

Targeting a paradigm shift in stroke rehabilitation

Martin Jamieson | CEO & Chairman of the Board | Nexstim Mikko Karvinen | CFO | Nexstim

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Nexstim's NBS System is cleared by the FDA for assessment of the motor and speech cortices for pre-procedural planning. The NBT System is not cleared for commercial distribution in the United States.

#### FORWARD-LOOKING STATEMENTS

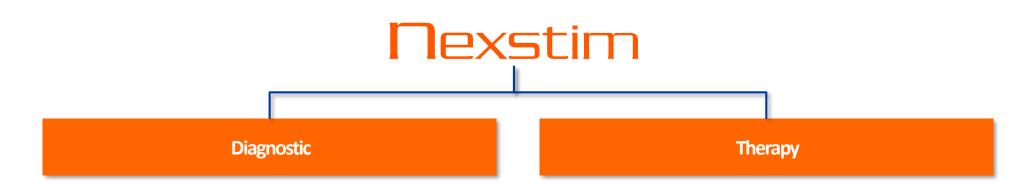
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## **Nexstim Plc at a Glance**

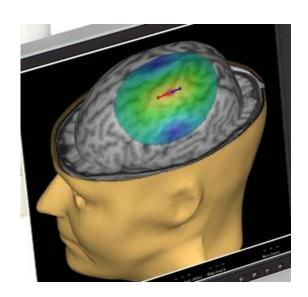
- Pioneering navigated brain stimulation technology (nTMS)
- Experienced management and international Board
- Listed in Nasdaq First North Finland
   & Sweden
- Offices in Finland, US and Germany
- Established in 2000



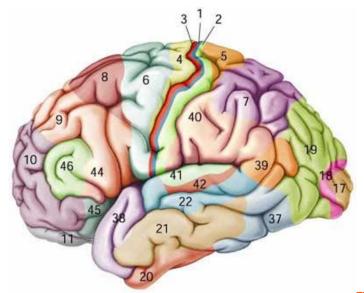
## **Nexstim Transcranial Magnetic Stimulation (TMS) platform**



#### **Navigated Brain Stimulation (NBS)**



#### **Navigated Brain Therapy (NBT®)**



## Platform protected with 27 patent families

- 89 granted patents, 61 pending
- Right to software: Nexstim owns rights to its NBT® and NBS Systems' software developed in-house.
- Core algorithms kept as trade secrets





pre-surgical mapping of brain tumours



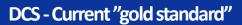
## **NBS Pre-Surgical Mapping Overview**

- Non-invasive system for mapping the Motor and Speech Cortex prior to tumour surgery
- Navigation is the key to accurate mapping
- The NBS system links
  - Brain anatomy (MRI)
  - Location of the E-Field induced by TMS (navigation)
  - Muscle response (EMG)
- Seamless workflow with BRAINLAB, Medtronic and Stryker neuronavigational systems
- CE marked and FDA cleared device has been sold to over 140 leading hospitals and research centres in the world



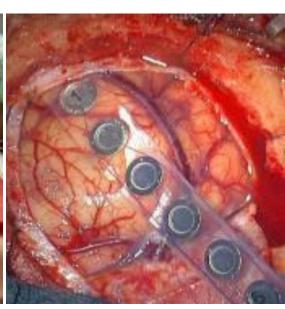
## NBS vs. Direct Cortical Stimulation (DCS) motor mapping

#### **Nexstim's NBS**









**Non-invasive** 

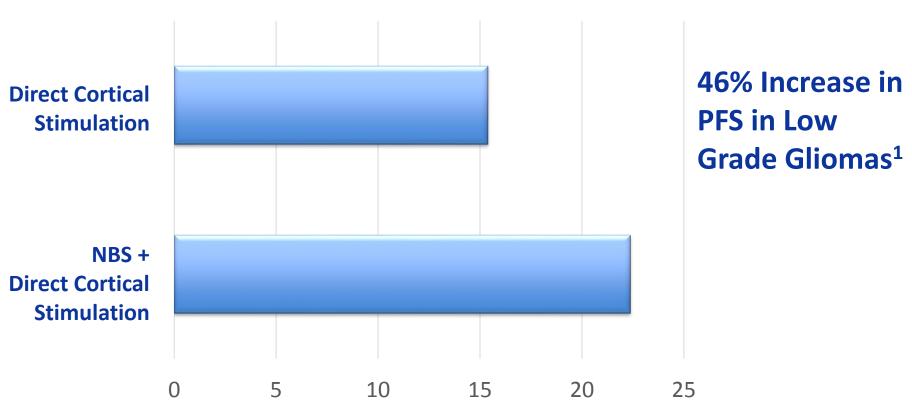
**Invasive** 

Mapping possible days or weeks prior to surgery

Mapping during surgery

# NBS Pre-Surgical Mapping makes the difference to clinical outcome





<sup>1</sup> Dietmar Frey, Peter Vajkoczy, and Thomas Picht Navigated transcranial magnetic stimulation improves the treatment outcome in patients with brain tumors in motor eloquent locations Neuro Oncology 2014: nou110v1-nou110

