

Nexstim

Update

Achieving commendable outcomes in depression

20 December 2018

Nexstim has tidied up its share structure, with a consolidation resulting in a 30:1 reduction in the number of shares in issue. Management is focussed on exploiting the commercial opportunity for its proprietary Navigated Brain Therapy (NBT) system in the sizeable major depressive disorder (MDD) segment. Installations are growing across the US, Europe and Asia, with the strategy to support further roll out across the US progressing well. We have updated valuation model to reflect the fewer number of shares and value the company at €35.9m, or €11.04/share (€10.30/share diluted).

Year-end: December 31	2017	2018E	2019E	2020E
Sales (€m)	2.6	2.9	4.0	6.2
PBT (€m)	(7.4)	(6.5)	(6.7)	(5.6)
Net Income (€m)	(7.3)	(6.5)	(6.7)	(5.5)
EPS (€)	(2.81)	(2.03)	(2.06)	(1.70)
Cash* (€m)	8.5	6.0	3.7	12.2
EBITDA (€m)	(5.3)	(6.2)	(5.7)	(4.6)

Source: Trinity Delta. Note: *Our cash forecast assumes that Nexstim raises €5m in 2019 and €15m in 2020.

- Shares consolidated 30:1** Management has completed a share consolidation that has seen the number of shares in issue reduced by a factor of 30 to 1. On November 21 the proposal was made in order to improve market transactions and liquidity in the shares. This was completed on December 3 and all remaining treasury shares and 7,724 shares were annulled, with the final number of shares registered being 3.254m. The same ratios apply to outstanding warrants.
- Commercialising diagnostic and clinical applications** Nexstim's TMS imaging platforms are used for diagnostic and therapeutic applications, where they have extensive scientific validation (including FDA approvals), and have been shown to be highly accurate, reproducible, and clinically effective. Both the diagnostic Navigated Brain Stimulation (NBS) and clinical Navigated Brain Therapy (NBT) are being commercialised across Europe and the US. We expect NBT use in Major Depressive Disorder (MDD) will be the revenue driver over the medium term.
- MDD is a commercially attractive opportunity** The priority for Nexstim is to raise market awareness of the NBT system's worth in MDD, as we believe the growing appreciation of the value proposition (compelling patient outcomes and economic benefit to clinicians) will determine uptake. Management has initiated commercial plans, leveraging the strength of its installed base of NBS systems. It is making investment in marketing infrastructure, technology and process improvements, and business development initiatives.
- Maintaining our €35.9m valuation** We have updated our model for the reduced number of shares but all other elements are unchanged (notably end-June cash of €10.3m provides a c 12 month runway at current burn rates). Employing a risk-adjusted DCF and conservative assumptions, we value Nexstim at €35.9m or €11.04/share currently and €10.30/share diluted.

Price	€0.65
Market Cap	€2.12m
Enterprise Value	€3.6m
Shares in issue	3.25m
12 month range	€0.05-1.25
Free float	85.8%
Primary exchange	Helsinki
Other exchanges	Stockholm
Sector	Healthcare
Company Codes	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: inherent value is higher than perceived

Emphasis is on gaining traction in the treatment of depression

Whilst investors' recent focus has been on the [share reduction](#) that has been implemented (a 30:1 share consolidation), the underlying business has been gaining traction, particularly in the important US market. Management is implementing a focussed strategy to maximise the commercial potential of its highly accurate TMS ([Transcranial Magnetic Stimulation](#)) system as a therapy for major depressive disease ([MDD](#)).

We have detailed the technology and its clinical uses in previous notes ([Initiation](#) July 2018), with an extensive note examining its use in depression and the commercial prospects ([Update](#) October 2018). In this note we briefly re-cap on Nexstim's current opportunities and, more importantly, update our forecasts and valuation models.

rTMS platform used as diagnostic and as treatment

Two distinct opportunities, with persuasive clinical evidence

Nexstim's TMS platform is employed in two related albeit commercially separate divisions: Diagnostics and Therapeutics (Exhibit 1). The diagnostics division comprises the Navigated Brain Stimulation (NBS) system and is used, and extensively validated, in pre-surgical brain mapping, while the Navigated Brain Therapy (NBT) system has been optimised for therapeutic use.

