neural tissue repair



#### 2009

Dr. Silver and collaborators from Harvard co-discovered that CSPGs bind to protein tyrosine phosphatase sigma (PTPo), a receptor present in the brain and spinal cord and involved in CSPG-dependent inhibition of neuroplasticity



#### 2015

Dr. Silver's team designed a peptide (NVG-291-R) derived from PTPσ shown to relieve CSPG-mediated inhibition of nervous system repair.

NVG-291 is the humanized version of NVG-291-R



#### 2018

NervGen licensed NVG-291 global rights for development and commercialization in all indications from Case Western with intellectual property protection until 2037





### **NVG-291: Product Candidate Overview**

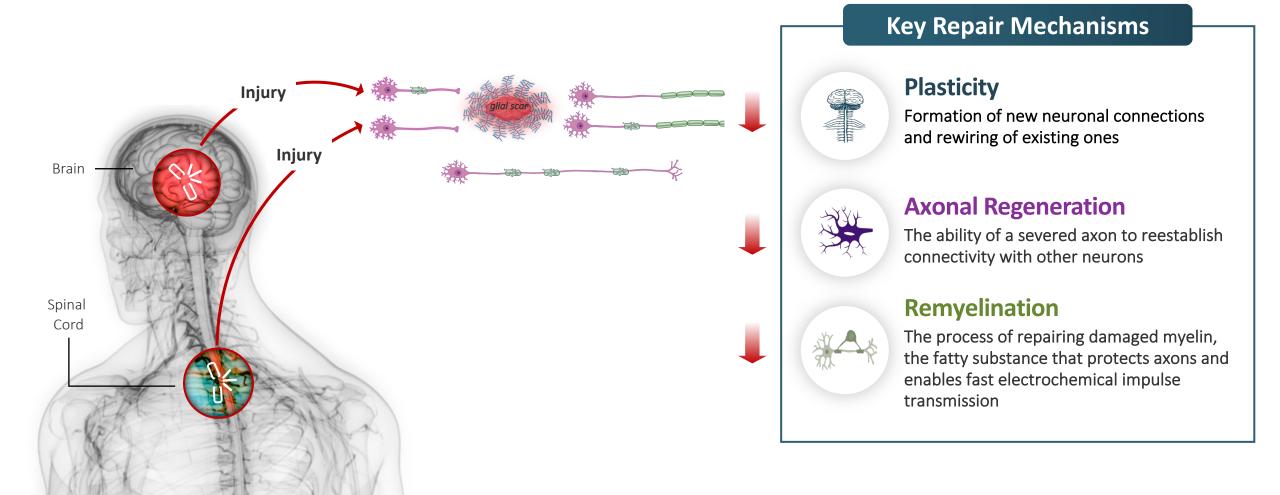


- Cell-penetrating peptide, 35 amino acids in length
- Designed to cross cell membranes for enhanced cellular uptake of the drug
- Route of administration is subcutaneous injection
- Manufactured by chemical synthesis
- Discovery focused on analogs with new composition of matter IP, improvements in pharmacology and cost of manufacturing



