Trinity Delta

Nexstim

Update

Hitting the right spot

22 May 2020

Nexstim's proprietary navigated transcranial magnetic stimulation (TMS) technology is at the core of its strategic review. Its accuracy, reliability, and reproducible effects are the key advantages and differentiating features vs the competition. These enable it to carve out a niche as a personalised and effective therapy (NBT) and diagnostic (NBS) for challenging brain disease and disorders. Nexstim's proposed €2.2m rights issue will strength its balance sheet and provide the resources to continue to support its existing NBS and NBT businesses, and invest in pilot studies to explore potentially highly lucrative new opportunities in severe depression and chronic neuropathic pain. The COVID-19 pandemic has prompted cost saving measures, although Nexstim's business remains resilient with a solid NBS installed base, flexible pricing models, and opportunities within NBT. Our Nexstim valuation is €31.2m (€0.50/share) valuation.

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)	(4.8)	(5.2)
Net Income (€m)	(6.2)	(6.8)	(5.7)	(5.1)
EPS (€)	(1.93)	(0.25)	(0.07)	(0.08)
Cash* (€m)	7.2	4.3	8.9	3.2
EBITDA (€m)	(5.9)	(6.0)	(3.9)	(4.1)

Source: Trinity Delta Note: *Our cash forecast assumes additional raises of €10m in FY20 and €5 in FY21

- **Expanding horizons for NBT** The COVID-19 pandemic will dampen the NBT commercial trajectory, with the near-term focus now on leveraging the current installed base of 23 active systems at end-2019 and recurring therapy revenues (66%). Funds from the proposed raise will be directed to pilot studies that explore the wider potential of NBT in treating hospitalised severe MDD patients who may have suicidal ideation, and in chronic neuropathic pain. No TMS system is approved yet for the former indication: NBT is well suited given intensive treatment protocols (such as the Stanford SAINT) and the need for accurate targeting.
- **NBS a stable revenue base in turbulent times** Commercial traction with NBS remains strong. The large global installed base of c 170 systems at world leading cancer centres means the NBS consumables and related sales provide a solid core of recurring high margin revenues. Capital sales may be impacted by COVID-19, but given the role of NBS in pre-surgical mapping, this is less of a discretionary spend.
- **Prudent cost control and investment** The impact of, and response to, COVID-19 means FY20 will deliver a lower operating loss than FY19. Cost savings should realise c €0.8m in April-June alone, which coupled with the cancellation of €0.9m in Business Finland R&D loans means Nexstim is funded to end-Q320. The €2.2m (net) rights issue will support investment into sales, product development, and clinical research, as well as general working capital and corporate purposes.
- **Valuation maintained at €0.50/share** Our DCF-based rNPV model ascribes a value of €31.2m or €0.50/share to Nexstim, with room for material upside from strategic execution such as growth or expansion of the MDD market opportunity for NBT. We intend to update our valuation for the impact of the rights issue once it closes.

Price	€0.02
Market Cap	€1.25m
Enterprise Value	€3.25m
Shares in issue	62.8m
12 month range	€0.02-0.22
Free float	39.5%
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: navigating towards a better future

Nexstim is focussed on exploiting the commercial potential of its SmartFocus NBT therapeutic system in major depressive disorder (MDD). Commercial traction with NBT is gaining momentum, despite the COVID-19 impacts, as market awareness of the proven clinical and economic benefits continues to rise. Clinical outcome data from the first 55 MDD patients to complete a therapy course show 40% of patients achieved remission and 71% a clinical response. Published data on the novel Stanford accelerated iTBS protocol suggest that this is ideally suited to NBT's accurate and reproducible targeting and could extend NBT's use into in-patient hospital treatment. The NBS pre-surgical mapping system continues to grow, showing strong resilience in challenging COVID-19 times. The rights issue, targeting a €2.2m raise, would bolster the balance sheet, support the NBS and NBT installed bases, and fund new pilot clinical trials in severe (suicidal) depression and chronic neuropathic pain.

