

Nexstim

Update

Securing the commercial future of NBT in depression

18 March 2019

Nexstim is embarking on the next stage of its journey in commercialising its Navigated Brain Therapy (NBT) platform in MDD (major depressive disorder). The recently reported FY18 results confirmed operational progress was much as expected. A sizeable rights issue is planned, with the aim of securing sufficient funding to support the commercial roll-outs of NBT in depression in North America and Europe. It was also announced that the NBS pre-surgical mapping platform may be divested. We have updated our valuation and financial model to reflect the expected changes. We now value the company at €10.5m or €3.23 per share (also €3.23 diluted), against €32.0m, or €10.5/share (also €10.5 diluted) were financial risk removed.

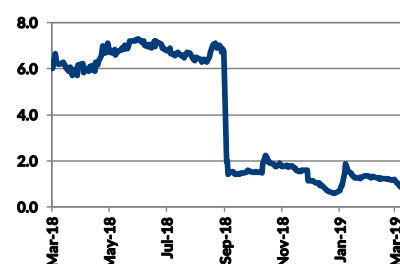
Year-end: December 31	2017	2018	2019E	2020E
Sales (€m)	2.6	2.7	4.0	6.0
PBT (€m)	(7.43)	(6.2)	(6.8)	(6.1)
Net Income (€m)	(7.3)	(6.2)	(6.7)	(6.1)
EPS (€)	(2.77)	(1.93)	(2.06)	(1.87)
Cash* (€m)	8.5	7.2	4.4	12.3
EBITDA (€m)	(5.3)	(5.9)	(6.0)	(5.3)

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

- Gaining traction but financing tight** FY18 results saw revenues flat at €2.7m, but sustained cost control resulted in the net loss reducing from €7.3m to €6.2m. Cash outflow was €6.2m, vs an outflow of €5.4m in FY17, largely reflecting investment in the commercial infrastructure. The cash position at December was €7.2m, against €8.5m the previous year; this includes the €4.0m loan from Kreos Capital. Projected cash burn suggests a funding requirement of around €6m, through equity issuance and possibly asset sales, to execute the commercial plans.
- Developing the MDD opportunity** NBT's use in Major Depressive Disorder (MDD) is set to be the revenue driver over the medium term. The focus is on raising market awareness of the platform's value, notably the compelling patient outcomes and economic benefit to clinicians. Management has initiated commercial plans, making investment in marketing infrastructure, technology, and process improvements. Gaining traction in the key US market will be the major determinant of success.
- Rights issue and possible sale of diagnostic unit** Management's priority is to secure the funding required to commercialise effectively NBT's MDD indication. The proposed rights issue may be augmented by the divestment of the NBS pre-surgical mapping unit, but we have not factored this into our expectations. The clinical evidence supporting NBT's use in MDD is convincing. Transcranial magnetic stimulation is increasingly being recognised as a therapy for c 6m MDD patients, and NBT is the only system that can deliver accurate and reproducible treatment.
- Valuation updated to reflect financial risk** We have updated our DCF model for FY18 results and the financial risks now present. This values Nexstim at €10.5m or €3.23/share currently and diluted (in the money options only). This compares to €35.9m or €11.04/share and €10.30/share diluted previously.

Price	€0.88
Market Cap	€2.9m
Enterprise Value	€5.0m
Shares in issue	3.3m
12 month range	€0.05-0.40
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 its commercial roll out in the US, Europe and Asia.

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Nexstim: preparing the pathway for the future

Emphasis is on securing sufficient funding to address the treatment of severe depression

Nexstim's management is seeking to secure a solid financial foundation for its commercial future. Following last year's disappointing result in the pivotal E-FIT Phase III stroke trial, the strategy was re-focussed on maximising the market potential of its highly accurate TMS ([Transcranial Magnetic Stimulation](#)) system as a treatment for major depressive disease ([MDD](#)).

The recent publication of FY18 results showed that revenues were €2.672m, vs €2.645m in FY17 and our forecast of €2.934m. Good cost control saw the net loss fall to €6.154m, from €7.328m the prior year and beat our expected €6.487m. The loss per share was €1.93 from €2.77, and similarly better than our forecast €2.03. The operating cash flows showed an outflow of €6.193m as a result of the residual R&D spend of the stroke programme, coupled with continuing investment in expanding the sales and marketing infrastructure. The outflow in FY17 was €5.403m, and our FY18 forecast was €7.122m.