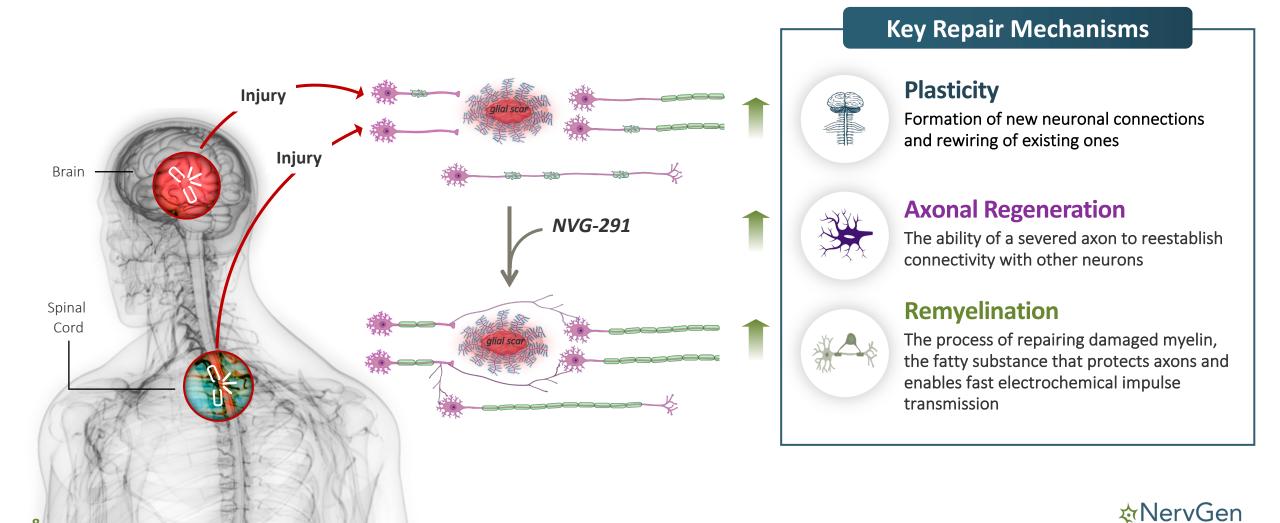
### Nervous System Damage Has Limited Treatment Alternatives

Glial scars and accumulation of CSPGs suppress CNS repair



## Novel Therapy Under Development to Repair Nervous System Damage

**NVG-291** targets negative effects of CSPGs on CNS repair



## Multiple Preclinical Studies Using NVG-291-R\* Report Improved CNS/PNS Repair

Enhanced Plasticity, Repair (Axonal, Myelination), and Recovery of Function

Conditions Modeled	ACUTE SPINAL CORD INJURY	CHRONIC SPINAL CORD INJURY	STROKE (Ischemic, Hemorrhagic)	MULTIPLE SCLEROSIS (EAE)	PERIPHERAL NERVE INJURY	OPTIC NERVE DEMYELINATION
Functional Endpoints	Motor Sensory Bladder	Motor	Motor Sensory Object recognition	Motor	Motor Sensory	Visual Behavioral
	<ol> <li>Lang, B.T. et al., Nature, 518, 404–408. (2015).</li> <li>Rink, S. et al., Experimental Neurology, 309, 148–159. (2018).</li> <li>Ham, T.R. et al., Ann Biomed Eng, 47, 744–753. (2019).</li> <li>Ham, T.R. et al., Materials Science and Engineering: C, 110, 110656. (2020).</li> </ol>	1. Milton et al., bioRxiv, doi:10.1101/2022.08.01.502398 (not peer-reviewed)	1. Luo et al., Cell Reports Volume 40, Issue 4, 111137, 2022 2. Yao et al., Journal of Neuroinflammation 19:207, 2022	1. Luo, F. et al., Nature Communications, 9, 1–16. (2018).	<ol> <li>Li, H. et al., Scientific Reports, 5, 1–14. (2015).</li> <li>Yao, M. et al., Neuropharmacology, 144, 208–218. (2019).</li> </ol>	Niknam, P. et al., Molecular and Cellular Neuroscience, 99, 103391. (2019).



## Nervous System Damage Markets and Opportunity

### Significant medical costs and morbidity

	2000			Chillian St.	
	SCI	Ischemic Stroke	ALS	MS	AD
Incidence*	18,000	795,000	~7,000	10,000	500,000
Prevalence*	291,000	9.4M	~25K-30K	~1M	6.7M
Lifetime Cost*	\$1M-\$4M+	\$140,000+	\$1.4M	\$4M+	\$400,000
System Cost*	\$50B+	\$57B	\$250M-\$1.0B	\$85B	\$320B-\$345B
Current Treatment*	Decompressive surgery and rehabilitation	TPA must be given within hours of stroke; rehabilitation	Disease modifying agents (e.g. riluzole, edaravone) to slow progression – none stop progression	Immunomodulatory/ immunosuppressive therapies to reduce relapses and/or slow progression	Symptomatic therapies (e.g. cholinesterase inhibitors) to temporarily improve cognition; anti- beta mAbs to slow progression
Unmet Needs*	Effective treatments to enhance recovery	Effective treatments to enhance recovery	Treatment that improve function	Treatments to remyelinate axons and improve function	Treatments to effect enduring improvements



