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## 2020 North American Neuromodulation Society Investor Update

### Maulik Nanavaty

President and Senior Vice President, Neuromodulation Jesse Feinkind Vice President, Global Pain Milad Girgis

Vice President, Global Brain Modulation



# Safe Harbor for Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could differ materially from the expectations and projections expressed or implied by our forward-looking statements.

Factors that may cause such differences can be found in our most recent Form 10-K and Forms 10-Q filed or to be filed with the Securities and Exchange Commission under the headings "Risk Factors" and "Safe Harbor for Forward-Looking Statements." Accordingly, you are cautioned not to place undue reliance on any of our forward-looking statements. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which they may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.



# Financial & Regulatory Disclaimers

#### **Financial Disclaimers**

**Market Estimates:** 

Unless noted otherwise, all references to market sizes, market share positions, and market growth rates are BSX internal estimates.

#### **Non-GAAP Financial Measures:**

This presentation contains non-GAAP measures (denoted with \*) in talking about our company's performance. The reconciliations of those non-GAAP measures to their most comparable GAAP measures are contained within this document including appendices attached to the end of this presentation.

#### **Revenue Growth:**

2019 Revenue figures are based on preliminary, unaudited sales results issued January 14, 2020

All growth rates are operational unless otherwise noted. Operational growth rates are non-GAAP measures that exclude the impact of foreign currency fluctuations. Organic growth rates are non-GAAP measures that exclude the impact of foreign currency fluctuations and the sales from the acquisition of Vertiflex, Inc. in the periods for which there are no prior period related sales.

Amounts reported in millions within this presentation are computed based on the amounts in thousands. As a result, the sum of the components reported in millions may not equal the total amount reported in millions due to rounding. Certain columns and rows within tables may not add due to the use of rounded numbers. Percentages presented are calculated from the underlying numbers in dollars.

#### **Regulatory Disclaimers**

Next Gen DBS Programming with Visualization & StimView<sup>™</sup> XT available for sale in EU and international countries. U.S. - Caution: Investigational Device. Limited by Federal (or U.S.) law to investigational use only. Not available for sale.

Next Gen DBS Platform & Programmer: Device under development. Not available for use or sale worldwide.

Use of BSC products in Alzheimer's disease, stroke rehabilitation, depression and OCD applications is investigational.



## Neuromodulation:

Leading in pain therapies and brain modulation

## Exciting, highly underpenetrated and high-growth market

### **Pain Therapies**

- Category leadership with innovative, evidenced-based platforms Spectra WaveWriter<sup>™</sup> SCS system, Vertiflex<sup>®</sup> procedure, and RF therapy focused on personalizing the evolving pain care continuum
- Redefining pain treatment paradigm with COMBO RCT, HALO, NAVITAS/ENVISION, FAST RCT

### **Brain Modulation**

- Transforming Deep Brain Stimulation (DBS) therapy with highly innovative Vercise<sup>™</sup> Directional Systems with Cartesia<sup>™</sup> leads and STIMVIEW<sup>™</sup> XT visualization backed by robust clinical data
- Differentiated technology and clinical insights to improve Parkinson's disease workflow and unlock DBS therapy for Alzheimer's disease, stroke rehabilitation, and Depression

## Market size<sup>†</sup>: \$3.6B growing 8-10% from 2019-2022



	Image: Constrained state stat		Image: Constraint of the second se		
Spinal Cord	RF	<b>Vertiflex</b> ®	DBS for Movement		
Stim	Ablation		Disorders		
<b>Return to Growth</b>	10%+ Mkt Growth	Untapped Mkt	10%+ Mkt Growth		
3M+ with chronic	10M+ with severe	6M with moderate	1.2M with Parkinson's disease U.S.4		
neuropathic pain U.S. <sup>1</sup>	joint pain U.S. <sup>2</sup>	lumbar stenosis U.S. <sup>3</sup>			
Opportunity to move up	Versatile, fast, effective,	Fast growing minimally invasive therapy	New technology and		
therapy continuum	safe procedure		Indication expansion		

### BSC Neuromodulation 2019 Revenue Growth: 13% operational\*, 7% organic\*

2019 revenue figures are based on preliminary, unaudited sales results issued January 14, 2020

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# Pain Therapies: Category leadership with a winning, diverse, evidence-based portfolio

### Providing solutions for the evolving patient care continuum



### 20+ ongoing clinical research studies & RCTs<sup>1</sup>

**COMBO RCT**: Parallel-group RCT to demonstrate **value of multiple modalities** and combining mechanisms using Spectra WaveWriter<sup>™</sup>

FAST RCT: Parallel-group RCT to demonstrate the value of fastacting subperception therapy

NAVITAS/ENVISION: Characterize relationship between **objective metrics** and clinical outcomes