A sizeable rights issue is planned

The cash position at December 2018 was €7.175m, against €8.474m the previous year; this includes the €4.0m loan from Kreos Capital. Management estimates it will require a minimum of €3m to maintain its going concern basis (sufficient through to December 2019) if the terms of the Kreos loan agreement are maintained. The amount required would rise to around €6m, including outstanding interest and fees, if Kreos were enabled to call the loan in prematurely.

Management's priority is to strengthen its financial position and is evaluating options that include equity funding and the divestment of non-core assets.

Focussing on commercialising the MDD indication

Future attention will be on exploiting the platform's value in treating major depression

We detailed Nexstim's proprietary TMS technology and its clinical applications in previous notes (notably our comprehensive [Initiation](#) July 2018), with an extensive note examining its use in depression and its commercial prospects ([Update](#) October 2018). To recap briefly, the platform is currently employed in two related albeit commercially separate divisions: Diagnostics and Therapeutics (Exhibit 1). The diagnostics division comprises the Navigated Brain Stimulation (NBS) system which 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 160 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 an accepted and valued indication

NBS is principally used as a diagnostic tool in pre-surgical mapping ([PSM](#)), where it provides greater mapping precision, allowing surgeons to be more aggressive in tumour resection, thus improving treatment outcomes. The NBS system was launched in 2003 and has subsequently developed an impressive, and supportive, client list. The global installed base is around 160 NBS systems, including

Divestment of the NBS unit is being considered

numerous world-renowned cancer centres (for instance: Mayo Clinic, Karolinska, MD Anderson, Charité, Great Ormond Street Hospital, and UCSF).

Management's stated strategy is to focus on the NBT clinical applications and is considering viable options for the NBS unit, including its divestment through a partnership or trade sale, although the details have yet to be made public. The suggestion is that the available options will be discussed at the AGM, scheduled for March 25.

We value this at €6.2m but appreciated the realisable value may be lower

As yet, management has not indicated what the likely divestment value will be. We value the NBS unit, using a risk-adjusted DCF model, at €6.2m. This figure does not include the specific direct and indirect costs, particularly regulatory and field support and R&D efforts, as these were allocated across the whole company. Allowing for these, and to reflect the reduced negotiating room management has, we estimate the realisable value to be around €3m to €4m.

Refractory MDD is a clear unmet clinical need and NBT is well placed to address it

MDD is clinically, and commercially, attractive

The Navigated Brain Therapy (NBT) platform 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.

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.

Commercialisation will be direct in major markets and distributors in the others

In the US, the commercial strategy is direct sales, with ten people currently in the sales team addressing four key geographic areas (North East states, South East states, Texas, and California) where TMS is already established and high-volume psychiatric practices appear primed. 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 in large specialist centres is key to driving uptake

The 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. Growing understanding of the value proposition (ie improved patient outcomes and economic benefit to clinicians) should be a key driver of uptake.

We value NBT's use in treating MDD, again using our risk-adjusted DCF model, at €21.5m. This is based on peak sales of €22.4m being achieved in 2028, which should be attainable through the use of a targeted sales team in the direct markets and well-motivated distributors in the other territories. Arguably this figure should

be reduced to reflect the larger cost contribution this business area would carry to reflect the possible divestment of the NBS unit, but we are assuming overheads will be trimmed. In fairness, we are already employing conservative assumptions throughout (notably regarding clinical adoption), so the effect is, in any case, relatively minor.

Neuropathic pain is an earlier stage programme

The treatment of chronic neuropathic pain is currently the largest application in the neuromodulation market. 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 was evaluating potential clinical trials for neuropathic and related chronic pain. The pressing need to finance adequately the depression opportunity suggests that, despite the clinical potential, pursuing the neuropathic pain indication will be a lesser priority.