# **Spinal Cord Injury**

No FDA approved drug to enable sustained functional recovery

- Goal is improved motor, bladder, bowel, sexual and/or sensory function
- NVG-291 has shown positive preclinical results
- Significant unmet medical need





### **SCI Demographics**

- Average age: ~43
- Male (78%), female (22%)
- Cause: vehicle (38%); fall (33%); violence (15%); sports (8%)
- Annual hospitalization (30%): UTI, pneumonia, decubitus ulcer
- Duration of hospitalization and rehabilitation: 2 to 3 months
- Chance of depression: 25%
- Significant urinary and sexual dysfunction

#### **TREATMENT**

**Surgery** (decompression)

**Rehabilitation** (regain function)



## **SCI Facts and Figures**

#### **Incidence and Prevalence**

There are approximately **18,000 spinal cord** injuries every year in the US<sup>1</sup>

In 2019, there were just under **300,000 people living in the US** who have suffered a spinal cord injury<sup>1</sup>

Worldwide, the **annual incidence** is estimated to be **250,000 to 500,000**<sup>2</sup>

### **Economic Impact**

Individuals with SCI face a difficult and expensive journey through the healthcare system; that journey begins with **2-3 months in rehabilitation** and costs \$200,000 or more per patient<sup>3</sup>

Each individual with SCI faces an expected lifetime cost of care between \$1M and \$4M, depending on severity and age at injury<sup>4</sup>

In addition to the enormous economic costs, individuals with SCI face a **shorter expected lifespan, higher unemployment, higher chance of bankruptcy**<sup>5</sup>



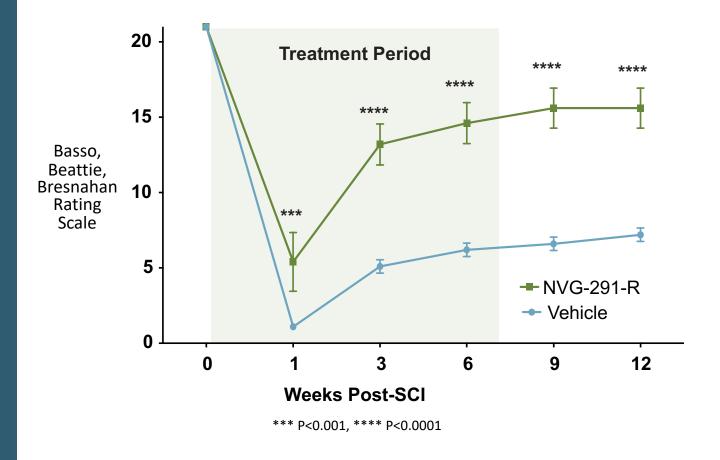
## Acute SCI Preclinical Study

### **Overview**

- T8 compression injury
- 500 μg/day x 7 weeks
- Treatment began 1 day post injury

### Results

- Significant recovery of locomotor and bladder function
- Enhanced neuroplasticity (i.e. axonal sprouting) near and far from injury
- Functional improvements persist after treatment
- NVG-291-R can promote recovery in acute SCI

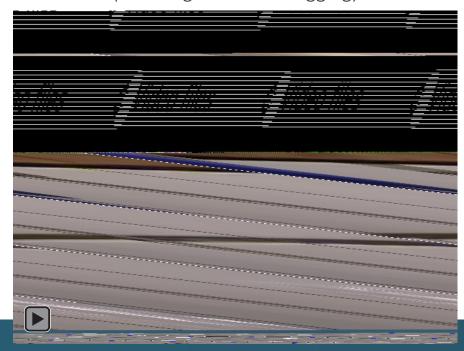




## NVG-291: Severe Spinal Cord Injury Model

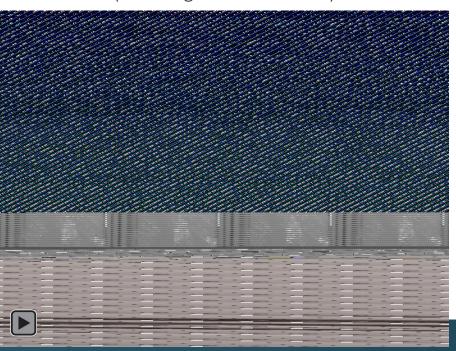
### **Representative of Placebo Group**

(Back Legs and Tail Dragging)



