



Insider Information: Nexstim Plc Announces Planned Alzheimer's Collaboration with Sinaptica Therapeutics, Inc.

Company announcement, Helsinki, 7 June 2024 at 9 AM (EEST)

Nexstim Plc (NXTMH:HEX) ("Nexstim" or "Company") announces that it has successfully negotiated and signed a Letter of Intent (LOI) to exclusively collaborate with Sinaptica Therapeutics, Inc. ("Sinaptica") to develop, manufacture and supply Sinaptica's patented precision neuromodulation system custom-based upon the Nexstim NBS 6 system with its advanced TMS-EEG and precision neuronavigation capabilities, in the field of Alzheimer's Disease (AD). According to the LOI, the Sinaptica system will have a proprietary workflow, integrate a third-party EEG device, and connect to Sinaptica's proprietary MAINTAIN™ cloud-based personalization engine among other modifications.

The planned partnership contemplates a worldwide, 10-year exclusive arrangement (renewable in 3-year increments). In the first phase, Nexstim would provide R&D resources to develop the integrated system, designed to meet the needs for Sinaptica's Phase 3 pivotal clinical trial, estimated to commence in 2025. Nexstim would manufacture and deliver at least 20 Sinaptica precision neuromodulation systems and provide certain maintenance services for clinical trials.

The estimated total value of the first phase of the partnership is approximately EUR 6 million for the first two years of the agreement after signing of the definitive agreements. The financial structure of the agreement consists of an upfront exclusivity signing fee, milestone-based development project, and clinical system sales. The clinical trial systems would also generate recurring revenue for Nexstim during the trial period, based on hardware and software service & support, as well as consumables. The LOI is non-binding, and the closing of this transaction is subject to finalization and approval of the definitive agreements.

Sinaptica and its scientific co-founders have worked over a decade to optimize their brain stimulation therapy using TMS-EEG-based ML-derived algorithms to customize neuromodulation targeting the Default Mode Network (DMN) in the brain via stimulation of the precuneus, which the company refers to as "nDMN" therapy. Their scientific co-founders' work has resulted in unprecedented clinical outcomes in two Phase 2 studies in mild/moderate Alzheimer's patients, one of which is published in the Oxford journal *Brain* and earned the company Breakthrough device designation by the FDA. Sinaptica now intends to run a pivotal Phase 3 trial to achieve FDA clearance in the U.S., aiming to be the first TMS-based system in the market to treat Alzheimer's, and the only to offer closed-loop personalization via its patented TMS-EEG personalization software, which it calls "MAINTAIN™".

Through Sinaptica's investment in the referenced Pivotal Study and eventual de novo FDA clearance, the Company will be creating a new market for the integrated use of TMS, EEG and neuronavigation technology and a new therapeutic option for patients with AD.

Following a successful Pivotal trial, the parties are planning to collaborate exclusively to develop a commercial system in a further R&D project, and for Nexstim to manufacture and supply Sinaptica with the commercial systems and support Sinaptica's commercialization in the field of the diagnosis and treatment of Alzheimer's disease, worldwide.

"This agreement marks an important step for Sinaptica, as we solidify access to Nexstim's world-class TMS platform, adding our workflow, treatment protocol and patented closed-loop personalization, which has enabled extremely promising Phase 2 data in Alzheimer's," said Ken

Nexstim

Mariash, CEO of Sinaptica. *“Collaborating with Nexstim allows us to leverage their industry-leading, high-precision neuronavigation technology and foundational TMS-EEG capabilities, which will provide an accelerated path to initiating our Phase 3 clinical trial next year and establishes a collaborative development, manufacturing and supply relationship that will allow us, upon clearance, to commercialize our system worldwide.”*

Mikko Karvinen, CEO of Nexstim, comments: *“We warmly welcome this exclusive strategic collaboration opportunity with the Sinaptica team in enabling the use of our new NBS 6 therapy system and our unique EEG visualization software tailored for their breakthrough treatment of Alzheimer’s disease patients. There has been a continued and increasing interest towards using our navigated TMS technology in TMS-EEG research, and we are happy to see the growing number of our systems being used in the pursuit of novel therapies for new clinical indications. Nexstim’s technology is a world-leading solution for neuroscience studies, allowing the gathering of location-specific diagnostic data and offering reliable, precise, and accurate therapy delivery. We very much look forward to the possibility of supporting Sinaptica first with the development project and trial systems and on their subsequent steps on the path towards a commercial future in the huge unmet need for safe and effective Alzheimer’s disease treatments.”*

Further information is available on the website www.nexstim.com, or by contacting:

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The Company’s Certified Advisor is Carnegie Investment Bank AB (publ).

About Sinaptica Therapeutics, Inc.

Sinaptica Therapeutics is a clinical-stage neuromodulation company leading the development of a new class of personalized therapeutics to revolutionize the treatment of Alzheimer’s and other neurodegenerative diseases. The company utilizes a patented novel, non-invasive approach to treating Alzheimer’s via precision neurostimulation of a key brain network involved in memory, the Default Mode Network. This novel approach slowed disease progression by >80% on all four gold-standard cognitive and functional clinical endpoints in a placebo-controlled Phase 2 clinical study, with results published in the peer-reviewed Oxford University Press journal, *Brain*. The technology was granted Breakthrough Device Designation by the FDA in 2022 and the company is preparing for a pivotal randomized controlled clinical trial in 2025. Sinaptica’s mission is to bring a safe, effective, and non-invasive neuromodulation therapy to Alzheimer’s patients that can help to significantly slow the progression of both cognitive and functional decline. Learn more at sinapticatx.com and follow us on [LinkedIn](#) and X [@SinapticaTX](#).

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

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 5 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 NBS System 6 which is FDA cleared for marketing and commercial distribution for the treatment of major depressive disorder (MDD) in the United States. In Europe, the NBS 6 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

Forward-Looking Statements

This company announcement contains forward-looking statements, including, without limitation, statements regarding Nexstim's strategy, business plans and focus. The words "may", "will", "could", "would", "should", "expect", "plan", "anticipate", "intend", "believe", "estimate", "predict", "project", "potential", "continue", "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this announcement are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this announcement, including, without limitation, any related to Nexstim's business, operations, supply chain, strategy, goals and anticipated timelines, competition from other companies, and other risks described in the Report of the Board of Directors and Financial Statements for the year ended December 31, 2023 as well as our other past disclosures. Nexstim cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Nexstim disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this announcement represent Nexstim's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.