

Nexstim

Planning the next phase of growth

Nexstim is well placed to benefit from the novel accelerated rTMS (transcranial magnetic stimulation) therapy protocols being developed for severe depression and chronic neuropathic pain. Its accurately navigated SmartFocus TMS NBT technology could provide the precision and reproducibility required for clinical success. Promising data, expected in Q121, from the ongoing pilot study in severe depression would guide the format of a proposed double-blind multi-centre trial. Success would open sizeable new treatment opportunities for the NBT platform. Revenues from both NBT and NBS diagnostic systems have proven to be remarkably resilient during the COVID-19 pandemic which, coupled with careful cost control, suggests FY20 results will be in line with our forecasts. Strategic delivery prompts us to upgrade our valuation to €38.4m (€0.09/share), with room for further upside.

Year-end: December 31	2018	2019	2020E	2021E
Sales (€m)	2.7	3.3	3.7	6.6
Adj. PBT (€m)	(6.2)	(6.8)	(3.8)	(4.5)
Net Income (€m)	(6.2)	(6.8)	(3.7)	(4.4)
EPS (€)	(1.93)	(0.25)	(0.01)	(0.01)
Cash* (€m)	7.2	4.3	1.9	7.2
EBITDA (€m)	(5.9)	(6.0)	(4.0)	(3.7)

Source: Trinity Delta Note: *Our cash forecast assumes additional fund raise of €10m in FY21

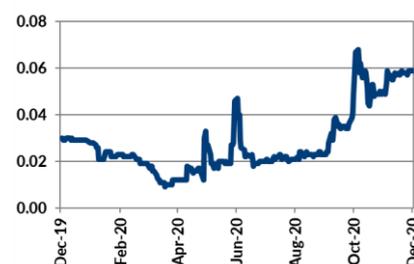
- Sizeable opportunities with accelerated protocols** Successful outcomes in clinical studies exploring accelerated treatment protocols in severe depression and chronic pain could materially shift the rTMS world towards greater targeting accuracy. Nexstim's NBT platform is acknowledged as providing highly precise, reliable, and reproducible navigation to a target site. Whilst this would underpin medium-term growth, the near-term should benefit from the strengthening evidence base generated by the patient registry (currently [>100 treatments](#)). For NBS, obtaining US pre-surgical mapping reimbursement would drive future revenue growth.
- Five-year strategy focussed on growth** Organic growth prospects should be bolstered by improved profitability as utilisation of the existing installed base (c 170 NBS systems, 28 NBT systems) increases. Understandably, focus is on the unfolding NBT opportunities, yet the outlook for NBS is also promising. Wider applications for motor and speech mapping, new prototype development, and gaining US reimbursement codes, would sustain double-digit growth through the next decade.
- Funding required to unlock potential** Nexstim has successfully navigated a difficult period, with a resilient performance throughout the COVID-19 pandemic supporting an expected reduction in FY20 operating loss. The cash runway extends to end-Q121 and our forecasts suggest a funding requirement of c €10m to support the necessary pivotal trials for the accelerated treatment protocols.
- Valuation increased to €0.09/share** Our rNPV valuation of €38.4m (€0.09/share), up from €32.2m (€0.07/share), reflects strategic delivery despite COVID-19 impact. Ahead of near-term pilot study data, on conservative assumptions, the accelerated protocol MDD opportunity could add €8.4m (€0.02/share) to our core valuation.

Update

10 December 2020

Price	€0.06
Market Cap	€26.6m
Enterprise Value	€30.1m
Shares in issue	439.6m
12 month range	€0.01-0.07
Free float	55%
Primary exchange	Helsinki
Other exchanges	Stockholm
Sector	Healthcare
Company Code	NXTMH/NXTMS

Corporate client Yes



Company description

Nexstim is a targeted neuro-modulation company that has developed a proprietary navigated rTMS platform for use in diagnostics (NBS) and therapeutics (NBT). NBS is used in planning brain surgery while NBT is focused on depression and chronic pain. FDA approval for depression was given in 2017, and the focus is on commercial roll out in the US, Europe, and Asia.

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Nexstim: gaining meaningful market traction

Nexstim has successfully transitioned a difficult period and enters 2021 well placed to accelerate revenue growth through leveraging its acknowledged navigated TMS (transcranial magnetic stimulation) technology. The NBS (Diagnostic) pre-surgical brain mapping business provides a stable, and rising, revenue stream, while the NBT (Therapy) business is expected to be the near- and medium-term growth driver. In both cases it is the accuracy, reliability, and, importantly, reproducibility of the navigation that distinguishes Nexstim from its TMS peers. The 2020-24 strategic plan centres on generating compelling data-led evidence to demonstrate improved clinical outcomes for patients and material health economic benefits for payors. The shares have performed well of late, reflecting the progress achieved, and whilst funding remains an issue, we believe investors are sufficiently reassured that they will be supportive. We raise our previous €32.2m valuation (equivalent to €0.07/share) to €38.4m (€0.09/share).