#### **Representative of NVG-291 Group**

(Back Legs and Tail Active)



Remarkable and robust repair across multiple models



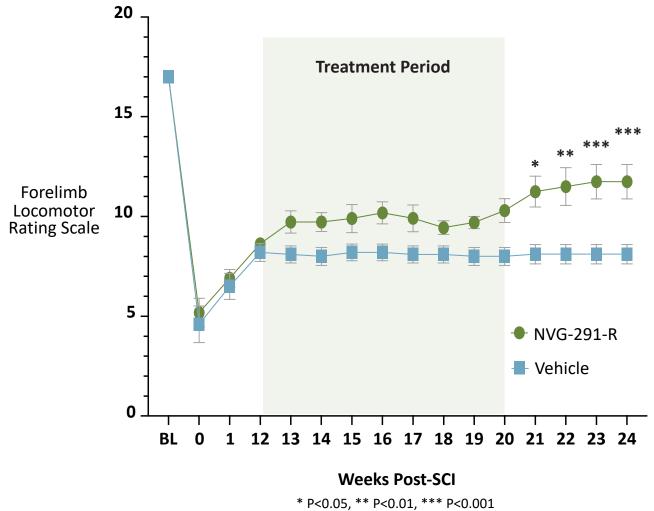
## Chronic SCI Preclinical Study

### **Overview**

- C2 lateral hemisection
- 500 μg/day x 8.5 weeks
- Treatment began 12 weeks post-injury

### Results

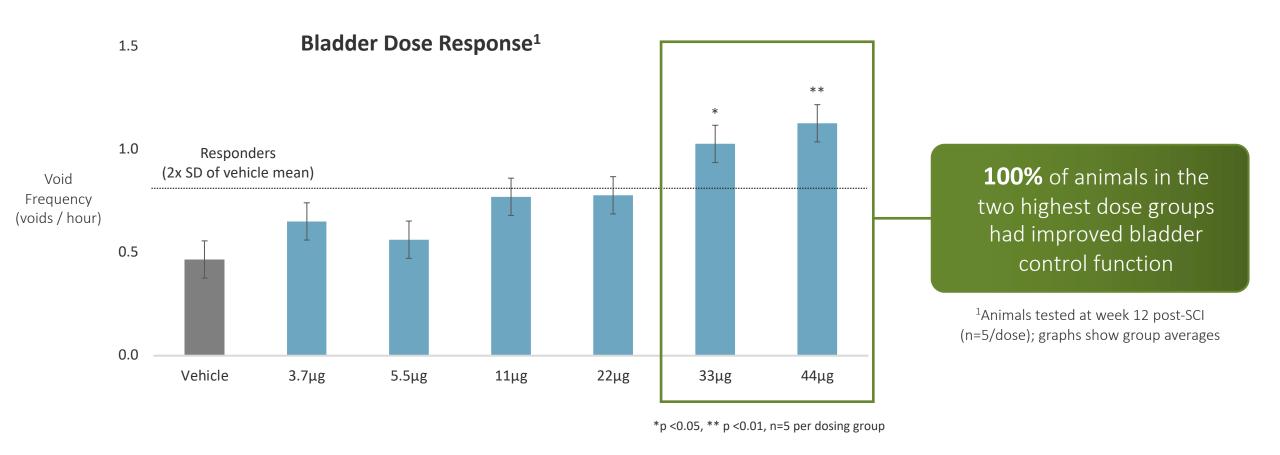
- Significant recovery of forelimb locomotor function
- Functional improvements persist after treatment
- NVG-291-R can promote recovery in chronic stages of SCI





