



# Nexstim

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 @NexstimOyj

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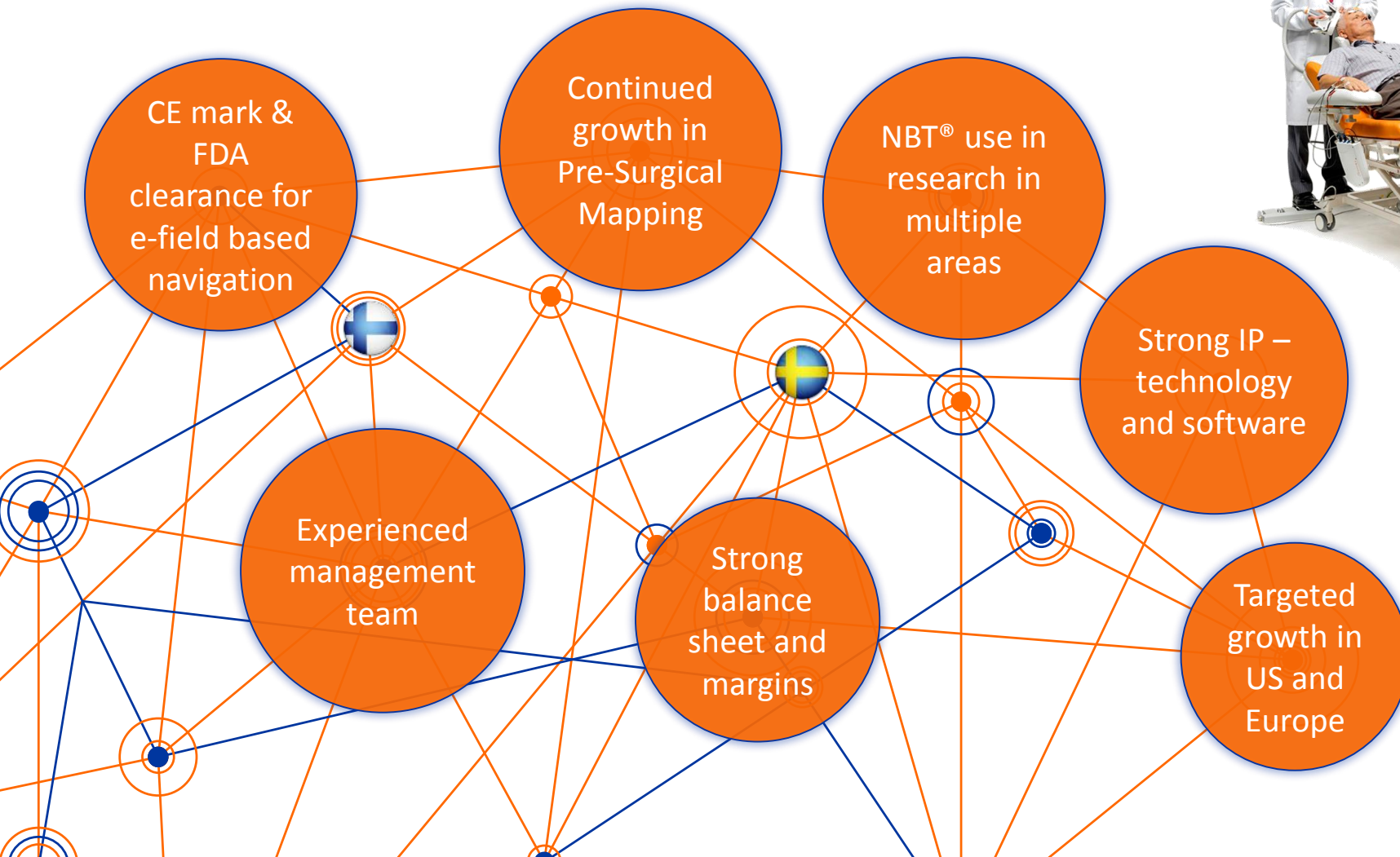
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Nexstim's NBS System is cleared by the FDA for assessment of the motor and speech cortices for pre-procedural planning. The NBT System is not cleared for commercial distribution in the United States.

