



## Corporate Backgrounder

### Our Mission

Founded by recognized experts in intrathecal drug therapies, CNS Therapeutics develops, markets and distributes pharmaceuticals intended for site-specific administration to the central nervous system. The company's first FDA-approved product is Gablofen® (baclofen injection), indicated for use in the management of severe spasticity. For complete prescribing information, see [www.gablofen.com](http://www.gablofen.com). The company also has a novel higher concentration of Gablofen in development and is investigating therapies for treating Parkinson's disease and chronic pain. CNS Therapeutics is dedicated to advancing intrathecal pharmaceuticals designed to improve the quality of life for patients and create efficiencies in the clinical environment for the healthcare providers who treat them.

Founded in 2007, CNS Therapeutics is a privately-held company headquartered in St. Paul, Minnesota.

### Spasticity Market Overview

Spasticity is a condition in which certain muscles are continuously contracted, causing stiffness or tightness of the muscles which may interfere with movement, speech and manner of walking. It is usually caused by damage to the portion of the brain or spinal cord that controls voluntary movement and may occur with spinal cord injury, multiple sclerosis, cerebral palsy, stroke, brain trauma, and severe head injury.<sup>1</sup>

Of the 500,000<sup>2</sup> people in the U.S. suffering from severe spasticity, approximately 60,000 are treated with intrathecal baclofen. The number of severe spasticity patients treated with baclofen is expanding by approximately 10,000 new patients per year, and the need for intrathecal baclofen therapy is life long since it does not cure the cause of spasticity. Baclofen, originally developed in the 1920s as a potential antiepileptic drug, was also found to be safe and effective for reducing spasticity.<sup>3</sup> In the early 1980s, baclofen was discovered to be much more effective when delivered intrathecally<sup>4</sup>, a method of delivering the therapy directly and continuously into the central nervous system via an implanted drug pump. The use of site-specific drug delivery holds tremendous promise for the treatment of many neurological disorders and pain. Delivering compounds directly to the central nervous system avoids the blood brain barrier, results in increased efficacy at dramatically lower doses, and significantly reduces the main side effects of systemic (oral) administration. Baclofen injection was first approved in 1992 as an orphan drug and is now considered the standard of care for the treatment of severe spasticity of spinal and cerebral origin.

Severe spasticity is a complicated condition to manage for both patients and their healthcare providers. Patients with limited mobility must travel frequently to their doctors for medication pump refills, putting a strain on both them and their caregivers. This can potentially burden the medical staff as well because pump fillings are one of the least flexible appointments to manage. Also, packaging poses problems for providers administering intrathecal baclofen therapy. Glass ampules used to package current baclofen formulations can potentially injure the person preparing the medication and/or contaminate the medication with shards of glass. As a result, nurses must double filter the medication to ensure it is not contaminated before they inject the drug into the pump.

## About Gablofen

Compatible with Medtronic's SynchroMed®II programmable drug pumps, Gablofen is available in the same standard concentrations as Lioresal® Intrathecal (baclofen injection) (50 mcg/mL, 500 mcg/mL and 2000 mcg/mL), a drug manufactured by Novartis and marketed exclusively by Medtronic.

Collaborating with neurologists, physiatrists, pharmacists and nurses, CNS Therapeutics developed Gablofen to offer:

- **Nurses:** a convenient, easy-to-administer therapy that features prefilled vials and syringes rather than glass ampules that must be broken to access the medication. This will reduce refill preparation time and the risk of medicine contamination
- **Pharmacists:** more streamlined drug preparation and processing, simplified ordering and greater shelf space
- **Patients:** a new cost-effective intrathecal baclofen which may result in lower copays and improved access to therapy

## Looking Ahead

CNS Therapeutics also has a new drug application for a higher concentration of Gablofen under FDA review. Beyond commercialization of Gablofen, CNS Therapeutics is collaborating with the University of Helsinki on novel intrathecal therapies for Parkinson's disease. This research is in part funded by a grant from the Michael J. Fox Foundation. CNS Therapeutics is also investigating treatments for the management of chronic pain.

## Important Gablofen Safety Information

*[See full prescribing information for complete boxed warning.]* WARNING: DO NOT DISCONTINUE ABRUPTLY. Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional post implant clinician and patient information.

The most common adverse reactions in patients with spasticity of spinal origin were somnolence, dizziness, nausea, hypotension, headache, convulsions and hypotonia. The most common adverse reactions in patients with spasticity of cerebral origin were agitation, constipation, somnolence, leukocytosis, chills, urinary retention and hypotonia.

