Trinity Delta

Nexstim

Update

A possible new opportunity in severe depression

9 October 2019

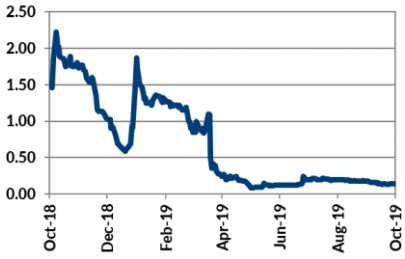
Nexstim is progressing with plans to fully exploit the promise of its SmartFocus TMS system in major depressive disorder (MDD). It recently announced that discussions are underway with a leading California-based academic institution to license their technology to treat hospitalised patients with severe depression who may be suicidal. While disclosure is limited, management have stated that this tie-up could open a new TMS market for treatment resistant depression that is distinct from the current out-patient MDD opportunity. If Nexstim's NBT TMS system is approved for severe MDD, competition in this market is likely to be limited due to the need for accurate targeting. Based on conservative assumptions, we estimate this could be worth €0.23/share (fully diluted) on top of our current €0.41/share valuation.

Year-end: December 31	2017	2018	2019E	2020E
Sales (€m)	2.6	2.7	3.4	5.4
PBT (€m)	(7.3)	(6.2)	(7.0)	(6.4)
Net Income (€m)	(7.3)	(6.2)	(7.1)	(6.4)
EPS (€)	(2.77)	(1.93)	(0.36)	(0.13)
Cash* (€m)	8.5	7.2	4.1	5.8
EBITDA (€m)	(5.3)	(5.9)	(6.1)	(5.3)

Source: Trinity Delta Note: *Our cash forecast assumes that all the warrants issued with the rights issue are exercised at €0.115 raising €1.8m in Q419 and Nexstim raises an additional €10m in FY20.

- **NBT provides an edge over the competition** The key differentiating feature of Nexstim's NBT platform is that it is the only FDA approved TMS (transcranial magnetic stimulation) device with built-in navigation, enabling accurate and reproducible treatment. This precision is critical to delivering improved patient outcomes and supports Nexstim's strategy of driving NBT revenues from MDD. It is also likely to be the reason that the Californian academic institution is interested in collaborating with Nexstim, rather than with one of its competitors.
- **TMS yet to be approved for severe MDD** In the US, c 6m MDD patients are considered treatment resistant and use of repetitive TMS (rTMS) is an accepted second-line therapy. However, it is not yet approved for the treatment of severe MDD with possible suicidal ideation, partly because the treatment course is too long. A shorter, more intense TMS treatment protocol – which we believe could be the goal of the proposed licencing transaction - could lend itself to this setting.
- **Hospitals represent a major new TMS opportunity** In the US, c 160k patients/year are currently treated across c 650 hospitals, and in-patient psychiatric therapy for MDD is reimbursed. The main treatments used currently are electroconvulsive therapy (ECT) and ketamine-based medications, both of which have limitations. If a short and effective TMS protocol can be developed, it could become an important treatment modality for major depressive events.
- **Core valuation of €0.41/share with significant upside potential** Our core valuation of Nexstim is €19.0m or €0.41/share diluted (in the money options or warrants only). This valuation could be materially increased should Nexstim secure a deal with the Californian academic partner; our calculations suggest it could be conservatively worth €0.23/share (fully diluted) on an rNPV basis.

Price	€0.14
Market Cap	€5.0m
Enterprise Value	€6.6m
Shares in issue	35.4m
12 month range	€0.07-2.40
Free float	86.5%
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: A significant new opportunity

Prioritising the commercial opportunity in MDD

Nexstim's commercial priority is fully exploiting the market potential of its highly accurate TMS (Transcranial Magnetic Stimulation) system as a treatment for major depressive disorder (MDD). Its Navigated Brain Therapy (NBT) platform was approved for MDD in December 2017 and launched in the US in May 2018. Recent activities have been focused on two main areas:

- **Raising market awareness of its NBT system:** A key driver of uptake is the growing understanding of the NBT value proposition in terms of both improved patient outcomes and economic benefits to clinicians. Growth in patient registry data in MDD (including a comparative element with non-navigated systems) as well as case reports (such as the recent Island Psychiatry white paper) will supplement the body of clinical outcomes evidence and should support a shift from existing treatment practices and increase adoption of NBT.

Improvements in technology/ process could open new market opportunities

- **Technology/process improvements**: Investment in technology or process development has the goal of improving patient outcomes and/or the economics benefits. For example, NBT has been cleared by the FDA for treatment of MDD utilising various treatment paradigms including the 37-minute standard, and shorter 3-minute ThetaBurst and 19-minute Dash protocols. Incorporation of alternative treatment protocols could expand the addressable patient population, opening additional market opportunities. We believe the potential licencing transaction with the California-based academic institution could be an example of the latter.

Valuing the potential new hospital market opportunity

Limited disclosures about partner or potential…

Nexstim has understandably made limited disclosures about the potential market opportunity presented by the possible combination of its NBT TMS technology with that of the Californian academic institute. However, we have used publicly available information to assess the value of this potential opportunity for Nexstim.

