



SPINALON™

(First-in-class Central Pattern Generator-Activating Drug Treatment)

- **Brief description:** No treatment has been developed for the irreversible condition that is Spinal Cord Injury (SCI). All other drug candidates in development aim essentially at repairing the spinal cord. At Nordic, we are developing instead a chronic drug treatment constituting a *first-in-class* Central Pattern Generator-activating therapeutic.
- It was found to acutely (within 15 min) induce locomotor activity on a treadmill in completely spinal cord-transected (low-thoracic level) animals. The effects were found to last approximately 45 min. This innovative technology may be utilized clinically to promote activity-based rehabilitation and, thus, to prevent physical inactivity-related health complications (immune deficiency, hormonal problems, depression, muscular atrophy, osteoporosis, obesity, type II diabetes, etc.).
- **Primary market:** SCI in the U.S.: New cases, 10,000/yr; prevalence, 1.27 million U.S. patients (worldwide: probably more than 20 M).
- **Type of technology:** Combinatory drug treatment composed of already known small non-peptidergic active molecules. Specifically, it comprises levodopa, carbidopa and buspirone.
- **Formulation:** Systemically administered compounds (i.p., s.c., p.o.). Intended final formulation is a single oral tablet including all active molecules.
- **Level of development:** In preparation for Phase I/IIa in 51 spinal cord-injured patients. *In vivo* Proof-of-Concept data obtained in complete paraplegic mice and turtles (2004-05). Efficacy data following repeated administrations on health parameters in paraplegic mice (2008-09).

Preliminary evidence of safety in humans (a case report reported in a monoplegic patient)(2009). Preclinical toxicology and pharmacology testing in vitro and in vivo (supported by NIH RAID grant) have been completed (2010).

- **Next milestones:** IND (Q3-2011) and PI/II clinical trials (Q4-2011).
- **Funded by:** Fondation pour la Recherche sur la Moelle Épineuse (Québec – 2002-04); Christopher Reeve Foundation (US - 2004-05); **Canadian Institutes of Health Research (2004-2010); Fond de la Recherche en Santé du Québec (2001-2012);** International Institute for Research in Paraplegia (Switzerland – 2006-07); NIH/NINDS (US – 2009-10); Department of Defense/US Army (US – 2011-14).
- **Advantages:** Low-risk/low cost project. Effective doses are within the range used safely in patients (levodopa/carbidopa and buspirone are used and approved against Parkinson’s disease and anxiety, respectively). No preliminary evidence of drug-drug interactions has been found during the NIH-conducted preclinical studies (<https://commonfund.nih.gov/raid/ApprovedPr14.aspx>).
- **IP:** Université Laval (Quebec City, Canada, owner) and Nordic LSP (exclusive licensee).
- **Patent:** PCT filed in 2005. National entry phases in Canada, Europe, US in 2007 (March). Patent granted by US authorities (2011).
- **Opportunities:** Co-development deal, selling or out-licensing.

Research . Discovery . PoC . Optimization . Efficacy . Toxicity . IND . PI . PII

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