EDISON

Nexstim

Initiation of coverage

Game-changing stroke treatment

Healthcare equipment & services

Nexstim's Navigated Brain Therapy System could transform the rehabilitation of hemiplegic stroke patients. Success in the ongoing Phase III trial may enable a US launch in late 2017. We expect the NBT system to gradually capture a third of the €1.6bn market opportunity and value Nexstim at €112m based on a 70% probability of success.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	2.2	(10.3)	(2.34)	0.0	N/A	N/A
12/15e	2.4	(9.7)	(1.36)	0.0	N/A	N/A
12/16e	3.8	(8.7)	(0.79)	0.0	N/A	N/A
12/17e	7.5	(11.0)	(0.93)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

Transformative tool for stroke therapy

Nexstim has developed a technology platform for diagnosis (NBS) and treatment (NBT) of vital motor and speech cortices in the brain. While we see NBS as a niche product, NBT targets a €1.6bn market for the rehabilitation of millions of post-acute stroke patients (three to 12 months after stroke), poorly served by costly occupational and physical therapies.

Impending clinical trial results may prove a catalyst

A proof-of-concept study indicated a threefold improvement in upper limb mobility using NBT, a vast improvement over all alternative therapy modalities. Interim results from a US Phase III trial are due in the coming months, which may offer valuation catalysts and pave the way for a US launch of NBT in late 2017. In our view, the first data, due in Q315, are most likely to support a continuation of the trial.

Financials: Strong, long-term profit potential

We believe the consumables-driven NBT business should allow Nexstim to become highly profitable long term, but see €50m extra funding needs for an assumed self-commercialisation of NBT, prior to profitability in 2020e. Our 70% probability of NBT obtaining FDA approval may be revised with publication of interim data. Other sensitivities include enlarged indications, eg chronic stroke patients and pain, expansion into non-western markets, stiffer competition and the speed of securing reimbursement coverage.

Valuation: Potential to more than double

Based on our probability-adjusted DCF, we value Nexstim at €112m, equivalent to €15.7 per outstanding share. We assume a third of eligible stroke patients will receive NBT therapy (96% of value) and the sale of NBT consumables to represent 91% of gross profits in FY30e. We forecast Nexstim needing €50m in additional financing. Assuming this was raised via equity at the current market price and full cashless exercise of existing options, the valuation per share would be €10.3.

10 September 2015

Price	**€6.53**
Market cap	**€46m**

Net cash (€m) at 30 June 2015	6.1
Shares in issue	7.1m
Free float	35%
Code	NXTMH
Primary exchange	Nasdaq First North Finland
Secondary exchange	Nasdaq First North Sweden

Share price performance

%	1m	3m	12m
Abs	10.8	10.8	N/A
Rel (local)	18.0	13.9	N/A
52-week high/low		€7.00	€4.80

Business description

Nexstim has developed a non-invasive brain stimulation technology (nTMS) used as a diagnostic device for brain surgery planning (NBS System, currently marketed); and as an aid to promote rehabilitation after stroke (NBT System, in Phase III trials).

Next events

NBT interim data 1	September 2015
NBT interim data 2	Q116

Analysts

Hans Bostrom	+44 (0)20 3681 2522
Christian Glennie	+44 (0)20 3077 5727

healthcare@edisongroup.com

Edison profile page

Nexstim is a research client of Edison Investment Research Limited

Investment summary

Company description

Nexstim is a Finnish medtech company focused on improving the precision of brain surgery and the rehabilitation of stroke patients, using non-invasive brain stimulation. Initially, it used its navigated transcranial magnetic stimulation (nTMS) to map motor and speech cortices in the brain (navigated brain stimulation, NBS). Based on the same technology, Nexstim is now developing navigated brain therapy (NBT), for the much larger stroke therapy market. NBT focuses stimulation on targeted locations in the brain to enhance stroke rehabilitation by removing natural barriers to recovery.

Valuation: Potential to double

Based on a probability-adjusted DCF, we value Nexstim at €112m, €15.7 per outstanding share or €10.3 per diluted share, conservatively assuming €50m funding requirements FY16-20e, (largely to meet SG&A costs as part of a self-commercialisation strategy), are raised at the current share price. Cash flow during the FY15-30e forecast period represents 33%, the terminal value 63% and existing cash 4% of the value of the company. We use a 2% terminal growth rate and 12.5% risk-adjusted discount rate. As much as 96% of our valuation pertains to NBT for post-acute stroke therapy and 4% to NBS for pre-surgical planning. Our model excludes potential future indications, such as neuropathic pain and tinnitus, chronic stroke patients (>12 months after stroke) and markets outside the US and Europe, which represent potential upside. We see the biggest downside in ambiguous Phase III trial data, possibly necessitating further trials and thus resulting in a delay in bringing NBT to the market, and secondly, funding needs over and above our forecasts.

Financials: Strong growth requiring further funding

We forecast Nexstim to generate 75% revenue CAGR FY15-20e with the EBITDA margin expanding from loss making to +5%. We see the profitability improvement spurred by a subproportional but still considerable 20% CAGR in operating expenses, as it sets up a commercial infrastructure internationally, as well as a 5pt increase in the gross margin from 69% to 74%, reflecting growing sales of high-margin consumables. We forecast a 75-fold rise in group revenues to €185m by 2025e and an average EBITDA margin 2020-30e of 32%, in line with mature software-driven medtech equipment suppliers such as Intuitive Surgical and Varian Medical Systems.