Two related but distinct applications for nTMS platform

Nexstim's nTMS (Navigated Transcranial Magnetic Stimulation) platform's primary differentiation against competing TMS systems is the in-built SmartFocus navigation. This highly accurate mapping ensures rapid, reliable, and reproducible treatment. The clinical benefit is seen as proven improved patient outcomes, with faster treatment times resulting in material cost advantages for the operator. The commercial strategy presently addresses two related, albeit technically separate, indications: Diagnostics and Therapeutics. 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, notably in major depressive states.

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 170 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

NBS provides a dependable, high-margin revenue stream

NBS is ideally positioned for pre-surgical brain mapping

The value of NBS in pre-surgical mapping (PSM) of the brain ahead of, typically, tumour removal is acknowledged and results in impressive survival benefits as surgeons can be more aggressive in their tumour resections. NBS is the only nTMS system that is FDA cleared and CE marked for the PSM of the speech and motor cortices of the brain. The commercial traction has remained strong, with the global installed base now being c 170 systems, including world-renowned cancer centres such as Mayo Clinic, Karolinska, MD Anderson, Charité, Great Ormond Street Hospital, and UCSF.

The NBS system pricing of c €200k-300k (dependent on functionality and support equipment) makes it a capital purchase for most buyers. Hence, the sales cycle is

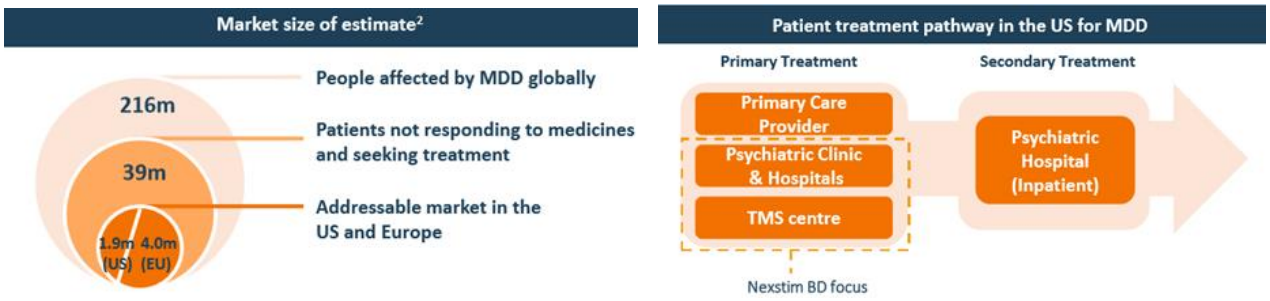
longer than an equivalent NBT system, with the clinical decision maker (typically a neurosurgeon) preparing a case that is subject to a thorough budgetary review. The COVID-19 pandemic has understandably impacted these capital sales, however the large installed base means that NBS consumables and related sales provide a solid core of recurring high-margin revenues. Management's clear near-term aim is to focus on the commercialisation of NBT in depression, but NBS will maintain its technical and sales/marketing support as it remains an attractive business with solid medium- and longer-term growth prospects.

NBT addresses sizeable therapeutic opportunities

NBT is for the higher growth therapeutic applications

The therapeutic use of TMS is a substantially larger market opportunity, with Nexstim actively addressing major depressive disorders and chronic pain. The decision to focus on depression, particularly Major Depressive Disorder (MDD), is driven by several important clinical and commercial considerations. Depression remains one of the most widespread and debilitating forms of mental illness despite major pharmacological advances. Treatment resistant depression (ie that unresponsive to pharmacological anti-depressant medication) has a current addressable market of c 6m patients (c 1.9m US and c 4.0m Europe) and is growing rapidly. Use of rTMS is increasingly accepted as a viable second-line therapy and it is commonly reimbursed in the US and various European countries.

Exhibit 2: Nexstim business opportunity in major depressive disorder



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

Impressive remission rates in difficult to treat patients

In depression, the activity of the left dorsolateral prefrontal cortex (DLPFC) is abnormally low. The DLPFC is associated with cognitive or executive functions, such as the maintenance of working memory, intention formation, goal-directed action, abstract reasoning, attentional control, and emotion. The use of rTMS in MDD allows for stimulation of the left DLPFC of the brain without the seizures or risks associated with electroconvulsive therapy (ECT), nor the potential side effects and risks of pharmacological augmentation strategies, such as monoamine oxidase inhibitor (MAOI) therapy. Remission rates are 30-40% and the effect duration is comparable with other interventions and medications. Importantly, rTMS is a simple and straightforward outpatient treatment so can be used in an office setting, without any need for anaesthesia or fear of serious adverse effects.

