Nexstim Targeting a paradigm shift in stroke rehabilitation

Janne Huhtala | CEO | 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.

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Introduction to Nexstim

Pioneered Use of Navigated Brain Stimulation Technology for Stroke Rehabilitation Therapy



Company Overview

Nexstim

Navigated Brain Therapy (NBT)

Uses validated navigation technology for post-acute stroke rehabilitation

- 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 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
- Initiated multicenter Ph. III trial (NICHE) earlier this year in 198 patients
- Aim to obtain FDA clearance for marketing NBT device for post-acute stoke treatment

Navigated Brain Stimulation (NBS)

Validates the navigation technology in demanding diagnostic indication

- Only CE marked and FDA cleared non-invasive solution to pre-surgical mapping of the motor cortex
- Combines Magnetic Resonance Imaging (MRI-based imaging) guidance with non-invasive TMS and Electromyography (EMG) measurement 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

Overview of Key Personnel

Management



Janne Huhtala CEO



Henri Hannula VP, Sales Europe



John Hardin VP. Global PSM Commercialisation



Rainer Harjunpää VP, Quality Assur. and Regulatory Affairs, After Sales/Services



Gustaf Järnefelt VP, R&D



Mikko Karvinen CFO



Jarmo Laine VP, Medical Affairs



Petriina Puolakka VP, Legal Affairs

Richard L. Harvey, MD Lead Investigator



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

Olli Riikkala Chairman (Independent)

Board of Directors



Juha Vapaavuori Sitra



Dr Johan Christenson HealthCap



Dr René Kuijten Life Sciences Partners



Juliet Thompson Independent



Ken Charhut Independent



Dr Ekaterina Smirnyagina





Company Highlights

- Stroke Rehabilitation Phase II Data published in International Stroke Conference
- Successful listing of the company's shares to Nasdaq First North Finland and Nasdaq First North Sweden raising new equity of EUR 15.3 million in November 2014
- Pivotal Phase III multi-centre trial in the US for stroke therapy progressing according to plans
 - Primary end point at six months follow up between active and sham group response rates achieving clinically meaningful improvement in upper extremity motor function
 - First interim signal shows that safety criteria are met and trial now further derisked to continue without any modifications towards the primary endpoint of demonstrating a clinically important functional improvement with NBT[®]
 - Successfully enrolling patients on time with next milestone interim analysis expected in Q1 2016

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 120 devices installed worldwide and FDA clearance – same technology now applied in stroke rehabilitation

Positioned within Stroke Care Path



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.

Nexstim's unique technology provides distinct benefits

Integration of TMS and navigation



- TMS-navigation integration
- Navigation is the key differentiator

Several distinct benefits



- Improved accuracy
- Dosing precision
- Repeatability
- Non-invasive procedure

Enhanced limb move



 Substantially improved hand movement after treatment demonstrated in Nexstim's Phase II trial

Nexstim 11

Highlights in Stroke Rehabilitation (NBT[®])

Huge unmet need	 2.1m strokes each year in the US and Europe Stroke is the leading cause of long-term disability in Western world
Few effective alternatives	 While current standard treatment of physical/occupational therapy is not very effective, \$8.5bn is still currently spent on stroke rehab in the US
Potential blockbuster market	 \$1.8bn is estimated value of Nexstim's target market (US and Europe)
Promising, validated technology	 Statistically significant efficacy in stroke rehabilitation vs. sham treatment (standard therapy) Navigation already validated by NBS
Clear execution strategy	 <u>Phase III trial on track</u>: Establish efficacy in Phase III to obtain FDA clearance and KOL support <u>Commercialisation strategy</u>: Convince users of benefits, providers of economic benefits and obtain reimbursement coverage from payers

Nexstim 12

Current Development Status and Outlook

Progressing as planned with milestones



Efficacy demonstrated in Phase II trial

The Phase II clinical trial in brief:

- Single centre at Rehabilitation Institute of Chicago (#1 rehabilitation hospital in US for 25 consecutive years)
- 29 patients of which 19 (10) in treatment (sham) group
- End-point = 6 months post-treatment

Change in upper extremity Fugl Meyer score from baseline



l lexsti

14

Note: "Robotics", "Intensive conventional rehab" and "Non-navigated rTMS" data come from different studies. While not directly comparable, included in the above chart for illustrative purposes. | (1) Data for "Treatment group" and "Sham group" from Nexstim Phase II clinical trial (Harvey et al, 2013) – per protocol figures. | (2) Data for "Robotics" and "Intensive conventional rehab" from published multi-center trial (Lo et al, NEJM 2010) | (3) Data for "Non-navigated rTMS" from published multi-center trial (Kakuda et al, J Neuroeng Rehab 2012), 6 month follow-up not done. Responder rate = % of group that had improvements above the 5 point minimal clinically important difference threshold.