## **NBS Pre-Surgical Mapping Major Centers**



























BERN UNIVERSITY HOSPITAL































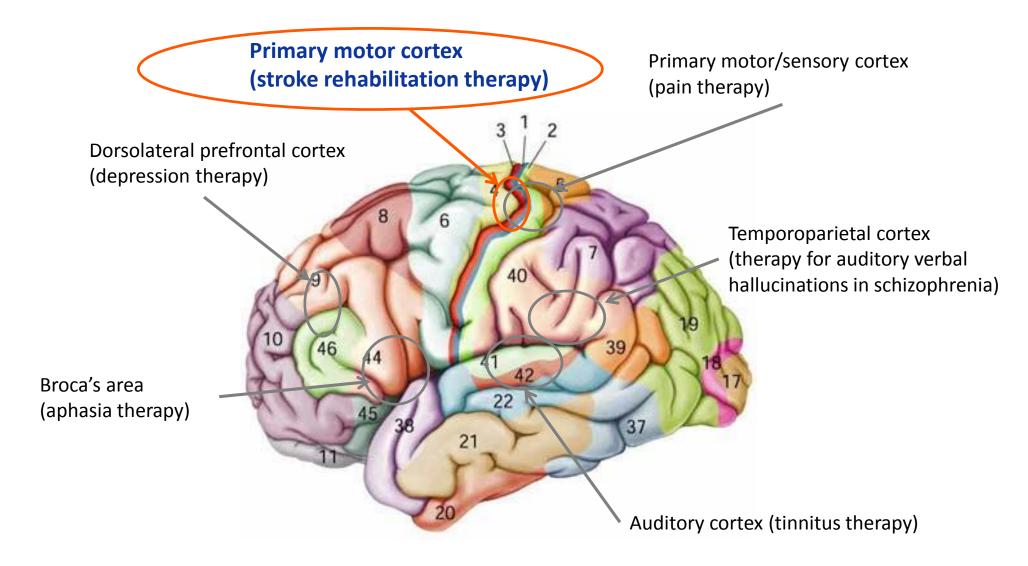






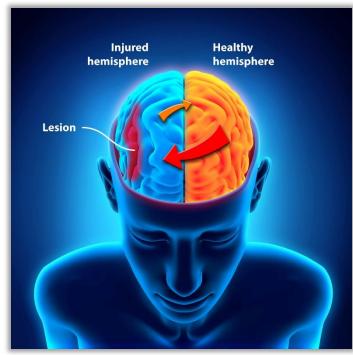


## NBT® (Navigated Brain Therapy) has potential for multiple therapeutic applications due to precise navigation

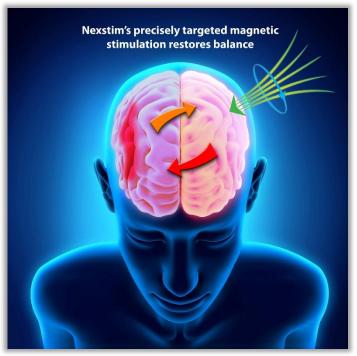


## NBT® for stroke rehabilitation – how it works

#### Validated e-Field Navigation gives Competitive Edge



Using a patient's own MRI scan as a guide, Nexstim provides precisely targeted, personalized, magnetic stimulation to temporarily inhibit the healthy side of the brain, normalising the balance between the hemispheres.



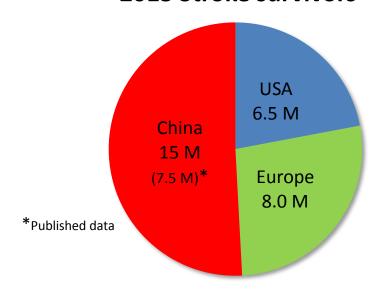
Because the injured side is no longer dominated by the healthy side of the brain, it is more responsive the physiotherapy. This results in limb movement being potentially restored more quickly to better functionality.

