

Targeting a paradigm shift in stroke rehabilitation

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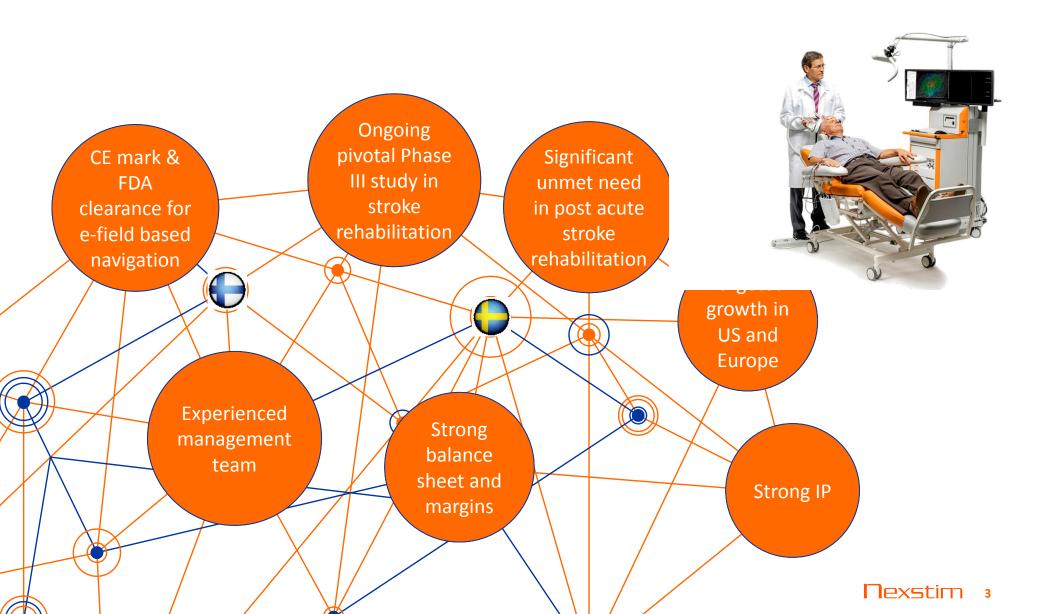
Nexstim's NBS System is cleared by the FDA for assessment of the motor and speech cortices for pre-procedural planning. The NBT System is not cleared for commercial distribution in the United States.

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### **Introduction to Nexstim**

Novel medtech company with strong position in brain navigation technology and software



### Company Highlights, January – June 2015

- Phase III multi-centre trial in the US for stroke therapy progressing according to plans
  - Successfully enrolling patients on time with first milestone interim analysis expected in Q3 2015
- 55.4 % revenue growth vs H1 2014
- Board appointments
  - Olli Riikkala as Chairman
  - Juliet Thompson as a new independent NED





#### Conducted at 12 top US rehab sites



#### 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)

# **Stroke Therapy**

**Huge unmet need and commercial opportunity** 



### **Positioned within Stroke Care Path**

**Days 0-10** 

**Days 10-90** 

3-12 months from stroke

12 months onwards

Acute care

Stabilisation and spontaneous recovery

**Broken care path** 

Post-acute rehab, chronic patients

Acute care to prevent the damage 90 % of the patients survive

Early rehab and normal healing process

40-60% will have motor impairment after 90 days of the stroke

Nexstim data suggest that plateau of the recovery can be raised higher than previously expected and results can be reached post normal spontaneous recovery.

Rehabilitation resources should be allocated post this phase, but, before patients get chronic, to have continuous patient flow for effective therapy

**Nexstim NBT®** 

Currently, patients are discharged from acute care but with limited follow up and rehabilitation until 12m from stroke.

This gap in the care path doesn't allow effective continuous care to maximize the efficacy of resources and funds

Nexstim's solution is NBT® paired with occupational therapy, in an outpatient setting, to improve rehabilitation outcome and lower the need for long term care

Annual rehabilitation therapy, inpatient or outpatient
Better 1st year therapy response potentially lowers the long term need for therapy and support

### 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** 



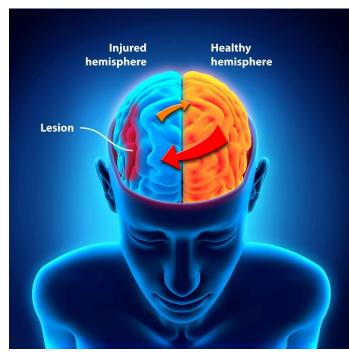
...with a potential game-changer technology

Promising efficacy demonstrated in completed Phase II clinical trial

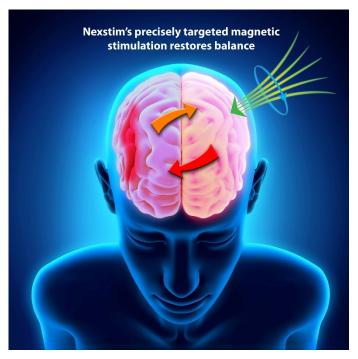
**Technology already validated** – Pioneered the technology to map motor and speech centers, with 120 devices installed worldwide and FDA clearance – same technology now applied in stroke rehabilitation

