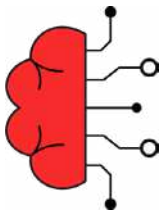
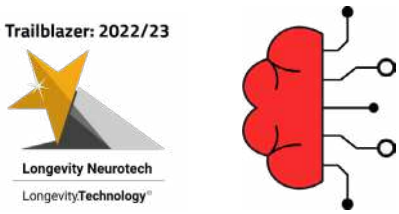


Neurosoft Bioelectronics

Company Profile

Neurosoft Bioelectronics, a spin-out company from EPFL, the Swiss Federal Institute of Technology in Lausanne, is laser focused on developing new implantable electrode technologies to interface with the nervous tissue. With over 9 years of neurotech expertise, research, and development, the team at Neurosoft has developed small, thin implantable electrodes that can both stretch, flex and reducing dramatically the foreign body reaction and scarring associated with traditional implantable devices. These unique mechanical properties allow enhanced long-term performance, even in hard-to-reach areas such as the brain sulci and can reduce scar tissue formation around the electrodes. When implanted, these soft, thin, and flexible electrodes can both record and stimulate the brain, which Neurosoft believes may be able to help in indications such as tinnitus and epilepsy. Ultimately, the goal of Neurosoft is to leverage its technology and build fully implantable brain-computer interfaces to treat severe neurological disorders.

"Therapeutic outcomes from clinical neural implants are limited by their mechanical properties. Their stiff and rigid designs present a mechanical mismatch compared to the soft and curved tissues they interface with, thereby constraining the physiological motion dynamics of the nervous system. At Neurosoft Bioelectronics, we are addressing this issue by engineering elasticity in thin film materials to manufacture implantable electrodes that are much softer and flexible, and that can seamlessly interface with the nervous system."

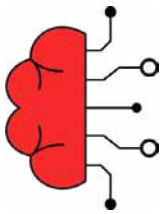


Founder of Neurosoft Bioelectronics, Nicolas Vachicouras, always dreamt about the possibilities of biomedical engineering since he learned about the mechanisms of the retina at high school. To pursue this dream, Nicolas threw himself into studies of microelectronics at EPFL and in 2012 he joined the Laboratory for Soft Bioelectronic Interfaces, ran by Professor Stéphanie Lacour, where he worked on soft microelectronics for neural interfaces. Inspired by the medical potential of these devices, he pursued various research projects in that field at EPFL and Harvard Medical School, and eventually started a PhD with Prof. Lacour on the translation of these technologies to the clinic. He initiated the start-up one year before the end of his PhD and in 2018 Ludovic Serex, a long-time classmate of Nicolas', joined the team to share his expertise in microtechnologies (specifically cleanroom microfabrication).

Neurosoft is a pioneering company in soft bioelectronic interfaces. Other companies competing in this area tend to use plastic-based technologies which can be flexible but, due to the intrinsic rigidity of these materials, must be manufactured very thin and can have very sharp edges. When creating an interface with the brain, sharp edges and stiff materials can cause damage to brain vessels and put a patient's safety at risk. Neurosoft Bioelectronics is one of the only companies in the world that are developing truly soft, stretchable, and flexible electrodes. This soft electrode technology can drastically reduce the risk of damaging neural structures, as the devices are 1000x softer and 2x thinner than current clinical electrodes. Additionally, they are MRI compatible and can easily be folded in the sulci, allowing unprecedented access to typically unreachable brain regions. Finally, the electrode sites integrated on the devices can be 100x smaller in surface area, providing high resolution for both recording and stimulation. Patients implanted with Neurosoft's electrodes should benefit from the lower risk of scarring and device failure, avoiding complications which can require costly surgical device removal and re-implantation. Furthermore, the high resolution recording performance of these electrodes improves the ability to detect disease-related electrical biomarkers such as for epilepsy. Moreover the high-resolution stimulation reduces the risk of off-target stimulation which can typically lead to unwanted side-effects. Neurosoft Bioelectronics has a portfolio of 24 patents, including 11 granted in the USA, Europe and China, relating to its proprietary connector technology, its soft electrode technology and other specific embodiments of their technology. With more than nine years of research and development already completed, the level of expertise in this field will be hard for another company to emulate.