Exhibit 1: Unique navigated TMS system for diagnostic and therapeutic applications

Use	Application	Europe	US	Commercial status
Diagnostic (NBS)	Pre-surgical mapping	CE Marked	FDA approved	Installed base of over 150 systems
Therapeutics (NBT)	Depression	CE Marked	FDA approved	Multiple systems installed in the EU and US
	Chronic neuropathic pain	CE Marked	Phase II clinical trials evaluated	Multiple systems installed in the EU

Source: Nexstim, Trinity Delta

Pre-surgical mapping is a proven indication with revenue growth

Understandably, most commercial traction has been gained in the more established use of NBS as a diagnostic in pre-surgical mapping ([PSM](#)). NBS provides greater mapping precision, allowing surgeons to be more aggressive in tumour resection, thus improving treatment outcomes. The NBS system was launched in 2003, with marketing efforts targeted at universities and teaching hospitals with a strong key opinion leader (KOL) presence in neurosurgery and radiology. It has subsequently attracted an impressive client list, which routinely uses the tool in pre-surgical mapping. The global installed base is over 150 NBS systems, including numerous world-renowned cancer centres (eg Mayo Clinic, MD Anderson, Charite, Great Ormond Street Hospital, and UCSF).

Therapeutic indications offer attractive prospects

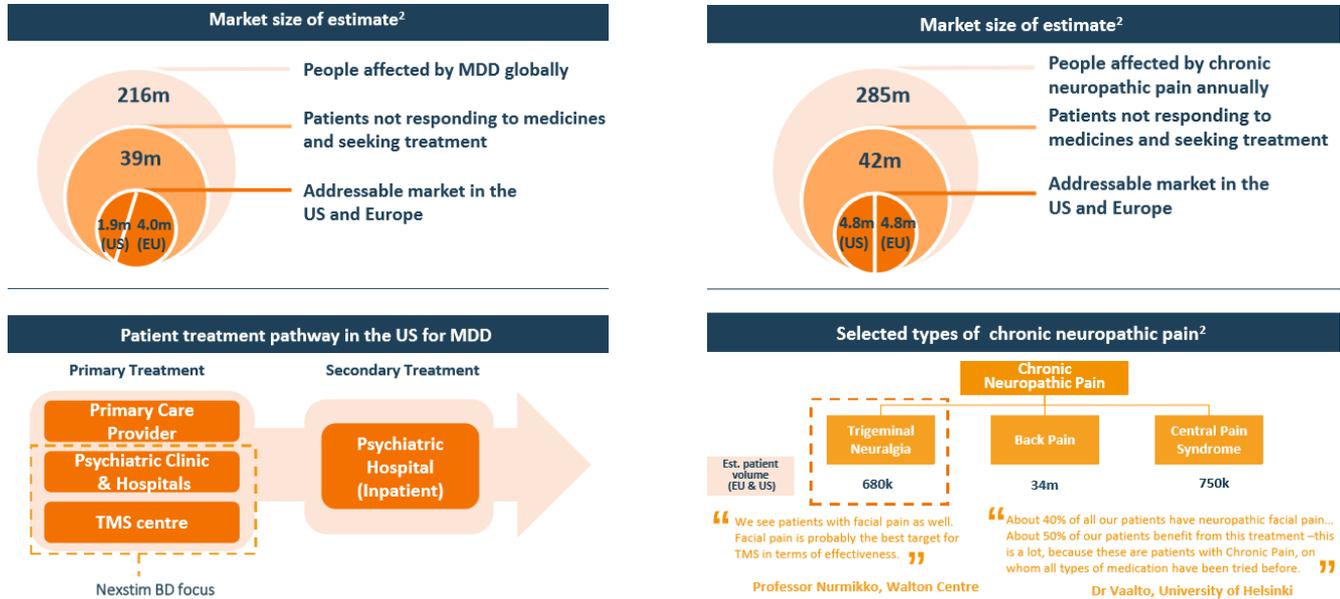
Therapeutic use offers a greater market opportunity