In H115, Nexstim delivered 55% revenue growth to €643k, attributable to growth in sales of NBS, with a strong seasonal improvement to €2.4m expected in H2. The operating loss widened by 59% from €3.1m to €4.9m and the operating cash outflow increased from €2.5m to €5.3m, substantially explained by a €1.7m rise in R&D expenses for the NBT Phase III trial. Starting from €6.1m liquid resources in H115 and €9.6m cash burn in FY15e, we assume Nexstim will need to raise €25m in H116. In total, we expect it to require €50m funding in FY16-20e to fund the launch of NBT.

Sensitivities: Success of NBT launch is key

Our forecasts and valuation are predicated on the conclusion of the Phase III trial scheduled for Q316, the receipt of FDA approval in H117, a US launch of NBT in late 2017 and in Europe in 2019. The key factors dictating our long-term forecasts are favourable clinical research results as well as Nexstim being able to secure attractive reimbursement and to change existing diagnostic and treatment practices to allow adoption of its products. Given the expected lucrative business model with over 90% gross margin expected on sale of disposables, we consider it likely that competition will rise over time. Nexstim should however benefit from its time lead and major efforts to safeguard its intellectual property. We expect Nexstim to need additional funding for the commercialisation of NBT. However, a worsening of market conditions may jeopardise such transactions.

Company description: Revolutionising stroke therapy

Investment case

We believe Nexstim's non-invasive brain stimulation technology offers the potential to transform the treatment of post-acute (three to 12 months) stroke patients on which western nations spend tens of billions of dollars annually, with limited benefits. Results from a multi-centre trial are due to be published over the coming quarters, which may offer potential valuation catalysts. Based on its current spending plans, we see Nexstim's €6m cash resources lasting until H116. It therefore looks likely to require further equity funding to finance a possible US market launch of NBT in late 2017.

Background and Strategy

Nexstim has developed a technology platform for diagnosis (NBS) and treatment (NBT) of vital cortices in the brain. The core of its technology is the combination of a navigation system driven by proprietary software algorithms with a transcranial magnetic stimulator (TMS) and electromyography (EMG), which measuring the muscle response activated by the stimulation.

The company was formed in 2000 by Risto Ilmoniemi, a professor at the Helsinki University of Technology. He remains a shareholder in Nexstim. However, the company has primarily been backed by venture capital firms specialising in the healthcare industry. So far, shareholders have invested €35m and the Finnish Funding Agency for Innovation, Tekes, has contributed a €500k capital loan. In the coming years, we envisage that Nexstim will look to broaden its shareholder base outside the Nordic region concomitant with its international business expansion. It may over time consider listing its shares outside the Nordic markets.

Exhibit 1: Nexstim history

Year	
2000	Company founded by Academy Professor Risto Ilmoniemi and Pekka Puolakka, based on research at the low temperature physics laboratory at the Helsinki University of Technology.
2003	First commercial product launched, first CE mark and first device sold to University of Wisconsin, Madison, US.
2006	Winner of the European Information Society Technology (IST) Prize.
2007	Completion of the first Nexstim NBS System. First unit placed in Germany at Charité Berlin Neurology Department and first motor mapping of brain tumour done followed by surgery.
2008	Subsidiaries established in the US, UK and Germany.
2009	First FDA clearance received to market NBS System for motor mapping in the US.
2010	Proof of concept trial of NBT System in the US launched.
2012	FDA clearance received to market NBS System for speech mapping in the US. FDA's positive response to multi-centre stroke trial received. CPT III reimbursement code in the US and OPS reimbursement code in Germany for pre-surgical mapping obtained for the NBS System.
2013	Proof of concept trial of NBT System reaches endpoint.
2014	Pre-surgical mapping study shows positive outcomes in clinical patient care. Proof of concept data of NBT System published in February. Multi-centre trial for NBT System launched in the US.

Source: Nexstim

Since obtaining the CE-mark in 2003 and FDA clearance in 2009 for NBS, Nexstim's commercial strategy has been to target key opinion leaders at leading universities and teaching hospitals, eg the Charité Hospital in Berlin and University of Wisconsin. However, the company's focus has shifted in recent years towards developing the even bigger market for its technology for stroke therapy (NBT). In the longer term, Nexstim may investigate whether nTMS can also be applied in the treatment of neuropathic pain as well as tinnitus.

NBT seeks to rehabilitate hand and arm movement, which affects the vast majority of the 15 million people suffering a stroke annually, according to the WHO, with primarily those in the western world receiving rehab treatment. In a proof-of-concept (Phase II) trial, the use of NBT in conjunction with occupational therapy (standard of care) produced a threefold improvement in upper body movement over a six-month observation period. Based on the promising results, in mid-2014 Nexstim initiated a two-year, multicentre trial (Phase III) at twelve rehabilitation sites in the US. The study is designed to secure not only an FDA approval but also health economic data underpinning

Nexstim's reimbursement strategy. In our view, a US launch may be possible by late 2017 on the assumption that it can pursue a 510(k) De Novo regulatory pathway.

Nexstim is the only company with clinical proof of treatment of motor and speech cortices with an nTMS device. Currently there are no direct competitors, but indirect ones that offer alternative diagnostic and therapeutic methods. However, none of these are widely used. Nexstim has until now outsourced most of its operations such as production. In August, it announced a new production partnership with US-based Sanmina Corporation, which will take over from Finnish Innokas Medical as a preferred supplier.

Outlook for stroke therapy (NBT)

In spite of limited efficacy, Clearstate suggests $8.5bn is spent pa on rehab of stroke patients in the US alone, mainly on occupational and physical therapy. In our view, a more efficacious and health economic way of treating post-acute stroke patients would attract considerable funding. We assess the market potential in the US and Europe alone at €1.6bn annually for NBT and €0.1bn for NBS.