Comprehensive strategy to exploit navigated rTMS opportunities

Nexstim has two related, but distinct, businesses that are based on its proprietary navigated TMS ([Transcranial Magnetic Stimulation](#)) technology: the NBS ([Navigated Brain Stimulation](#)) system is employed in accurate pre-surgical mapping of the brain; and the NBT ([Navigated Brain Therapy](#)) system is used in clinical indications such as major depression and chronic pain. In August 2020 management articulated its strategic goals for 2020-24, detailing its plans to support the organic growth of both businesses and, notably, the initiatives to develop novel accelerated treatment regimens for various depression indications.

Exhibit 1 highlights the steps to improve profitability and the applications on which it will focus. These form the first phase of the longer-term strategy that we explore in this Update note.

Exhibit 1: Nexstim's 2020 strategic objectives

General	NBT (Therapy)	NBS (Diagnostic)
Decrease the operating loss through a focus on achieving profitable revenue growth and strict cost control	Initiate two new pilot studies in treating severe depression and/or chronic pain patients using accelerated therapy treatment protocols	Continue developing the US NBS pre-surgical mapping reimbursement process
Obtain further funding from capital markets and/or via strategic partnerships	Develop and execute a deeper profitable partnership business model in the key therapy markets together with valued partners	Continue search for a strategic partner for the diagnostic business
	Build the patient data registry of over 100 completed treatment sessions of depression patients	

Source: Nexstim, Trinity Delta,

Quality and reproducibility of the navigation is a key differentiator

Nexstim is differentiated from its TMS peers through the capabilities of its proprietary e-field navigation technology. This means the localisation and visualisation of a targeted area of the brain is highly accurate and, importantly, can be reproduced in a reliable and dependable manner (across operators and treatment centres). Such consistency and personalisation results in clinical outcomes that are materially improved in both diagnostic and treatment

applications, with a sizeable body of real-world evidence now in place to support its uses. This differentiation from competition, coupled with strong endorsement from KOLs (key opinion leaders), underpins the sustained growth that has been reported and offers the prospects for widening the overall market opportunities.

Attractive market opportunities as treatment paradigms shift

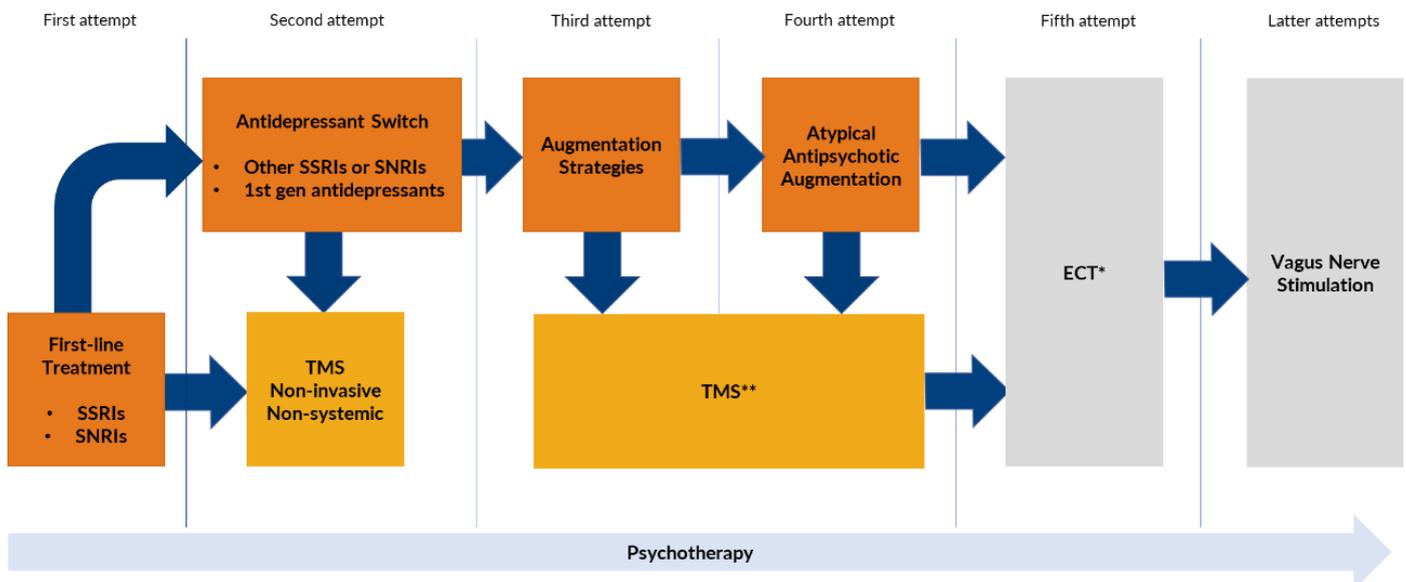
Nexstim plans to leverage the use of its TMS platform into broader indications and treatment settings. Our [January 2020 Outlook](#) note provides greater detail on the background to the technology, the competitive landscape, and market opportunities. The next sections summarise the near- and medium-term activities, notably the shift towards accelerated treatment protocols, that should drive sustained growth and achieve profitability.