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# Introduction to Nexstim



# Company Overview

## Nexstim

### 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 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

### 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 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
- The clinical Phase III multi-center trial in post-acute stroke therapy is continuing
- Other potential research indications for use of the technology platform include chronic pain and tinnitus

# 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*

## Board of Directors



Martin Jamieson  
*Chairman (Independent)*



Olli Riikkala  
*Deputy Chairman (Independent)*



Juha Vapaavuori  
*Sitra*



Dr Johan Christenson  
*HealthCap*



Dr René Kuijten  
*Life Sciences Partners*



Juliet Thompson  
*Independent*



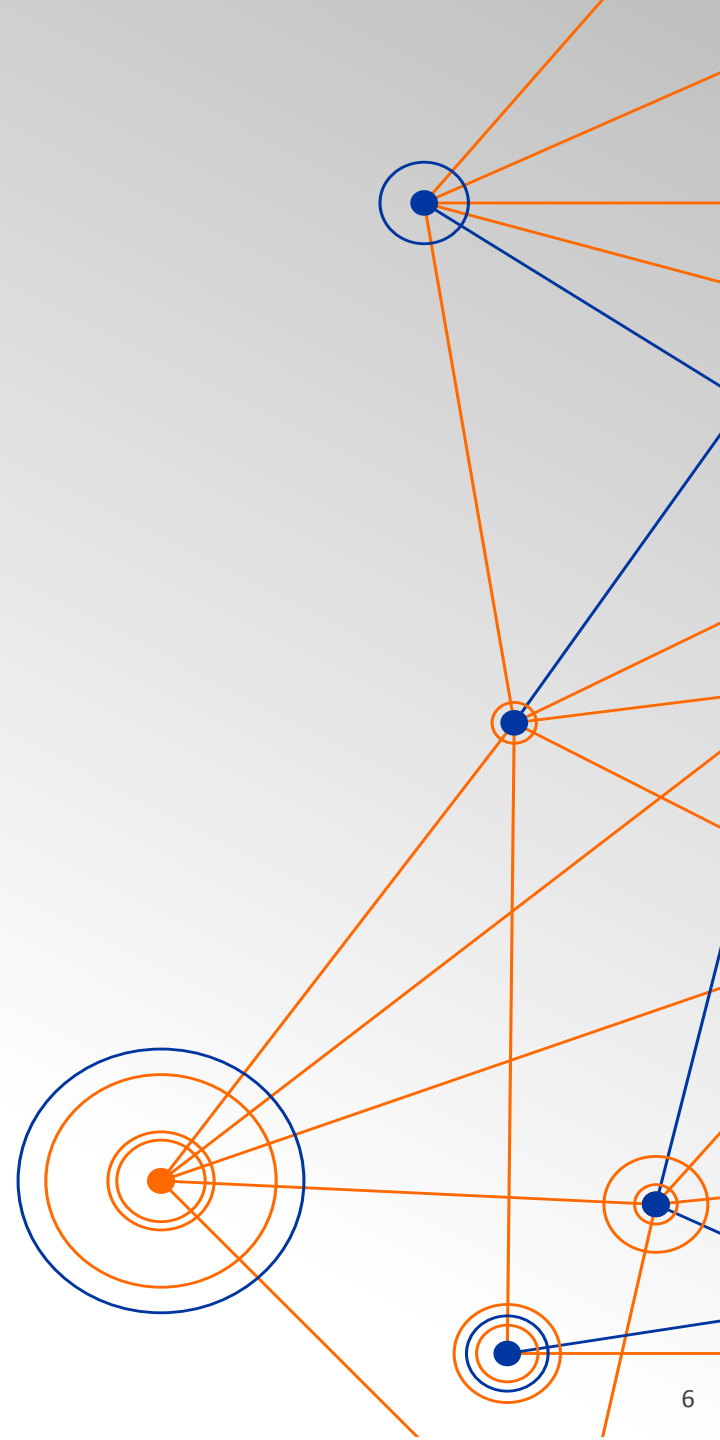
Ken Charhut  
*Independent*



Dr Ekaterina Smirnyagina  
*Capricorn*

# Pre-Surgical Mapping

A revolutionary non-invasive device for pre-surgical mapping



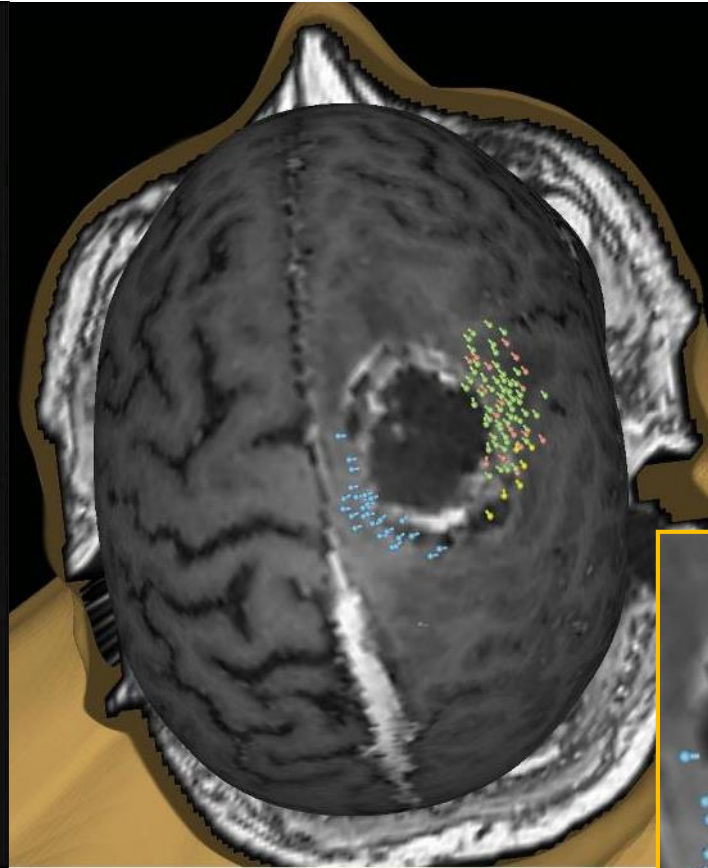
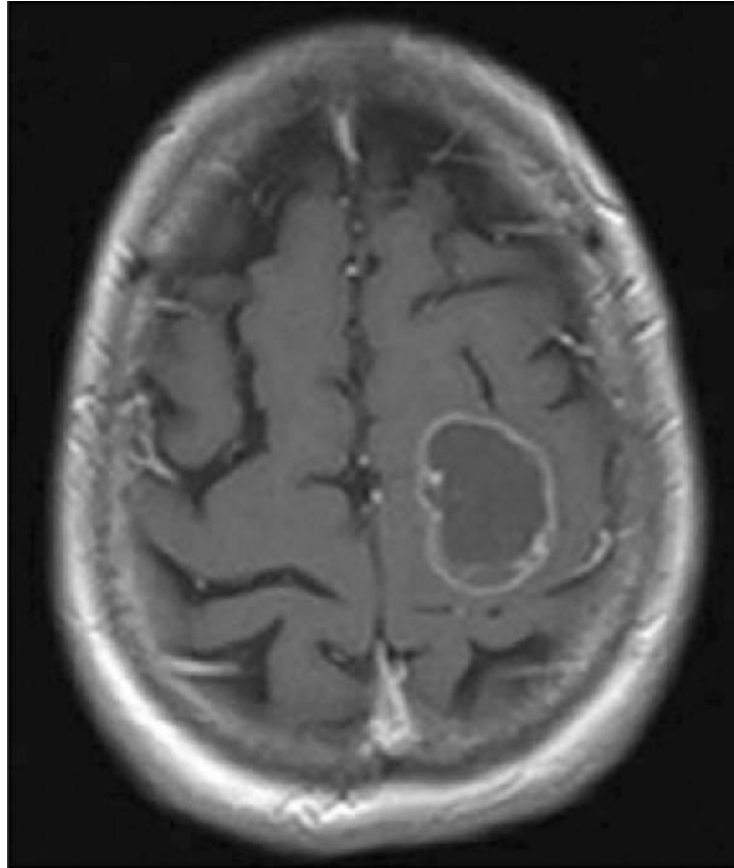
# Pre-Surgical Mapping

