

Nexstim

Funded and back on stroke trial track

A key uncertainty for Nexstim was removed in December as the FDA confirmed that only one additional stroke rehabilitation trial in 60 patients will be required to seek de novo 510(k) regulatory approval for the NBT system. US approval might be obtained during Q418. Nexstim has used €8.8m from the Bracknor/Sitra funding arrangement and had €8.2m in cash in December. A further €3.2m can be raised from the arrangement. Excluding 30m issued warrants, this could fund Nexstim until late 2018. The NBS system achieved €2.5m in sales in 2016, with modest increases anticipated by Nexstim for 2017; new US distributors have been appointed.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	2.53	(9.55)	(119)	0.0	N/A	N/A
12/16	2.48	(6.48)	(54)	0.0	N/A	N/A
12/17e	2.56	(4.59)	(8)	0.0	N/A	N/A
12/18e	2.98	(2.83)	(5)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. EPS is estimated after current dilution only.

Going for de novo in stoke rehabilitation

Nexstim anticipates that this trial will report in Q118. The FDA confirmed that Nexstim's 60-patient supplementary stroke rehabilitation trial (E-FIT), costed by Nexstim at about €2m, will be sufficient, pooled with data from the Phase III NICHE trial, to seek regulatory approval for Navigated Brian Therapy (NBT). The trial could complete by March 2018 allowing a spring de novo 510(k) application and launch by late 2018. The NICHE trial showed meaningful clinical improvements in 66% of patients in both the active and sham (placebo) arms. Nexstim has developed a non-active sham procedure instead of the active sham used in NICHE. Nextstim will apply for 510(k) approval in 2017 for use of NBT in depression; there are three predicate devices to act as benchmarks. A pain indication is also being developed.

Finnish share storm

The financing arrangements with Bracknor and Sitra (see our note <u>FDA de novo</u> <u>filing, funding package</u> published on 27 July 2016) have been extensively used, raising €8.8m (€7.7m equity, €1.1m unconverted loans) in H216. Shares in issue rose 39m from 8.1m in June 2016 to 47.1m in December 2016. A further 10.2m shares were issued to 28 February, taking the total to 57.3m. There are now 31.2m warrants and 1.3m management options, with €3.2m of potential drawdown funding remaining plus any warrant proceeds. Cash on 30 December was €8.2m; H2 cash burn was cut to €2m.

Valuation: Tough call while waiting for 2018 data

Sales over 2016 of Navigated Brain Stimulation (for brain mapping) were about 10 units, worth €2.5m. New distributors should enable modest 2017 sales growth. Forecasts have been updated with 2016 results. On an unchanged indicative value of €28.6m and using 89.8m fully diluted shares in issue (current level), the indicative value is about €0.3/share, formerly €0.58 share. There may be further share and warrant issues; more cash will be needed for the NBT launch in 2019.

FY16 results and update

Healthcare equipment & services

7 March 2017 **Price** €0.20 €11m Market cap Net cash (€m) at 31 December 2016 8.2 Shares in issue 57.3m Free float 98% Code NXTMH, NXTMS Primary exchange Nasdag First North Finland Secondary exchange Nasdaq First North Sweden

Share price performance



Business description

Nexstim sells its navigated brain stimulation (NBS) system to plan brain surgery; the system is sold in the US and EU. The therapeutic stimulation system (NBT) is in clinical development for stroke rehabilitation, with data due in Q118 and a possible de novo 501(k) approval by late 2018.

Next events

Start of E-FIT trial	Q117
E-FIT data	Q118
NBT stroke de novo 510(k) filing	Q218
NBT stroke de novo 510(k) approval	Q418

+44 (0)20 3077 5735

Analyst

Dr John Savin MBA

healthcare@edisongroup.com

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Exhibit 1: Financial summary

	€'000s 2015	2016	2017e	2018e
Year end 30 June	FAS	FAS	FAS	FAS
PROFIT & LOSS				
Revenue	2,528	2,483	2,560	2,983
Cost of Sales	(821)	(645)	(1,025)	(1,162)
Gross Profit	1,707	1,837	1,535	1,821
EBITDA	(9,984)	(6,436)	(4,590)	(2,804)
Operating Profit (before GW and except)	(10,096)	(6,446)	(4,600)	(2,814)
Intangible Amortisation	(274)	(250)	(250)	(250)
Exceptionals	-	-	-	-
Operating Profit	(10,370)	(6,696)	(4,850)	(3,064)
Other	-	-	-	-
Net Interest	544	(34)	16	(15)
Profit Before Tax (norm)	(9,552)	(6,480)	(4,585)	(2,828)
Profit Before Tax (FRS 3)	(9,826)	(6,730)	(4,835)	(3,078)
Tax	(1)	(2)	-	-
Profit After Tax (norm)	(9,553)	(6,483)	(4,585)	(2,828)
Profit After Tax (FRS 3)	(9,827)	(6,733)	(4,835)	(3,078)
Average Number of Shares Outstanding (m)	8.0	12.0	55.0	57.0
EPS - normalised (c)	(119)	(54)	(8)	(5)
EPS - FRS 3 (€)	(1.23)	(0.56)	(0.09)	(0.05)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	67.5	74.0	60.0	61.1
EBITDA Margin (%)	-394.9	-259.2	-179.3	-94.0
Operating Margin (before GW and except.) (%)	-399.4	-259.7	-179.7	-94.3
BALANCE SHEET				
Fixed Assets	974	911	911	911
Intangible Assets	631	652	652	652
Tangible Assets	333	249	249	249
Other	10	10	10	10
Current Assets	8,233	9,506	4,574	1,396
Stocks	421	292	292	292
Debtors	659	789	789	789
Cash	6,875	8,156	3,224	46
Other	277	268	268	268
Current Liabilities	(2,417)	(2,137)	(2,140)	(2,140)
Creditors	(1,084)	(397)	(400)	(400)
Short term borrowings	(384)	(1,012)	(1,012)	(1,012)
Short term leases	0	0	0	0
Other	(948)	(728)	(728)	(728)
Long Term Liabilities	(3,245)	(3,802)	(3,702)	(3,602)
Long term borrowings	(3,197)	(3,778)	(3,678)	(3,578)
Long term leases	0	0	0	0
Other long term liabilities	(47)	(24)	(24)	(24)
Net Assets	3,545	4,479	(356)	(3,434)
CASH FLOW				
Operating Cash Flow	(9,065)	(7,250)	(4,587)	(2,804)
Net Interest	(544)	25	16	(15)
Tax	0	0	0	0
Capex	(380)	(310)	(260)	(260)
Acquisitions/disposals	(300)	0	(200)	(200)
Financing	5,280	7,700	0	0
Dividends	0	0	0	0
Other	100	0	(100)	(100)
Net Cash Flow	(4,609)	165	(4,932)	(100)
Opening net debt/(cash)	(4,609) (7,945)	(3,293)	(3,366)	
HP finance leases initiated	(7,940)	(3,293)	(3,300)	1,466
Other	(43)	(92)	- 100	- 100
Closing net debt/(cash)	(3,293)	(3,366)	1,466	4,544

Source: Nexstim accounts, Edison Investment Research forecasts



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Frankfurt +49 (0)69 78 8076 960

Schumannstrasse 34b

60325 Frankfurt

Germany

Sydney +61 (0)2 8249 8342 Level 12, Office 1205, 95 Pitt Street Sydney NSW 2000 Australia

London +44 (0)20 3077 5700 280 High Holborn London, WC1V 7EE United Kingdom New York +1 646 653 7026 245 Park Avenue, 39th Floor 10167, New York US