

# 3WIN NV

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**Written By** Bob Kronemyer (Contributor)  
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**Summary:** Technology originally developed for one of the most sophisticated and advanced active implantable medical devices - cochlear implants - has been key to the development of 3WIN NV's deep brain stimulation device. The Flemish start-up's neurostimulator Synapse is designed to reduce collateral stimulation through the precise delivery of an electrical charge; as well as record the neural response to better target therapy for movement disorders.

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## **3WIN NV**

### **Precisely targeted deep brain stimulation**

Galileilaan 18

B-2845 Niel, Belgium

Phone: +32 3 443 7980

Web Site: [www.3win.be](http://www.3win.be)

Contact: Nick van Ruiten, CEO

Industry Segment: Neuromodulation

Business: Deep brain stimulation for movement disorders

Founded: March 2004

Founders: Nick van Ruiten; Stefaan Peeters, PhD, CTO; Andrzej Zarowski, MD, CMO

Employees: 25

Financing to Date: \$16.8 million

Investors: Founders; Management; Private investors; Antwerp Innovation Centre (AIC); Vinnof

Technology originally developed for one of the most sophisticated and advanced active implantable medical devices – cochlear implants – has been key in the development of **3WIN NV**'s deep brain stimulation (DBS) device. The Flemish start-up's neurostimulator *Synapse* is designed to reduce collateral stimulation through the precise delivery of an electrical charge, as well as record the neural response to better target therapy.

"Currently, the main indication for DBS is in movement disorders such as Parkinson's disease, dystonia and tremor," says CEO Nick van Ruiten, who served as CEO of cochlear-implant maker Antwerp Bionic Systems NV from 1995 to 1999 and as director of European business development for neurostimulation at Advanced Bionics Corp. from 2001 to 2003.

3WIN's target market is patients who no longer can be effectively treated with medication. For movement disorders (of which Parkinson's is the largest share), this currently represents roughly a \$100 to \$120 million market in Europe alone. The market for DBS is also expected to continue to grow through the adoption of new indications currently in clinical research.

"We have the potential of applying current steering, which tries to control the electrical field to the target in the brain," explains Chief Technology Officer Stefaan Peeters, a professor of medical electronics at the University of Antwerp, who co-founded Antwerp Bionic Systems in 1989 as a natural progression of his research on cochlear implants at the university. (Antwerp Bionic Systems was acquired by Cochlear Corp. in 2000.) Furthermore, the internal recording system of *Synapse* "allows for recording of several different points, including electrical fields along the electrode and neural responses on the stimulation pattern, which can be transmitted to the clinician for fine-tuning of the desired stimulation patterns. To be able to determine exactly where you are stimulating and how efficiently you are stimulating helps to reduce side effects significantly.

By reducing side effects, our technology becomes available for a much larger market like depression."

Peeters, van Ruiten and Chief Medical Officer Andrzej Zarowski, an ENT surgeon specializing in cochlear implants, had hoped to develop a middle ear implant for hearing impairment. "But while working on this implant, we realized it would be quite technically challenging with the requirements of an implantable microphone and an activator," van Ruiten recalls. The lack of reimbursement for such a device also gave the founders pause. "So we decided to develop an electronics platform that could be used for anything in the active implant field," van Ruiten continues. DBS was chosen because "it is the fastest-growing segment of neurostimulation, with only one major player [**Medtronic Inc.**] and with room for innovation and improvement of the therapy." Reimbursement for DBS is also already in place. "The most challenging aspect of developing our device was the internal central chip. It was custom made by our company in collaboration with IMEC, an electronics research center here in Flanders," he says.

CE mark for Synapse is expected by the end of the year, followed in 2013 by FDA approval (probably PMA). The company has seven patents (two issued, five pending) and does not share royalties/revenues with another entity.

Synapse will be the thinnest DBS device on the market, according to van Ruiten, measuring a mere 7.9 mm. The implantable pulse generator (IPG) contains the electronics and the battery. There is also an extension cable that transmits electric current from the IPG to potentially 32 independent electrodes that are placed in a specified area of the brain (the subthalamic nucleus for Parkinson's, for instance). The three external components of the device are a wireless remote control for the patient, a battery charging system (as the battery is rechargeable) and a wireless programming system for the clinician to customize therapy for each patient.

For Parkinson's disease, the patient is under conscious sedation during the implant procedure, so that the neurosurgeon can assess tremor response to ensure proper placement of the electrodes. The electrodes (each 0.9 mm in diameter) are inserted through a small hole in the skull and are wedged into the brain, then connected to the extension cable. Similar to a pacemaker, the cable is tunneled right under the skin until it reaches the collarbone, where it is connected to the IPG. Surgery takes between three and seven hours, depending on the neurosurgeon's procedure. Because the surgery is technically challenging, it is mostly confined to larger university clinics that have high case loads.

The patient remains in the hospital a few days. Then, usually within the week, he visits a neurologist for Synapse to be activated with the external programming system.

Away from the office, the patient can adjust the intensity of the stimulation and turn the device on or off. "However, by providing constant current stimulation, it is doubtful that the Parkinson's patient will need to make any adjustments to the programming," Peeters states. "Although the exact mechanism of effect that current stimulation offers a patient is still not clearly known, it appears that by stimulating the cells the symptoms of Parkinson's disease diminish or sometimes disappear, most notably the tremor often seen, the posture of the body and how the patient walks."

If the patient is able to function well with Synapse, the IPG will likely be replaced only once in 10 years. "That's one of the advantages of a rechargeable device," Peeters says. The electrodes and extension lead are permanent implants. The first implantation of Synapse in a human is expected in the near future.

Medtronic's competing DBS device, *Activa*, comes in two versions: one with a primary battery and the other with a rechargeable battery. **St. Jude Medical Inc.** (*Brio*) has a similar device to Medtronic's. "However, in general, the competing technology is less sophisticated than ours," van Ruiten notes. "These do not allow as precise a delivery of electrical charge as Synapse. Additionally, they do not have the capability to record neural responses."

Sales of Synapse will commence in Europe within the year, using a direct sales force in some countries and distributors in others. The selling price is comparable to other DBS rechargeable devices on the market, and in most instances the therapy is reimbursed.

3WIN's \$16.8 million raised to date represents five rounds of financing and includes grants and subordinated loans from the Flemish government. A new round of \$5.6 to \$8.4 million should close by October, targeting both VC firms and industrial companies.

Because Synapse is a platform technology, 3WIN is also in active discussions with other businesses to assess if it can benefit other neurostimulation applications, such as spinal cord, sacral nerve and vagus nerve stimulation (to treat epilepsy). "Our aim is to remain a European entity because DBS was invented in Europe, even though neurostimulation technology today is basically an American industry," van Ruiten concludes. – Bob Kronemyer