Nexstim Targeting a paradigm shift in stroke rehabilitation

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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.

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Introduction to Nexstim – a brain stimulation company



Technology platform overview



Navigated Brain Stimulation (NBS)

Validated navigation technology in demanding diagnostic indication

- Only CE-marked and FDA-cleared non-invasive solution to pre-surgical mapping of the motor and speech cortex
- Combines Magnetic Resonance Imaging (MRI-based imaging) guidance with non-invasive TMS and Electromyography (EMG) for response measurement
- System integration, proprietary e-field algorithms and 3D visualization provide unrivalled accuracy of targeting stimulation
- Multiple clinical studies have proven that NBS, as an adjunct to direct cortical stimulation, results in a 40% increase or greater, in the rate of gross total resection in surgery of brain tumors

Navigated Brain Therapy (NBT)

Uses validated navigation technology platform in multiple areas

- Navigation is achieved by visualizing the electric field (e-field) generated by the TMS coil in a 3D image rendered from the patient's MRI scan
- Using a stroke patient's own MRI scan as a guide, NBT[®] System provides precisely targeted, personalised, magnetic stimulation to temporarily inhibit the healthy side of the brain, normalising the balance between the hemispheres
- Nexstim will submit the FDA 510(k) De Novo based on the Phase III multi-centre stroke therapy trial clinical data in the second quarter 2016
- Other potential research indications for use of the technology platform include chronic pain and tinnitus

Pre-Surgical Mapping

A revolutionary non-invasive device for pre-surgical mapping, validating the technology in clinical use



Validated vs. current "gold standard" of motor mapping

Nexstim's novel method



- Current "gold standard" is using only direct cortical stimulation for mapping the motor area, whereby the motor area is mapped only during the actual surgery
- By using the NBS System for mapping the motor area days or weeks prior to surgery (direct cortical stimulation is still needed during the actual surgery⁽¹⁾), pre-surgical planning and surgical outcome have been shown in several studies to be considerably improved (see next slide)
- As the NBS System has been shown to be as accurate as direct cortical stimulation for motor mapping while still being non-invasive and considerably easier to use than direct cortical stimulation, the NBS system opens the door for a more extensive use of motor mapping

 The NBS System is only FDA cleared for use in combination with direct cortical stimulation

Current "gold standard"

Pre-Surgical Mapping – giving surgeons precise knowledge ahead of tumour resection and other surgeries

- Only CE-marked and FDA-cleared non-invasive solution to presurgical mapping of the motor and speech cortex
- NBS adds navigation to transcranial magnetic stimulation (nTMS), creating a precise map of the eloquent cortex superimposed on a patient-specific MRI
- Current sales to strategic customers in neurosurgery such as teaching hospitals and universities that have a strong Key Opinion Leader presence
- NexSpeech[®] with the NBS System 5 is a robust, intuitive technique for speech mapping and offers a non-invasive method to reliably determine non-eloquent speech areas prior to a surgical procedure
- Nexstim estimates that the total potential maximum market size for the NBS System in the US and Europe is around USD 625 million



NBS Pre-Surgical Mapping Makes the Difference...Extent of Resection



¹ Sandro M. Krieg, **Preoperative motor mapping by navigated transcranial magnetic brain stimulation improves outcome for motor eloquent lesions** Neuro Oncol first published online February 9, 2014 doi:10.1093/neuonc/nou007 3 Krieg et al.: Presentation DGNR May 2014

² 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 Presurgical Mapping makes the difference... clinical outcome



Progression-free Survival (Months)

1 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

NBT Therapy Potential



Platform benefits for therapy

Accuracy

• Proven proprietary accuracy validated with neurosurgery provides accuracy for multiple therapeutic stimulation indications

Repeatability

 Accuracy provides inter-session repeatability for therapeutic protocols to maximize the effect

Dose Control

 Accuracy and repeatability enable dose control to ensure safety and maximize the dose delivered to the intended anatomic target

Nexstim Platform provides new approach to non-invasive neuromodulation

Platform protected with 26 patent families

79 granted patents77 pending patents

Right to software: Nexstim owns rights to its NBT[®] and NBS Systems' software developed inhouse.