Lead Investigator Profile

Dr. Richard L. Harvey, PI for Contrastim & Niche trials





(EARS STRAIGHT

• Medical Director, Center for Stroke Rehabilitation, Rehabilitation Institute of Chicago (RIC)

- Wesley and Suzanne Dixon Stroke Chair, RIC
- Director, Stroke Program, RIC

Biography

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

Nexstim 15

Phase III trials - Laying the groundwork for commercialisation



Conducted at 12 top US rehab sites



- Including post-acute stroke patients, 3-12months post stroke, hemiparesis and moderate/moderately severe upper extremity impairment
- Primary end-point at 6 months post-treatment, difference between active and sham group response rate achieving clinically meaningful response
- NBT[®] is used 3 times per week for six weeks adjunct to task-oriented Occupational Therapy (OT)

Status of Clinical Development

Progressing as Planned

- The clinical Phase III multi-center trial is progressing and enrolling according to plans.
- First interim data analysis by an independent Data Safety Monitoring Board shows that safety criteria are met and trial now further de-risked to continue without any modifications towards the primary endpoint of demonstrating a clinically important functional improvement with NBT[®]
- The next interim analysis milestones is estimated to be reached Q1 2016 and the clinical evidence is assumed to be ready by the end of 2016



Simplified timeline Phase III multi-centre stroke therapy trial

Overview of Interim Phase III Results

- Interim data analysis by an independent Data Safety Monitoring Board shows that safety criteria are met
- Trial now further de-risked and to continue without any modifications towards the primary endpoint of demonstrating a clinically important functional improvement with NBT[®]
 - Nexstim has received a recommendation from the Data Safety Monitoring Board (DSMB), an independent committee of experts monitoring the trial, to continue the Phase III stroke therapy NICHE trial, without any modifications towards the goal of achieving its primary endpoint.
 - The first interim analysis on the NICHE (Navigated Inhibitory rTMS to Contralesional Hemisphere) trial using Nexstim's Navigated Brain Therapy (NBT[®]) was performed after 81 patients reached their primary safety outcome assessment, on track, at six months post-treatment.
 - The safety data was assessed on all patients 160 recruited to-date.
- The second interim analysis is expected to occur in Q1 2016 and the study is scheduled to complete in Q3 2016 when full data will be disclosed.

IP position

67 granted patents71 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



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

Regulatory Interaction

Nexstim is proceeding with De Novo 510(k) –process according to original plans

- Phase II interim data was initially presented to FDA with Phase III protocol to get feedback
- FDA responded that NBT device and use of the device in patients with stroke according to the NICHE trial protocol is Non-Significant Risk (NSR) Application and Market Clearance does NOT require PMA or IDE process.
 - NICHE protocol was indicated to be sufficient to show efficacy and safety in relation to De Novo 510(k) process
- FDA indicated that since there is NO predicate device for stroke therapy, Nexstim should pursue De Novo 501(k) route for market clearance
 - This would allow Nexstim to develop FDA Guidelines with FDA to use navigated rTMS in the stroke therapy based on the clinical data and NBT specification as NBT will be the predicate device for following 510(k) processes
- The Pivotal Phase III trial, NICHE, was started with local IRB's from local ethical committees
 - Two trial sites verified independently the IRB route from FDA and got the approving responses
- Nexstim has submitted the technical part of the De Novo 510(k) process and waiting currently response from FDA based on normal process.
- Once the NICHE data shows efficacy, the data set will be submitted as part of the De Novo submission as a final major step for FDA clearance

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



Key Performance Indicators

EUR in thousands	H1 2015 6 months	H1 2014 6 months	FY 2014 12 months	
Net sales	643.2	413.9	2,210.4	
Personnel expenses	-1,906.1	-1,641.9	-3,660.2	
Depreciation and amortisation	-168.7	-125.3	-377.4	Includes 1.745.4
Other operating expenses	-3,422.9	-1,672.3	-5,498.5	of Phase III trial
Profit/ -Loss for the period	-4,555.0	-5,127.3	-10,445.4	expenses
Earnings per share (EUR)*	-0.64	-1.44	-2.37	Includes 2,006.2
Diluted earnings per share (EUR)*	-0.58	-1.34	-2.16	of one time financial expenses
Cash flows from operating activities	-5,275.3	-2,508.1	-7,785.2	
Cash in hand and at banks	6,071.1	1,522.1	11,483.7	
Total equity	3,712.0	-4,077.3	8,589.9	
Equity ratio (%)	50.44	-87.19	65.29	
Number of shares in the end of the period (pcs)* Average number of shares during the period (pcs)*	7,130,758	3,685,290 3 561 908	7,130,758	
Diluted number of shares in the end of the period (pcs)*	7,917,698	4,016,936	7,917,698	
Diluted average number of shares during the period (pcs)*	7,917,698	3,836,910	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