Exhibit 2: Post-stroke treatment therapies and assessment

Therapy/assessment method	Description
Fugl-Meyer Assessment (FMA)	The most widely used scale used by physiotherapists and occupational therapists to evaluate individuals recovering from stroke. The FMA consists of five sub-scales that relate aspects, such as motor, balance, sensation, range of motion and pain. The upper extremity Fugl-Meyer Scale measures the functionality of hand and arm movement on a scale of 0-66, where 0 corresponds to no movement and 66 to full functionality. Its limitations include the omission of some potentially relevant items and weighting of the arm more than the leg
Occupational therapy (OT)	Assesses and treats people with a physical, mental, or cognitive disorder to develop or recover daily living and work skills. Occupational therapy focuses on practical solutions by adapting the environment, modifying the task, provide auxiliary tools and educating the patient and their family in order to improve performance of daily activities, such as dressing or shopping.
Physiotherapy physical therapy/(PT)	Aims to remediate impairments and promote mobility, function, and quality of life through diagnosis and physical intervention, using physical agents, mechanical force, adaptive devices, and movements.

Source: NHS Direct, Nexstim and Edison Investment Research

Stroke therapy market

Stroke is one of the leading causes of disability in the world, affecting 15 million people and causing 5 million deaths annually, according to the WHO. Stroke survivors face multiple challenges. A majority (80%) suffer weakness in one side of the body (hemiparesis), but many also have reduced cognitive and emotional functions, social disability as well as difficulty in walking and caring for themselves.

The healthcare industry's attempts to develop treatments for post-acute stroke have had limited success, owing to a short treatment window after the event and elevated mortality (eg tissue plasminogen activators). As stroke is one of the leading causes of death, pharma companies have shifted their focus to the prevention and acute care of stroke. Therapy approaches include those that lower the risk for cardiovascular diseases, such as lipid lowering agents (eg statins) and anti-hypertensives, as well as clot dissolving agents seeking to restore blood flow. Despite these efforts, the annual growth of stroke patients is estimated to be as high as 4-5%.

The treatment of post-acute stroke varies by geography, but typically involves occupational and physical therapy. In certain parts of Europe, stroke patients are often subject to prolonged (up to 60 days) hospital-based monitoring, with the aim to minimise the risk of recurrence of stroke and to ensure compliance with rehabilitation therapies. In the US, stroke patients are normally discharged after a brief (three to four days) hospital stay but are given access for an extended period (three to four months) to an out-patient centre. Nexstim intends to initially focus on the US market, due to well-developed reimbursement structures and healthcare facilities dedicated to stroke care.

In order to restore upper limb function, the first three months after a stroke are crucial. The recovery pattern is predictable and tends to level off after three months; a modest one-two point

improvement on the FMA score is typical and rarely more than four-five points even with intense rehab. In fact, 55-75 % of patients present upper limb hemiparesis three to six months after the stroke.

Exhibit 3: Stroke market model

	Stroke treatment cost	Prevalence	Incidence	NBT eligible*	Consumables potential**	Clinics	Equipment potential***
US	€33.2bn	3.1m	0.8m	270k	€540m pa	8,700	€99m pa
Europe	€42.4bn	5.9m	1.3m	442k	€884m pa	10,000	€72m pa
Total	€75.6bn	9.0m	2.1m	712k	€1.42bn pa	18,700	€171m pa

Source: Nexstim and Edison Investment Research. Note: *Incidence only, **€2k per patient, ***€80k per unit replaced every seven years.

Our assessment of the market potential is based on the annual incidence of stroke in the US and Europe, adjusted for acute deaths. It assumes that a conservative 40% of patients affected by upper limb hemiparesis three months after a stroke are suitable for NBT treatment. Further, our model takes into account 4-5% annual patient growth, reflecting ageing and improved acute care, offset by price deflation. However, therapists may also seek to treat chronic stroke patients, for whom natural improvement no longer occurs. They are four times as numerous as the number of new patients on an annual basis. Adding existing chronic patients over a 10-year period would boost our annual market estimates by 40%. Market data and access to stroke rehabilitation are patchy outside the US and Europe. Based on demographics however, the global market potential may be double the market potential for US and Europe.

NBT technology

The vital cortices relating to muscle control in the left and right hemispheres of the brain are interconnected. Stroke tends to cause lesions on one side of the brain, which triggers a strong inhibitory response from the healthy side that challenges the recovery of motor function.

The NBT System applies a low-frequency magnetic field (1Hz) to the non-lesioned side with the purpose of mitigating the natural inhibition of the lesioned side. Nexstim's approach is based on findings that the identification of vital cortices in the brain is easier in the unaffected hemisphere than on the damaged side. Further, low frequency magnetic fields are seen as safer than high frequency (10Hz, which lead to higher risk of seizures and disruption of the healing process).

Navigation is the key differentiator

The core of the NBT system is proprietary algorithms that produce a 3D model of a patient's brain based on MRI scans. This allows the medical practitioner, usually a nurse or occupational therapist, to visualise the precise area of stimulation in real time. Navigation is the key differentiating factor of NBT, since it ensures precision, ease of use and reproducibility over multiple treatment episodes.

