



FLASH NOTE

Nexstim OYJ (NXTMH-FI)

E-FIT trial results indicate no clinical improvement

KEY TAKEAWAY

Today, Nexstim Oyj released results from its E-FIT trial in stroke. The results indicate no statistically significant difference in clinical improvement between active and sham trial arms. Nexstim will now fully focus on the commercialisation of NBT in depression, which is FDA approved and CE marked. We remind investors, that it is the only personalised navigation approach for targeted TMS in this application. We will review our valuation and adjust our target price to reflect the termination of commercialisation in stroke. However, given this business is cash generative and has two sales lines for diagnostics and therapy - we remain positive and maintain our OUTPERFORM recommendation. In response to today's news we put our target price under review.

Trial results indicate no clinical improvement for stroke patients

In a primary efficacy analysis, which combined the E-FIT trial dataset with data from the active trial arm of the previously completed Phase III NICHE trial showed no statistically significant difference in clinical improvement between active and sham trial arms. Similarly, a secondary analysis of the E-FIT data excluding the previous NICHE results showed no significant differences between treatment arms on a statistical level (60% vs. 50%, active and sham NBT, respectively, $p=0.62$). Full results are expected to be published in H1/2019E.

Evidence against concept of inhibition in stroke rather than NBT system functionality

The fact that the results in both trial arms exceeded the literature based response expectation of approximately 1/3 in occupational therapy alone, could be explained by the possible patient selection bias by only including highly-motivated non-depressive stroke individuals and / or by the Hawthorne effect, when patients behave different when they know they are tested. This is important to highlight, as the results provide evidence against the concept of inhibition of the contralateral hemisphere in stroke rehabilitation rather than functionality of Nexstim's NBT system. While hemisphere inhibition is normally applied globally, the company has always been more focused on developing an approach to accurately stimulate specific brain regions and this remains the key aspect where Nexstim has a differentiated approach compared with the competition.

Shift in commercial focus on treatment of depression

As a result of today's announcement, management has indicated a larger focus on therapeutic applications in disorders where stimulation of specific areas of the brain have proven effective, such as depression. This frees up important capacities and means that efforts and funds can now be fully focused on the commercial development in depression. Due to FDA approval for depression earlier this year and with 4 systems sold in the US since launch in Q2/2018, this application represents a lower-risk application and a viable commercial avenue for Nexstim. Since the NBT system remains the only FDA approved personalised navigation approach for targeted TMS in depression to date, the company should be able to increase the US sales rapidly going into 2019E.

Target price under review

In response to today's news we put our target price under review reflecting the termination of commercialisation in stroke. However, depression, which already generates sales in the US might yield higher valuation given we expect a stronger commercial push.

OUTPERFORM

Price target €1.23

Price €0.23

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COMPANY DESCRIPTION

Nexstim, a medical technology company, provides rehabilitation for stroke patients through the use of non-invasive brain stimulation. The company offers navigated brain stimulation ("NBS") system, a navigated trans cranial magnetic stimulation device for pre-surgical mapping of the speech and motor cortices. The company is also promoting navigated brain therapy ("NBT") system, which is in the market in the EU and final stage development in the US for stroke rehabilitation and depression. Nexstim was founded in 2000 and is headquartered in Helsinki, Finland.

SWOT

Strengths - Validated technology. Existing NBS business with potential to grow. Very profitable NBT business model in lucrative market.

Weakness - Clinical proof of NBT in stroke rehabilitation is missing. High cost base compared to existing sales level. Lack of financial resources to fully commercialise the technology.

Opportunities - Strategic co-operations and sales partnerships outside Europe and US. New therapeutic indications for NBT (pain) and use of the technology as a platform. M&A could lead to faster commercialisation and sales growth.

Threats - Failure of E-FIT trial would lead to financing crisis. New emerging competition with bigger financial resources. Due to the company history and low share price, the company may end up being acquired at below fair value.

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Companies Mentioned in this report

- Medical Technology (MT)
- Nexstim OYJ (NXTMH-FI)

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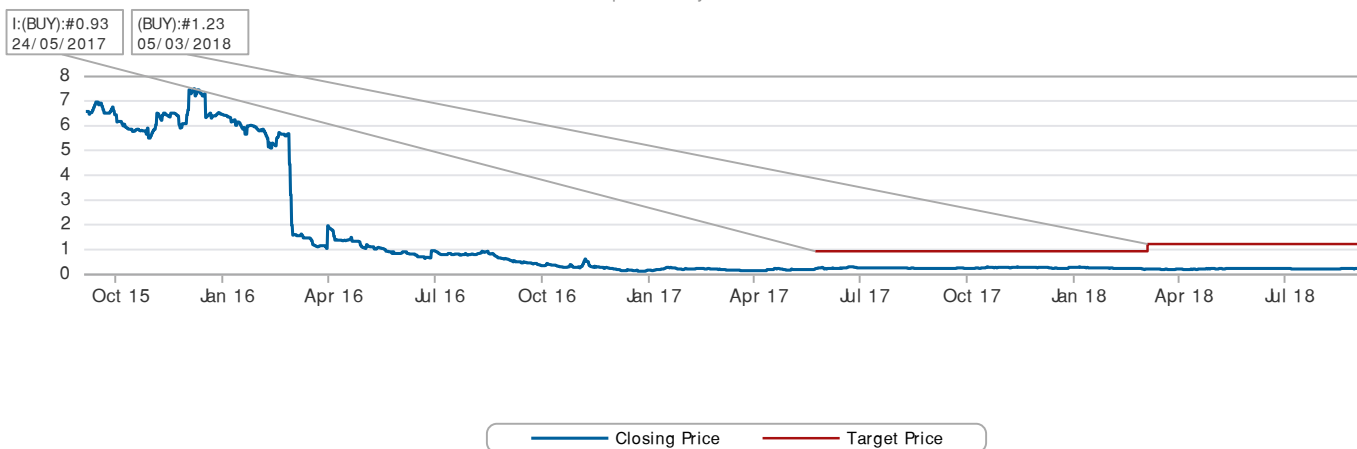
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Nexstim OYJ Rating History as of 31/08/2018

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GPSL has received compensation from Nexstim OYJ for the provision of research and advisory services within the previous twelve months.

NXTMH-FI

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