- Only CE-marked and FDA-cleared non-invasive solution to pre-surgical mapping of the motor 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



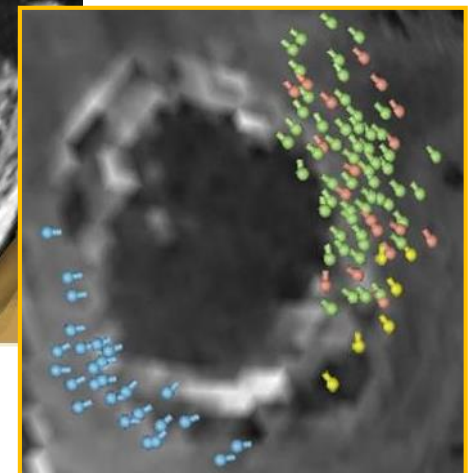
# Navigated Brain Stimulation Defining Surgical Strategy

Do we always know where the motor functions are?



Hand:  
APB = green  
ADM = yellow  
FDI = purple

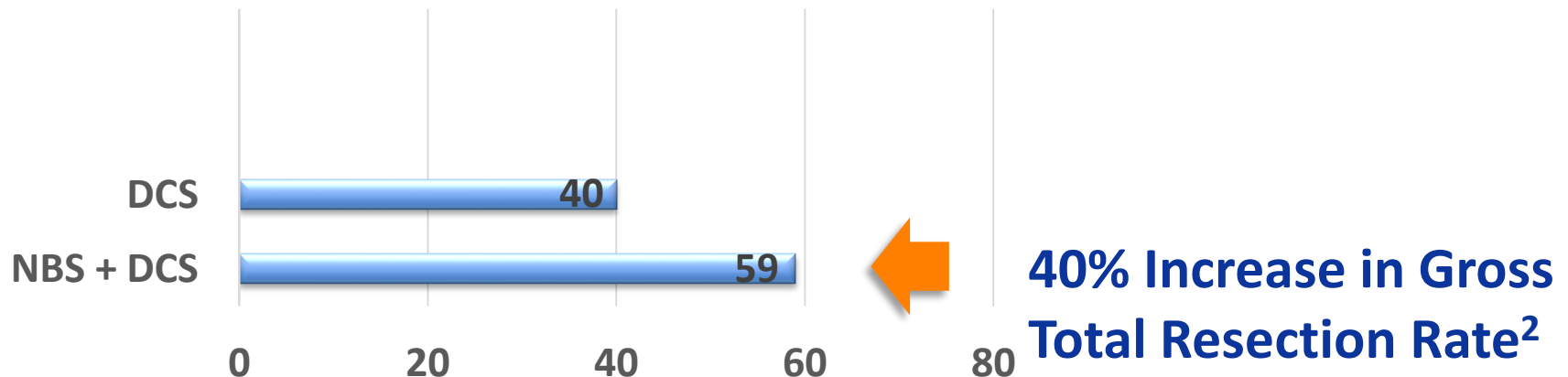
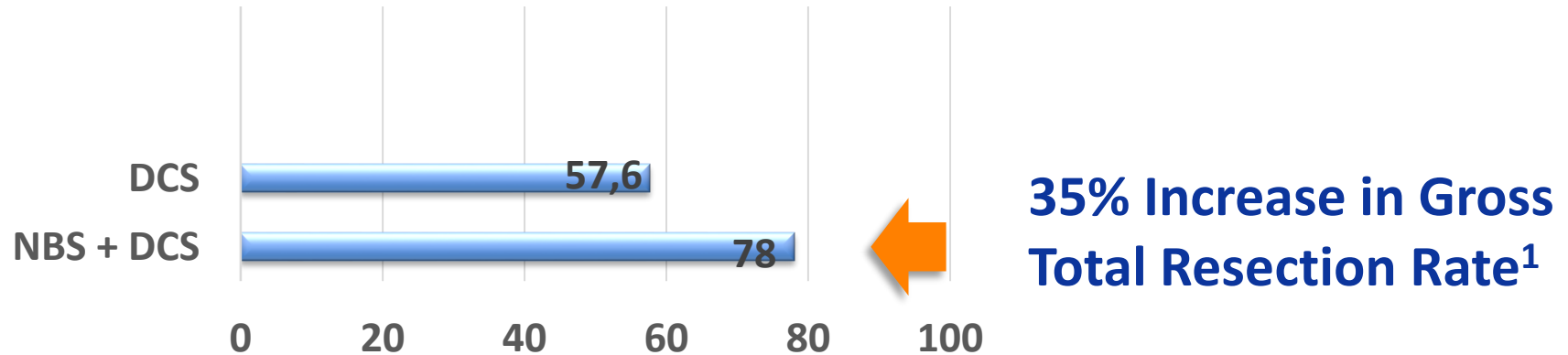
Foot:  
TA = blue