### **NBT®** for stroke rehabilitation – How it works

### Validated e-Field Navigation gives Competitive Edge



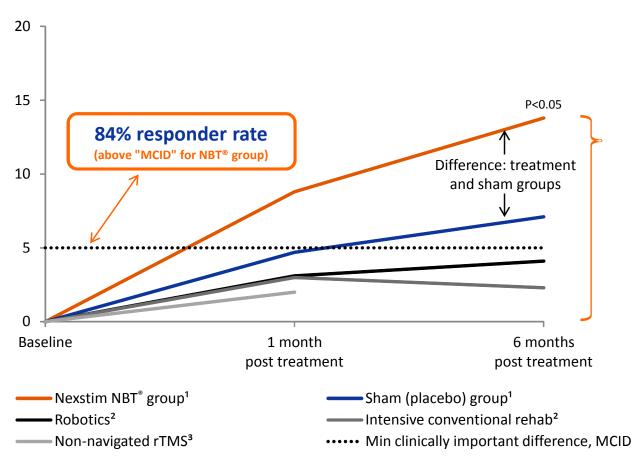
Using a patient's own MRI scan as a guide, Nexstim provides precisely targeted, personalized, magnetic stimulation to temporarily inhibit the healthy side of the brain, normalising the balance between the hemispheres.



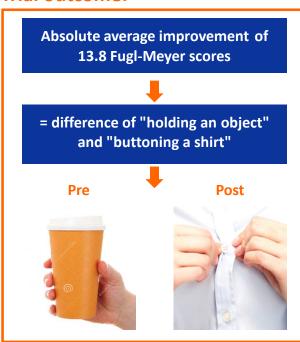
Because the injured side is no longer dominated by the healthy side of the brain, it is more responsive to the physiotherapy. This results in limb movement being potentially restored more quickly to better functionality.

# **Efficacy demonstrated in Phase II trial**

#### Change in upper extremity Fugl-Meyer score from baseline



#### **Trial outcome:**



#### The Phase II clinical trial in brief:

- Single centre at Rehabilitation Institute of Chicago (#1 rehabilitation hospital in US for 24 consecutive years)
- 29 patients of which 19 (10) in treatment (sham) group
- End-point = 6 months post treatment

Note: "Robotics", "Intentive 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.



# 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

# 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**

- Phase III trial on track: Establish efficacy in Phase III to obtain FDA clearance and **KOL** support
- Commercialisation strategy: Convince users of benefits, providers of economic benefits and obtain reimbursement coverage from payers

# **Current Status and Outlook**

**Progressing as planned with milestones** 



### Phase III trials - Laying the groundwork for commercialisation

### Study in brief

- Establish clinical efficacy of NBT® in upper-limb motor rehabilitation
- Up to 198 patients
- 12 top US rehab sites RIC is central site (#1 US rehabilitation hospital for 24 years)
- Dr. Richard L. Harvey lead investigator – one of the top experts in the field
- FDA reviewed protocol

### Study goals



 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 commercialisation

### Conducted at 12 top US rehab sites









#### Rehabilitation Institute of Chicago (central site)

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Ohio State University (Columbus, OH)

Rancho Los Amigos National Rehabilitation Center

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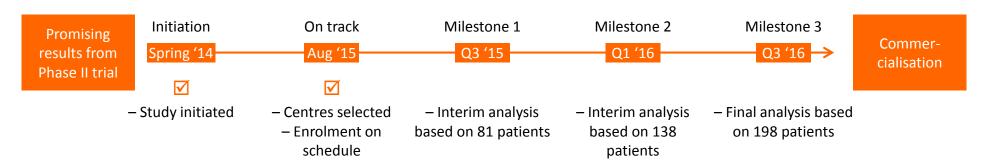
Mayo Clinic (Phoenix, AZ)

## **Status of Clinical Development**

### **Progressing as Planned**

The clinical Phase III multi-center trial is progressing and enrolling patients according to plans. The next interim analysis milestones are estimated to be reached Q3 2015 and 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



### **IP** position

# 66 granted patents 72 pending patents

**Right to software:** Nexstim owns ri NBT® and NBS Systems' software d house.

**Creating hurdles for competitors:** patent protection on different part products and making it more diffic potential competitors to create cor products

Core algorithms kept as trade secr patenting the core algorithms to av and loss of trade secrets



# **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
epreciation and amortisation	-168.7	-125.3	-377.4
ther operating expenses	-3,422.9	-1,672.3	-5,498.5
ofit/ -Loss for the period	-4,555.0	-5,127.3	-10,445.4
rnings per share (EUR)*	-0.64	-1.44	-2.37
iluted earnings per share (EUR)*	-0.58	-1.34	-2.16
h flows from operating activities	-5,275.3	-2,508.1	-7,785.2
sh in hand and at banks	6,071.1	1,522.1	11,483.7
tal equity	3,712.0	-4,077.3	8,589.9
quity ratio (%)	50.44	-87.19	65.29
umber of shares in the end of the period (pcs)*	7,130,758	3,685,290	7,130,758
verage number of shares during the period (pcs)*	7,130,758	3,561,908	4,406,572
iluted 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

<sup>\*</sup>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 interim data due in Q3 2015 and 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





Targeting a paradigm shift in stroke rehabilitation

Thank you