Latest real-world data confirms the clinical benefits

In April 2020 Nexstim reported positive clinical outcomes data from the first 55 patients to complete treatment with its NBT 2 System for MDD at US clinical sites. The patient registry data showed NBT treatment resulted in better than typical clinical outcomes. Of the 55 patients completing treatment, 22 (40%) achieved clinical remission and 39 (71%) a clinical response at the end of their treatment. This compares very favourably with remission rates of 26.5% to 28.7% and response rates of 41.5% to 56.4% with rTMS in MDD as reported in a 307-

patient multi-site study. In addition, patients reported that the NBT treatment process was generally very positive, with a mean 8.7/10 score. This is encouraging given the implications for patient retention and the likely completion of treatment courses in a difficult patient group such as MDD.

Better and consistent targeting is the key differentiator

Nexstim's NBT is well placed in this segment as it can target the DLPFC 100% of the time vs 30% with other TMS approaches. The competing systems typically depend on a simplistic anatomical approach - the '5cm rule' - and so are subject to significant inter-patient variability, and achieving consistently accurate positioning over repeated imaging procedures has been problematic. The first FDA approved treatment used a standard 37.5-minute protocol. Shorter therapy protocols have since been approved, including the three-minute ThetaBurst (a patterned form of rTMS that requires less time and lower intensity to administer) and the 19-minute Dash (involving shorter periods between pulse sequences, thus compressing the overall treatment time). During 2019, Nexstim secured FDA approvals for these shorter therapy protocols to be used with NBT.

Business model targets high annual revenue per system

Nexstim's NBT business model targets a high annual revenue stream per system (€100k in active established customer sites) with high utilisation rates. There were 23 NBT systems installed and operating at end-December 2019, with an average 12-month therapy revenue per NBT system of €85k (up from €81k at Q319). Management believes it can achieve its target through its flexible pricing models, which include pay-per-use leasing, monthly unlimited use leasing, or capital sale (with additional fees from head tracker sales and servicing). Interestingly, the company has found that, prior to COVID-19 effects, the NBT sales cycle in MDD is more rapid than NBS due to this pricing flexibility.

Stanford innovative approach widens possibilities

Stanford protocol opens up a whole new application

The Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) proposal is an accelerated, high-dose MRI–guided iTBS protocol for treatment-resistant depression that was recently published in The American Journal of Psychiatry. An impressive 19 of 22 patients evaluated (86.4%) achieved clinical remission, with no notable side-effects (including no cognitive impairment). Further double-blinded sham-controlled trials are required to confirm these initial findings but, if confirmed, this would introduce wider rTMS usage into the in-patient psychiatric hospital setting. The three key elements of the approach are employing multiple treatment sessions per day, applying a higher overall pulse dose of stimulation, and, importantly, the precision targeting of the DLPFC to the subgenual anterior cingulate cortex (sgACC) circuit.

Nexstim's NBT appears well placed to benefit from this approach. It is the proven ability of the NBT system to accurately and reproducibly stimulate a desired area of the DLPFC that is a key differentiator over other TMS systems. As patients with treatment resistant MDD who may have suicidal ideation are 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 management has indicated that the US market opportunity would cover c 650 hospitals treating an estimated 160k patients annually. Funding permitting, the plan is to explore pilot clinical studies using these innovative accelerated treatment protocols in various forms of severe

depression, including suicidal MDD patients. As yet no TMS device has been approved by the FDA for patients with 'suicide plan or recent suicide attempt'.