Picht et al Acta Neurochir 2012



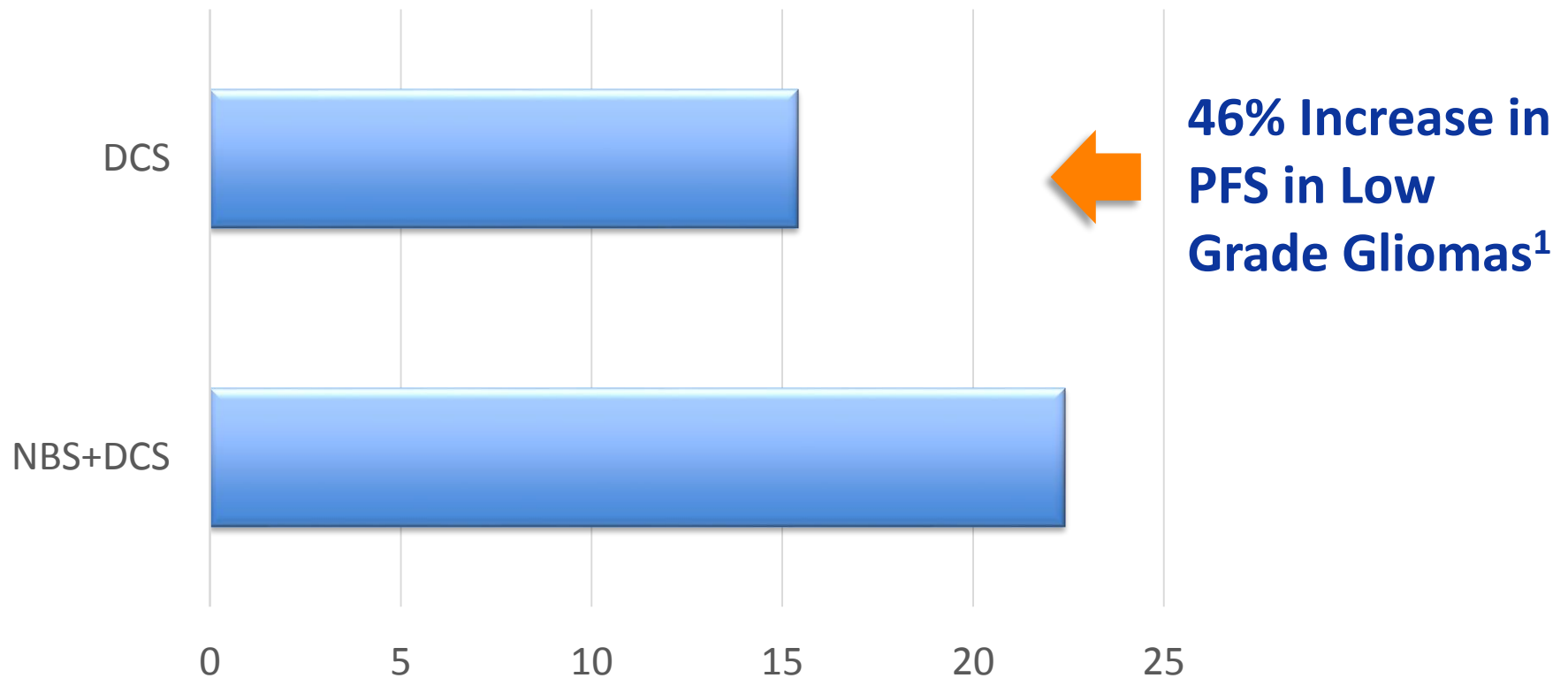
# NBS Presurgical Mapping Makes the Difference...Extent of Resection