NBT: aiming to broaden therapy applications

Benefits of TMS in depression are increasingly accepted ...

The use of TMS is increasingly gaining traction for the treatment of recalcitrant depression in Europe and, notably, in the US. Nexstim's NBT platform is approved in Europe (CE marked) and the US (FDA approved and widely reimbursed) for the treatment of major depressive disorder (MDD). Depression remains one of the most widespread and debilitating forms of mental illness despite major pharmacological advances. First-line therapy of antidepressant medication, typically SSRIs (selective serotonin reuptake inhibitors), is prescribed by a primary care physician, with or without psychotherapy.

Exhibit 2: MDD patient continuum of care



Source: Trinity Delta, Neuronetics Note: * ECT (electroconvulsive therapy) may be used earlier in the patient continuum of care in patients experiencing catatonia, acute suicidal behaviours, or psychotic symptoms; ** TMS may be used at any point along the continuum of care following one or more failed treatment attempts

... with a clear need for additional effective treatment options

Referral to a psychiatrist occurs after treatment failure(s) and it is estimated that 15-40% of all MDD patients are treatment resistant (ie refractory to any pharmacological therapy), and periods of remission and relapse are common over a lifetime. Treatment-resistant depression is acknowledged as a leading cause of disability, with high levels of morbidity and mortality. The therapeutic strategies, including intrusive techniques such as Vagus Nerve Stimulation (VNS) and Electroconvulsive Therapy (ECT), reflect this. For context, ECT is associated with

Depression indication approved for a decade before gaining traction in recent years

notable side effects and remains the most stigmatized treatment available in psychiatry, yet c 100,000 patients receive ECT annually in the US alone.

The FDA first authorised TMS for depression in 2008, when [Neuronetics'](#) Neurostar focal iron core coil platform was approved as a *de novo* device. It took a decade to achieve the milestone of 1.7m treatments on 50,000 patients in the US. Further approvals, using Neurostar as the predicate device followed in 2013 ([Brainsway's](#) H-Coil), 2015 ([Magstim's](#) Horizon and [MagVenture's](#) MagVita), with Nexstim's NBT approved in December 2017 and launched in mid-2018. Within two years Nexstim has established an installed base of 28 NBT systems globally, focussed on primary care (outpatient) centres in clinics and hospitals. These posted growth of 18% at H120 (despite COVID-19 restrictions).

Understanding of the role of the DLPFC is improving

Treatment with rTMS usually comprises daily out-patient sessions lasting about 30 minutes, typically for two to six weeks. In depression, the activity of the left dorsolateral prefrontal cortex ([DLPFC](#)) is reduced. DLPFC is primarily associated with cognitive or executive functions, such as the maintenance and manipulation of working memory, intention formation, goal-directed action, abstract reasoning, attentional control, and emotion. It is the reappraisal and suppression of negative affect that is believed to be a protective mechanism against depression, in other words depression is associated with abnormally low levels of left DLPFC activity.

NBT's SmartFocus navigation is a key differentiator

Accurate targeting is a major determinant of therapy success

One of the real limitations clinically of rTMS is the poor localisation of the target. This is typically based on a rather simplistic anatomical approach; namely 5cm anterior to the primary motor cortical representation of the hand (which corresponds anatomically to [Brodmann](#) areas [9](#) and [46](#)). This "standard procedure" fails to take into consideration the wide inter-individual variations in brain morphology. Case studies have consistently shown that the variations in location can be quite significant; for instance, a well-cited patient study¹ showed the prefrontal target was situated 8.3cm anterior to the hand motor cortex (a 3.3cm variation on an original 5cm measurement).

Key opinion leaders are driving awareness of benefits

Such variations in targeting underline the need for accurate navigation as part of each patient's treatment protocol. The issue has been known for some time², with the correct stimulation area only being addressed in around 30% of patients. It is thought³ that the variable efficacy seen in many of the earlier depression trial analyses is due to this inconsistent approach to targeting, not simply between patients, but also within individual patient's treatment regimens. Yet despite such known limitations, the safety benefits and relative efficacy of rTMS has resulted in a good market reception among clinicians.

