

# Nexstim

## **Nexstim Plc Business and Clinical Update Q1 2023**

*Press release, Helsinki, 3 May 2023 at 9 AM (EEST)*

Nexstim Plc (NXTMH:HEX) ("Nexstim" or "Company") announces the key highlights of the Company's business and clinical operations during Q1 2023.

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

After the first profitable financial year in the history of the Company, our business has continued to show positive progress during the first quarter of 2023. In line with our main strategic goal, we have continued focusing on profitable net sales growth, leading to a positive EBITDA for the financial period while minimizing future capital needs. To ensure this positive profitability development, we carried out change negotiations in the company during January and February 2023 as part of our adoption of a global process organization, which will serve our customers better and more efficiently and generate long-term growth in shareholder value. Our selected therapeutic applications (MDD, severe depression and chronic pain) represent indications where our unique technology is already delivering recognizable clinical outcomes and customer profitability, but we are also continuing discussions concerning new strategic partnerships to further scale the use of our technology in health care.

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 January and March 2023, we had delivered a total of 2 new NBS systems and 2 new NBT® systems. In addition to these already delivered systems we had an open backlog of undelivered systems total of one NBS system at the end of Q1 2023.

In the Diagnostics Business, about 220 NBS systems have been sold to research universities and leading hospitals across the world to date. In our sales and marketing activities, we have continued investing in the most significant international events in our field. In February, we participated in the EANS symposium held by the European Association of Neurosurgical Societies in Verona, Italy, and in an international brain stimulation conference held in Lisbon, Portugal. 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 Q1 2023 there were a total of 64 Nexstim systems with therapy capabilities installed worldwide (22 in the U.S. and 42 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 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.

Our second key strategic goal for 2023 is launching the new NBS 6 product, enabling easy-to-use systems and the use of future additional modules in the same system. The launch and development of the new product generation is an essential part of Nexstim's operations during the 2020-2024 strategy period.

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The NBS 6 is a combined system that has been built on Nexstim's unique, clinically established technology. The modular product design allows for an expansion of system capabilities over time. The new solution creates long-term value for Nexstim's customers and investors. The first release in April-May concerns therapy applications. In the United States, the NBS 6 is currently indicated for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Nexstim will be unveiling the NBS 6 system at the Clinical TMS Society 11th Annual Meeting, held in Colorado Springs, United States on May 4 – 6. More information on the NBS 6 system is already available on Nexstim's website: [www.nexstim.com/healthcare-professionals/nbs-6](http://www.nexstim.com/healthcare-professionals/nbs-6).

Our third key strategic goal for 2023 is expanding the network of Nexstim exclusive collaboration clinics primarily in the USA and Europe. This would mean installing Nexstim systems in neuroscience clinics, in line with our revised strategy, mainly in cooperation with our partners. Our new partnerships focus on strategic investments in service organisations, especially on the vast US market, but partnerships are also possible to make targeted investments in the European market.

We are very pleased with the beginning of our cooperation with Dr Kuluva and his clinic, and we believe that our cooperation creates excellent conditions for future growth. Our joint venture, PNC Management Services LLC, is our first agreement on a strategic partnership and the acquisition of a minority interest in the joint venture is our first step on this important strategic development path. This partnership allows us to work close to the patients and collect accurate information at the patient interface. In addition, the purpose of our private equity company is to further expand the network of Nexstim's neuroscience centers in the United States. We are looking forward to continuing our cooperation with Dr Kuluva's team of experts. Through our cooperation, Nexstim's TMS technology can be used to treat a growing number of patients in the United States. We are currently involved in negotiations with several potential partner clinics in both the United States and Europe, and we are working hard to be able to grow our network.

In October last year, 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 in 2023.

The pilot study at Kuopio University Hospital continues. It examined 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 for several weeks. In the continuation of the previously reported pilot study, the effectiveness of the accelerated iTBS protocol is

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tested in an additional 20 patients. The treatments as part of the continued pilot study have been concluded at the end of 2022, and a follow-up phase is currently ongoing. Nexstim is actively monitoring the situation and the results will be announced as soon as possible after the completion of the follow-up and result analysis phases of the pilot study.

While investing in growth, we are actively monitoring the global political situation, which has changed due to the war in Ukraine. We continue to 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 2023 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 the situation in Ukraine as we grow 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) Sackeim, 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 Nasdaq First North Growth Market Finland.

For more information, please visit [www.nexstim.com](http://www.nexstim.com)