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)



<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

# NBT Therapy Potential

Platform gives Accuracy, Repeatability and Dose Control for multiple therapeutic indications



# Platform Benefits for Therapy

## Accuracy

- Proven proprietary accuracy validated with diagnostic gives accuracy for multiple therapeutic stimulation indications

## Repeatability

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

## Dose Control

- Accuracy and repeatability give dose control to give safety and maximize to dose given according to the selected location

**Nexstim Platform gives new approach to non-invasive neuromodulation**

# 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**

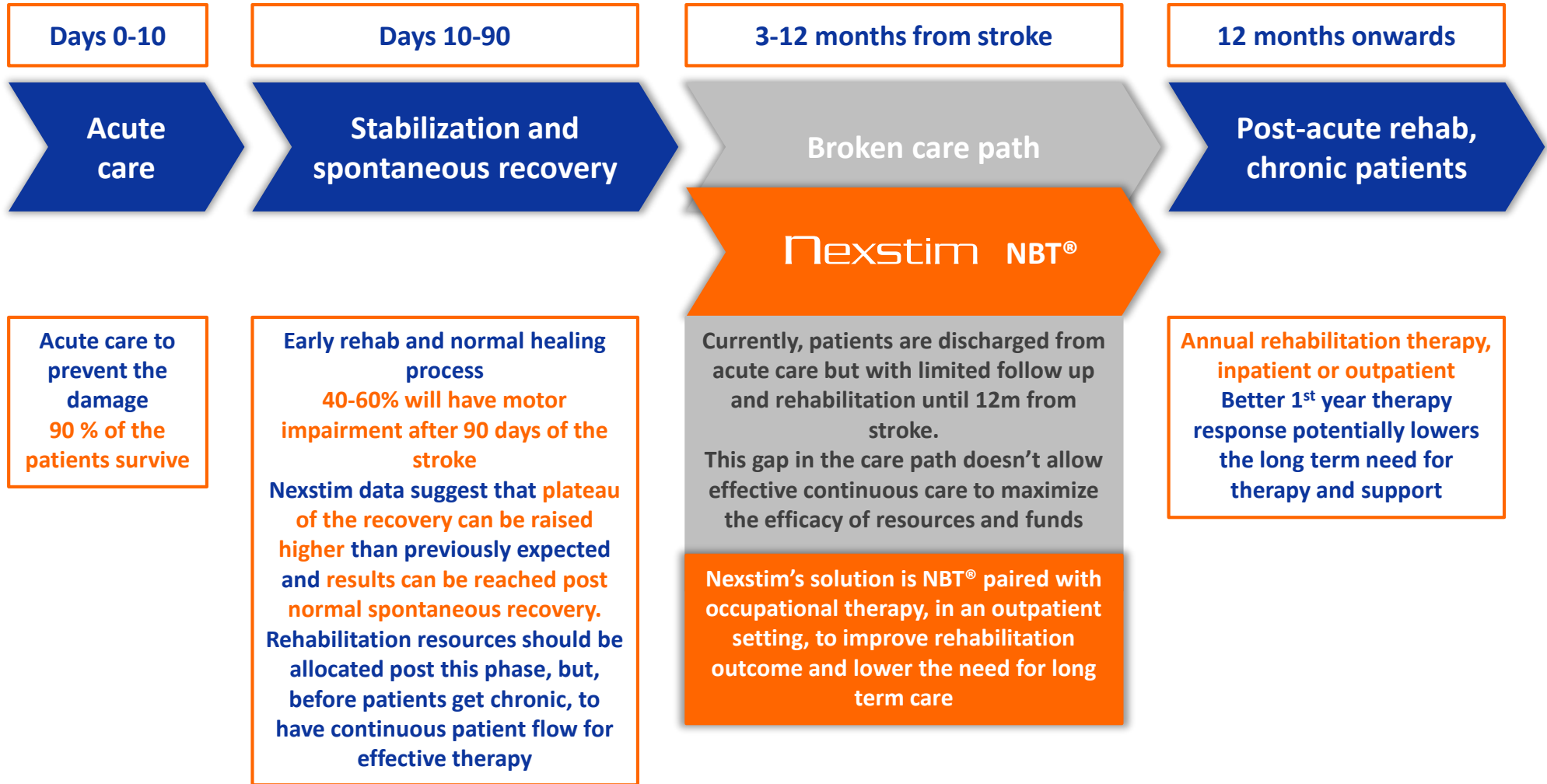


## ...with a potential game-changer technology

**Promising efficacy** demonstrated in completed Phase II clinical trial

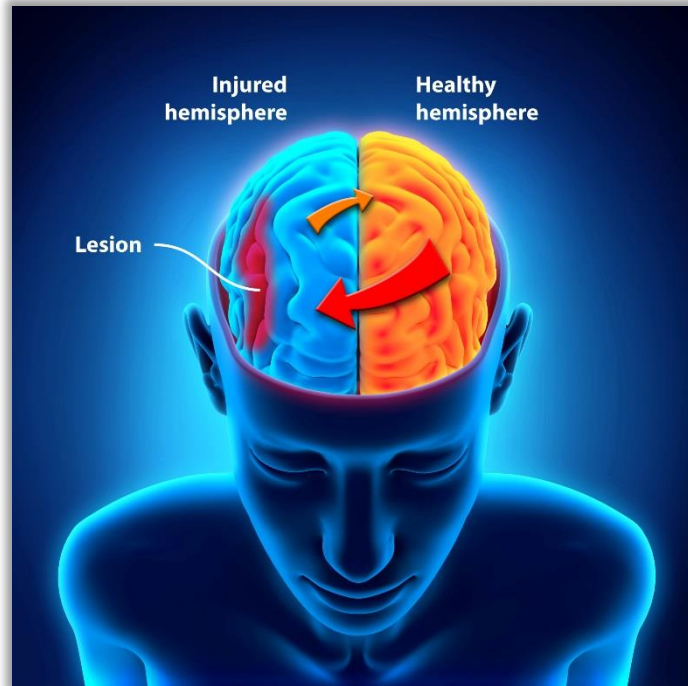