## **Spinal Cord Injury**

### Bladder function improved following NVG-291-R treatment in preclinical animal studies



Bladder function is a key quality of life measure in the paralyzed population



### NVG-291 Phase 1 Clinical Trial Results

### **Study Design**

#### **Single Dose**

- 37 subjects
- 6 dose levels
- Assessed through Day 8

#### **Multiple Dose**

- 33 subjects
- 4 dose levels
- Subjects dosed subcutaneously once/day for 14 days
- Assessed through Day 21

### **Safety Results**

- Well tolerated across all doses
  - Maximum tolerated dose (MTD) not reached
- No treatment discontinuations
- No serious/severe adverse events (AE) in NVG-291 group
- Most common AE was injection site related (ISR)
- No clinically significant effects related to NVG-291 treatment across all study parameters



## Phase 1b/2a Proof of Concept Trial in SCI

#### **Study Design**

#### **Two Cohorts**

Randomized 1:1 to NVG-291 and placebo

#### **Chronic SCI**

~20 individuals (1-10 years post injury)

#### **Subacute SCI**

~20 individuals (10-49 days post injury)

#### **Administration / Trial**

- Once daily subcutaneous injection
- 16-week trial (12-wk treatment, 4-wk noninterventional period)
- Exercise over 16 weeks
- Single center, Shirley Ryan AbilityLab (Chicago, IL)
  - Decrease variability of electrophysiological assessments
  - Ensure standardized exercise program





### **Safety Objectives**

# **Co-Primary Endpoints: Quantitative Measure of Motor Connectivity**

- Hand muscle group
- Leg muscle group

#### **Secondary Endpoints**

- Clinical measures based on performance tests (walking speed, hand function) and neurological assessment
- Electrophysiological measures of electrical connectivity

#### **Exploratory Endpoints**

- Autonomic (e.g. bladder function)
- Spasticity (lower extremities)
- Mobility
- Quality of life
- Plasma biomarkers