Targeting a Paradigm Shift in Stroke Rehabilitation

- World-leading medical technology and software with game changing potential in stroke rehabilitation
- Good progress since IPO
- NBT[®] Phase III study proceeding well with next interim data due in Q1 2016
- Based on its business forecast and sensitivity analysis the Company expects its net sales from the sale of NBS Systems (Pre-Surgical Mapping, PSM) to grow during FY2015 and operating profit to be positive during second half of the FY2017 at the earliest



Appendix

Management and owners



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
	John Hardin US	VP, Global PSM Commercialisation 2014	MBA at William Woods U. (1996)	Previously served as VP, global sales and marketing of Mindframe before joining Nexstim in 2014
	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
8	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)	Director of clinical operations 2008-2013. Held several directorial positions at Finnish Red Cross Blood Service
R	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

Management and owners

The Board

	Name Nationality		Education	Relevant experience
	Olli Riikkala, Chairman Finland	2007 Independent	MSc Helsinki U. of Technology (1974), MSc Helsinki School of Economics (1976), MBA at Claremont Graduate U. (1978)	Currently board member of several Finnish medical industry firms. He has served 26 consecutive years in publicly listed company board of directors including Oriola-KD Oyj as chairman.
P	Juha Vapaavuori Finland	2006 Sitra	MSc at U.Helsinki (1978)	Chairman of the board of directors of KC-Holding 3 and member of the board of FIT Biotech
-	Dr Johan Christenson 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
	Dr René Kuijten Netherlands	2007 Life Sciences Partners	PhD at U.Penn (1992), PhD at U.Amsterdam (1992), MBA at Insead (1994), MD and MSc at U.Utrecht	Co-owner and GP of Life Sciences Partners. Previously at McKinsey & Company as co-leader of European Health Care and Pharmaceuticals Practice
	Juliet Thompson UK	2015 Independent	Chartered Accountant ACA; Chartered Institute for Securities (ASCI); BSc Economics (Bristol University)	Founding partner of Code Securities. Currently heading the healthcare team at Oriel and previously having been Managing Director of Corporate Finance at Nomura Code
Q	Ken Charhut US	2013 Independent	BSc at Cornell (1980) and MBA from U.Chicago (1988)	Chairman of the board at two medical industry firms. CEO at Compellon. Previously CEO at other medtech firms
3	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

Value-adding owners with commercial and medtech industry expertise, possessing indispensable networks

Owner	Initial investm.	IPO lock-up	Brief description
HealthCap	2007	1 yr	 Among largest specialized VCs in life sciences in Europe Raised €900m+ since inception in 1996
SITRA	2001	1 yr	 The Finnish Innovation Fund Sitra is an independent public foundation supervised by the Finnish Parliament Invests in early-stage companies with commercial potential
Capricorn VENTURE PARTNERS	2011	1 yr	 Independent European VC/PE investing in i.a. health-tech Experienced investment managers with deep technology expertise and a broad industrial experience
LIFE Sciences Partners	2007	1 yr	 One of the first European PE funds dedicated to providing knowledge-based funding exclusively to human life science firms Invested in 75+ firms since its inception 25 years ago
LUNDBECKFOND VENTURES	2011	1 yr	 VC specialising on life science investments investing up to €50m/yr Focus on later stage drug development and medtech
ILMARINEN	2011	1 yr	 Finnish mutual pension insurance company Equity and shares portfolio of €14.3bn
关 Teollisuussijoitus	2007	1 yr	 A government-owned investment company that promotes Finnish business and economic growth through VC and PE investments Has invested €1bn since inception in 1995

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Details of completed single-centre Phase II clinical trial

Contrastim stroke study details



- Basic study information Phase II clinical trials (Contrastim) funded by Nexstim and performed at the Rehabilitation Institute of Chicago (voted the no.1 rehabilitation hospital in the US for past 24 years) by Professor RL Harvey.
- 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.

Nexstim 31

Overview of Competitive Landscape

Device	Efficacy*	Comment*
Nexstim NBT System	Multi-centre clinical trial structure in place with 12 US sites (Phase III trials).	Promising Phase II results published in February 2014.
Non-navigated rTMS	Repetitive transcranial magnetic stimulation given without the use of navigation. Ineffective as correct point of stimulation is unknown. Promising short-term effects. Less effects than with NBT. No long-term studies in place	Difficult to repeat therapy to an area due to lack of navigation.
Other navigated rTMS	Navigated repetitive transcranial magnetic stimulation using other forms of navigation. No published studies. Research ongoing.	Similar or more complex than NBT. No integrated systems available.
Transcranial direct current stimulation (tDCS)	Form of neurostimulation using constant, low current delivered to the brain via small electrodes. Research stage. Conflicting outcomes reported	-
Cortical implants	Method of stimulating the brain through implants placed directly on the cortex. Failed Phase III clinical trials.	Difficult, requires invasive surgery.
Other (e.g. robotics)	No conclusive evidence of any technology improving rehab outcomes beyond intensive conventional rehabilitation	

*Subjective measure, represents the Company's opinion

Nexstim Targeting a paradigm shift in stroke rehabilitation

Thank you