"Many of the technologies that are on the market today are all made with the same materials and techniques, regardless of what neurological target they have. It's my core belief that having soft devices is a smarter way if you are interfacing with softer tissues, like the brain or spinal cord"

Nicolas Vachicouras, Founder and CEO of Neurosoft Bioelectronics



One of Neurosoft's main goals is to treat severe tinnitus using cortical neuromodulation. To ensure this goal is met, the company have partnered with one of the leading experts in the world, Prof. de Ridder, who pioneered cortical neuromodulation for tinnitus, and showed that there is strong scientific evidence of neuromodulation efficacy [312] when applied to tinnitus , but didn't pursue this further when he lacked the correct electrode materials for interfacing with neural tissue. Other academic and research collaborations include partnerships with EPFL and Stéphanie Lacour's laboratory, where most of the company's infrastructure and manufacturing capabilities currently reside. The company also has a strong relationship with the Wyss Center, a private foundation that helps start-up companies in the field of neurotech and is known as one of the best neurotech incubators in Europe. Its soft electrode technology is also currently being tested with other clinical collaborators at Harvard Medical school and Massachusetts Eye and Ear Infirmary. To ensure it can collect data on its materials and devices, Neurosoft Bioelectronics has also made strategic relationships with various hospitals and clinics, including Utrecht medical centre, which is one of the largest epilepsy centres in Europe, the Geneva University Hospital (HUG) and the Lausanne University Hospital (CHUV).

Flagship Product Deep Dive: Soft ECoG and SOFT TINNIT

Neurosoft Bioelectronics has two main products in development, one for epilepsy and brain tumours, SOFT ECoG, and one for severe tinnitus, SOFT TINNIT.

SOFT ECoG

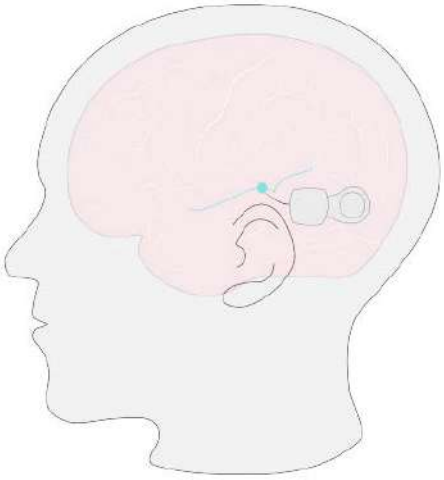
SOFT ECoG is an implantable subdural electrode that can come in various shapes and sizes, and each device can integrate up to 64 electrode sites. The devices are made of extremely soft and thin silicone membranes with a proprietary stretchable coating on top of the electrodes proving high electrochemical surface area for improved recording and stimulation capabilities.

The soft and stretchable devices can be placed on the brain either intraoperatively or for a maximum duration of 30 days. SOFT ECoG Subdural Electrodes connect to an external intra-operative monitoring unit outside of the body, preventing any need for any implantable active electronics. The device can be used for either recording or stimulation of the brain surface and can be used for two main indications: monitoring during brain tumour resection surgery and localization of epileptogenic regions in refractory epilepsy patients.

For use in brain tumour resection surgeries, the electrodes are placed intraoperatively and can either stimulate or record parts of the brain, effectively acting as neuronavigation tool. This ensures that the surgeon can identify critical regions during invasive surgeries and helps to prevent operative damage.