¹ The value of navigation-guided rTMS for the treatment of depression: An illustrative case. *Neurophysiologie Clinique/Clinical Neurophysiology* 37(4):265-71 2007

² TMS in therapy studies: examination of the reliability of "standard" coil positioning by neuronavigation. Herwig et al. *Biol Psychiatry* 2001 50(1):58-61

³ Comparison of "standard" and "navigated" procedures of TMS coil positioning over motor, premotor and prefrontal targets in patients with chronic pain and depression. Ahdab et al. *Neurophysiol Clin* 2010 40(1):27-36

NBT is the only FDA approved TMS device in depression with built-in navigation

Nexstim's nTMS platform, the 'SmartFocus' Navigated Brain Therapy system, has been optimised for therapeutic applications and was FDA approved for MDD in December 2017, with US launch in May 2018. It is the only FDA approved device with built-in navigation, ensuring accurate, reliable, and reproducible treatment. SmartFocus technology can precisely map the motor cortex and uses proprietary e-field modelling to account for distortion caused by bone and brain tissue, accurately visualising the exact location, orientation, and magnitude of the stimulation.

Supportive clinical data from patient registry is a valuable endorsement

The precision of SmartFocus makes it well placed for such treatment and management is undertaking a [patient registry](#) to generate the clinically validated data to support its wider adoption. The first data from 108 patients who have completed MDD therapy at US clinics show that 42% achieved a clinical remission and 74% showed a clinical response. Although the data from such registries is not as robust as a double-blind placebo trial, it does compare favourably with historical meta-analyses from other TMS studies⁴ that showed reported remission rates of 26.5% to 28.7% and response rates of 41.5% to 56.4%.

Novel protocols improve patient outcomes and experience, plus bring cost benefit

Accelerated treatment protocols are game changing

More relevantly, the newer treatment regimens are increasingly favouring accurate navigation and the novel approaches being evaluated to accelerate the timelines of therapy appear to be particularly well-suited to the SmartFocus navigation. An apt example is iTBS ([intermittent theta-burst stimulation](#)), an accelerated treatment protocol that was FDA approved in 2018. Typically, rTMS consists of 20-30 sessions of 37.5-minute duration, five days a week for five/six weeks whereas with iTBS each session is shortened to c three minutes. Clinically iTBS has been shown to be [comparable](#) to rTMS, but with clear patient benefit and, importantly, cost and productivity advantages for the clinic.

Stanford approach looks particularly impressive

The iTBS approach is being developed further by Stanford University through a programme known as SAINT ([Stanford Accelerated Intelligent Neuromodulation Therapy](#)). This aims to improve response rates within a simpler and easier to deliver protocol through a three-step approach: treating patients with multiple sessions per day at optimally spaced intervals; applying a higher overall pulse dose of stimulation; and, most importantly, precision targeting of the left DLPFC to subgenual anterior cingulate cortex ([sgACC](#)) circuit. The results, reported in April 2020, of an initial open-label 22 patient [study](#) were impressive, with an 86.4% remission rate. These preliminary findings need corroboration by a double-blind placebo (sham treatment) trial, where a positive outcome would support the use of TMS in a broader range of depression indications (including the more severe and treatment resistant).

Nextim's pilot study data should be available in Q121

Nexstim is supporting an investigator-led trial at Kuopio University Hospital using its SmartFocus nTMS system with an accelerated iTBS protocol comparing the responses of 10 patients on a regimen of multiple daily sessions over one week against those seen in 10 patients undertaking conventional TMS. The top line data

⁴ Carpenter L. et al. Transcranial magnetic stimulation (TMS) for major depression: a multisite, naturalistic, observational study of acute treatment outcomes in clinical practice. *Depress Anxiety*. 2012 Jul;29(7):587-96

was originally expected to be available by end-2020, however, it is clear that COVID-19 related restrictions have affected the study and it will now likely to complete slightly later, during Q121. If the data are positive this would be expected to lead to a double-blind, sham controlled study carried out across multiple centres in the US and Europe. We would expect such a trial to involve at least 100 patients in the active arm, in order to support an FDA filing. Clearly Nexstim would require additional funds to support such a study.

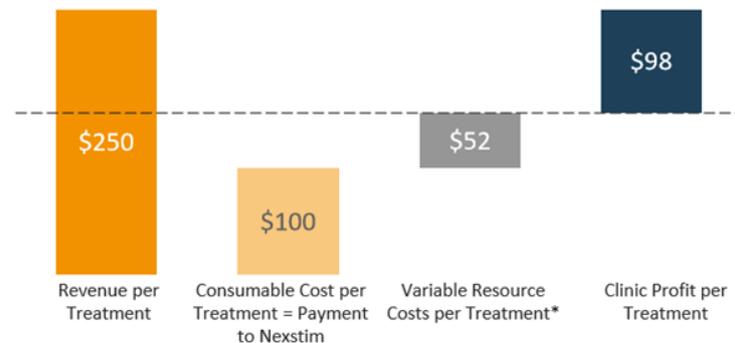
SmartFocus NBT being explored in further applications

Nexstim has been granted a €0.4m R&D loan from Business Finland, a government body to support innovation, to develop and optimise the SmartFocus nTMS system for use in accelerated iTBS protocols. These efforts should be completed during H221 and will likely be ready to be employed in the potential multi-centre trial.