We value the pain indication at €5.4m, with peak sales of around €25.8m by 2033 and a success probability of only 25% (reflecting the early nature of the clinical studies). We should note that this indication is the one most sensitive to Nexstim's financial position, where limited funds would, rightly in our view, be channelled towards commercialising MDD.

Valuation

We believe a risk-adjusted DCF model is the most appropriate method to value Nexstim, and this shows that the company is undervalued at current levels. However, realistically, the single major consideration lies in ensuring sufficient financing is in place to execute the commercial plans for the MDD indication.

Neuropathic pain is also a large segment with high unmet needs...

...but earlier stage means more clinical development is required

Risk adjusted DCF-model is best valuation tool for Nexstim

Exhibit 2: Updated DCF-based valuation of Nexstim

	Total NPV (€m)	Success probability	rNPV (€m) excluding financial risk	rNPV (€m) with financial risk	rNPV/ share (€)	Notes
NBS	6.2	100%	6.2	2.2	0.67	Peak sales: €4.1m. Launch year: N/A
NBT in MDD	21.5	100%	21.5	7.5	2.32	Peak sales: €22.4m. Launch year: FY18
NBT in Chronic Pain	21.5	25%	5.4	1.9	0.58	Peak sales: €25.8m. Launch year: FY23
Net cash	(1.1)		(1.1)	(1.1)	(0.34)	At FY18
Total (undiluted)	48.2		32.0	10.5	3.23	
Total (diluted)			38.6	10.5	3.23	Based on in-the-money options/warrants exercise
Discount rate					12.5%	
Tax rate					20%	From 2026
Financial risk adjustment					35%	
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.

The financial uncertainty surrounding the company is understandable, weighs heavily on the share price, and does cloud our investment case. To reflect this, we

have maintained our previous assumptions based on sufficient funding being in place to support the commercial operations adequately. However, to this clean operational scenario we have added a further risk probability to present the possibility that the necessary funds will not be available in a timely manner.

In order to maintain the desired transparency in our modelling we show two valuation figures for each business unit: the first is based on the commercial outcomes we would expect if funding were not an issue; and the second introduces a risk adjustment for the current funding uncertainties. Obviously, assuming the funding picture becomes clearer, the second valuation figure should converge with the first valuation over time.

Full risk adjusted DCF-based valuation of €10.5m or €3.23/share

NBT MDD is the largest element, with the “commercial” valuation being \$21.5m, but reducing to €7.5m when we overlay our “financial risk” adjustment. The NBS diagnostic unit is valued at €6.2m and reduces to €2.2m after risk adjustment. Similarly, the NBT Pain indication is valued at €5.4m and €1.9m respectively. Obviously, the net cash/debt position remains at -€1.1m under both scenarios. This results in our valuation for the company being €10.5m, which is equivalent to €3.23/share and also €3.23/share diluted (based on in-the-money options and warrants). This compares to €32.0m or €10.5/share were the financial risk removed. For context, our previously published valuation was €35.9m or €11.04/share and €10.30/share diluted.

It is worth highlighting that we always seek to 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 clinical assets with potential supplementary clinical indications and off-label usage excluded. Additionally, as before, we have also sought to account for the known dilution from the outstanding warrants and options.

Execution of commercialisation plans depend on funds raised

Nexstim had net cash of around €1.1m at December 2018 which, despite the cessation of clinical work on stroke and other cost cutting, means the need for funding is pressing in our view. Although still unclear, our forecasts (based on the Kreos loan facility being in place) suggest that Nexstim needs around €6m 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 3: Summary of financials