The SOFT ECoG device can also be used for patients with epilepsy. Epilepsy is one of the earliest applications of neurotech at large and is supported by a wide body of scientific literature. One-third of epilepsy patients do not respond to drug treatments and must undergo invasive surgery to remove the part of the brain that is tiggering the seizures. However, it can be difficult to identify, using traditional methods such as MRI, what exact area of the brain is causing the seizures. In these cases, the implanted electrodes go over an area where the seizures are suspected to arise and then the patient remains in the hospital for an extended period and is monitored continuously. The device records seizures that happen spontaneously or, alternatively, the device can stimulate parts of the brain to elicit seizures. The brain activity that is recorded allows the clinician to triangulate where the seizure is coming from prior to surgery. The use of the device is under 30 days in both scenarios, so safety and performance are much easier to demonstrate for first-in-human trials and regulatory clearance. Neurosoft is targeting first-in-human testing for 2022. And expects FDA clearance in 2023 for SOFT ECoG implantation into a patient for under 30 days.

SOFT TINNIT



Late 2023 will be the year that Neurosoft Bioelectronics expects clinical proof-of-concept of its second product, SOFT TINNIT, an implantable brain-computer interface to treat severe tinnitus through cortical neuromodulation. Invasive neuromodulation has been used previously to suppress tinnitus, however, the studies had to be halted as the electrodes were not suitable as they were too rigid for the soft environment of the brain.

Neurosoft's compliant materials enable manufacturing of implants that can achieve exceptional long-term bio-integration in the body, conforming to the static and dynamic mechanics of neural tissue. This could be particularly useful in cases such as tinnitus, where a prime neurological target is located in a hard-to-reach area in the depth of the Sylvian Fissure. Due to the flexibility of Neurosoft's devices, that region could be accessed and stimulated to enable a therapy for the currently untreatable tinnitus.

Evidence of safety and efficacy

Neurosoft's technology has been demonstrated in 18 peer-reviewed articles. To date, the soft bioelectronic material has been tested on various neurological targets in mice, rats, pigs, monkeys and human cadavers. Each study strengthens certain characteristics of the material.

1. Stimulation reliability: The soft arrays could be easily handled during surgery and functioned over 1 month when implanted in mice for stimulation of the auditory brainstem. When inserted in human cadavers the soft arrays showed good electromechanical and electrochemical stability and a larger dynamic range compared to clinical auditory brainstem implants (Vachicouras et al. 2019). Long-term functionality for electrical stimulation of the spinal cord was also demonstrated in pigs (6 months) and monkeys (6 weeks) (Schiavone et al. 2018, Schiavone et al. 2020, respectively).

2. Recording reliability: The ability to record with a higher resolution using micro-electrodes was demonstrated in a pig study (Fallegger et al. 2019). Further, the soft implants successfully extracted cortical states in freely behaving animals, making them suitable for brain-machine interface applications (Minev et al. 2015)