Exhibit 3: Nexstim business opportunity in MDD

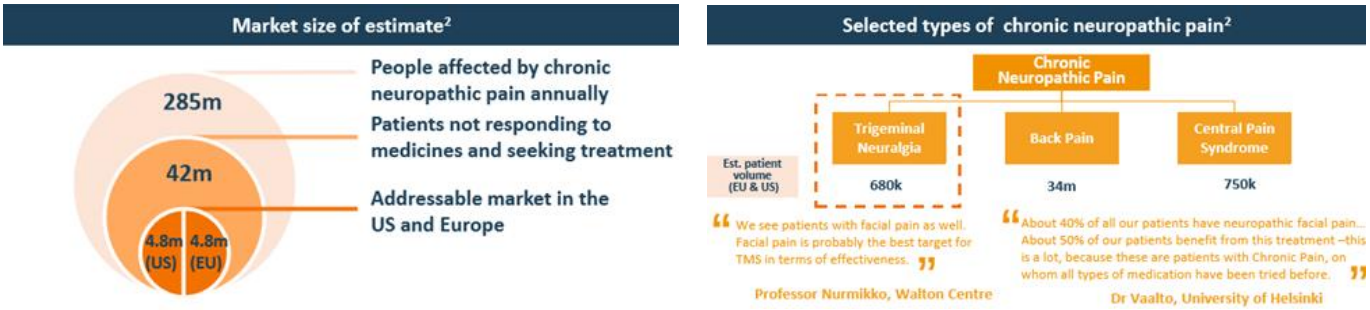
Source: Nexstim

Chronic pain is an under-rated prospect

Chronic pain is an obvious segment to develop more fully

Understandably, Nexstim is prioritising investment into fully exploiting the NBT opportunity in MDD. However, the treatment of chronic neuropathic pain is the largest market segment in the neuromodulation market, with around 10m addressable patients in the US and Europe. The lack of effective pain relief for a large proportion of patients, coupled with the growing awareness of the issue of opioid misuse and addiction, means new therapeutic modalities are actively being sought. Five Finnish university hospitals are already using NBT to treat depression and pain and a management objective is to widen this into other geographies.

Exhibit 4: Nexstim business opportunity in chronic neuropathic pain



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

NBT is CE Marked, but no TMS system is FDA approved in pain

Exhibit 4 summarises the potential addressable market for Nexstim's NBT system. NBT is CE Marked for chronic neuropathic pain, but the FDA is yet to approve any rTMS device for this indication, which largely reflects the fact that no large, multi-centre, randomised clinical trials have to date been undertaken by any manufacturer. An exploratory 39-patient Phase II study at The Walton Centre, Neuroscience Research Centre, Liverpool (detailed in our Initiation) delivered encouraging results, prompting Nexstim to evaluate potential clinical trials for neuropathic and related chronic pain. Due to ongoing resource constraints, clinical development in chronic pain is currently lower priority, despite the potential. Again, given suitable funding, management aims to explore performing pilot trials in chronic neuropathic pain.

Valuation

DCF model gives a valuation of €31.2m or €0.50 per share

We value Nexstim using a risk-adjusted DCF-based model for the cash flows for each of the business areas and employ conservative assumptions regarding patient populations, market sizes and growth rates, net pricing, adoption curves, and peak market penetration. The risk adjustments range from a success probability of 100% for pre-surgical mapping to 25% for the early-stage pain indication. This yields a company valuation of €31.2m (€0.50/share). Within this the NBS (Diagnostics) operation is valued at €4.2m, the NBT (Therapy) depression indication forms the bulk of the value and is worth €24.6m, and the NBT in chronic pain indication is a modest €4.4m.

Funding issues add a further layer of risk adjustment

As detailed in our January 2020 Outlook note, Nexstim has made considerable progress in strengthening its balance sheet, although a degree of financial uncertainty remains and continues to weigh on the share price. We continue to base our modelling assumptions on adequate funding being in place to support the commercial operations; however, to this clean operational scenario we apply a further risk probability to present the possibility that the necessary funds will not be available in a timely manner.

Exhibit 5: DCF-based valuation of Nexstim

	Total NPV (€m)	Success probability	rNPV (€m)	rNPV/ share (€)	Financial rNPV (€m)	Financial rNPV / share (€)	Notes
NBS	5.6	100%	5.3	0.09	4.2	0.07	Peak sales: €4.1m. Launch year: N/A
NBT in MDD	32.8	100%	32.8	0.52	24.6	0.39	Peak sales: €22.4m. Launch year: FY18
NBT in Chronic Pain	23.6	25%	5.9	0.09	4.4	0.07	Peak sales: €25.8m. Launch year: FY23
Net cash	(2.0)		(2.0)	(0.03)	(2.0)	(0.03)	Net cash at FY19
Total (undiluted)	**62.8**		**42.3**	**0.67**	**31.2**	**0.50**	
Discount rate				12.5%			
Tax rate				20%			From 2026
Financial risk adjustment				75%			
Terminal growth rate				2%			From 2035

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

Two values shown for each element to highlight impact

To maintain modelling transparency, we show two valuation figures for each business unit: the first is based on the commercial outcomes we would expect in the absence of funding concerns; with the second introducing a risk adjustment for the current funding uncertainties. As the funding picture becomes clearer, the second valuation figure should converge with the first valuation over time.