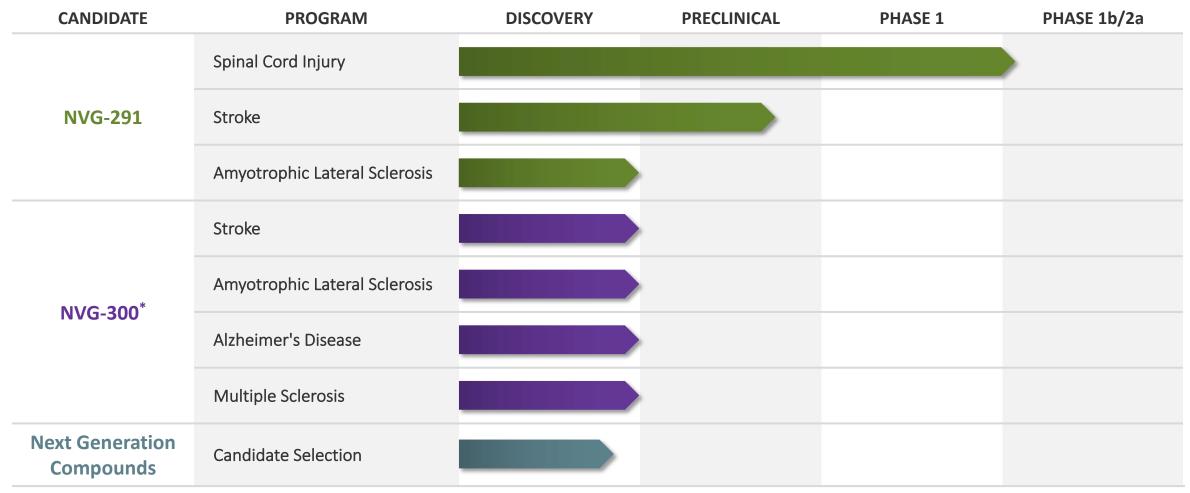
# SCI Clinical Advisory Board

James Guest, MD, PhD, FACS	Professor of Neurological Surgery at the University of Miami and The Miami Project to Cure		
Steven Kirshblum, MD	Professor and Chair of the Department of Physical Medicine and Rehabilitation at Rutgers New Jersey Medical School Chief Medical Officer for Kessler Institute for Rehabilitation and Kessler Foundation		
Brian Kwon, MD, PhD, FRCSC	Professor in the Department of Orthopedics at the University of British Columbia, the Canada Research Chair in Spinal Cord Injury		
Linda Jones, PT, PhD	Collaborating Investigator at Spinal Cord Outcomes Partnership Endeavor (SCOPE) Chair of the Research Committee of the American Spinal Injury Association (ASIA)		
Daniel Lammertse, MD	Clinical Professor of Physical Medicine and Rehabilitation at the University of Colorado School of Medicine Emeritus Clinical Scientist at Craig Hospital in Englewood Colorado		



## **Product Pipeline**

### Multiple development opportunities





## Board and Key Partnerships



**Bill Radvak**Chairman & Co-Founder



**Glenn Ives**Former Partner, Deloitte LLP



**Krista McKerracher**Former Global Franchise Head, Novartis



Harold Punnett, DMD
Co-Founder



Randall Kaye, MD
CMO, Longboard Pharmaceuticals



Adam Rogers, MD
Former CEO & Co-Founder, Hemera



**Brian Bayley**Director, Earlston Investments



Mike Kelly
President & CEO, NervGen



**Craig Thompson**CEO, Cerevance

#### **KEY PARTNERS**









## **Key Value Drivers**

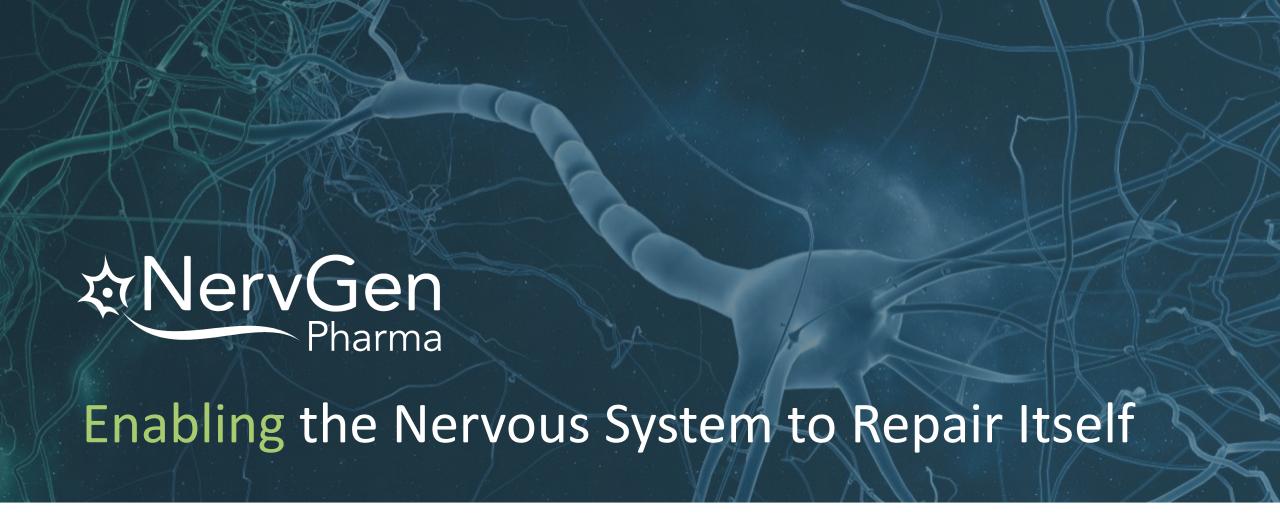
Phase 1b/2a clinical trial: IRB approval and first patient dosed (2023)

Preclinical data in multiple indications (2023/24)

Next generation compound progress (2023/24)

Proof of concept readout in chronic SCI (mid-2024)





www.nervgen.com