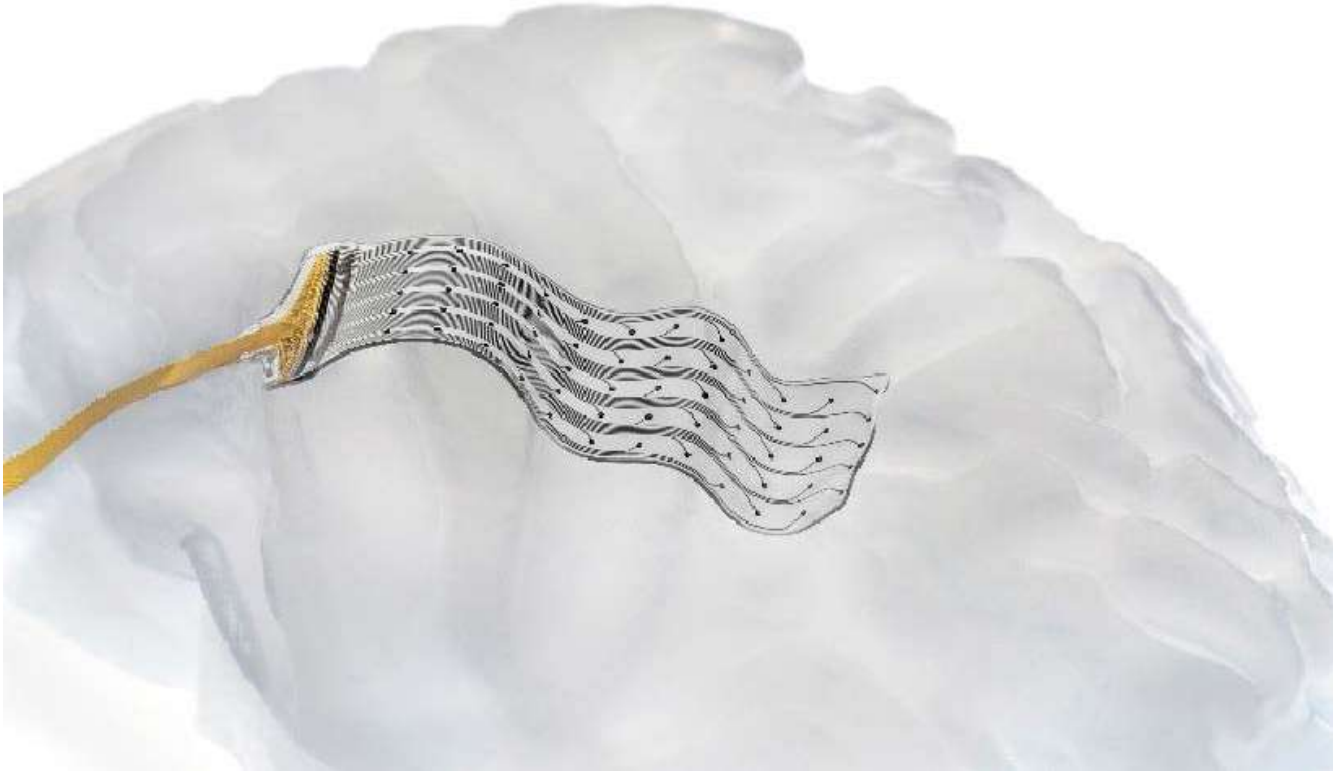
3. Safety: In terms of safety, due to the soft material being more biocompatible, studies on the central nervous system have shown a reduction in scar tissue in comparison to other rigid electrodes for 6 weeks of implantation. This advantage was shown at the level of the spinal cord in rats, where the use of a soft material has proven to be beneficial, reducing the spinal cord compression which could instead be observed when using a more rigid material (Minev et al. 2015).

Future development

Advances in technology: Neurosoft Bioelectronics has had a lot of focus on continuously developing its soft electrodes, but it is now also focusing on integrating them with the active electronics for recording and stimulation to build a fully operational implantable Brain-Computer Interface.

Advances in software: On the software side, Neurosoft Bioelectronics has been gathering pre-clinical data in the context of various neurological disorders and is now working on projects to automatize the identification of biomarkers for neurological disorders such as epilepsy and traumatic brain injury. As Neurosoft starts gathering clinical data, Artificial Intelligence and machine learning are going to be a big component of its activities.

Future indications: The company is focusing on investigating its product for severe tinnitus but foresees the use of its cortical electrode for other disorders. In particular, due to the current anatomical targets, a natural progression for Neurosoft would be to investigate the products effectiveness for deafness, in patients who are not eligible for cochlear implant. Cases of tinnitus are usually linked to hearing loss. “There is a lot of things that we will learn in our journey with tinnitus, including patient management, that we believe can then be applied to deafness as an indication”, Nicolas.

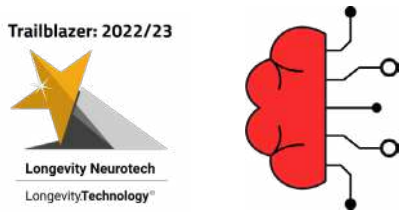


Target Market

Market size for SOFT ECoG: Refractory epilepsy is the drug resistant type of epilepsy, impacting around 1 million in the US. Based on prevalence data, Neurosoft Bioelectronics estimates that around 180,000 patients in the US and in Europe could be candidates for a surgical procedure. For use in surgery for patients with brain tumours, Neurosoft estimates around 200,000 surgical candidates around the world. This equates to a market size of $400M.