NBT's stereotactic navigation is achieved by recording three predefined points of reference on the model with a registration tool. With the aid of proprietary algorithms and information from MRI scans concerning the anatomy of the patient's head, NBT calculates how the magnetic coil moves in relation to the head and where the induced e-field stimulation is delivered. A head tracker with a built-in encrypted radio frequency marked (RFID) chip is required for the running of the system. The need for a personalised tracker for each treatment episode creates a lucrative revenue stream for Nexstim.

The stimulation coil induces an electric field in the cortex. The resulting signal to the corresponding muscle group is measured and mapped onto the 3D model through an integrated electromyogram (EMG) attached to the activated muscle. The strength of stimulation can be adjusted to the patient's motor threshold, which is the level where the muscle response can be measured with EMG.

Competing technologies

Highly labour-intensive physical and occupational therapies are currently the only widely used treatments for post stroke motor disabilities. Therapy using medical technology has remained at a research stage. Importantly, all previous studies have been performed with investigational TMS devices without the aid of sophisticated navigation. Delivered blindly, they rely on observed muscle movements, which may be uncomfortable for the patient compared to EMG. In our view, NBT's accurate navigation is the most challenging feature for competitors to reproduce. Recovery of motor control appears to depend on stimulation of the exact same area over multiple therapy sessions.

Exhibit 4: Methods used in stroke rehabilitation/hemiplegia

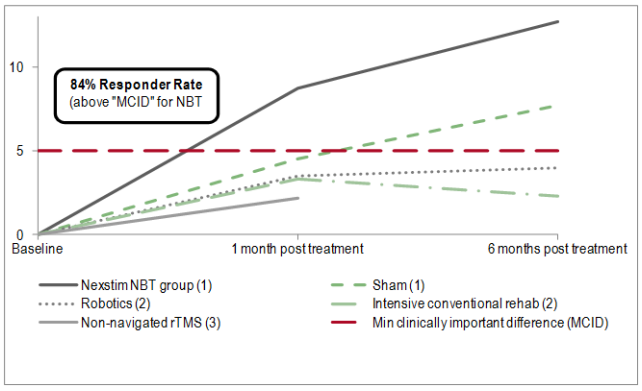
Device (provider)	Comment
NBT System (Nexstim)	Threefold increase in upper body mobility shown in Phase II trial. Multi-centre clinical trial ongoing at 12 US sites.
Non-navigated repetitive transcranial magnetic stimulation, rTMS (Neuronetics)	Promising short-term effects albeit less than NBT. Difficult to repeat therapy to identical area due to lack of navigation.
Navigated rTMS (Mag & More, neuroConn, Brain Science Tools, Brainsway*)	No integrated systems available and accuracy is uncertain. Research ongoing into other forms of navigation, such as line navigation.
Transcranial direct current stimulation, tDCS	Neurostimulation using constant, low current delivered to the brain via electrodes. Mixed outcomes in research.
Cortical implants	Method of stimulating the brain through implants placed directly on the cortex. Difficult, requires invasive surgery.
Robotics/exoskeletons (Ekso Bionics, Rewalk, Rex Bionics)	No conclusive evidence that peripheral nerve stimulation using exoskeletons improve rehab outcomes beyond intensive conventional rehabilitation.

Source: Nexstim and Edison Investment Research. Note: *$12.1m revenue and $26.0 operating loss in FY14.

Clinical data: Encouraging results in proof-of-concept study

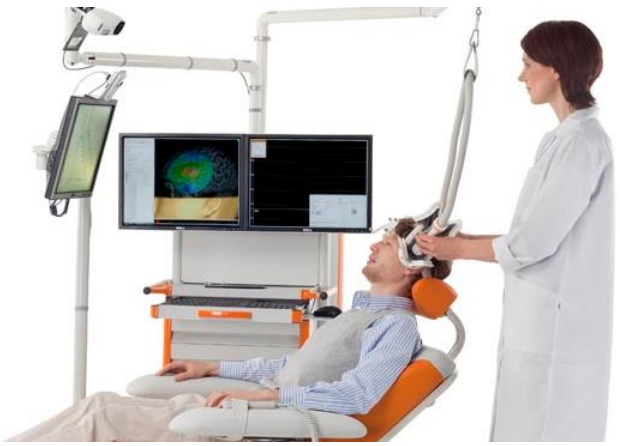
A proof of concept study (Phase II) of NBT was conducted 2010-13 at the Rehabilitation Institute of Chicago, the top ranked rehabilitation hospital in the US and led by Dr Richard L Harvey, a leading expert in the field. In this study, NBT showed statistically significant improvement in hand and arm functionality ($p<0.05$) in 84% of participants, with the minimally clinically important difference (MCID) set as a five point improvement of the FMA score over a six-month observation period. In the blinded study, all patients received occupational therapy in conjunction with either NBT or sham treatment. Patients were recruited between three and 12 months after their stroke with a mean of seven months. The study suggested a remarkable 13.8 point average improvement of the FMA score for the NBT group. In practical terms this represents the difference between being able to hold an object and being able to button a shirt. The FMA score improvement in the sham group of 7.1 points compares to a usual increase of 3-4 points, with the strong improvement in the sham group likely explained by intense conventional therapy and possibly also by the small sample size (10).

Exhibit 5: Changes in upper extremity Fugl-Meyer score from baseline (Phase II trial)



Source: Nexstim, (1) Harvey et al, 2013 (2) Lo et al, NEJM 2010 (3) Kakuda et al, J Neuroeng Rehab 2012.