Patients are encouraged to report any negative side effects to their health care provider. To report SUSPECTED ADVERSE REACTIONS, contact CNS Therapeutics Inc. at 1-877-384-0857 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

For complete prescribing information please visit [www.gablofen.com/prescribing-info.php](http://www.gablofen.com/prescribing-info.php)

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## **MANAGEMENT TEAM**

### ***John Foster, Chief Executive Officer, Co-Founder***

John Foster has more than 25 years of executive management expertise in developing and bringing biotechnology, pharmaceuticals and medical devices to market. Before founding CNS Therapeutics with Dr. Penn and Mr. Bronson, Mr. Foster was senior vice president of commercial operations at Restore Medical, which made its initial public offering in 2006 and was later acquired by Medtronic. Prior to that, he held key management positions with Advanced Respiratory, Medtronic's Neuromodulation business, and Genentech, a pioneer in biotechnology. Mr. Foster has a B.A. in history and business from Oral Roberts University and completed the University of Minnesota Executive Development program.

### ***Richard Penn, M.D., Chief Scientific Officer, Co-Founder***

Richard Penn, M.D. has more than 30 years of experience practicing neurosurgery and is well known for his research and clinical work in drug delivery to the nervous system and surgical treatments for movement disorders. He pioneered the use of implanted drug pumps to deliver medications directly to the spinal cord, implanting the first programmable pump for cancer pain and developing a highly successful medicine for spasticity. Dr. Penn also has contributed to the treatment of movement disorders with early studies on neuro-transplantation for Parkinson's disease and Huntington's disease. He was one of the first neurosurgeons in the United States to use deep brain stimulation for tremor and has extensive experience with stimulation of other brain sites to relieve bradykinesia and dystonia.

In addition to his role as co-founder at CNS Therapeutics, Dr. Penn is a professor of neurosurgery at Rush University Medical Center and an adjunct professor of bioengineering at the University of Illinois at Chicago. Dr. Penn graduated from Columbia College of Physicians and Surgeons in New York, NY.

### ***Scott Bronson, Chief Financial Officer, Co-Founder***

Scott Bronson has 34 years of financial experience in the medical device field. Prior to founding CNS Therapeutics with Dr. Penn and Mr. Foster, he held key financial positions at Medtronic including vice president of finance for global business services, the neurological and diabetes sector and the interventional vascular sector. Prior to Medtronic, he held various accounting positions with TSI, Inc. Mr. Bronson is a certified management accountant and has a B.S.B. in accounting and a MBA in finance from the University of Minnesota.

### ***Thomas Prentice, Vice President, Technical Affairs***

Thomas Prentice has 25 years of broad-based experience in design and manufacturing engineering, project management, quality systems and global supply chain expertise. Prior to joining CNS Therapeutics, Mr. Prentice held numerous management positions with Medtronic in global leadership of manufacturing IT, supply chain and manufacturing. Mr. Prentice has a B.S. in Mechanical Engineering and an MS in management technology from the University of Minnesota.

**Michael Post, Vice President of Marketing**

Michael Post has 15 years of experience in the health care and consulting industry. Before joining CNS Therapeutics, he held key sales and marketing positions at Eli Lilly in areas including brand development, product launches, market research, lifecycle management, business development and sales management. Prior to that, he worked at Arthur Andersen in the corporate recovery consulting group. Mr. Post has a B.S. from Miami University and M.B.A. from the University of Michigan.

**David Youngberg, Vice President of Business Development**

David Youngberg has 15 years of successful sales and sales management experience in the medical device market and has held numerous key sales positions at Medtronic and Restore Medical. He has been in sales and management for Horizon Medical Products and Ethicon Endo-Surgery business. Before his career in medical sales, he was an officer of the United States Navy. Mr. Youngberg has a B.A. in economics from the University of Minnesota.

**Joy Frestedt, Ph.D., RAC, CCTI, Regulatory Advisor**

Joy Frestedt, Ph.D., has more than 30 years of scientific, clinical and regulatory experience in the health care, pharmaceutical and medical device industries. She previously served as vice president of scientific and clinical affairs at BridgePoint Medical and Humanetics Corporation and has held other key positions with Johnson and Johnson, Medtronic, Mayo Clinical Trial Services, AstraZenca Pharmaceuticals and Orphan Medical. Dr. Frestedt has a B.A. in biology from Knox College and a Ph.D. in pathobiology from the University of Minnesota Medical School.

## **BOARD OF DIRECTORS:**

### ***Nina Kjellson, General Partner, InterWest Partners***

Nina Kjellson has been a partner in InterWest's life sciences team since 2002. Ms. Kjellson currently serves on the boards of Alvine Pharmaceuticals, Inc., Cebix, Inc., Eiger Biopharmaceuticals, Lycera, Inc., PrimeraDx, Sequel Pharmaceuticals and Trius Therapeutics, Inc. Prior to joining InterWest, she was an investment manager at Bay City Capital, a life sciences merchant bank, and a research associate at Oracle Partners, a healthcare-focused hedge fund. She began her career conducting health policy and survey research with the Kaiser Family Foundation. Ms. Kjellson holds a B.S. degree in human biology from Stanford University.