WaveWriter Outcomes: Real world, multi-center observational series

**SOLIS (H2:2020)**: Parallel-group RCT to demonstrate effectiveness of SCS for **non-surgical back** 

SCOPE: FDA post-approval study for  $\mathsf{Vertiflex}^{\texttt{B}}$  procedure with  $\texttt{Superion}^{\texttt{B}}$  IDS

PRESS: Real world evidence for Vertiflex procedure

Superion Outcomes: Evaluation of Vertiflex procedure adjunct to SCS usage

RF Outcomes: Real world applications of RF ablation therapy

Comprehensive portfolio to help physicians find the right treatment for the right pain generator



# Pain Therapies Vertiflex<sup>®</sup> procedure fills untapped therapy gap

### Vertiflex<sup>®</sup> Procedure: Superion<sup>®</sup> Indirect Decompression System



### Accelerating physician access and training for treatment of moderate Lumbar Spinal Stenosis (LSS)

- Seeing strong overall demand and increased utilization
- Synergies from physician education, field support, and digital marketing

# RCT provides strong, Level I, 5-year clinical and efficacy data<sup>1,2</sup>

- 84% (74/88) of patients experienced clinical success; 90% (79/88) patient satisfaction
- 80% (68/85) leg and 65% (55/85) back pain success rates
- **85% decrease** in the proportion of patients using **opioids**

# Real world data also demonstrate benefits of the Vertiflex procedure<sup>3</sup>

80% (296/368) of patients at 12 months reported satisfaction with the procedure



# Pain Therapies Pioneering neural dosing of sub-perception therapy



**CONTOUR™** 



Contour provides simple, efficient, and effective sub-perception therapy



# Pain Therapies: COMBO RCT: Combination therapy provides an unparalleled level of clinical success



<sup>tt</sup>Patient Global Impression of Change <sup>9</sup>



# Pain Therapies Redefining SCS: Better relief + more responders





# Pain Therapies

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# Transformative results from next gen innovative therapy

# FAST<sup>™</sup>: <u>Fast Acting Subperception Therapy</u>





# Pain Therapies: The Future Is Now Beyond VAS to automated deep personalization

algorithms personalizing therapy for each patient

**NAVITAS/ENVISION<sup>1</sup>**: Next: Predictive therapy with deep **Today:** 3 years of study endeavors Subjective pain analytics personalization Partnership with IBM Research Trial Implant **Composite metrics** Study continuing Overall Pain Visual Analog Scale (VAS) with up to 1700 subjects at 30 sites . A MA Using up to Sleep Quality 15 objective and NO PAIN MILD MODERATE SEVERE WORST qualitative data streams/sources to personalize therapy for Effective Mobility each patient **Consistently improving** No biomarker or objective Automated personalized therapy - Opioid Usage measures for pain functional outcomes Opioids impactful for patients, Al-generated predictive physicians, and payors

Time (months)



## Brain Modulation Large, underpenetrated Parkinson's population<sup>1,2,3</sup>



## Improved outcomes and innovation will drive access



# Brain Modulation Meaningful innovation redefines the market



### **Over 10,000 Global DBS Procedures**



Worldwide leader in directionality



#1 market share in Europe



Strong momentum in the US; #2 market share



Agile innovation: 3 systems in 7 years



RCT with long-term data and real world evidence



# Brain Modulation Innovation backed by strong clinical data



#### 25+ ongoing clinical research studies & RCTs<sup>1</sup>

- INTREPID Long-term: Only double-blind RCT with sham control, following subjects up to 5 years post-implant
- DBS Directional: Evaluated therapeutic advantages of Cartesia<sup>™</sup> Directional Lead with Vercise PC DBS System
- DBS Registry: Comprehensive registry of real world outcomes to establish improvement in quality of life
- Workflow Study (H2:2020): Demonstrate outcome improvements with integrated Vercise directionality and advanced visualization
- Investments in indication expansion studies: Stroke rehabilitation, Alzheimer's disease, depression, others



# Brain Modulation Vercise<sup>™</sup> Therapy: Differentiated patient outcomes



### **INTREPID US RCT**

At 1 year, greater improvement in ON time vs. competitive devices. Successful outcomes and medication reduction sustained through 2-year follow up.

