

# Nexstim

## **Nexstim Plc Business and Clinical Update Q1 2021**

*Press release, Helsinki, 22.04.2021, 12.00 pm (EEST)*

Nexstim Plc (NXTMH:HEX, NXTMS:STO) ("Nexstim" or "Company") announces the key highlights of the Company's business and clinical progress during Q1 2021.

### **CEO Mikko Karvinen's Business and Clinical Update**

Glad to inform that our operational business has had the best start of the year ever while beginning our first full year of executing our renewed strategy. During the first months of 2021, we have continued to invest in the growth of our diagnostic and therapeutic business with the recruitment of two new sales team members to our US organization. At the same time, we are extremely pleased to see that our existing NBS and NBT® System customer base has increased the utilisation rate of our installed base to a record level. High utilization of the systems leads into growing levels of high margin recurring revenue, an important element in our profitable growth strategy.

Parallel to focusing on growth efforts we will actively keep monitoring the COVID-19 pandemic environment. Despite the COVID-19 business environment still present we have continued our work in increasing the numbers of both NBS Systems used for pre-surgical mapping of the brain and NBT® Systems installed mainly for use in the treatment of MDD. The focus has been particularly on the large U.S. market, but also in a targeted manner in the EU. Between January-March 2021, we had delivered a total of 4 new NBS systems and a total of 2 new NBT® Systems. As a result, there were at the end of Q1 2021 a total of 33 NBT® Systems installed worldwide (18 in the U.S. and 15 in Europe and the rest of the world) for the treatment of depression and chronic neuropathic pain.

The clinical year got a great start with news about a new study published in the journal *Cancers* in January presenting impressive results of nTMS language mapping in a large number of patients<sup>1</sup>. The study published by a neurosurgical team at Technical University of Munich (TUM) in Germany included 140 consecutive patients with suspected language-eloquent brain tumours. Nexstim SmartFocus® nTMS pre-operative language mapping was performed on all these patients. In a very high number of patients tumour could be removed to the maximum extent, with gross total resection (GTR) achieved in 82.3% of cases.

The clinical news flow continued in March with Nexstim providing encouraging results of the initial pilot study in severe depression at Kuopio University Hospital. Nexstim announced that all 10 patients treated with the accelerated iTBS protocol had completed their 5-day treatment and 7 had completed at least 5 weeks of their planned 12-week follow-up. The 10 patients were treated with shortened treatment sessions to ensure patient safety with the accelerated protocol and no study discontinuations or serious adverse events issues have occurred. All ten patients showed improvement of symptoms on the clinician administered Hamilton Depression Rating Scale (HAMD-17) outcome measure at the end of treatment (mean decrease in score from baseline 37%,  $p < 0.001$ ). 1 of 10 patients (10%) had reached clinical remission and 3 of 10 (30%) a clinical response defined as >50% improvement on the measure. As the accelerated treatment protocols and their development are in the core strategic development path of our business, we will continue these trials with an increased number of patients.

In addition to the above the Company reported in March very promising clinical outcomes of the 159 patients who had completed Nexstim SmartFocus® rTMS treatment with Nexstim NBT® system for major depressive disorder (MDD) at participating clinical sites in the U.S. Treatment outcomes of these

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159 patients were good: 47.2 % were in remission at end of treatment and 76.1 % had obtained a clinical response. These outcomes are clearly higher than what is usually reported for MDD: In a well-conducted multisite study, remission rates were 26.5-28.7 % and the patient-reported response rates were 41.5-56.4 %<sup>2</sup>. The patient-reported remission and response rates are also higher than those reported in a large >3800 patient series for patients completing clinical rTMS treatment (remission 29.7-36.2%, response 62.7-70.4%)<sup>3</sup>. We continue to gather this important clinical outcome data as we aim for a patient data registry of over 200 completed treatment sessions of depression patients before the end of the year 2021.

Finally, I once again thank the shareholders for their trust in the spring 2021 rights issue. We are very happy with the final results of the share issue, and with the funds raised, for the possibility to continue executing our renewed strategy. The Nexstim team will work hard to increase shareholder value over the long-term in the form of stronger competitive advantages, faster growth, and better financial results. While again being optimistic about the year 2021, we will closely continue to monitor the development of the COVID-19 pandemic as we operate our business.

1) Ille S, et al. Non-Invasive Mapping for Effective Preoperative Guidance to Approach Highly Language-Eloquent Gliomas—A Large Scale Comparative Cohort Study Using a New Classification for Language Eloquence. *Cancers* 2021, 13, 207.  
<https://doi.org/10.3390/cancers13020207>

2) Carpenter L. et al. Transcranial magnetic stimulation (TMS) for major depression: a multisite, naturalistic, observational study of acute treatment outcomes in clinical practice. *Depress Anxiety*. 2012 Jul;29(7):587-96. Epub 2012 Jun 11.

3) Sackheim, H. et al. Clinical outcomes in a large registry of patients with major depressive disorder treated with Transcranial Magnetic Stimulation. *Journal of Affective Disorders* 277 (2020) 65–74.

**Further information is available on the website [www.nexstim.com](http://www.nexstim.com), or by contacting:**

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## **About Nexstim Plc**

Nexstim is a Finnish, globally operating medical technology company. Our mission is to enable personalized and effective therapies and diagnostics for challenging brain diseases and disorders.

Nexstim has developed a world-leading non-invasive brain stimulation technology called SmartFocus®. It is a navigated transcranial magnetic stimulation (nTMS) technology with highly sophisticated 3D navigation providing accurate and personalized targeting of the TMS to the specific area of the brain.

SmartFocus® technology is used in Nexstim's proprietary Navigated Brain Therapy (NBT®) system, which is FDA cleared for marketing and commercial distribution for the treatment of major depressive disorder (MDD) in the United States. In Europe, the NBT® system is CE marked for the treatment of major depression and chronic neuropathic pain.

In addition, Nexstim is commercializing its SmartFocus® based Navigated Brain Stimulation (NBS) system for diagnostic applications. The NBS system is the only FDA cleared and CE marked navigated TMS system for pre-surgical mapping of the speech and motor cortices of the brain. Nexstim shares

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are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.

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