Valuation rises to €42.3m if financial position improves

Exploring the difference this makes we can see the effects this has. NBT MDD has a "commercial" valuation of €32.8m that reduces to €25.4m when we overlay our "financial risk" adjustment. The NBS diagnostic unit is valued at €5.6m, reducing to €4.2m after risk adjustment. Similarly, the NBT Pain indication is valued at €5.9m and €4.4m. This results in a company valuation of €31.2m (€0.50/share), compared to €42.3m (€0.67/share) were the financial risk removed.

Post the November 2019 warrant exercise, there are no outstanding in the money options or warrants.

Financials

Solid commercial performance shown in FY19

FY19 results saw net revenues grow by 25% from €2.67m to €3.35m, with NBT revenues up 131% from €650.9k to €1.52m. The NBT therapy system installed base grew to a total of 23 systems, with 10 in the US and 13 in Europe and RoW. Recurring revenue was 66% of the total therapy revenue, and the average therapy revenue per NBT system rose to €85k. The operating loss widened slightly from €6.32m to €6.52m, driven mainly by the recruitment of commercial staff in the US. The net loss also widened, from €6.19m to €6.68m; however, due to the €6.6m equity raise during 2019, the loss per share fell from €1.92 to €0.25.

Extensive COVID-19 cost savings plan implemented

Management have indicated that they expect FY20 to deliver a lower full year operating loss vs FY19. Revenues growth is likely to be lower due to COVID-19 and the cost saving measures enacted in response to the pandemic should result in a decrease in operating costs during FY20, with savings of around €0.8m expected during the April to June period alone, and a consequent reduction in the reported loss. These, together with Business Finland cancelling its €0.9m R&D loans, means there is sufficient working capital until the end of Q320.

€2.3m rights issue is currently underway

Equity raise to support commercial expansion plans

Nexstim announced a €2.3m gross (€2.2m net) subscription rights issue, with pre-emptive rights, in May. The proceeds will be used to support the existing NBS pre-surgical mapping business by ensuring installed based service business; support NBT business revenue growth mainly via better utilisation of the existing NBT system installed base; repay existing loans; and start new pilot clinical trials which may include new accelerated treatment protocols in both severe (suicidal) depression and chronic neuropathic pain. The clinical data is particularly relevant as, if as positive as expected, should improve the NBT system's market positioning and provide compelling differentiation over competing TMS systems.

Major shareholders have indicated support

A maximum of 376,719,780 new offer shares may be issued. Current shareholders will receive one subscription right for each share held, which entitles the holder to subscribe for six offer shares at a price of €0.006 or SEK0.06 per offer share. The subscription period ends on 27 May in Finland and 25 May in Sweden. Subscription commitments for €0.634m (c 28% of the offer) have been made by major shareholders Capricorn Healthtech Fund, Kaikarhenni Oy and Ossi Haapeniemi (with related party companies), together with certain board members and management of Nexstim.