## Market opportunity in stroke rehabilitation



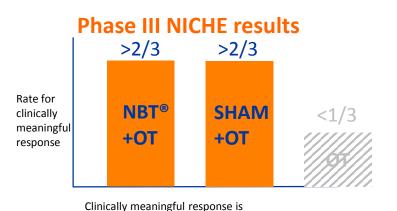
## **USA** 0.8 M China Europe 2.5 M 1.2 M

#### 2015 Stroke survivors

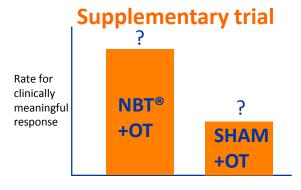


- Large and rapidly growing market
- 50% of stroke survivors will have upper limb paralysis with few available treatment options
- Focus on the period over 3 months post stroke

## Clinical data comparing NBT® + occupational therapy (OT) with OT



- 199 patients 12 leading US centres
- Excellent results in active group
- Sham coil in control group proved active
- Safety endorsed by DSMB



>5points in UEFM score

Clinically meaningful response is >5points in UEFM score

- 60 patients 5 leading US centres
- FDA approved trial protocol December 2016
- Study commences February 2017 with expected completion by March 2018
- Data from Phase III and supplementary trial to be pooled

## **Timeline of US Regulatory Development for Stroke**

December	February	March	April	H2
2016	2017	2018	2018	2018
FDA approval of Trial Protocol	Expected Trial Commence	Expected Trial Completion	Expected FDA 510(k) de novo filing	Expected FDA 510(k) de novo clearance

### Other indications

#### **Chronic pain**

- CE mark for treatment.
- Chronic neuropathic pain trial with Nexstim's NBT® has been completed. The study demonstrated 44% of patients obtained clinically meaningful pain relief of at least 3 weeks' duration
- Second study using Nexstim's technology at The Walton Centre, the only specialist neuroscience centre in the NHS, to show long term effect of NBT® in chronic pain

#### **Depression**

- NBT® CE-marked for use in treatment of depression
- KOLs use to treat severe cases instead of ECT

#### **Tinnitus**

- Promising conclusions from pilot study done by Turku University Hospital, Finland
- Preliminary observations suggest that E-field rTMS may improve the current treatment options for intractable tinnitus

## **Key performance indicators**

#### **EUR** in thousands

Net sales

Personnel expenses

Depreciation and amortisation

Other operating expenses

Profit/ -Loss for the period

Earnings per share (EUR)\*

Diluted earnings per share (EUR)\*

Cash flows from operating activities

Cash in hand and at banks

**Total equity** 

Equity ratio (%)

Number of shares in the end of the period (pcs)

Average number of shares during the period (pcs)

Diluted number of shares in the end of the period (pcs)

Diluted average number of shares during the period (pcs)

H1 2016 6 months	H1 2015 6 months	FY 2015 12 months	
	o monens	12 1110111113	_
892.5	643.2	2,527.9	
-2,214.6	-1,906.1	-3,969.8	
-168.8	-168.7	-386.0	
-2,410.8	-3,422.9	-7,843.1	
-4,226.5	-4,555.0	-9,827.0	
-0.53	-0.64	-1.37	
-0.47	-0.58	-1.24	
-5,240.7	-5,275.3	-9,608.6	
1,815.6	6,071.1	6,874.7	
-588.1	3,712.0	3,545.1	
-3.24	50.44	44.16	-
8,116,833	7,130,758	8,010,758	
8,031,740	7,130,758	7,154,868	
9,497,698	7,917,698	8,797,698	
8,936,160	7,917,698	7,941,808	

Net sales increase of 38.8 percent

Includes EUR 1,227.4 thousand of Phase III trial expenses

The financing arrangements with Bracknor and Sitra, combined with the strategic changes in the organization (targeting annual savings of EUR 2.3 million), is estimated to finance the Company until beginning of financial year 2018.

## **Nexstim Funding**

- Accelerated pace in the two year funding arrangement with Bracknor Investment and Finnish Innovation Fund Sitra
- Funding arrangement is a combination of:
  - EUR 5 million of convertible bonds 100% funded
  - EUR 6.5 million stand-by equity facilities ~50% funded
  - EUR 0.5 million direct share issue 100% funded
  - EUR 9.8 million warrants strike range EUR 0.14 0.85
- Costs aligned to therapy strategy, targeting annual savings of EUR 2.3 million



## **Nexstim Strategic Actions**

- Move to distributor model in US for Pre-surgical mapping
- Focus on therapeutic applications Primarily Stroke,
   Depression and Pain
- File 510(k) for depression during H1 2017
- Exploit CE marked approval in Stroke EU sales to begin in H1
   2017
- Stroke rehabilitation 510(k) de novo clearance expected in Q4 2018
- Partner agreements to include major Asian territories
- Prepare funding plan for US therapy commercialisation