Profitability set to rise through greater utilisation and new placements

Nexstim's NBT business model targets a high annual revenue stream per system with high utilisation rates. There are currently 28 NBT systems installed globally, with the prospect of growing the recurring revenues through existing installations and from placing new systems with both new and existing TMS providers. Clinical data from the patient registry will undoubtedly contribute in the near- and medium-term as the improved outcomes help cement NBT's benefits; however, we see the shift towards the accelerated protocols as a likely key driver in the medium-term. Whilst the demonstrable improvement in patient outcomes is the vital element in the NBT value proposition, the economic benefits to service providers should not be over-looked (Exhibit 3).

Exhibit 3: Economic benefit to TMS/Psychiatric Centre (pay-per-use lease)



- In a pay-per-use lease, no initial investment is required for clinics so **clinics make profit from first patient**
- A clinic could achieve annual profit of **\$147,500**, assuming 30 treatments per patient and 50 patients per year
- Nexstim can make a revenue of **\$150,000** for contracted clinic in pay-per-use lease

Source: Nexstim Note: * includes estimated cost of facilities and technician for 45 minutes per treatment, MD costs (3x per patient, 45mins biweekly) and MRI cost of \$500/patient divided by amount of treatment. 40% overhead applied.

US market offers attractive opportunities in depression

Cost effectiveness studies have already shown that introduction of rTMS therapy after a single failed antidepressant treatment attempt produces greater cost savings and better outcomes than the current practice of continued successive medication attempts. Consequently, rTMS is widely reimbursed in the US for MDD, with 100% Medicare coverage and coverage by >95 major US commercial

payors. Current Procedural Terminology (CPT) codes are available for therapeutic rTMS treatments, supporting reimbursement of \$200-500 per session.

Exhibit 4: Nexstim business opportunity in MDD



Source: Nexstim

A flexible approach has seen the economic benefits appreciated

Nexstim has retained flexible pricing models for NBT, which include pay-per-use leasing, monthly unlimited use leasing, or capital sale (with additional fees from head tracker sales and servicing). This flexibility has resulted in a more rapid sales cycle for NBT in MDD than with NBS. The utilisation rate is the main revenue driver for each installed system and, as detailed earlier, the trends in clinical practice are particularly favourable. Interestingly, the economics of NBT therapy are suitably attractive, especially in the US, that Nexstim is exploring ways to establish joint-ventures and partnerships with treatment centres. The likely format has yet to be detailed, but we expect Nexstim would forego its leasing income in exchange for a share of the profit generated.

Chronic pain is NBT's next clinical focus

Chronic pain is a greater opportunity, but is less advanced than depression

Given current resource constraints, Nexstim has prioritised its efforts on exploiting the NBT opportunity in MDD. However, the segment with the greatest commercial potential in the neuromodulation market is the treatment of chronic neuropathic pain, with around 10m addressable patients in the US and Europe. The lack of effective pain relief for such a large proportion of patients, coupled with the growing awareness of the issue of opioid misuse and addiction, means new therapeutic options are sought. NBT is CE Marked for chronic neuropathic pain, but the FDA is yet to approve any rTMS device for this indication. This largely reflects the fact that no large, multi-centre, randomised clinical trials have to date been undertaken by any manufacturer.

More trial data will help drive understanding and set clinical practice

The use of rTMS is seen as a safe and effective treatment, with around a dozen [clinical trials](#) involving c 350 patients supporting its use published in the past decade. The issues limiting more widespread therapeutic use centre around the relative infancy of the body of clinical evidence; for instance, there are differing views affecting fundamental points such as what the primary target should be within the brain (cortical reorganisation is a key factor) and the stimulation parameters (number of pulses and frequency). In part this shows the heterogeneity of neuropathic and chronic pain but, increasingly, the consensus is that rTMS is a valuable, effective, safe, and, because of its non-invasive nature, particularly attractive as a long-term treatment.

Nexstim's pilot study data should be available in H121

Nexstim has previously undertaken an exploratory 39-patient Phase II study at The Walton Centre, Neuroscience Research Centre, Liverpool (detailed in our [Initiation](#)) which delivered encouraging results. In Q420, a pilot study involving 5-10 patients was started at Helsinki University Hospital, which, replicating the advances seen in depression, uses an accelerated iTBS protocol. The patients selected have not benefitted from the standard 10Hz rTMS treatment targeted to the motor cortex that Helsinki University Hospital typically employs. This pilot study should complete in H121, with top line results released shortly after. These data, if positive, will guide a larger definitive multi-centre trial.