Although the NBS diagnostic application is attractive, and high margin, there is a materially larger commercial potential in the NBT therapeutic uses. The focus is now on two currently poorly addressed indications: depression and chronic neuropathic pain. Exhibit 2 overleaf summarises Nexstim's commercial assessment for NBT in these indications.

The opportunity in MDD is material and timely. Treatment resistant depression (ie unresponsive to pharmacological anti-depressant medication) has a current

addressable market of c 6m patients but is growing rapidly. The use of repetitive TMS (rTMS) is accepted as a second-line therapy, with the first FDA approval occurring in 2008 ([Neuronetics' Neurostar](#) focal iron core coil TMS platform). It is also reimbursed in the US and various European countries.

Exhibit 2: Nexstim business opportunity in major depressive disorder (left) and chronic neuropathic pain (right)



Source: Nexstim. Note: ² PMSI Consulting analysis, expert interviews and estimates.

Clear differentiation compared to other treatment methods

Nexstim's Navigated Brain Therapy (NBT) system 'SmartFocus' was FDA approved for MDD in December 2017 and launched in the US in May 2018. It is the only FDA approved device with built-in navigation, ensuring accurate and reproducible treatment. This is achieved through precise mapping of the motor cortex, and via 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. This means NBT can target the DLPFC (dorsolateral prefrontal cortex) 100% of the time vs [30% with other TMS approaches](#). Early indications are that the benefits of accurate navigation are readily understood by clinicians.

Potential to leverage neurosurgical KOL networks

Leveraging the existing neurosurgical KOL network developed in pre-surgical brain mapping is an important facet of Nexstim's commercial plan in MDD. To date NBT systems for MDD have been installed at multiple sites across 3 continents at prominent psychiatric and neuroscience centres. In the US, the commercial strategy is direct sales, while in Europe and Asia, a mixed direct and distributor model is being deployed, with the recent Ampere Medical distribution deal for Hong Kong demonstrating progress in developing new markets.

Raising market awareness is key to driving uptake

Nexstim's commercial priority is to raise market awareness of its NBT system. Growth in patient registry data in MDD (including a comparative element with non-navigated systems) will supplement the body of clinical outcomes evidence and should support a shift from existing treatment practices and increase adoption of NBT. The company plans to publish registry data in a series of White Papers, which should help with raising the profile of the NBT system and its capabilities. Growing appreciation of the value proposition (ie improved patient outcomes and economic benefit to clinicians) will be a key driver of uptake.

Neuropathic pain is also a large segment with high unmet needs

Although chronic neuropathic pain is currently the largest application segment in the neuromodulation market, it is depression that is expected to be the major opportunity, despite its lower incidence, for medium-term growth. While Nexstim's NBT is CE Marked for chronic neuropathic pain, the FDA has yet to approve any rTMS device for this indication. This largely reflects the fact that no large, multi-centre, randomised clinical trials have yet been undertaken by any manufacturer. Following encouraging results from an exploratory 39-patient Phase II study at The Walton Centre, Neuroscience Research Centre, Liverpool (detailed in our [Initiation note](#)), Nexstim is currently evaluating potential clinical trials for pain.

Valuation

Risk adjusted DCF-model is best valuation tool for Nexstim

Nexstim's share price fell sharply following the failure of the pivotal E-FIT stroke trial for understandable reasons but now has, in our view, over-reacted. Examining the details underlying our DCF-based valuation model (see also our previous reports: [Initiation](#) July 2018 and [Update](#) October 2018), shows how the existing diagnostic and therapeutic indications comfortably exceed the current share price.