### ***Pete McNerney, Managing Partner, Thomas, McNerney & Partners***

Pete McNerney is a co-founder and managing partner of Thomas, McNerney & Partners. Previously, Mr. McNerney co-founded Coral Ventures, where he was responsible for health care investing. Mr. McNerney is currently a board member of AxioMed Spine Corporation, M2 Group Holdings, Inc., Intuity Medical, Inc., Torax Medical Inc. and Ascent Healthcare Solutions. Prior to joining Coral, he was a co-founder and managing partner of The Kensington Group, a firm specializing in providing management services to early stage companies in the health care field. Mr. McNerney received a B.A. from Yale and an M.B.A. from Stanford University and is a certified public accountant.

### ***Howie Rosen, Independent Member***

Howie Rosen is a consultant, serving on the board of directors of AcetRx Pharmaceuticals, Inc., PaxVax, Inc. and Pearl Therapeutics, Inc. Prior to that, he was the former vice president of commercial strategy at Gilead Sciences, Inc. where his responsibilities included strategic marketing, global brand management, health economics, competitive intelligence, market research and Gilead's overall portfolio and business planning. Prior to joining Gilead, Mr. Rosen was president of ALZA Corporation where he was responsible for all aspects of managing ALZA as an independent 1000-person operating company within the Johnson & Johnson Family of Companies. Mr. Rosen holds an M.B.A. and a B.S. in Chemical Engineering from Stanford University and a M.S. in Chemical Engineering from MIT.

### ***Pratik Shah, Ph.D., Partner at Thomas, McNerney & Partners***

Dr. Pratik Shah is a partner with Thomas, McNerney & Partners in San Francisco and has been with the firm since 2004. He is currently a board member of Altair Therapeutics, Auspex Pharmaceuticals, CNS Therapeutics, Cebix, Inc. and Ocera Therapeutics. Prior to joining the firm, he was the chief business officer and co-founder of Kalypsys, Inc., a biopharmaceutical company, where he was responsible for the overall strategy, business development and operations of the company and oversaw raising more than \$130 million in equity financings and corporate deals. Before that, Dr. Shah was at McKinsey & Company's San Francisco office where he focused on biotechnology and venture capital projects. He was formerly co-founder and vice president of operations at NephRx Corporation, a start-up company focused on the discovery of therapeutic proteins for renal disease. Dr. Shah holds a B.S. in biological sciences from the University of California at Irvine and both a Ph.D. in biochemistry & molecular biology and an M.B.A. from the University of Chicago.

**Dr. James Campbell, Board Observer**

Dr. Campbell serves as Executive-in-Residence at InterWest Partners, CEO of Arcion Therapeutics, and Professor of Neurosurgery (part-time) at John Hopkins University. In addition to his work with CNS Therapeutics, he serves on the Board of Directors of Amplimmune. He founded the American Pain Foundation and now serves as Chairman of the Board Emeritus of that nonprofit organization.

He has a long record of accomplishment in academic neurosurgery. He previously served as Director of the Residency Training Program and Vice Chair for the Department of Neurosurgery at Hopkins. He edited several books, published well over 100 peer-reviewed papers, and has served on the editorial board of several academic journals. Dr. Campbell has received many national awards for research and public service, including the Jacob Javits Neuroscience Investigator Award from the National Institutes of Health, Bristol-Myers Squibb Pain Research Award, the Creative Leadership Award from the American Pain Foundation, and the Grass Award from the Society of Neurological Surgery. He also has received several awards from the American Pain Society. He holds several drug/device patents currently in clinical development.

Dr. Campbell received his B.A. from the University of Michigan with High Honors and High Distinction, his M.D. degree from Yale University, and is Diplomate of the American Board of Neurological Surgery.

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For additional information contact:

Melissa Zipin  
Lois Paul & Partners  
781-782-5726  
[melissa\\_zipin@lpp.com](mailto:melissa_zipin@lpp.com)

*Gablofen<sup>®</sup> is a registered trademark of CNS Therapeutics Inc.*

*Lioresal<sup>®</sup> is a registered trademark of Novartis Pharmaceuticals Corp.*

*SynchroMed<sup>®</sup> is a registered trademark of Medtronic Inc.*

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<sup>1</sup> <http://www.ninds.nih.gov/disorders/spasticity/spasticity.htm>; Accessed on 11.15.2010

<sup>2</sup> [http://www.wemove.org/spa/spa\\_epi.html](http://www.wemove.org/spa/spa_epi.html); Accessed on 11.15.2010

<sup>3</sup> <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682530.html>; Accessed on 11.15.2010

<sup>4</sup> P. Rawlins et. al (2004) 'Intrathecal Baclofen Therapy Over 10 Years' Journal of Neuroscience Nurses. 36 (6): 322-327