**Technology already validated** – Pioneered the technology to map motor and speech centers, with 130 devices installed worldwide and FDA clearance – same technology now applied in stroke rehabilitation

# Positioned within Stroke Care Path

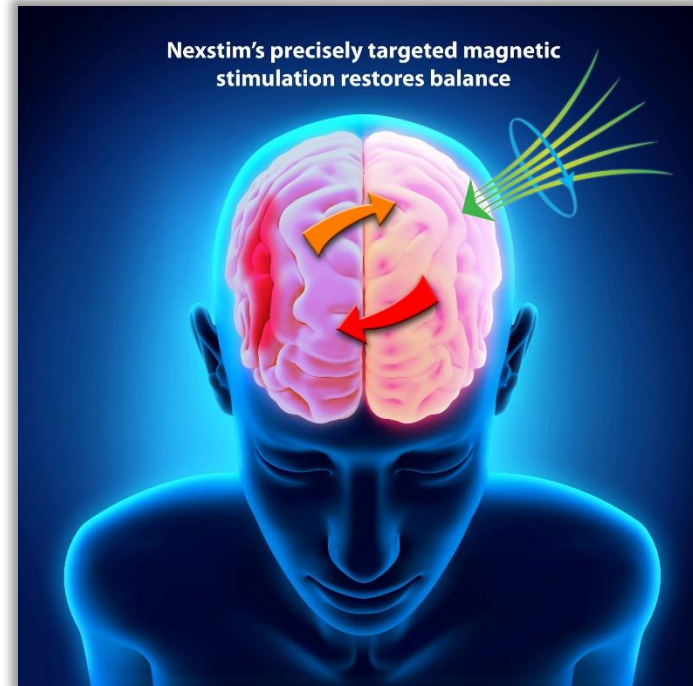


# NBT<sup>®</sup> for stroke rehabilitation – How it works

## 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
  - Chronic neuropathic pain trial in co-operation with The Walton Centre, UK is progressing according to plans
  - Trial using Nexstim's Navigated Brain Therapy (NBT®) system for pain relief in patients suffering from chronic neuropathic pain
  - 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
  - Nexstim intends to obtain a CE mark for use of its NBT® device in treatment of chronic neuropathic pain and to add chronic neuropathic pain to its indication pipeline
- Tinnitus