Thank you



### **Appendix**

## **The Board**

	Name Nationality		Education	Relevant experience
	Martin Jamieson, Chairman UK	2015 Independent	University of the Arts (CDT) London Higher National Diploma - Business Studies (1979)	Currently board member of C-Major Ltd, LightPoint Medical Ltd and Medway NHS Foundation Hospital Trust. Previously Managing Director Smiths Medical International and CEO at Rayner Group.
0	Dr Johan Christenson, Deputy Chairman Sweden	2007 HealthCap	4 years of clinical specialist training at Karolinska Institute, PhD at Karolinska Institute (1991) in neuroscience	Partner at HealthCap and positions on several private company boards. Previously supervised health care portfolio at SEB Företagsinvest.
	Ken Charhut US	2013 Independent	BSc at Cornell (1980) and MBA from U.Chicago (1988)	Member of the Board at two medical industry companies. CEO at Compellon. Previously CEO at other medtech firms.
	Rohan Hoare Australia	2016 Independent	Ph.D. in Physics from Harvard University where he was a Fulbright Scholar	Most recently the President, Neuromodulation at LivaNova. At Cyberonics, Rohan was the COO. Numerous leadership positions at St Jude Medical culminating in President, Neuromodulation Division.
	Dr Ekaterina Smirnyagina France	2013 Capricorn	Postdoctoral fellow at Stanford, PhD at U.Wisconsin-Madison (1996), BSc from Moscow State U (1988)	Partner of Health-Tech Fund Venture Fund at Capricorn Venture Partners. Previously partner at Alta Partners, a healthcare focused VC firm.
	Juliet Thompson UK	2015 Independent	Chartered Accountant ACA; Chartered Institute for Securities (ASCI); BSc Economics (Bristol University)	Experience includes senior roles (Managing Director, Head of Corporate Finance and Partner) at Stifel Financial Corp, Nomura Code Securities, WestLB Panmure, ICI PLC, Deloitte and Touche and HM Treasury.
1	Juha Vapaavuori Finland	2006 Sitra	MSc at U.Helsinki (1978)	Chairman of the Board of Directors of FIT Biotech and member of the Board of Directors of KC-Holding 3.

## **Management team**

	Name Nationality	Current position (Nexstim since)	Education	Relevant experience
9	Martin Jamieson UK	CEO & Chairman of the Board 2016	University of the Arts (CDT) London Higher National Diploma - Business Studies (1979)	Currently board member of C-Major Ltd, LightPoint Medical Ltd and Medway NHS Foundation Hospital Trust. Previously Managing Director Smiths Medical International and CEO at Rayner Group.
	Henri Hannula Finland	VP, Sales Europe 2001	MSc in technology from Helsinki U. of Technology (2001)	Various roles at Nexstim starting 2001 and VP, Sales Europe since 2013. Comes from position as director of sales
	Rainer Harjunpää Finland	VP, Quality Assur. and Regulatory Affairs, After Sales/Services , 2010	MSc in biomedical engineering from Tampere U. of Technology (1993)	Current position since 2013, previously as director and manager of quality and regulatory affairs
	Gustaf Järnefelt Finland	VP, R&D 2008	MSc at Helsinki U. of Technology (1988)	R&D director 2008-2014. Previously held managerial positions at GE Healthcare Finland
	Mikko Karvinen Finland	CFO 2014	MSc in economics at Helsinki School of Economics (2001)	Previously held CFO and deputy CEO positions at two Nasdaq OMX listed tech-firms
	Jarmo Laine Finland	VP, Medical Affairs 2008	MBA at Helsinki U of Technology (2007) and PhD at U.Helsinki (1995), MD U. Helsinki (1991)	Director of clinical operations 2008-2013. Held several directorial positions at Finnish Red Cross Blood Service
	John Liedtky US	VP, Commercialization, General Manager US, 2016	MBA in marketing at San Diego State University and BA in economics at Indiana University	Previously held Global Marketing Vice Presidency Roles at DJO Global, COVIDIEN and BREG Inc.
9	Petriina Puolakka Finland	VP, Legal Affairs 2001	Master of Law at U.Lapland (2001)	Previously director of legal affairs and HR and manager of administration and legal affairs

## **Nexstim Active NICHE coil vs. SHAM coil**

- Nexstim Active Coil creates a cone—like magnetic field to induce the stimulating electric field. This allows NBT to be accurate with stimulation area and dose to be titrated to evoke MEP's from pyramid tracts in the motor cortex.
- This is the normal TMS coil/magnetic field shape and there are 8.000+ publications with similar coils.
- Nexstim SHAM coil creates a donut-like magnetic field to induce a weak stimulating electric field which is around 30% of the Active coil e-field with same simulator output.
- The donut-like field, when navigated to be exactly around target on the motor cortex, may induce a stimulating field leading to surround inhibition on the pyramid tracts located in the void in the middle.