Year-end: December 31	€'000s	2015	2016	2017	2018	2019E	2020E
INCOME STATEMENT							
Revenues		2,528	2,483	2,645	2,672	4,031	6,046
Cost of goods sold		(821)	(689)	(552)	(710)	(803)	(1,120)
Gross Profit		1,707	1,794	2,093	1,962	3,228	4,927
Wages and salaries		(3,292)	(3,602)	(2,903)	(3,353)	(4,204)	(4,835)
Social security expenses		(677)	(651)	(431)	(584)	(736)	(846)
Other expenses		(7,843)	(3,908)	(4,118)	(3,986)	(4,385)	(4,604)
Depreciation & amortisation		(386)	(372)	(341)	(424)	(425)	(610)
Underlying operating profit		(10,492)	(6,739)	(5,701)	(6,386)	(6,521)	(5,968)
Other revenue/expenses		122	43	109	70	70	70
EBITDA		(9,984)	(6,324)	(5,251)	(5,892)	(6,027)	(5,288)
Operating Profit		(10,370)	(6,696)	(5,592)	(6,316)	(6,451)	(5,898)
Financial income		544	(34)	(1,733)	163	(245)	(171)
Profit Before Taxes		(9,826)	(6,730)	(7,325)	(6,153)	(6,696)	(6,070)
Adj. PBT		(9,948)	(6,774)	(7,434)	(6,223)	(6,766)	(6,140)
Current tax income		(1)	(2)	(3)	(2)	(4)	(6)
Net Income		(9,827)	(6,733)	(7,328)	(6,154)	(6,700)	(6,076)
EPS (€)		(41.20)	(16.90)	(2.77)	(1.93)	(2.06)	(1.87)
Adj. EPS (€)		(41.72)	(17.01)	(2.81)	(1.93)	(2.06)	(1.87)
DPS (€)		0.00	0.00	0.00	0.00	0.00	0.00
Average no. of shares (m)		0.2	0.4	2.6	3.2	3.3	3.3
<i>Gross margin</i>		68%	72%	79%	73%	80%	81%
<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	8,757	6,858	15,335
Cash and cash equivalents		6,875	8,156	8,474	7,175	4,364	12,298
Accounts receivable		937	1,057	1,465	1,324	1,988	2,485
Inventories		421	292	387	259	506	552
Other current assets		0	0	0	0	0	0
Non-current assets		974	911	718	905	1,498	2,029
Property, plant & equipment		333	249	167	465	669	936
Intangible assets		631	652	541	430	820	1,083
Current liabilities		(2,417)	(2,137)	(1,786)	(2,793)	(8,187)	(23,271)
Short-term debt		0	0	0	(1,104)	(6,104)	(21,104)
Accounts payable		(1,084)	(397)	(961)	(597)	(990)	(1,074)
Other current liabilities		(1,332)	(1,740)	(824)	(1,092)	(1,093)	(1,094)
Non-current liabilities		(3,245)	(3,802)	(3,737)	(7,163)	(7,163)	(11,163)
Long-term debt		(3,197)	(3,778)	(3,724)	(7,163)	(7,163)	(11,163)
Other non-current liabilities		(47)	(24)	(13)	0	0	0
Equity		3,545	4,478	5,521	(294)	(6,994)	(13,070)
Share capital		23,662	31,773	38,599	39,561	39,561	39,561
Other		(20,117)	(27,294)	(33,078)	(39,855)	(46,555)	(52,631)
CASH FLOW STATEMENTS							
Operating cash flow		(9,609)	(7,225)	(5,403)	(6,192)	(6,793)	(5,925)
Profit before tax		(9,827)	(6,733)	(7,328)	(6,154)	(6,700)	(6,076)
Non-cash adjustments		432	(106)	3,618	(361)	669	782
Change in working capital		330	(411)	(1,555)	721	(515)	(454)
Interest paid		(544)	25	(138)	(398)	(245)	(171)
Taxes paid		0	0	0	0	(3)	(6)
Investing cash flow		(380)	(310)	(148)	(611)	(1,018)	(1,142)
CAPEX		(380)	(310)	(148)	(611)	(1,018)	(1,142)
Other investing cash flows		0	0	0	0	0	0
Financing cash flow		5,380	8,817	5,868	5,505	5,000	15,000
Proceeds from equity		5,280	7,700	6,765	962	0	0
Increase in loans		100	1,117	(897)	4,543	5,000	15,000
Other financing cash flow		0	0	0	0	0	0
Net increase in cash		(4,609)	1,282	318	(1,298)	(2,811)	7,934
Exchange rate effects		0	0	0	0	0	0
Cash at start of year		11,484	6,875	8,156	8,474	7,176	4,364
Cash at end of year		6,875	8,156	8,474	7,176	4,364	12,298
Net cash at end of year		3,677	4,378	4,750	(1,092)	(8,903)	(19,969)

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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