Creating hurdles for competitors: e.g. by seeking patent protection on different parts of the products and making it more difficult for potential competitors to create competing products

Core algorithms kept as trade secrets: Not patenting the core algorithms to avoid publicity and loss of trade secrets



Stroke Therapy

Huge unmet need and commercial opportunity



Targeting a paradigm shift in stroke rehabilitation

Nexstim's Navigated Brain Therapy[®] solution for stroke rehabilitation



Targeting a blockbuster market... (market for post-acute stroke treatment)

2.1 million strokes each year in US and Europe
 712,000 patients is Nexstim's target # of patients
 \$1.8 billion market potential for Nexstim
 Few effective alternatives...
 ...still \$8.5bn currently spent on stroke rehab in the US

Huge unmet need and commercial opportunity

...with a potential game-changer technology

Promising efficacy demonstrated in completed Phase II clinical trial

Technology already validated – Pioneered the technology to map motor and speech centers, with 130 devices installed worldwide and FDA clearance – same technology now applied in stroke rehabilitation

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 to the physiotherapy. This results in limb movement being potentially restored more quickly to better functionality.

Other Indications

Application of world-leading technology and software



Other indications

- Nexstim may also use its technology platform to build new applications for other indications, such as chronic pain and tinnitus
- Chronic pain targeting CE mark for treatment and further studies
 - Chronic neuropathic pain trial with Nexstim's NBT[®] is progressing according to plans
 - 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
 - Previous study demonstrated 44% of patients obtained clinically meaningful pain relief of at least 3 weeks' duration
- Tinnitus
 - Promising conclusions from pilot study done by Turku University Hospital and University of Turku, Finland
 - Preliminary observations suggest that E-field rTMS may improve the current treatment options for intractable tinnitus
- Depression
 - NBT[®] CE-marked for use in treatment of depression

Additional platform potential with proven navigation



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Current Development Status and Outlook



Phase III trials – laying the groundwork for commercialisation

Study in brief

- Establish clinical efficacy of NBT[®] in upper-limb motor rehabilitation
- Up to 199 patients
- 12 top US rehab sites RIC is central site (#1 US rehabilitation hospital for 25 years)
- Dr. Richard L. Harvey lead investigator – one of the top experts in the field
- FDA reviewed protocol

Study goals

Outcome data

FDA clearance

KOL support

- Document effects/efficacy of NBT on upper-limb motor rehab
- Obtain FDA De Novo 510(k) clearance for right to market and sell NBT[®] in US
- Build support from key opinion leaders (KOLs) to support commersialisation

Conducted at 12 top US rehab sites

	Reha
MEMARIA	TIRR
SPAULDING.	Spau
THE OHIO STATE UNIVERSITY	Ohio
RANCHO LOS AMIGOS	Ranc
Rehabilitation & Research	Burke
UKE UNIVERSITY MEDICAL CENTER	Duke
NYP	Colur
Shepherd Center	Shep
UNIVERSITY OF CINCINNAL	Unive
UNDERNA UNIVERSITY	India
MAYO CLINIC CUNIC	Mayo

Rehabilitation Institute of Chicago (central site) TIRR Memorial Hermann Hospital (Houston) Spaulding Rehabilitation Hospital (Boston) Ohio State University (Columbus, OH) Rancho Los Amigos National Rehabilitation Center Burke Rehabilitation Hospital (White Plains, NY) Duke University Medical Center (Durham, NC) Columbia Cornell New York Presbyterian Hospital Shepherd Center (Atlanta) University of Cincinnati Indiana University Indianapolis Mayo Clinic (Phoenix, AZ)

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Status of clinical development

• The clinical Phase III multi-center stroke trial has been stopped at end of March 2016

Timeline Phase III multi-centre stroke therapy trial



• Nexstim will submit the FDA 510(k) De Novo based on the clinical data in the second quarter 2016

Clinical evidence from NICHE, Phase III multi-center trial



Clinically meaningful response is >5points in UEFM score



Clinically meaningful response is >5points in UEFM score

Assumptions Based on:

- NBT phase I, showing the measurable neurological effect with NBT over non-navigated TMS. Indicating the hypothesis for lateral inhibition reached with inhibitory 1Hrz protocol to prime the brain for motor rehabilitation
- NBT+OT evidence from CONTRASTIM (Phase II) with 84% response rate, indicating the effectiveness over simple sham stimulation as control group (p=0.0184)
 - Simple sham to prevent stimulation to the cortex, not blinding the user and partial TMS blinding affect for the patient
- Clinical KOL experience and similar rehabilitation studies after first 3months, indicating only few points in UEFM after 3months post stroke, resulting less than third of patients potentially reaching 5points improvement in UEFM score
 - During first three months after stroke, the neurophysiological rehabilitation leads to recovery of function. After that, patient only learns to use the regained functions better. No additional function gained.