Exhibit 6: Nexstim's NBT System



Source: hightechfinland.com

An analysis of subgroups of patients that did not receive additional conventional therapy after the six-week treatment period (nine patients in the active group and six patients in the sham group) gave results more consistent with earlier findings. In the sham group 29% of patients were above the MCID hurdle of 5 points and they had an absolute average improvement of 2.9 points. In the active group, 80% had improvements above the MCID threshold with an average improvement of 14.5 points. However, the subgroup analysis was not shown to be statistically significant, due to the small patient number.

Exhibit 7: NBT proof-of-concept study (Phase II) with 29 patients

Inclusion criteria (>18 years of age, ischemic or haemorrhagic stroke three to 12 months prior)	Treatment	Study group	Outcome*	FMA increase (avg)	Control group	Outcome*	FMA increase (avg)
Moderate/severe one-sided upper limb impairment 3 to 6 on Chedoke scale (0 no function and 7 full function)	3x weekly for six weeks	19	84%	13.8	10	50%	7.1

Source: Nexstim. Note: *Measured as share of patients achieving MCID of 5 point improvement in Fugl-Meyer Assessment (FMA).

Phase III trial well underway with impending interim results

Based on the Phase II results, a two-year pivotal trial began in May 2014 at 12 rehabilitation sites in the US, also led by Dr Harvey. The purpose of this much larger trial is the same as the prior trial, namely to demonstrate a clinically important difference between the active and sham group at six months post treatment. The trial protocol includes two interim analyses, with the first data due to be released in September 2015. It can be concluded before all patients are enrolled, both for positive and negative reasons. As the FDA has reviewed the trial protocol, the attainment of the primary objective at any of these milestones could support an FDA filing. Trial recruitment appears to be on track with all patients for the second tranche out of three already recruited by July. However, variations in demographic profile of patients and clinical practices may temper the FMA score improvement in the Phase III trial compared to Phase II. Accordingly, a large sample size to reach statistical significance is likely needed and the first interim data are unlikely to meet the endpoint.

Exhibit 8: NBT multicentre (Phase III)

Inclusion criteria (>ischemic or haemorrhagic stroke three-12 months prior)	Treatment	Duration	Q315e**	Q116e	Q316e
Moderate/severe one-sided upper limb impairment in those >18 years of age, 3 to 6 on Chedoke scale (0 no function and 7 full function)*	3x weekly for six weeks	Two years	Interim data (81 patients)	Interim data (138 patients)	Final analysis (198 patients)

Source: Nexstim. Note *Two thirds of patients in study group vs sham. **Most likely to progress to the next stage.

Market strategy: De Novo 510(k) is likely to suffice for clearance

Should the results from the ongoing trial prove clinically meaningful, Nexstim envisages filing for FDA clearance by the end of 2016, which may pave the way for a 2017 US launch. While NBT is already CE marked, Nexstim is awaiting the US trial results and the 'quality endorsement' of an FDA approval before a European launch. We believe a six-month De Novo 510(k) process may be adequate. While there is strictly no predicate device for NBT, it is based on the technology utilised in NBS, which already enjoys FDA clearance. Indeed, in its review of the protocol for the ongoing trial, the FDA did not require Nexstim to make an investigational device exemption (IDE) filing for NBT, thus effectively precluding a lengthy (18-month) premarket approval (PMA) process.

Health economic strategy elaborated

The ongoing trial has been designed to generate outcome data for a health economics model to support reimbursement awards. First, the idea is to illustrate that using NBT as an adjunct to standard practice would improve clinical outcomes and lower overall costs, eg render a stroke patient able to work and demand less aftercare. Secondly, NBT may benefit hospital finances through growth in procedures that it facilitates, such as occupational therapy.

Reimbursement coverage for rehabilitation therapy for post-acute stroke varies greatly in the US and even more so in Europe. Therefore, we believe Nexstim will need to expend considerable resources on education and research over an extended time period to secure broad reimbursement

coverage. In our view, a gradual ramp-up of NBT sales in the next five to ten years is therefore the most likely scenario. We assume Medicare coverage will be established by 2019-20. In the early phase, Nexstim plans to target patients who can afford to pay for their own NBT treatment. Over time, we expect positive patient experiences, public relations efforts and further clinical data to ensure that the treatment becomes more widely known, thus encouraging private and public insurance coverage. Medicare, which covers nearly three quarters of stroke patients in the US, currently caps reimbursement at 20 outpatient visits. This is identical to the number of treatment episodes in the ongoing trial. While other markets are different, the work on securing coverage in the US should be useful for other markets.

Outlook for pre-surgical mapping of the brain (NBS)

The Navigated Brain Stimulation System was Nexstim's first commercialised product. It is the only FDA-cleared and CE-marked non-invasive device capable of providing accurate mapping prior to brain surgery. It can be used both in conjunction with conventional craniotomies or stereotactic radiosurgery, whether on brain tumours, intractable epilepsy or arterovenous malformations.

While the process of navigation is the same for NBS and NBT, they are not interchangeable. The activation and response measurement process differs: NBS offers more extensive diagnostic capabilities and user interface, while NBT houses specific applications focusing on targeting and dose calibration. To enable speech mapping, a NexSpeech module is added to NBS, which includes a separate monitor, an air-cooled coil and software to map and analyse the speech areas of the brain. Nexstim primarily generates revenues from equipment sales of NBS with only minor consumables and service revenues, whereas the opposite is expected to be the case with NBT.

NBS System technology

The current standard practice in pre-surgical mapping of motor and speech cortices is direct cortical stimulation (DCS). This involves placing electrodes directly on the brain tissue during the operation, but before brain tissue resection. DCS speech mapping is a stressful and difficult procedure, as it is invasive and requires the patient to be awake while electric stimulation is applied to the brain. Thus, DCS is impractical for pre-operative planning and is performed in only a few locations globally.