DCF-based valuation of €35.9m or €11.04/share

Our valuation of €35.9m remains unchanged but the share consolidation means this is now equivalent to €11.04/share and €10.30/share diluted (based on in-the-money options and warrants).

Exhibit 3: DCF-based valuation of Nexstim

	Total NPV (€m)	Success probability	rNPV (€m)	rNPV/share (€)	Notes
NBS	6.6	100%	6.6	2.03	Peak sales: €4.1m. Launch year: N/A
NBT in MDD	21.2	100%	21.2	6.52	Peak sales: €22.4m. Launch year: FY18
NBT in Chronic Pain	21.2	25%	5.3	1.63	Peak sales: €25.8m. Launch year: FY23
Net cash	2.8		2.80	0.86	Net cash at H118
Total (undiluted)	51.7		35.9	11.04	
Total (diluted)			42.8	10.30	Based on in-the-money options/warrants exercise
Discount rate				12.5%	
Tax rate				20%	From 2026
Terminal growth rate				2%	From 2035

Source: Trinity Delta; Note: Peak sales achieved after nine years in the US and 10 years in Europe. We assume the subscription prices for the 2018 options is the weighted average of existing options, which is €5.337.

Exhibit 3 provides a breakdown of the components of our valuation. We have employed risk-adjusted cash flows for the three main components: the NBS diagnostic pre-surgery brain mapping indication; the FDA approved major depression indication; and the earlier Phase II chronic pain indication.

Depression indication is the main valuation driver

The risk adjustments range from a success probability of 100% for the brain mapping application to 25% for the early-stage pain indication. The depression indication accounts for the largest element of the valuation, comprising 59% of total company value. Potential upsides include a more rapid execution of the US commercial strategy, and better rates of clinical adoption and sales progress.

It is worth highlighting that we apply conservative assumptions regarding patient populations, market sizes and growth rates, net pricing, adoption curves, and peak market penetration. Also, we only value the existing assets with potential supplementary clinical indications and off-label usage excluded. Additionally, as before, we have also accounted for the dilution from the outstanding warrants and options.

Execution of commercialisation plans depend on funds raised

Nexstim had cash of €10.3m in June which, following the cessation of clinical work on stroke and other cost cutting, we estimate is sufficient for c12 months at our current forecast burn rates. Although still unclear, our forecasts suggest that Nexstim needs around €5m over the next 12 months to properly execute its commercialisation plans for NBT in MDD. Depending on the level of subsequent investment needed in the commercial infrastructure and the level of sales performance, further funds may be required: we model €15m in FY20. However, the actual amount and timings will depend on the rate of clinical acceptance and institutional adoption on the one hand, and the investments in clinical data and marketing effort on the other.