Results on 138pts, after 2nd milestone:

- No safety concerns, NBT is considered to be safe for the patients
- Significant clinical response in both trial groups, over 2/3 of the patients responding
 - NBT group responding as expected
 - SHAM group well above expected OT level, indicating SHAM being active
 - Correct comparison group is normal clinical practice
- SHAM coil was changed from Phase II to comply better with TMS sham needs to provide all sham criteria (coil look & feel, stimulation sound and scalp sensation) for full blinding affect. Coil is designed to provide surface stimulation outside the core target area to make sure no stimulation is given to the motor area
 - NICHE SHAM+OT results indicate a hypothesis of novel stimulation method when providing weak TMS stimulation to surrounding cortical areas. Nexstim has filed patent application for this novel stimulation for protection.
- NBT+OT results were significantly better then current standard therapy (of OT alone)

Commercialisation strategy overview

Initial Demand

- Physicians determining the patient's treatment OR Patients themselves
- Clinical efficacy evidence drives initial entry
- Nexstim Strategy: Phase III trial to drive the efficacy evidence, engaging the patient advocacy groups and KOL's with selected trial sites. Timeline 2015-2017

"Outcomes data is the most important thing when you're talking about a technology." -Director of Supply Chain, Hospital with outpatient stroke unit

1. Patients& Physicians 3. Payers

Early adoption

- **Providers** to adopt based on the initial demand
- Clinical results in care path needed to support the benefits for Providers
 - Nexstim Strategy: Leveraging the NICHE sites as early adopter, engaging entry points for large provider chains with KOL and patient advocacy support. Timeline 2016-2017

 "Even if it's not reimbursable if it shows some major progress in outcomes it may be worth getting " -Physiatrist, Stroke Rehabilitation Hospital with Outpatient setting, FL

Expansion

- **Payers** engaged with support of Patients & Physicians and Providers. Initial entry point is Private Insurance Payers (25% of payers) and expanding to regional Medicare (14 regions, covering 65% of stroke rehab costs)
- Private insurers and Out-of-Pocket (OOP) payers represent c.30% of rehabilitation costs (c.\$2.6bn)
- HealthEconomic evidence required to show long term value benefits for payers
- Nexstim Strategy: Initially starting with Out-of-Pocket, engaging Private Insurance payer and then with built coverage evidence roll out to Medicare. Timeline 2017-2020

" Everyone pays differently. If it's someone with private insurance they can basically get whatever they want" -CFO, Non-Profit Provider, MD

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Key stakeholders & messaging

Nexstim positioned for Stroke Stakeholders with targeted messaging

- Outpatient treatment Facilities offer Occupational Therapy for post-acute stroke patients
 - Clear Entry Point targeted patient group with upper limb rehabilitation
- Physicians (PM&R) are key decision makers deciding the treatment method
 - Trend to use more outpatient therapy instead of inpatient to lower cost of care
- Patient & Patient Advocacy Groups
- Rehabilitation Clinicians
- Referring Clinicians and Social Workers
- Rehabilitation Providers
- Payors

- Clinical Efficacy: Improved functionality and quality of life with non-invasive procedure
- **Clinical Efficacy**: Improved care, safe and personalized therapy for unmet need
- Business Opportunity: Provide disruptive technology for unmet need and clinical efficacy. Potential to own the patient through care path from acute to postacute care
- Managing the care cost: potential to manage the patient treatment cost more effectively and improve before chronic phase

Financials

Financial Statement Release 2015



Key performance indicators

EUR in thousands	H2 2015	H2 2014	FY 2015	FY 2014	
	6 months	6 months	12 months	12 months	Net sales increase
Net sales	1,884.7	1,796.5	2,527.9	2,210.4	of 14.4 percent
Personnel expenses	-2,063.8	-2,018.3	-3,969.8	-3,660.2	
Depreciation and amortisation	-217.3	-252.1	-386.0	-377.4	
Other operating expenses	-4,420.3	-3,826.2	-7,843.1	-5,498.5	
Profit/ -Loss for the period	-5,272.0	-5,318.1	-9,827.0	-10,445.4	
Earnings per share (EUR)*	-0.73	-1.02	-1.37	-2.37	Includes 1,602.8
Diluted earnings per share (EUR)*	-0.66	-0.92	-1.24	-2.16	Increase of Phase III trial expenses
Cash flows from operating activities	-4,333.3	-5,277.1	-9,608.6	-7,785.2	·
Cash in hand and at banks	6,874.7	11,483.7	6,874.7	11,483.7	
Total equity	3,545.1	8,589.9	3,545.1	8,589.9	The company will
Equity ratio (%)	44.16	65.29	44.16	65.29	need more
Number of shares in the end of the period (pcs)*	8,010,758	7,130,758	8,010,758	7,130,758	funding after September 2016
Average number of shares during the period (pcs)*	7,178,584	5,237,468	7,154,868	4,406,572	
Diluted number of shares in the end of the period (pcs)*	8,797,698	7,917,698	8,797,698	7,917,698	
Diluted average number of shares during the period (pcs)*	7,965,524	5,799,236	7,941,808	4,826,140	