### VANTAGE European Study<sup>1</sup>

62.6% mean reduction in UPDRS III score at 26 weeks, sustained up to 52 weeks post-lead placement



## Brain Modulation: Vercise<sup>™</sup> Therapy: Learning ecosystem that is dynamic by design today and for the future



### Personalizing DBS therapy with highly innovative systems and solutions



# Brain Modulation Indications beyond Movement Disorders

#### **FUNCTIONAL** neuromodulation

### Alzheimer's disease (\$5B+)

- VC investment in Functional Neuromodulation
- Pilot study (42 patients) completed
- RCT initiated under IDE

### **Clinical Research**

- Depression
- Obsessive compulsive disorder (OCD)



### Stroke rehabilitation (\$3B+)

- VC investment in ENSPIRE
- Ongoing pilot study

## Opportunity for platform technology to unlock \$8B+ in new markets

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### **Podium Presentations**

### Exploration of High and Low Frequency Options for Sub-Perception Pain Relief: The HALO Study

Saturday, January 25 7:00AM - 7:10AM Session Title: Spinal Cord Stimulation II Simon Thomson, MBBS Octavius Ballrooms 12-16

#### Chronic Pain Outcomes Using a Neuromodulation System with Multiple Waveform and Programming Modalities in Australia

Friday, January 24 7:30AM - 7:40AM Session Title: Peripheral Nerve Stimulation Peter Georgius, MD, FFPMANZCA Octavius Ballrooms 7-10

### Paper Poster Presentations

#### Friday, January 24, 5:00PM – 7:00PM (Florentine Ballroom)

A Novel Sub-Perception Spinal Cord Stimulation Therapy Enabling Clinically Significant Pain Relief and Fast Onset (#114) Paper Poster Group 14 - Spinal Cord Stimulation II Clark Metzger, MD

#### Outcomes Using an SCS Device Capable of Delivering Combination Therapy and Advanced Waveforms/Field Shapes (#135) Paper Poster Group 16 - Spinal Cord Stimulation IV

Clark Metzger, MD Outcomes of a Prospective Randomized Controlled Trial Utilizing a Spinal Cord System

Capable of Multiple Neurostimulative Modalities (COMBO) (#106) Paper Poster Group 13 - Spinal Cord Stimulation I Mark Wallace, MD

Moving Beyond VAS into Deep Personalization: Advanced Analytics and Data Metrics Unlock Innovative Method for Assessing Chronic Pain in SCS Patients (#105) Paper Poster Group 13 - Spinal Cord Stimulation I Richard Rauck, MD

Outcomes Using SCS Device with Multiple Available Neurostimulative Modalities for Chronic Pain: Initial European Experience (#104) Paper Poster Group 13 - Spinal Cord Stimulation I Jan-Willem Kallewaard, MD

Improved Trial Success Rate Using a Novel Application to Monitor SCS Outcomes for Chronic Pain (#121) Paper Poster Group 15 - Spinal Cord Stimulation III Alison Weisheipl, MD

#### Manifold sensations perceived by patients during acute spinal cord stimulation evaluation using patterned pulse trains (#116) Paper Poster Group 14 - Spinal Cord Stimulation II Robert Frey, MD

Modeling the Effects of Stand-alone vs. Simultaneous Dorsal Column and Dorsal Horn-based Spinal Cord Stimulation (#17) Paper Poster Group 3 - Basic Science Tianhe Zhang, PhD

Analysis of Dorsal Column Responses to Traditional and New Sub-Perception SCS Field Shapes (#55) Paper Poster Group 7 - Computational Modeling/Mechanism of Action Rosana Esteller, PhD

### Electronic Posters (e-posters)

#### Accessible Using the 2020 NANS Annual Meeting Smartphone App

Posterior Lumbar/Sacral Nerve Root Stimulation for Treatment of Chronic Foot and/or Ankle Pain (PI: Stephen Pyles, MD)

Evaluation of CRPS Patients Using an SCS System with Multiple Waveform and Stimulation Frequency Options (PI: Joseph Atallah, MD)

Outcomes Following Utilization of a Device Adaptor in Previously-Implanted Patients Using SCS for Chronic Pain (PI: Thomas Yearwood, MD PhD)

Clinical Outcomes Using Radiofrequency Ablation (RFA) in Patients with Chronic Pain: A Real-World Observational Study (PI: Henry Vucetic, MD)

Clinical Experience Using Multiple Available SCS Waveforms and Field Shapes for Focal Lower Limb Pain (PI: Louis Raso, MD)

Four-Year Follow-Up of Customized Field Shape Using Sub-Perception Spinal Cord Stimulation in Chronic Pain Patients (PI: Jose F. Paz-Solis, MD)

Case-Series Assessment of New Percutaneous SCS Lead for Multi-Site and/or Evolutive Pain Patterns in Europe (PI: Jose F. Paz-Solis, MD)

Outcomes of a Prospective, Multicenter International Registry of Deep Brain Stimulation for Parkinson's Disease (PI: Jan Vesper, MD, PhD)

Real-World Clinical Outcomes Using a Novel Directional Lead from a DBS Registry for Parkinson's Disease (PI: Jan Vesper, MD, PhD)





#### Slide 5 (Exciting, large, underpenetrated and high-growth markets):

- 1. Bennett GJ. Neuropathic pain: an overview. In: Borsook D, ed. Progress in Pain Research and Management. Vol. 9. Seattle, Wa: IASP Press; 1997:109–113.
- 2. CDC Journal Morbidity and Mortality Weekly Report 2014
- 3. Data on file
- 4. https://www.apdaparkinson.org/article/parkinsons-disease-prevalence-study/