Exhibit 6: Summary of financials

Year-end: December 31	€'000s	2017	2018	2019	2020E	2021E
INCOME STATEMENT						
Revenues		**2,645**	**2,672**	**3,348**	**3,686**	**6,589**
Cost of goods sold		(552)	(710)	(1,043)	(722)	(1,166)
Gross Profit		**2,093**	**1,962**	**2,305**	**2,963**	**5,422**
Wages and salaries		(2,903)	(3,353)	(3,998)	(2,998)	(4,797)
Social security expenses		(431)	(584)	(715)	(525)	(816)
Other expenses		(4,118)	(3,986)	(3,648)	(3,283)	(3,939)
Depreciation & amortisation		(341)	(424)	(525)	(562)	(816)
Underlying operating profit		**(5,701)**	**(6,386)**	**(6,580)**	**(4,405)**	**(4,946)**
Other revenue/expenses		109	70	63	63	63
EBITDA		**(5,251)**	**(5,892)**	**(5,993)**	**(3,780)**	**(4,067)**
Operating Profit		**(5,592)**	**(6,316)**	**(6,517)**	**(4,342)**	**(4,883)**
Financial income		(1,733)	163	(259)	(358)	(225)
Profit Before Taxes		**(7,325)**	**(6,153)**	**(6,777)**	**(4,700)**	**(5,108)**
Adj. PBT		**(7,434)**	**(6,223)**	**(6,840)**	**(4,763)**	**(5,171)**
Current tax income		(3)	(2)	(6)	(4)	(13)
Net Income		**(7,328)**	**(6,154)**	**(6,783)**	**(4,703)**	**(5,121)**
EPS (€)		**(2.77)**	**(1.93)**	**(0.25)**	**(0.07)**	**(0.08)**
Adj. EPS (€)		**(2.81)**	**(1.93)**	**(0.25)**	**(0.07)**	**(0.08)**
DPS (€)		**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Average no. of shares (m)		2.6	3.2	27.6	62.8	62.8
Gross margin		*79%*	*73%*	*69%*	*80%*	*82%*
EBITDA margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
Underlying operating margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET						
Current assets		**10,326**	**8,757**	**6,431**	**10,846**	**5,699**
Cash and cash equivalents		8,474	7,175	4,266	8,876	3,234
Accounts receivable		1,465	1,324	1,680	1,515	1,986
Inventories		387	259	485	455	479
Other current assets		0	0	0	0	0
Non-current assets		**718**	**905**	**1,223**	**2,061**	**3,355**
Property, plant & equipment		167	465	859	1,071	1,939
Intangible assets		541	430	364	990	1,416
Current liabilities		**(1,786)**	**(2,793)**	**(3,106)**	**(3,061)**	**(3,329)**
Short-term debt		0	(1,104)	(989)	(989)	(989)
Accounts payable		(961)	(597)	(740)	(693)	(959)
Other current liabilities		(824)	(1,092)	(1,378)	(1,379)	(1,382)
Non-current liabilities		**(3,737)**	**(7,163)**	**(5,288)**	**(5,288)**	**(1,288)**
Long-term debt		(3,724)	(7,163)	(5,288)	(5,288)	(1,288)
Other non-current liabilities		(13)	0	0	0	0
Equity		**5,521**	**(294)**	**(740)**	**4,556**	**4,436**
Share capital		38,599	39,561	46,167	56,167	61,167
Other		(33,078)	(39,855)	(46,907)	(51,610)	(56,731)
CASH FLOW STATEMENTS						
Operating cash flow		**(5,403)**	**(6,192)**	**(6,681)**	**(3,991)**	**(4,532)**
Profit before tax		(7,328)	(6,154)	(6,783)	(4,703)	(5,121)
Non-cash adjustments		3,618	(361)	515	920	1,041
Change in working capital		(1,555)	721	268	152	(216)
Interest paid		(138)	(398)	(682)	(358)	(225)
Taxes paid		0	0	0	(3)	(11)
Investing cash flow		**(148)**	**(611)**	**(843)**	**(1,400)**	**(2,110)**
CAPEX		(148)	(611)	(843)	(1,400)	(2,110)
Other investing cash flows		0	0	0	0	0
Financing cash flow		**5,868**	**5,505**	**4,616**	**10,000**	**1,000**
Proceeds from equity		6,765	962	6,606	10,000	5,000
Increase in loans		(897)	4,543	(1,990)	0	(4,000)
Other financing cash flow		0	0	0	0	0
Net increase in cash		**318**	**(1,298)**	**(2,909)**	**4,609**	**(5,642)**
Exchange rate effects		0	0	0	0	0
Cash at start of year		8,156	8,474	7,176	4,267	8,876
Cash at end of year		**8,474**	**7,176**	**4,267**	**8,876**	**3,234**
Net cash at end of year		**4,750**	**(1,092)**	**(2,011)**	**2,599**	**957**

Source: Company, Trinity Delta Note: The accounts are produced according to Finnish GAAP. The short-term debt in FY20 and FY21 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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