SOFT TINNIT: Tinnitus is a common disorder (affecting 10-15% of the population) which consists in the perception of a loud ringing or buzzing noise which has no external source. While many manage to tolerate the sound, it is estimated that 7-9 million people have severe forms of the disorder, which significantly affects the social well-being and health of millions of people world-wide. It is estimated that close to 500’000 patients attempt to commit suicide every year due to the tinnitus. A high-profile case of this was the suicide of CEO Kent Taylor, whose son said “The tinnitus had progressively worsened to the point that it sounded like a jet airplane taking off in your ear 24 hours a day, seven days a week” when interviewed about his father’s death in Fortune [313]. This number may be even higher in the future, as nearly 15% of COVID patients surveyed described having the symptoms of tinnitus. In terms of an addressable market, Neurosoft Bioelectronics estimates there would be roughly 170,000 patients in the US and Europe that could benefit and who would be willing to use SOFT TINNIT. Based on a rough price for the device, Neurosoft estimates a market size of over $3B for US and Europe.

Future markets: Neurosoft’s electrodes offer a safer type of ECoG that can locate specific functions in the brain whether speech, movement, or vision. Neurosoft has the potential to apply its technology to a range of further neurological disorders such as deafness, blindness or tetraplegia.



Channels to market

For its first product, SOFT ECoG, Neurosoft Bioelectronics is looking at a B2B model selling to hospitals and neurosurgeons. Neurosoft is currently looking for distributors and partners in both the EU and US markets. For its second product, SOFT TINNIT, Neurosoft Bioelectronics seeks a strategic partnership with large ENT/Audiology/Neuro companies which could be either a licensing deal or acquisition.

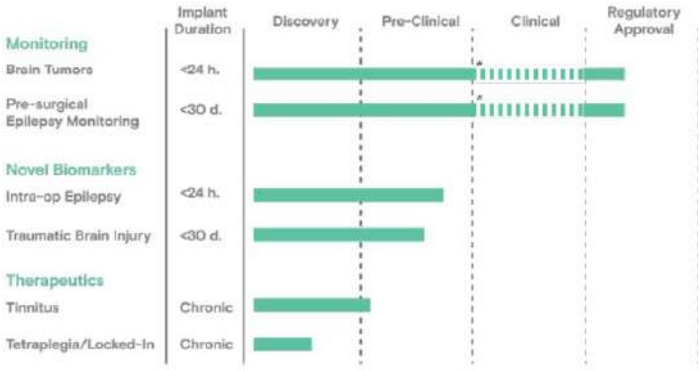
Success Factors

Team and Reputation

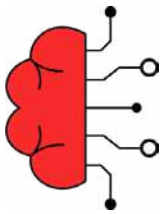
- Neurosoft's C-suite has a strong breadth of knowledge in the scientific areas of neuroprosthetics and bioelectronics;
- Nicolas Vachicouras, PhD, is co-founder and CEO of Neurosoft. Nicolas has 9-years' experience in neuroprosthetics and a PhD in application of microelectronics to soft neural interfaces from the laboratory of Prof. Stéphanie P. Lacour at EPFL. He holds a Certificate of Advanced Studies in the management of medtech ventures;
- Ludovic Serex, PhD, is co-founder and COO of Neurosoft with 7 years' experience in microfabrication and holds a PhD in microfluidics and microelectronics;
- Florian Fallegger, PhD, is a co-founder and advisor for Neurosoft and holds a PhD in microelectronics with a strong focus on soft neural interfaces. He developed and improved a large part of the technology used in the company during his PhD.
- The scientific advisory team includes Prof. Dirk de Ridder, MD PhD, who is the developer of the "burst" stimulation design for brain and spinal cord implants, commercialised by Abbott. Furthermore, he is recognized as the world-leading expert in tinnitus, pioneering cortical neuromodulation for its treatment. His years of experience and his world-wide collaborations have resulted in the publication of over 250 scientific articles and more than 30 scientific book chapters;
- The advisory panel also includes tinnitus and neuromodulation expert, Dr. Christian Hauptmann. Dr. Hauptmann is an experienced neuroscientist and developer with over 20 years of international experience in several start-up companies and universities, with more than 48 patent filings and 55 scientific publications. Dr. Hauptmann developed several innovative neuromodulation techniques, both invasive and non-invasive and transferred these into medical devices.
- Other key opinion leaders hold advisory positions at Neurosoft Bioelectronics, including Claude Clément, previous CTO of the Wyss Center with expertise in implantable medical devices and in particular brain-computer interfaces, and Stéphanie Lacour, Professor at EPFL and Director of the Center for Neuroprosthetics, who is a world leading expert in soft bioelectronic interfaces.