…but US opportunity would cover 160k severe MDD patients across 650 hospitals annually

We understand that the target patient population is treatment resistant patients with severe depression, who may have suicidal ideation, and have been hospitalised. As this patient group is treated in hospitals (either psychiatric hospitals, or those with inpatient psychiatric units) it is distinct from the subset of MDD patients treated in outpatient clinics where NBT is currently available. Nexstim have indicated, in the press release, that the US market opportunity would cover c650 hospitals treating an estimated 160k patients annually.

Shorter, more intensive TMS protocols would be more applicable to the hospital setting

We note that no TMS device has been FDA approved for patients with 'suicide plan or recent suicide attempt'. TMS used in the out-patient setting has a long duration of treatment, typically for 5 days per week over 6 weeks, which means it is not suitable for suicidal MDD patients. Hospital in-patients with severe MDD and possibly suicidal ideation are treated with either anti-depressant drugs, electroconvulsive therapy (ECT), or ketamine. However, it is common for MDD patients admitted to hospital to be refractory to one or more pharmacologic treatments. For rTMS to become more applicable to the hospital setting, a shorter albeit more intensive treatment protocol is needed.

Compelling patient and economic benefits would support adoption

In addition to potential patient benefit (increased remission rate or duration of remission, and better safety/profile), there may be a compelling healthcare economics benefit from TMS therapy in hospitals. Currently, DRG reimbursement for this patient group is 17 hospital days, according to Nexstim. Any therapeutic modality with a shorter treatment period than this would provide a financial incentive to hospitals for adoption, in addition to the economic and patient benefits from enabling more patients to be treated over a specific timeframe.

Severe/suicidal MDD treated in hospitals could be worth an additional €0.23/share

On the basis of the key assumptions laid out in Exhibit 1, if we also assume Nexstim ultimately captures 20% of the market (equivalent to annual peak sales of €46m) following launch of the new protocol in 2023 and generates €100,000 per NBT system/year (in line with our underlying assumption for our core valuation model), we calculate that the value of the potential hospital opportunity for the company could be worth an additional €0.23/share on an rNPV basis. Summary valuation outputs are shown in Exhibit 2.

Exhibit 1: Key assumptions in valuation model

Input	Assumption
No. of patients/year	160,000
Current Medicare reimbursement/session	$250
No. sessions/patient	30
No. sessions/day/hospital	10
Revenue per NBT system per annum	€100,000
Peak market penetration by NBT	20%
Likelihood of NBT being approved in severe MDD	40%
Launch year	2023

Source: Trinity Delta, Nexstim, Note: in the out-patient setting, patients currently receive TMS once a day (5 sessions per week) for 4-6 weeks. We assume that the clinical trial costs will largely be borne by the academic institution.

Exhibit 2: Valuation summary of potential Nexstim licensing transaction

	Value
Total market opportunity	$1.2bn
Nexstim market opportunity	$213m
NPV of Nexstim opportunity	€31.0m
rNPV of Nexstim opportunity	€12.4m
NPV/share (fully diluted)	€0.59
rNPV/share (fully diluted)	€0.23

Source: Trinity Delta Note: cost of capital of 12.5%; EUR/USD exchange rate of 0.9.

Various factors could increase the potential value to Nexstim

We believe this indicative valuation of the hospital opportunity in the US errs on the side of conservatism. It is solely based on the placing and use of NBT systems in hospitals. 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. We also highlight that this valuation relates to the primary treatment in hospitals only; it does not capture any additional revenue that may be generated by maintenance therapy of these same patients in the outpatient setting.

Nexstim likely to face limited competition in hospital based TMS…

Assuming NBT is approved for the treatment of severe MDD in hospitals, it is important to note that any competition Nexstim may face is likely to be limited. A high intensity TMS treatment protocol would probably require the accurate and reproducible stimulation of the appropriate part of the brain (the dorsolateral prefrontal cortex, DLPFC) by the TMS system. Other TMS instruments approved for the treatment of treatment resistant MDD in the out-patient setting, such as those from Neuronetics or BrainsWay, rely on the "5cm rule" (see August 2019 Update) and so are only able to identify the approximate position of the DLPFC.

…due to its superior precision vs other TMS systems

In contrast, Nexstim's 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. This means NBT can target the DLPFC (dorsolateral prefrontal cortex) 100% of the time vs 30% with other TMS approaches. This precision is the probable explanation for the interest from the leading California-based academic institution in a collaboration with Nexstim.

Our base case Nexstim valuation remains €0.41/share

Our base case Nexstim valuation, including a financial risk adjustment, is €19.0m or €0.54/share or €0.41/share diluted (in the money options or warrants only). Full details of our valuation methodology are provided in our August 2019 Update.