An attractive core business with solid growth opportunities

NBS: an important contributor to financial performance

NBS (Navigated Brain Stimulation) provides Nexstim with a dependable, high-margin revenue stream through its global installed base of c 170 systems at leading university and research hospitals. The NBS system, launched in 2003, is the only nTMS system that is FDA cleared and CE marked for the pre-surgical mapping ([PSM](#)) of the speech and motor cortices of the brain. PSM is typically undertaken ahead of tumour resection and NBS provides greater mapping precision, allowing surgeons to be more aggressive in tumour resection, thus improving treatment outcomes. However, there is scope to further develop the technology to map the speech and motor cortices of the brain ahead of other neurosurgical procedures (eg invasive epilepsy treatments).

US reimbursement codes will drive utilization and new sales

Revenues arise from capital sales of instruments and recurring revenues from consumables, albeit a smaller amount than used in NBT. The NBS system pricing is c €200k-300k (dependent on functionality and support equipment). The global installed base of around 170 NBS systems, includes numerous world-renowned cancer centres (for instance: Mayo Clinic, Karolinska, MD Anderson, Charité, Great Ormond Street Hospital, and UCSF). Nexstim's strategy for growing the profitability of the NBS business includes establishing new US reimbursement codes for pre-surgical mapping, leveraging the existing installed base, and securing new sales direct as well as potentially via a long-term strategic partnership to expand the current commercial reach.

Potential to explore new diagnostic applications

NBS may also have utility beyond its current pre-surgical mapping applications. A recent prototype research project, worth €0.9m, has been signed with an anonymous US-based research foundation to develop further novel applications for stimulating and diagnosing the brain. The deal includes the development and delivery of two prototype SmartFocus nTMS systems, which will be sited in two unnamed institutions, who will conduct the research, with Nexstim also providing technical support as required. Delivery of these systems, and revenue recognition, is expected to occur in H221.

Valuation

Valuation, based on conservative assumptions, raised to €38.4m, equivalent to €0.09/share

We value Nexstim using a risk-adjusted DCF model, forecasting NPVs for three revenue streams: NBT in depression, NBT in chronic pain, and NBS. The risk adjustments range from a success probability of 100% for pre-surgical mapping to 25% for the early-stage pain indication, reflecting its earlier nature. We employ conservative assumptions regarding patient populations, market sizes and growth rates, net pricing, adoption curves, and peak market penetration. In addition to considering development, execution and commercialisation risks, we also specifically included an adjustment for financial risk. This was, in our view, necessary due to the uncertainty at the time but has since abated, and we have improved this factor again from our last 75% to 85%. This, plus other updates to our model, sees the valuation rise from of €32.2m, equivalent to €0.07/share to €38.4m, equivalent to €0.09/share.

Exhibit 5: DCF-based valuation of Nexstim

	Total NPV (€m)	Success probability	rNPV (€m)	rNPV/ share (€)	Financial rNPV (€m)	Financial rNPV / share (€)	Notes
NBS	4.7	100%	4.7	0.01	4.0	0.01	Peak sales: €4.0m. Launch year: N/A
NBT in MDD	38.0	100%	38.0	0.09	32.3	0.07	Peak sales: €25.0m. Launch year: FY18
NBT in Chronic Pain	26.5	25%	6.6	0.02	5.6	0.01	Peak sales: €26.4m. Launch year: FY23
Net cash	(3.5)		(3.5)	(0.01)	(3.5)	(0.01)	Net cash at FY20e
Total (undiluted)	65.7		45.8	0.10	38.4	0.09	
Discount rate				12.5%			
Tax rate				20%			From 2026
Financial risk adjustment				85%			
Terminal growth rate				2%			From 2035

Source: Trinity Delta; Note: Peak sales achieved after nine years in the US and 10 years in Europe.

Significant upside if trial results are positive and commercial execution delivers

Exhibit 5 shows a breakdown of our valuation elements. We include risk-adjusted cash flows for the three main components:

- the NBS diagnostic pre-surgery brain mapping indication;
- the FDA approved major depression indication (EU and US sales); and
- the earlier Phase II chronic pain indication (EU only, US not included yet).

NBT MDD is the largest element of our valuation: its “commercial” valuation of €38.0m reduces to €32.3m when we overlay our “financial risk” adjustment. The NBS diagnostic unit is valued at €4.7m, reducing to €4.0m after risk adjustment. Similarly, the NBT Pain indication is valued at €6.6m and €5.6m respectively. Net debt is €3.5m under both scenarios. This results in a company valuation of €38.4m (€0.09/share), compared to €45.8m (€0.10/share) were the financial risk removed.

