



Nexstim Plc Business and Clinical Update Q3 2021

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Nexstim Plc (NXTMH:HEX, NXTMS:STO) ("Nexstim" or "Company") announces the key highlights of the Company's business and clinical progress during Q3 2021.

CEO Mikko Karvinen's Business and Clinical Update

I'm very happy to inform that following the strongest first half in the history of the company, our operational business has continued to show positive progress during the third quarter of the year. We have continued to focus on the growth of our Diagnostics Business (NBS) and Therapy Business (NBT®) new system sales in both of our key markets in the United States and Europe. At the same time, we have seen interest in our existing NBS and NBT® System customer base for system upgrades and continued to increase the utilisation rate of our installed base to a record level. This has led into steadily growing recurring revenue levels, which creates stability and a new kind of predictability for us. Our goal is financial success and minimizing future capital needs - we want to develop and evolve.

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 major depressive disorder (MDD). Between January-September 2021, we had delivered a total of 9 new NBS Systems and a total of 8 new NBT® Systems. In addition to the above mentioned already delivered systems we had an open backlog of undelivered systems total of 6 new NBS Systems at the end of Q3 2021.

In the Diagnostics Business, the NBS system has been sold to more than 190 research universities and leading hospitals across the world to date. We are happy to see that more and more of our customers seek to use the Nexstim system in both diagnostic and therapeutic applications. This has been made possible in the European markets where the new NBS deliveries to the hospitals enable neurosurgical diagnostics as well as MDD and pain therapy with the additional NBT software option. As an example of this progress, out of the 9 NBS systems delivered during January-September 2021, 5 had both diagnostics and therapy treatment applications in the system. We see this combined system as a clear competitive advantage and look forward to expanding with this platform approach to other key markets globally.

In the Therapy Business, at the end of Q3 2021 there were a total of 44 Nexstim systems with therapy capabilities installed worldwide (19 in the U.S. and 25 in Europe and the rest of the world) for the treatment of depression and chronic neuropathic pain. This number of systems includes both NBT® systems as well as NBS Systems with additional NBT software option. Nexstim's NBS System with SmartFocus® nTMS is highly differentiated from other currently available TMS products due to its unique and highly sophisticated 3D navigation that uses its proprietary E-field algorithm to visualize the exact location, orientation, and magnitude of the stimulation.

In August we reported clinical outcomes of the first 208 patients who had completed Nexstim SmartFocus® rTMS treatment with Nexstim NBT® system for major depressive disorder (MDD). Nexstim NBT® system is indicated for the treatment of MDD in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Treatment outcomes of these 208 patients were very good: 50.5% were in remission at end of treatment and 76.0% had obtained a clinical response. These outcomes are clearly higher than what

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is usually reported for MDD with TMS-systems: In a well-conducted multisite study, remission rates were 26.5-28.7% and the patient-reported response rates were 41.5-56.4%¹. 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%)².

The clinical news flow continued in August with announces the continuation of the pilot study on the use of accelerated iTBS protocol in treatment of severe depression with Nexstim NBT® System at Kuopio University Hospital. Accelerated iTBS means transcranial magnetic stimulation (TMS) therapy where stimulation is given several times per day for one week whereas in conventional TMS therapy, stimulation is given once a day during several weeks.

In the continuation of the previously reported pilot study, the effectiveness of the accelerated iTBS protocol will be tested in an additional 20 patients. The treatment parameters have been modified based on the analysis of the initial, previously reported results announced on 3 March 2021. The patient treatments in the continued pilot are estimated to be completed in mid-2022. The results will be announced as soon as possible after their completion.

After already having received encouraging initial information from the Kuopio University Hospital in relation to the pilot study, we are now looking forward to continuing the collaboration. Our system clearly differentiates from the TMS systems currently on the market that do not have navigation capabilities. In the future, the need for a navigation function is likely to be further emphasised in technology that could treat patients in hospital for severe, treatment-resistant depression (TRD) and possible suicidal ideation. This could potentially open a new TMS treatment market for Nexstim that is separate from the current treatment of patients with MDD. Getting more data on the patient treatment outcomes with the intensified accelerated treatment protocols is important for the strategic development path of our business.

In addition to the above the Company provided an update in late September on the pilot study on the use of accelerated iTBS protocol in treatment of chronic neuropathic pain with Nexstim NBT® System at Helsinki University Hospital. The treatment of all except one patient had been completed in this total of five patient pilot study by end of Q3 2021. Nexstim is pleased with the progress of the pilot study in the present extraordinary circumstances effected by the COVID-19 pandemic.

In the Helsinki University Hospital pilot study, the effectiveness of the accelerated iTBS protocol will be tested in 5 patients. They are suffering from therapy resistant, chronic neuropathic pain and have not benefited from prior 10 Hz rTMS treatment targeted to the motor cortex. The results of the pilot study will be made public once available.

We are still living in the prolonged COVID-19 pandemic, but feel positive about Q4 and 2021, the first full year of implementing our new strategy. At Nexstim, we purposefully continue our work to enable personalized and effective therapies and diagnostics for challenging brain diseases and disorders. We strongly believe that our work will support long-term growth in shareholder value in the form of stronger competitive advantages, rapid growth, and better financial results. While again being optimistic about the future, we will closely continue to monitor the development of the COVID-19 pandemic as we operate our business.

1) 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.

2) 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



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

For more information please visit www.nexstim.com