

# Nexstim

## **Nexstim Plc Business and Clinical Update Q3 2022**

*Press release, Helsinki, 20 October 2022 at 9 AM (EEST)*

Nexstim Plc (NXTMH:HEX, NXTMS:STO) ("Nexstim" or "Company") announces the key highlights of the Company's business and clinical operations during Q3 2022.

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

After the first positive operating result in the history of the Company in H1 2022, our business has continued to show positive progress during the third quarter of 2022. In line with our main strategic goal, we continue profitable net sales growth, leading to our first operational profit-making financial year while also minimizing future equity needs.

We have continued to grow our Diagnostics (NBS) and Therapy (NBT®) Businesses with new system sales in our key markets in the United States and Europe. Between July and September 2022, we had delivered a total of 4 new NBS systems and one new NBT® system. In addition to the above mentioned already delivered systems we had an open backlog of undelivered systems total of 2 NBS systems at the end of Q3 2022.

In the Diagnostics Business, the NBS system has been sold to more than 210 research universities and leading hospitals across the world to date. In our sales and marketing activities for the fall, we have invested in the most significant international events in our field as major travel restrictions related to the COVID-19 pandemic have been lifted. I would see our participation in the International Congress of Clinical Neurophysiology (ICCN), held in Geneva in September, and in the Congress of Neurological Surgeons (CNS) Annual Meeting in October in San Francisco, as the most influential of these events. In Finland, we took part in the Finnish clinical neurophysiology association's annual event celebrating the association's 50<sup>th</sup> anniversary this year. It has been great to meet both current and new potential customers. We are very happy about the continuously growing interest towards using the Nexstim system in both diagnostic and therapeutic applications.

In the Therapy Business, at the end of Q3 2022 there were a total of 62 Nexstim systems with therapy capabilities installed worldwide (24 in the U.S. and 38 in Europe and the rest of the world) for the treatment of depression and chronic neuropathic pain. This number includes both NBT® systems as well as NBS systems with additional NBT® software option installed. 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 February, we announced the sale of our technology license related to the NBT® system to Magnus Medical, Inc. The total value of the agreement is approximately EUR 17 million. The license agreement places Nexstim in a unique place to gain financial benefits, extend the use of our technology in patient care and allocate our resources to other business areas during the royalty period. In September, Magnus Medical announced having received 510(k) clearance from the U.S. Food & Drug Administration (FDA)

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for their SAINT™ technology. According to their media release, Magnus Medical expects the commercial launch of the technology to begin in 2023. We at Nexstim base our own estimations of the start of the licensing agreement's royalty period on this information that Magnus Medical has publicly released regarding their expectations on the commercialization schedule.

Our strategic main goals for 2022 also include expanding Nexstim's network of exclusive partner clinics, especially in the United States. This involves the installation of Nexstim systems in neuroscience centers in line with our revised strategy, mainly in cooperation with our partners. Our new partnerships focus on strategic investments in management services organizations (MSO), especially on the vast U.S. market, but partnerships are also possible to make targeted investments in European and Asian markets.

Our first strategic partnership in the U.S. with PNC Management Services, LLC and Dr. Kuluva has been off to a good start. We believe this co-operation creates excellent opportunities for us to continue to grow also in the future. To enable further growth by expanding the network of exclusive partner clinics in the United States, we have established a private equity company. As the end of 2022 approaches, we will keep up our hard work towards advancements in the expansion of the network. We look forward to these future partnerships enabling treatments for a growing number of patients in the United States with Nexstim's TMS technology.

Earlier in October, we reported clinical outcomes of the first 403 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 403 patients were excellent: approximately 50% were in remission at the end of the treatment and 76% had obtained a clinical response. These outcomes are clearly higher than what 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%<sup>1</sup>. The patient-reported remission and response rates are also higher than those reported in a large sample of more than 3,800 patients who completed clinical rTMS treatment (remission 29.7–36.2%, response 62.7–70.4%)<sup>2</sup>. We will continue to collect this invaluable data during the rest of 2022.

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 emphasized 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.

The pilot study at Kuopio University Hospital continues. It examines the use of accelerated iTBS protocol in treatment of severe depression with Nexstim NBT® system. 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

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protocol will be tested in an additional 20 patients. We currently estimate the treatments to continue until the end of 2022. Nexstim is actively monitoring the continuation of treatment, and the results will be announced as soon as possible after their completion.

While investing in growth, we are actively monitoring the global political situation, which has changed due to the war in Ukraine. We unequivocally condemn Russia's military action in Ukraine and hope for a quick, peaceful resolution of the conflict. Despite the international tension, our outlook for 2022 continues to be positive.

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 supports the growth of shareholder value over the long term, in the form of stronger competitive advantages, rapid growth, and better financial performance. While remaining optimistic about the future, we will continue to monitor closely both the situation in Ukraine and the coronavirus pandemic as we promote 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

**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 growth-oriented medical technology company. Our mission is to enable personalized and effective diagnostics and therapies for challenging brain diseases and disorders.

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

Nexstim's Diagnostics Business focuses on commercialization of the Navigated Brain Stimulation (NBS) system. 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's Therapy Business markets and sells the 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.

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

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