Accelerated protocols could unlock incremental value

Our current valuation considers Nexstim’s core business, although we acknowledge that with additional funding and positive preliminary pilot study data, the market opportunity for NBT could be broader due to the use of accelerated protocols. In our [January 2020 Outlook](#), we had previously provided an indicative rNPV valuation of the potential NBT opportunity in severe MDD patients who are treated in hospital, and are therefore highly suitable for

accelerated therapy protocols. We have revisited our assumptions, applying new timelines and potential development costs, but maintain the key assumptions outlined in Exhibit 6.

Exhibit 6: Key assumptions in accelerated therapy MDD opportunity

Input	Assumption
Number of patients/year	160,000
Current Medicare reimbursement/session	\$250
Number of sessions/patient	30
Number of sessions/day/hospital	10
Revenues/NBT system/year	€100,000
Peak market penetration by NBT	20%
Likelihood of NBT approval in severe MDD	40%
Launch year	2024

Source: Trinity Delta, Nexstim Note: in the outpatient setting, patients currently receive TMS once a day (5 sessions per week) for 4-6 weeks.

Based on conservative assumptions, accelerated protocols in MDD add €0.02/share or €8.4m to our Nexstim valuation

We believe that this indicative valuation of the US hospital opportunity is conservative. It is solely based on the placing and use of NBT systems for primary treatment in hospitals; it does not capture any additional revenue that may be generated by maintenance therapy of these same patients in the outpatient setting. Additionally, it assumed that reimbursement is in line with that of conventional TMS therapy. A higher reimbursement rate would result in larger revenues per system; alternatively, a greater number of sessions per patient could result in more NBT systems being placed. Nevertheless, based on the assumptions outlined above, this opportunity (summarised in Exhibit 7) could add an incremental €8.4m or €0.02/share to our core Nexstim valuation.

Exhibit 7: Summary of potential MDD accelerated protocol opportunity

	Value
Total market opportunity	\$1.2bn
Nexstim market opportunity	\$213m
NPV of Nexstim opportunity	€21.0m
rNPV of Nexstim opportunity	€8.4m
NPV/share	€0.04
rNPV/share	€0.02

Source: Trinity Delta Note: cost of capital of 12.5%; USD/EUR exchange rate of 0.8.

Financials

An impressive performance during challenging times

H120 marked a record interim performance with net sales of €1.6m (+33% on H119m: €1.2m), operating loss of €1.8m (H119: loss of €3.4m), and net loss of €1.2m (H119: loss of €3.7m).

Strong revenue performances despite headwinds

NBS sales increased an impressive 47% to €895k, with NBT revenues growing 18% to €720k. COVID-19 undoubtedly dampened the NBT commercial trajectory; however, the focus was on leveraging the current installed base to generate recurring revenues (ie excluding NBT capital system sales). As such H120 NBT sales were comprised solely of recurring revenues. On a rolling 12-month basis, Nexstim has achieved an average therapy revenue per NBT system of €70k, a lower figure than the €85k reported at FY19. NBS was impacted less as hospital neurosurgeries were largely unaffected. During the period, four new NBS systems (three in the US and one in Sweden) and five new NBT systems were installed.

Targeted cost savings were implemented across the board

Cost saving measures and new ways of working remotely that were implemented in response to the COVID-19 pandemic decreased operating costs, with operating cash flows showing a €1.6m outflow in H120 vs €3.7m in H119. Nexstim previously indicated that €0.8m in cost savings would be achieved in April-June 2020, with targeted annual savings of up to €3m.

FY20 guidance for higher net sales and lower operating loss vs FY19

Demand for Nexstim's products and services has remained strong during H220, with financial guidance for FY20 most recently updated on November 10. FY20 net sales are estimated to increase and the full year operating loss for FY20 is expected to be lower than in FY19.

Current cash resources extend into Q121

The end-June 2020 cash position of €4.8m (including the outstanding Kreos loan of €1.45m) provides sufficient funding through Q121, although execution on the 2020-24 corporate strategy will require additional funds. Our forecasts suggest that a further €10m would be required over the next 18 months to achieve near- and mid-term goals for NBT in depression (including further clinical evaluation of accelerated protocols), repay the Kreos loan (due December 2021) and to secure the company's financial future.

Further funding could arise from a number of sources

We have previously highlighted that Nexstim is evaluating various funding options, including non-dilutive funding from strategic partnership(s) or agencies (such as the Business Finland loan for development for SmartFocus nTMS system optimisation), and has engaged an international life sciences investment bank to assist in this process.