Clinical data

Research and clinical use have established that NBS has superior accuracy in locating the primary speech and motor cortices vs DCS. Also, NBS has shown to have a beneficial effect on operating decisions regarding the size and location of the operable area and has led to statistically significant reductions in residual tumours in difficult operations. Two German studies confirmed that NBS enables larger tumour resection volumes than DCS. The Charité study also suggested expanded surgical indications and increased progression-free time following resection of low-grade gliomas.

Exhibit 9: Comparative studies of NBS vs DCS

Institution	Study group	Control group	Resection increase	Surgical indication expansion	Progression-free time
Charité study of NBS vs DCS	350	215	42-59%	14.8%	From 15.4 to 22.4 months
Munich study of NBS vs DCS*	N/A	N/A	58-78%	N/A	N/A

Source: Nexstim Note:*Neuro-oncology (2014): nou110 by Frey, Dietmar, et al.

Market potential and strategy

Speech and motor cortex mapping with NBS require auxiliary technologies such as neuronavigators (visualisation aid of the brain) and stereotactic tools (3D coordinate system for disease targeting), used by an estimated 1,870 and 520 hospitals, respectively. Medtronic, Brainlab, Stryker, Elekta and Accuray are the main suppliers of such equipment and NBS is compatible with all of them.

The US and Europe represent around 80% of the global market potential and Japan commands most of the rest. Based on the US and Europe alone, we estimate potential market for NBS at €68m annually, driven chiefly by sales of equipment with replacements expected to occur every seven years. Of the total market we estimate the potential for consumables at €10m per annum.

Exhibit 10: NBS market model

Market	Eligible brain surgeries	Target hospitals	Annual units*	Price per unit (average)	Equipment sales pa	Consumable sales pa **
US	47,000	1,106	158	€210k	€33m	€4m
Europe	35,000	834	119	€210k	€25m	€6m
Total	82,000	1,940	277	€210k	€55m	€10m

Source: Nexstim and Edison Investment Research. *Replacement sales every seven years, **based on 31,400 and 50,340 procedures pa in the US and Europe, respectively.

To contextualise our NBS forecasts, Nexstim has sold 120 units over the last 10 years. Annual revenues FY12-14 have been €1.7m-€2.9m at an average price of €210k. Supported by greater marketing resources and the publication of further clinical studies, we forecast NBS sales to grow to €6.5-7.6m pa 2020-25e and the market penetration to rise from 6% in 2014 to 17% in 2030e.

Commercialisation strategy

So far, Nexstim has targeted KOLs at leading universities and teaching hospitals in the fields of neurosurgery and radiology, notably in the US and Germany. Due to strong interest for minimally-invasive techniques, Nexstim has required small sales and marketing resources. A major part of Nexstim's commercial initiatives is dedicated to coordinating hospitals and payers concerning reimbursement. Reimbursement codes for pre-surgical mapping using NBS already exist in the US in the form of an emerging technology code (CPT III) and in Germany (OPS).

Sensitivities

The most critical factor for Nexstim's financial development and valuation is the success of the ongoing Phase III trial to secure FDA clearance for NBT. Given the favourable results in the Phase II trial, we apply a 70% probability of regulatory approval. Nexstim's ability to turn into a profitable company in the medium term depends mainly on how it can change existing diagnostic and treatment practices to adopt its technology. This in turn depends on Nexstim's ability to secure reimbursement coverage and its success in establishing adequate commercial capabilities.

While there currently appears to be no direct competitors, Nexstim's potential commercial success and expected high profitability is likely to entice new entrants over time. The company has created hurdles for potential competitors by seeking patent protection on different parts of the products; it has 62 granted and 69 pending patents. It also possesses rights to the software for NBT and NBS, developed in-house. However, it has not patented the core algorithms to avoid publicity and loss of trade secrets. The company has no pending governmental, legal or arbitration proceedings. In our view, as a medtech company, the risk for these is likely to rise with time and profitability.

Valuation

We value Nexstim's equity at €112m or €15.7 per current outstanding share. We believe DCF is the most appropriate method to value the company, because we expect Nexstim to yield substantial positive cash flow in the medium term, after near-term investments. In our valuation, NBS represents 4% and NBT 96% of the company's total equity value. We assume a 70% probability of NBT receiving FDA approval in late FY17e and thus being able to deliver our financial forecasts.

We acknowledge that our diluted valuation is conservative as it is likely a €50m funding need would arise on the back of favourable clinical data for NBT, likely prompting a share price rise and, consequently, less dilution. Cash flow during 2015-30e represents 33%, the terminal value 63% and

existing cash 4% of the company's total valuation on a pre-dilution basis. Our terminal value is predicated on revenues and operating free cash flow of €310m and €62m, respectively, in 2030e.

Exhibit 11: DCF valuation

Valuation (€k) at 12.5% WACC	
Present value of FCFs 2015-30e	51,343
Terminal value of FCFs	600,513
Terminal growth rate	2.0%
PV of terminal value	99,643
Total PV of FCFs	150,986
Adjusted for 70% probability of success	105,690
Net debt/(cash) (H115)	(6,071)
Equity value	111,761
No of shares (m) (H115)	7.1
Value per outstanding share (€)	15.7
Equity value including €50m fund raise in FY16-18e	161,761
Total number of shares (m) including exercise of 0.8m cashless options and 7.7m new shares in total FY16e and FY18e	15.6
Value per diluted share (€)	10.3

Source: Nexstim and Edison Investment Research

Financials

So far, Nexstim's revenues have stemmed from the sale of NBS equipment, with only a modest contribution from after sales (spares, etc). With the expected launch of NBT, we forecast its sales mix will change comprehensively and become much more profitable. Indeed, at over 90% expected gross margin, we forecast disposable NBT head trackers to represent 59% and 83% of group revenues and 74% and 92% of forecast gross profits in 2020e and 2030e respectively. We expect NBT equipment (including monitor, probes and chair) to be sold at a discount to equivalent NBS equipment (€80k vs €210k per unit) so as to promote market adoption. We estimate the technical life for NBT/NBS equipment at seven years, offering a considerable replacement market over time.