#### Slide 6 (Pain Therapies: Category leadership with a winning, diverse, evidence-based portfolio):

1. Includes company and investigator-sponsored research

#### Slide 7 (Pain Therapies: Vertiflex® procedure fills untapped therapy gap):

- 1. Nunley PD, et al. Clinical Interventions in Aging. 2017:12 1409 1417
- 2. Nunley PD, et al. Journal of Pain Research. 2018:11 2943 2948
- 3. Tekmyster G, et al. Medical Devices: Evidence and Research. 2019:12 423 427

#### Slide 8 (Pain Therapies: Pioneering neural dosing of sub-perception therapy):

- 1. Thomson SJ, et al. Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial. Neuromodulation. November 2017
- 2. Paz-Solis J, et al. Exploration of High and Low Frequency Options for Sub-Perception Pain Relief: The HALO Study. North American Neuromodulation Society (NANS) Annual Meeting. January 2020

#### Slide 9 (Pain Therapies: COMBO RCT: Combination therapy provides an unparalleled level of clinical success):

1. Wallace M, et al. Outcomes of a Prospective Randomized Controlled Trial Utilizing a Spinal Cord System Capable of Multiple Neurostimulative Modalities (COMBO). NANS Annual Meeting. January 2020

#### Slide 10 (Pain Therapies: Redefining SCS: Better relief + more responders):

1. Weisheipl A, et al. Improved Trial Success Rate Using a Novel Application to Monitor SCS Outcomes for Chronic Pain. NANS Annual Meeting. January 2020



# Citations

#### Slide 11 (Pain Therapies: Transformative results from next generation innovative therapy):

1. Metzger C, et al. A Novel Sub-Perception Spinal Cord Stimulation Therapy Enabling Clinically Significant Pain Relief and Fast Onset. NANS Annual Meeting. January 2020.

#### Slide 12 (Pain Therapies: The Future is Now: Beyond VAS to automated deep personalization):

1. Rauck R, et al. Moving Beyond VAS into Deep Personalization: Advanced Analytics and Data Metrics Unlock Innovative Method for Assessing Chronic Pain in SCS Patients. NANS Annual Meeting. January 2020.

#### Slide 13 (Brain Modulation: Large, underpenetrated Parkinson's population):

- 1. Dinkelback et al., (2017). "How to improve patient education on deep brain stimulation in Parkinson's disease: the CARE Monitor study." BMC Neurology.
- 2. Hickey and Stacey (2016). "Deep brain stimulation: A paradigm shifting approach to treat Parkinson's Disease." Frontiers in Neuroscience. 10: 173; Market research.
- 3. https://www.apdaparkinson.org/article/parkinsons-disease-prevalence-study/

#### Slide 15 (Brain Modulation: Science-driven innovation backed by strong clinical data):

1. Includes company and investigator-sponsored research

#### Slide 16 (Brain Modulation: Vercise™ Therapy: Differentiated patient outcomes today):

- 1. Vantage: Timmermann et al., Multiple-source current steering in subthalamic nucleus deep brain stimulation for Parkinson's disease (the VANTAGE study): a non-randomised, prospective, multicentre, open-label study Lancet Neurology 2015; 14: 693–701
- 2. Okun et al., Lancet Neurol. 2012 Feb;11(2):140-9. Subthalamic deep brain stimulation with a constant-current device in Parkinson's disease: an open-label randomised controlled trial.
- 3. Follett et al., N Engl J Med. 2010 Jun 3;362(22):2077-91. Pallidal versus subthalamic deep-brain stimulation for Parkinson's disease.
- 4. Deuschl et al., N Engl J Med. 2006 Aug 31;355(9):896-908. A randomized trial of deep-brain stimulation for Parkinson's disease.
- 5. Oderkerken et al., Lancet Neurol. 2013 Jan;12(1):37-44. Subthalamic nucleus versus globus pallidus bilateral deep brain stimulation for advanced Parkinson's disease (NSTAPS study): a randomised controlled trial
- 6. Vitek et al., INTREPID: A Prospective, Double Blinded, Multicenter Randomized Controlled Trial Evaluating Deep Brain Stimulation with a New Multiple Source, Constant Current Rechargeable System in Parkinson's disease, Oral Presentation at American Academy of Neurology (AAN) 2018, Los Angeles, CA



# Supplemental Non-GAAP Disclosures

FY 2019 Revenue Growth <sup>1</sup> (unaudited) compared to FY 2018	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis	Less: Impact of Recent Acquisitions / Divestitures	Organic Basis
Neuromodulation	12%	-1%	13%	6%	7%

<sup>1</sup>Based on preliminary, unaudited sales results issued January 14, 2020