*The number of shares and subscription price have been adjusted to take account the effect of the merging of the share classes and share split on 29 September 2014, where the number of shares was increased 14-fold

Summary and future outlook

- World-leading medical technology and software with game-changing potential
- Growing sales of NBS Systems expected for pre-surgical mapping. Based on its business forecast the Company estimates its net sales to grow during financial year 2016 and a loss is expected for the financial year.
- Nexstim will submit the FDA 510(k) De Novo based on the clinical data in the second quarter 2016 and continue to engage with KOL's and payers to find route to help rehabilitation of the patients
- Nexstim will follow other potential indications for the platform



Appendix



Appendix

Management team

	Name Nationality	Current position (Nexstim since)	Education	Relevant experience
	Janne Huhtala Finland	CEO 2008	Master in economics at Turku School of Economics (2001)	CFO 2008-2013. Previously manager at financial consultant firm Gutta
	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
2	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
7	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
Q	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
R	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.
P	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

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.
-	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.
Q	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.
- Province of the second secon	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.
A	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.
P	Juha Vapaavuori Finland	2006 Sitra	MSc at U.Helsinki (1978)	Chairman of the Board of Directors of KC-Holding 3 and FIT Biotech.

The completed single-centre Phase II clinical trial – details

Contrastim stroke study details



Nexstim

- Basic study information Phase II clinical trials (Contrastim) funded by Nexstim and performed at the Rehabilitation Institute of Chicago
- Trial subjects The trial consisted of 30 post acute stroke patients (3-9months post stroke), of which 20 where in the group receiving NBT treatment and 10 received sham treatment.
- Trial objectives (1) To assess the use of Navigated Brain Therapy (NBT) in the clinical application of repetitive transcranial magnetic stimulation (rTMS) for motor recovery after stroke. (2)To determine if the addition of 1 Hz rTMS to non-injured hemisphere prior to task-oriented upper limb rehabilitation can improve motor control and functional arm use better than rehabilitation alone.

Upper extremity Fugl-Meyer

84% of NBT group above threshold



NBT group 13.8 point average improvement



Results discussion

At 6 months post treatment 84% of the active group showed improvement above the minimum clinically important difference of 5 Fugl-Meyer points against the sham group's 55%.

At 6 months post treatment the average improvement in the NBT group was 13.2 but as one patient did not come to the 6 month follow up the per protocol average was 13.8 vs 7.1 in sham group.

The sham group's results were much higher than what is seen normally (3-4 points) as additional therapy post treatment was not restricted.

Only 29% of the sham group excluding patients with additional therapy (6 patients) showed improvements above the threshold with an average increase of 2.9 points. In the NBT group which did not receive additional occupational therapy (9 patients) the respective figures were 80% and 14.5 points.

Dr. Harvey, PI for CONTRASTIM & NICHE trials

- Medical Director, Center for Stroke Rehabilitation, Rehabilitation Institute of Chicago (RIC)
- Wesley and Suzanne Dixon Stroke Chair, RIC
- Director, Stroke Program, RIC

Biography

- Doctor of Medicine, University of Michigan Medical School 1984-1988
- Residency in Physical Medicine and Rehabilitation, University of Toledo Medical Center 1988-1992
- Fellowship in Stroke Rehabilitation, RIC and Northwestern Feinberg School of Medicine 1992-1994
- Rehabilitation Medicine Scientist Development Program, National Institutes of Health (K12) 1997-2000
- Principal Investigator, Contrastim Stroke Study 2010-2013







IPR strategy



3-level approach to protect our proprietary Efield navigation

- The Core is the algorithms and integration to allow precise E-field based navigation with user friendly visualization
- Next level is the IPR portfolio
- And the outer rim is the clinical evidence to validate and to support our approach in clinical use



Illustrative description of the IPR families

Nexstim

Thank you



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