Our financial forecasts are based on our market models of pre-surgical mapping and the bigger opportunity in post-acute stroke therapy in the US and Europe. Importantly, we assume a gradual penetration of the market. This reflects the growth of Nexstim's commercial infrastructure, the hurdles of securing reimbursement with a multitude of payers (crucially Medicare in the USA) and the inertia to changes in existing treatment paradigms, typical for a labour-intensive clinical practice such as occupational therapy. We assume a steady deflation in both prices and production costs with European prices 25% below the US level. Characteristic for the razor/razor-blade model proposed for NBT, we expect the majority of profits to be generated by disposable head trackers.

Exhibit 12: Key modelling assumptions

	Sales (€m)			Gross profit	Penetration		Inflation pa 2015-30e		US price per unit in 2017 (€)
	FY14	FY20e	FY30e	FY20e (€m)	FY20e	FY30e	Cost	Price	
NBS System	2.2	7.0	9.6	3.70	10.8%	17.1%	-2%	-2%	186,027
NBT equipment	0.0	9.3	42.3	3.46	2.5%	22.1%	-3%	-3%	80,000
NBT consumables	0.0	23.5	259.0	21.95	3.8%	33.2%	-1%	-6%	90

Source: Nexstim and Edison Investment Research estimates

In H115, Nexstim generated 55% growth in net sales from €414k to €643k and a 59% increase in the operating loss from €3.1m to €4.9m, largely as a function of €1.7m additional expenses relating to the Phase III trial for NBT. Nexstim ended H115 with a cash position of €6.1m.

Our revenue forecast is driven mainly by the expected launch of NBT in late FY17e (57pp of 60% revenue CAGR 2014-20e) and to a lesser degree growth in NBS sales. As the €6m Phase III trial is due to end mid-2016, we expect other operating expenses to level off, while growth in personnel expenses should accelerate as Nexstim builds up its commercial organisation in preparation for a US and a later European market launch. We expect the company to generate a maiden operating profit (EBITDA) in FY20e and turn cash flow positive in FY21e. We expect the business momentum

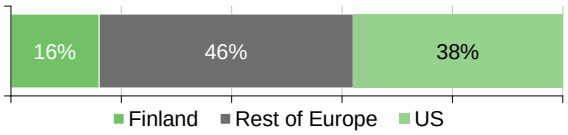
to remain strong in the 2020s and estimate 23% revenue CAGR FY20-30e with an average EBITDA margin of 32%, similar to mature innovative medtech players with a strong software base, eg Intuitive Surgical and Varian Medical Systems. We expect Nexstim to benefit from accrued tax losses, amounting to €38m in FY14, and we forecast another €51m of tax losses to be generated in FY15-20e. Since tax losses expire after 10 years, we estimate about €70m of tax losses can be utilised. We expect Nexstim to pay tax at a rate of 28% (average of US and Finland) in 2025e.