Intellectual Property

- Neurosoft Bioelectronics is one of the only companies in the world that are developing truly soft, stretchable, and flexible electrodes;
- Neurosoft has 24 patents, including 11 granted patents relating to its soft electrode technology, in particular around its connector solutions, in addition to application-specific embodiments;
- Neurosoft's subdural electrodes can cover larger parts of the brain/cortex (more than 10x compared to a single Neuralink device), which is much more suitable for applications that require recording/ stimulation of networks of neurons across different and/or large brain regions;
- Its devices are less invasive than Neuralink as it does not penetrate any brain tissue, instead coating the surface of the neural tissue;
- Neurosoft have demonstrated in vitro and in vivo that their devices can be used for recording and stimulation;
- Neurosoft have a wide range of electrode sizes from mm sized down to hundred on microns. Having larger electrodes is important for efficient stimulation, while micro-electrodes are critical for high-resolution recordings in order to segment more precisely pathological tissues from healthy ones, for example in the context of epilepsy resection surgery;



- Neurosoft devices are suitable to access sulci (which represent more than 50% of the cortex). Tinnitus is a good example of an application which requires access to a sulcus. Other basic functions of the brain are hidden in sulci such as part of the auditory cortex or the leg area in the motor cortex;
- The materials used in a Neurosft device are 1000x softer than conventional electrodes, which has an impact on long-term biointegration;
- Neurosoft's surgical approaches are compatible with existing and known surgical approaches, which is important for faster adoption by neurosurgeons, as they don't require specific tools;
- Neurosoft hopes to have FDA clearance in 2023 for SOFT ECoG implantation into a patient for <30 days for its first indications of brain tumour surgery monitoring and pre-surgical epilepsy monitoring;
- The company is currently further developing the technology for novel biomarkers in intra-op epilepsy and traumatic brain injury, as well as pursuing the technology as a therapeutic for severe tinnitus;
- Proof-of-concept of the use of its product SOFT TINNIT will begin in 2023;



Funding

- Neurosoft Bioelectronics has raised more than $5M to date, 90% is non-dilutive and 10% is convertible loans.
- The biggest grant to date is from the EIC accelerator grant, which is around 2.5M Swiss francs.
- The company is seeking to close a $12M Series A venture funding round in 2022.

Investment opportunity

Series A investment round

Equity investment	**$12,000,000** ($6M in soft commitment)
Expected close	Q3 2022
Milestones & Expected Deliverables	**1. FDA 510(k)** Certification of SOFT ECOG **2. CE Mark** of SOFT ECOG under MDR **3. Breakthrough Designation** of SOFT TINNIT with FDA **4. Proof of Concept Clinical Trial for Tinnitus** in 10-15 patients with SOFT ECOG **5. Chronic electrodes:** Finalise development of chronic electrodes for SOFT TINNIT
Funding so far	**>$5,000,000** in non-dilutive grants (incl. $2.78M SERI funded EIC Accelerator Grant – Q1 2022) **+ $540,000** in convertible loans **+ $110,000** in founder capital