Exhibit 8: Summary of financials

Year-end: December 31	€'000s	2017	2018	2019	2020E	2021E
INCOME STATEMENT						
Revenues		2,645	2,672	3,348	3,665	6,554
Cost of goods sold		(552)	(710)	(1,043)	(1,194)	(1,591)
Gross Profit		2,093	1,962	2,305	2,471	4,962
Wages and salaries		(2,903)	(3,353)	(3,998)	(3,013)	(4,158)
Social security expenses		(431)	(584)	(715)	(571)	(707)
Other expenses		(4,118)	(3,986)	(3,648)	(2,959)	(3,906)
Depreciation & amortisation		(341)	(424)	(525)	(475)	(525)
Underlying operating profit		(5,701)	(6,386)	(6,580)	(4,547)	(4,334)
Other revenue/expenses		109	70	63	79	79
EBITDA		(5,251)	(5,892)	(5,993)	(3,993)	(3,729)
Operating Profit		(5,592)	(6,316)	(6,517)	(4,468)	(4,255)
Financial income		(1,733)	163	(259)	595	(169)
Profit Before Taxes		(7,325)	(6,153)	(6,777)	(3,872)	(4,424)
Adj. PBT		(7,434)	(6,223)	(6,840)	(3,952)	(4,503)
Current tax income		(3)	(2)	(6)	(3)	(13)
Net Income		(7,328)	(6,154)	(6,783)	(3,875)	(4,437)
EPS (€)		(2.77)	(1.93)	(0.25)	(0.01)	(0.01)
Adj. EPS (€)		(2.81)	(1.93)	(0.25)	(0.01)	(0.01)
DPS (€)		0.00	0.00	0.00	0.00	0.00
Average no. of shares (m)		2.6	3.2	27.6	266.7	439.6
<i>Gross margin</i>		79%	73%	69%	67%	76%
<i>EBITDA margin</i>		N/A	N/A	N/A	N/A	N/A
<i>Underlying operating margin</i>		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Current assets		10,326	8,757	6,431	4,079	9,810
Cash and cash equivalents		8,474	7,175	4,266	1,855	7,181
Accounts receivable		1,465	1,324	1,680	1,506	1,975
Inventories		387	259	485	718	654
Other current assets		0	0	0	0	0
Non-current assets		718	905	1,223	1,245	1,562
Property, plant & equipment		167	465	859	648	810
Intangible assets		541	430	364	597	753
Current liabilities		(1,786)	(2,793)	(3,106)	(3,038)	(3,256)
Short-term debt		0	(1,104)	(989)	(638)	(638)
Accounts payable		(961)	(597)	(740)	(1,093)	(1,308)
Other current liabilities		(824)	(1,092)	(1,378)	(1,307)	(1,309)
Non-current liabilities		(3,737)	(7,163)	(5,288)	(4,704)	(14,972)
Long-term debt		(3,724)	(7,163)	(5,288)	(4,704)	(14,972)
Other non-current liabilities		(13)	0	0	0	0
Equity		5,521	(294)	(740)	(2,417)	(6,855)
Share capital		38,599	39,561	46,167	48,391	48,391
Other		(33,078)	(39,855)	(46,907)	(50,808)	(55,245)
CASH FLOW STATEMENTS						
Operating cash flow		(5,403)	(6,192)	(6,681)	(4,117)	(4,099)
Profit before tax		(7,328)	(6,154)	(6,783)	(3,875)	(4,437)
Non-cash adjustments		3,618	(361)	515	(1,060)	695
Change in working capital		(1,555)	721	268	85	(177)
Interest paid		(138)	(398)	(682)	734	(169)
Taxes paid		0	0	0	(1)	(11)
Investing cash flow		(148)	(611)	(843)	(497)	(843)
CAPEX		(148)	(611)	(843)	(497)	(843)
Other investing cash flows		0	0	0	0	0
Financing cash flow		5,868	5,505	4,616	2,202	10,268
Proceeds from equity		6,765	962	6,606	2,224	0
Increase in loans		(897)	4,543	(1,990)	(22)	10,268
Other financing cash flow		0	0	0	0	0
Net increase in cash		318	(1,298)	(2,909)	(2,412)	5,326
Exchange rate effects		0	0	0	0	0
Cash at start of year		8,156	8,474	7,176	4,267	1,855
Cash at end of year		8,474	7,176	4,267	1,855	7,181
Net cash at end of year		4,750	(1,092)	(2,011)	(3,487)	(8,429)

Source: Company, Trinity Delta Note: The accounts are produced according to Finnish GAAP. €10m of short-term debt in FY21e is indicative of our view of the company's funding requirement; the balance reflects the Business Finland loan. Our sales forecasts do not include any contribution from indications yet to be approved. Historic EPS, DPS and Average no. of shares have been adjusted to reflect the 30:1 share consolidation in December 2018

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