Exhibit 4: Summary of financials

Year-end: December 31	€'000s	2015	2016	2017	2018E	2019E	2020E
INCOME STATEMENT							
Revenues		2,528	2,483	2,645	2,934	4,022	6,189
Cost of goods sold		(821)	(689)	(552)	(756)	(914)	(1,261)
Gross Profit		1,707	1,794	2,093	2,178	3,108	4,929
Wages and salaries		(3,292)	(3,602)	(2,903)	(3,165)	(3,645)	(4,010)
Social security expenses		(677)	(651)	(431)	(552)	(620)	(682)
Other expenses		(7,843)	(3,908)	(4,118)	(4,750)	(4,611)	(4,841)
Depreciation & amortisation		(386)	(372)	(341)	(322)	(428)	(478)
Underlying operating profit		(10,492)	(6,739)	(5,701)	(6,611)	(6,195)	(5,082)
Other revenue/expenses		122	43	109	47	47	47
EBITDA		(9,984)	(6,324)	(5,251)	(6,242)	(5,720)	(4,557)
Operating Profit		(10,370)	(6,696)	(5,592)	(6,564)	(6,148)	(5,034)
Financial income		544	(34)	(1,733)	80	(543)	(498)
Profit Before Taxes		(9,826)	(6,730)	(7,325)	(6,484)	(6,691)	(5,533)
Adj. PBT		(9,948)	(6,774)	(7,434)	(6,532)	(6,739)	(5,580)
Current tax income		(1)	(2)	(3)	(3)	(4)	(6)
Net Income		(9,827)	(6,733)	(7,328)	(6,487)	(6,695)	(5,539)
EPS (€)		(1.37)	(0.56)	(0.09)	(0.07)	(0.07)	(0.06)
Adj. EPS (€)		(1.39)	(0.57)	(0.09)	(0.07)	(0.07)	(0.06)
DPS (€)		0.00	0.00	0.00	0.00	0.00	0.00
Average no. of shares (m)		7.2	12.0	79.5	95.6	97.5	97.5
<i>Gross margin</i>		68%	72%	79%	74%	77%	80%
<i>EBITDA margin</i>		N/A	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	N/A
BALANCE SHEET							
Current assets		8,233	9,506	10,326	8,169	6,263	15,360
Cash and cash equivalents		6,875	8,156	8,474	6,044	3,703	12,195
Accounts receivable		937	1,057	1,465	1,607	1,984	2,544
Inventories		421	292	387	518	576	622
Other current assets		0	0	0	0	0	0
Non-current assets		974	911	718	901	1,204	1,650
Property, plant & equipment		333	249	167	403	596	935
Intangible assets		631	652	541	488	598	705
Current liabilities		(2,417)	(2,137)	(1,786)	(1,925)	(7,017)	(22,100)
Short-term debt		0	0	0	0	(5,000)	(20,000)
Accounts payable		(1,084)	(397)	(961)	(1,035)	(1,127)	(1,209)
Other current liabilities		(1,332)	(1,740)	(824)	(890)	(890)	(891)
Non-current liabilities		(3,245)	(3,802)	(3,737)	(7,510)	(7,510)	(7,510)
Long-term debt		(3,197)	(3,778)	(3,724)	(7,510)	(7,510)	(7,510)
Other non-current liabilities		(47)	(24)	(13)	0	0	0
Equity		3,545	4,478	5,521	(366)	(7,061)	(12,600)
Share capital		23,662	31,773	38,599	39,561	39,561	39,561
Other		(20,117)	(27,294)	(33,078)	(39,927)	(46,622)	(52,161)
CASH FLOW STATEMENTS							
Operating cash flow		(9,609)	(7,225)	(5,403)	(7,122)	(6,610)	(5,584)
Profit before tax		(9,827)	(6,733)	(7,328)	(6,487)	(6,695)	(5,539)
Non-cash adjustments		432	(106)	3,618	(118)	971	976
Change in working capital		330	(411)	(1,555)	(209)	(339)	(518)
Interest paid		(544)	25	(138)	(306)	(543)	(498)
Taxes paid		0	0	0	(2)	(4)	(6)
Investing cash flow		(380)	(310)	(148)	(505)	(731)	(924)
CAPEX		(380)	(310)	(148)	(505)	(731)	(924)
Other investing cash flows		0	0	0	0	0	0
Financing cash flow		5,380	8,817	5,868	5,198	5,000	15,000
Proceeds from equity		5,280	7,700	6,765	962	0	0
Increase in loans		100	1,117	(897)	4,236	5,000	15,000
Other financing cash flow		0	0	0	0	0	0
Net increase in cash		(4,609)	1,282	318	(2,430)	(2,341)	8,492
Exchange rate effects		0	0	0	0	0	0
Cash at start of year		11,484	6,875	8,156	8,474	6,044	3,703
Cash at end of year		6,875	8,156	8,474	6,044	3,703	12,195
Net cash at end of year		3,677	4,378	4,750	(1,466)	(8,807)	(15,315)

Source: Nexstim, Trinity Delta Note: The accounts are produced according to Finnish GAAP. The short-term debt in FY19 and FY20 is indicative of our view of the company's funding requirement. Our sales forecasts do not include any contribution from indications that are 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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