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**	**3,411**	**5,401**
Cost of goods sold		(821)	(689)	(552)	(710)	(807)	(988)
Gross Profit		**1,707**	**1,794**	**2,093**	**1,962**	**2,604**	**4,413**
Wages and salaries		(3,292)	(3,602)	(2,903)	(3,353)	(3,838)	(4,274)
Social security expenses		(677)	(651)	(431)	(584)	(714)	(748)
Other expenses		(7,843)	(3,908)	(4,118)	(3,986)	(4,197)	(4,715)
Depreciation & amortisation		(386)	(372)	(341)	(424)	(407)	(609)
Underlying operating profit		**(10,492)**	**(6,739)**	**(5,701)**	**(6,386)**	**(6,551)**	**(5,934)**
Other revenue/expenses		122	43	109	70	66	66
EBITDA		**(9,984)**	**(6,324)**	**(5,251)**	**(5,892)**	**(6,078)**	**(5,258)**
Operating Profit		**(10,370)**	**(6,696)**	**(5,592)**	**(6,316)**	**(6,485)**	**(5,868)**
Financial income		544	(34)	(1,733)	163	(560)	(572)
Profit Before Taxes		**(9,826)**	**(6,730)**	**(7,325)**	**(6,153)**	**(7,046)**	**(6,439)**
Adj. PBT		**(9,948)**	**(6,774)**	**(7,434)**	**(6,223)**	**(7,112)**	**(6,505)**
Current tax income		(1)	(2)	(3)	(2)	(8)	(5)
Net Income		**(9,827)**	**(6,733)**	**(7,328)**	**(6,154)**	**(7,053)**	**(6,445)**
EPS (€)		**(41.20)**	**(16.90)**	**(2.77)**	**(1.93)**	**(0.36)**	**(0.13)**
Adj. EPS (€)		**(41.72)**	**(17.01)**	**(2.81)**	**(1.93)**	**(0.36)**	**(0.13)**
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	28.1	51.5
Gross margin		*68%*	*72%*	*79%*	*73%*	*76%*	*82%*
EBITDA margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
Underlying operating margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET							
Current assets		**8,233**	**9,506**	**10,326**	**8,757**	**6,271**	**9,057**
Cash and cash equivalents		6,875	8,156	8,474	7,175	4,081	5,771
Accounts receivable		937	1,057	1,465	1,324	1,682	2,663
Inventories		421	292	387	259	508	623
Other current assets		0	0	0	0	0	0
Non-current assets		**974**	**911**	**718**	**905**	**1,350**	**2,073**
Property, plant & equipment		333	249	167	465	645	1,266
Intangible assets		631	652	541	430	696	797
Current liabilities		**(2,417)**	**(2,137)**	**(1,786)**	**(2,793)**	**(3,120)**	**(3,073)**
Short-term debt		0	0	0	(1,104)	(1,456)	(1,456)
Accounts payable		(1,084)	(397)	(961)	(597)	(995)	(948)
Other current liabilities		(1,332)	(1,740)	(824)	(1,092)	(669)	(669)
Non-current liabilities		**(3,245)**	**(3,802)**	**(3,737)**	**(7,163)**	**(6,537)**	**(6,537)**
Long-term debt		(3,197)	(3,778)	(3,724)	(7,163)	(6,537)	(6,537)
Other non-current liabilities		(47)	(24)	(13)	0	0	0
Equity		**3,545**	**4,478**	**5,521**	**(294)**	**(2,035)**	**1,520**
Share capital		23,662	31,773	38,599	39,561	44,947	54,947
Other		(20,117)	(27,294)	(33,078)	(39,855)	(46,983)	(53,427)
CASH FLOW STATEMENTS							
Operating cash flow		**(9,609)**	**(7,225)**	**(5,403)**	**(6,192)**	**(7,354)**	**(6,977)**
Profit before tax		(9,827)	(6,733)	(7,328)	(6,154)	(7,053)	(6,445)
Non-cash adjustments		432	(106)	3,618	(361)	894	1,181
Change in working capital		330	(411)	(1,555)	721	(526)	(1,137)
Interest paid		(544)	25	(138)	(398)	(665)	(572)
Taxes paid		0	0	0	0	(4)	(5)
Investing cash flow		**(380)**	**(310)**	**(148)**	**(611)**	**(853)**	**(1,333)**
CAPEX		(380)	(310)	(148)	(611)	(853)	(1,333)
Other investing cash flows		0	0	0	0	0	0
Financing cash flow		**5,380**	**8,817**	**5,868**	**5,505**	**5,113**	**10,000**
Proceeds from equity		5,280	7,700	6,765	962	5,387	10,000
Increase in loans		100	1,117	(897)	4,543	(274)	0
Other financing cash flow		0	0	0	0	0	0
Net increase in cash		**(4,609)**	**1,282**	**318**	**(1,298)**	**(3,094)**	**1,690**
Exchange rate effects		0	0	0	0	0	0
Cash at start of year		11,484	6,875	8,156	8,474	7,175	4,081
Cash at end of year		**6,875**	**8,156**	**8,474**	**7,176**	**4,081**	**5,771**
Net cash at end of year		**3,677**	**4,378**	**4,750**	**(1,092)**	**(3,912)**	**(2,222)**

Source: Nexstim, Trinity Delta Note: The accounts are produced according to Finnish GAAP. In FY19, we assume that all the warrants associated with the May 2019 capital raise are exercised in November at a strike price of €0.115 and the short-term debt in 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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