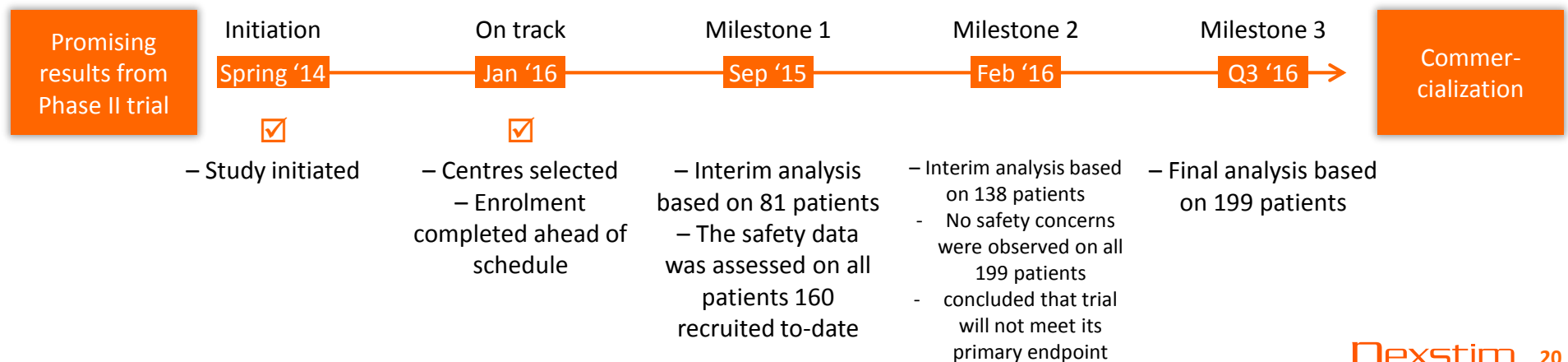
# Current Development Status and Outlook



# Status of Clinical Development

- The clinical Phase III multi-center stroke trial is continuing
- Enrolment of patients is complete and the final analysis is assumed to be ready by the end of 2016
- The DSMB second interim analysis of Phase III Stroke Therapy Trial concluded that trial will not meet its primary endpoint. No safety concerns were observed
- The DSMB recommended that the study team and subjects remain blinded and data collection be completed. Nexstim will analyse the DSMB recommendation further before deciding upon the continuation of the Phase III trial

## Simplified timeline Phase III multi-centre stroke therapy trial



# IP position

**79 granted patents**

**76 pending patents**

**Right to software:** Nexstim owns rights to its NBT® and NBS Systems' software developed in-house.

**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



# Financials

Financial Statement Release 2015



# Key Performance Indicators

EUR in thousands

	H2 2015 6 months	H2 2014 6 months	FY 2015 12 months	FY 2014 12 months	
Net sales	1,884.7	1,796.5	2,527.9	2,210.4	Net sales increase 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 increase of Phase III trial expenses
Diluted earnings per share (EUR)*	-0.66	-0.92	-1.24	-2.16	
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	
Equity ratio (%)	44.16	65.29	44.16	65.29	The company will need more funding after September 2016
Number of shares in the end of the period (pcs)*	8,010,758	7,130,758	8,010,758	7,130,758	
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.
- The DSMB second interim analysis of Phase III Stroke Therapy Trial concluded that trial will not meet its primary endpoint. No safety concerns were observed. DSMB recommends the study team and subjects remain blinded and the data collection be completed
- Nexstim will now conduct a review of the future strategy for NBT<sup>®</sup> as part of the Company's wider strategy and an update announcement will be made in due course. The Company estimates that more detailed information related to its long-term financial and commercial goals will be given as part of the update.















# Nexstim

Thank you









# 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
	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
	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
	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

# 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.
	Olli Riikkala, Deputy 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.
	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
	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
	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