Exhibit 13: Financial summary

€000s	2013	2014	2015e	2016e	2017e	2018e
Year end 31 December			FAS*			
PROFIT & LOSS						
Revenue	1,871	2,210	2,434	3,817	7,501	11,959
Cost of Sales	(661)	(638)	(746)	(1,170)	(2,674)	(3,898)
Gross Profit	1,210	1,572	1,688	2,646	4,827	8,061
EBITDA	(4,197)	(7,422)	(9,300)	(8,407)	(10,389)	(8,494)
Operating Profit (before GW and except)	(4,413)	(7,654)	(9,633)	(8,720)	(10,930)	(9,178)
Intangible Amortisation	(22)	(146)	(150)	(234)	(461)	(675)
Exceptionals	-	-	-	-	-	-
Operating Profit	(4,435)	(7,800)	(9,782)	(8,955)	(11,391)	(9,853)
Other	-	-	-	-	-	-
Net Interest	(80)	(2,646)	(93)	(13)	(72)	(4)
Profit Before Tax (norm)	(4,493)	(10,300)	(9,725)	(8,733)	(11,003)	(9,183)
Profit Before Tax (FRS 3)	(4,515)	(10,445)	(9,875)	(8,967)	(11,464)	(9,857)
Tax	-	-	-	-	-	-
Profit After Tax (norm)	(4,493)	(10,300)	(9,725)	(8,733)	(11,003)	(9,183)
Profit After Tax (FRS 3)	(4,515)	(10,445)	(9,875)	(8,967)	(11,464)	(9,857)
Average Number of Shares Outstanding (m)	2.8	4.4	7.1	11.0	11.8	15.6
EPS - normalised (€)	(1.62)	(2.34)	(1.36)	(0.79)	(0.93)	(0.59)
EPS - FRS 3 (€)	(1.63)	(2.37)	(1.38)	(0.82)	(0.97)	(0.63)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	64.7	71.1	69.3	69.3	64.4	67.4
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets	497	979	981	1,115	1,265	1,504
Intangible Assets	108	83	61	60	59	81
Tangible Assets	56	442	555	691	847	976
Other	334	454	366	363	359	447
Current Assets	2,550	13,014	3,379	19,912	9,372	24,126
Stocks	336	247	288	452	1,033	1,389
Debtors	871	930	856	1,189	2,037	2,770
Cash	1,010	11,484	1,881	17,917	5,948	19,613
Other	333	354	354	354	354	354
Current Liabilities	(1,228)	(1,928)	(1,975)	(2,494)	(3,393)	(3,137)
Creditors	(739)	(1,382)	(1,429)	(1,948)	(2,847)	(2,591)
Short term borrowings	0	0	0	0	0	0
Short term leases	0	0	0	0	0	0
Other	(489)	(546)	(546)	(546)	(546)	(546)
Long Term Liabilities	(4,202)	(3,475)	(3,405)	(3,405)	(3,405)	(3,405)
Long term borrowings	(4,108)	(3,405)	(3,405)	(3,405)	(3,405)	(3,405)
Long term leases	0	0	0	0	0	0
Other long term liabilities	(94)	(71)	0	0	0	0
Net Assets	(2,382)	8,590	(1,019)	15,128	3,839	19,088
CASH FLOW						
Operating Cash Flow	(3,904)	(7,146)	(9,128)	(8,372)	(10,847)	(9,835)
Net Interest	(80)	(640)	9	90	30	98
Tax	0	0	0	0	0	0
Capex	(239)	(860)	(484)	(682)	(1,152)	(1,598)
Acquisitions/disposals	0	0	0	0	0	0
Financing	1,775	19,821	0	25,000	0	25,000
Dividends	0	0	0	0	0	0
Other	0	0	0	0	0	0
Net Cash Flow	(2,447)	11,177	(9,602)	16,036	(11,969)	13,665
Opening net debt/(cash)	626.7	3,098	(8,079)	1,523	(14,512)	(2,543)
HP finance leases initiated	0	-	-	-	-	-
Other	(24)	-	-	-	-	-
Closing net debt/(cash)	3,097.9	(8,079)	1,523	(14,512)	(2,543)	(16,208)

Source: Nexstim historical data and Edison Investment Research estimates. Note: *FAS is Finnish accounting standards.

EDISON

Contact details	Revenue by geography
Elimäenkatu 9 B 00510 Helsinki Finland +358 9 2727 1710 www.nexstim.com	

Management team

CEO: Janne Huhtala

Janne Huhtala was appointed CEO of Nexstim in 2013 and been a member of its management team since 2008. Previously, he was the CFO of Nexstim since December 2008 and acted as a financial advisor to the Nexstim in a financing round in 2007. From 2004 to 2008, Huhtala was employed as manager by Gutta, a provider of financial consulting services to mid-sized and large companies. He worked as CFO and CEO at Viola Systems, a provider of wireless M2M network services, from 2002 to 2004, and as an investment director at private equity and venture capital firm Fenno Management from 1999 to 2002. Huhtala holds a master's degree in economics from Turku School of Economics.

CFO: Mikko Karvinen

Mikko Karvinen was appointed CFO and member of the management team of Nexstim in 2014. Prior to joining the company he served as the CFO and deputy CEO of Innofactor from 2012 to 2014. Karvinen was the CFO and deputy CEO of Tectia, later known as SSH Communications Security, between 2009 and 2012 and CFO of Automaster between 2008 and 2009. Prior to Automaster, he was working at Vaisala as a controller from 2006 to 2008, as treasury manager from 2005 to 2006 and as financial analyst from 2001 to 2003. Karvinen holds a MSc in economics from Helsinki School of Economics.

Vice president R&D: Gustaf Järnefelt

Gustaf Järnefelt has served as vice president, R&D since joining Nexstim in 2008. Prior to this, he spent 18 years with Instrumentarium then GE Healthcare holding several manager, director and general manager positions in design, R&D, engineering and business integration. He has an education background from both Karlsruhe Germany Universität TH Karlsruhe (Institut für Werkzeugmaschinen und Betriebstechnik) and holds a MSc from Helsinki University of Technology.

Chairman of the board of directors: Olli Riikkala

Olli Riikkala was appointed as the chairman of the board of directors in 2015, and has been a member of the board since 2007. He has held board positions in the following Finnish listed companies: board member of Tieto from 2004 to 2012, chairman of Comptel from 2005 to 2012 and Oriola-KD from 2006 to 2013. Mr. Riikkala is also currently a member of several boards of directors of Finnish companies in the medical industry. He holds an MSc in engineering from the Helsinki University of Technology, an MSc in economics from Helsinki School of Economics and an MBA from Claremont Graduate University.

Principal shareholders	(%)
Svenska Handelsbanken AB (publ), Branch Operation in Finland*	29.6%
The Finnish National Fund for Research and Development Sitra	21.1%
Nordea Pankki Suomi*	15.8%
Clearstream Banking S.A.*	8.8%
Lundbeckfond Invest A/S	4.7%
Ilmarinen Mutual Pension Insurance Company	4.5%

*Nominee registered shareholders

Companies named in this report

Accuray (ARAY), Ekso Bionics (EKSO), Elekta (EKTA-B), Intuitive Surgical (ISRG), Medtronic (MDT), ReWalk (RWLK), Rex Bionics (RXB), Stryker (SYK), Varian Medical Systems (VAR)

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. Edison is authorised and regulated by the Financial Conduct Authority (www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

DISCLAIMER

Copyright 2015 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Nexstim and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2015. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand