

## PROFILE:

**A LOT OF NERVE:**

*A dramatic shift in NeuroMetrix's strategy is helping people with diabetes—and creating major new opportunities for the company*



**Dr. Shai Gozani**  
Founder and CEO of NeuroMetrix

**N**euroMetrix may be a sixteen-year old company, but now it's acting more like a hungry start-up. Just over a year ago, NeuroMetrix's founder and CEO Dr. Shai Gozani made a dramatic shift in strategy. With his original nerve testing business in decline, he decided to refocus on diabetes. He rapidly sharpened the company's business plan, developed new products, and raised more money. The move is paying off. Now NeuroMetrix is poised to be the industry leader in diagnosing one of the worst complications of diabetes—the nerve damage that leads to foot ulcers and amputations—and in treating patients' debilitating pain. "We are very optimistic about the opportunities in this new business," he says.

Such a remarkable change in strategy is unusual. Normally, struggling companies fade away or are acquired. But what sets NeuroMetrix apart is that Gozani had both a unique underlying technology and a compelling vision. "There is

no other medical device company that can do what we can do for people with diabetes," he says.

Those technological capabilities were forged back in the 1990s when Gozani was a research fellow at MIT. As both an MD and a PhD, Gozani knew that nerves offer a window into many diseases and conditions. When the nervous system works correctly, electrical signals flow from nerve cell to nerve cell at a speed over about 100 miles per hour. But when problems like carpal tunnel syndrome arise, these signals travel slower and get weaker. In some diseases, like diabetes, those signals virtually disappear, leaving patients with little feeling in their feet.

When Gozani started his work, such electrical signals could only be detected with complex, expensive equipment operated by specialists. "It's a pretty basic measurement, but it's hard to do because the signals are tiny—one-thousandth to one-millionth of a volt," he explains. Go-

els down the nerves.

In 1996, Gozani founded NeuroMetrix to commercialize the technology. "It was a great product, and physicians loved it," Gozani recalls. Primary care doctors could diagnose carpal tunnel syndrome and other nerve ailments in their own offices, for a cost of \$80-100 for the disposable electrodes used for each test. Within 10 years, the company had revenues of \$55 million per year and a market capitalization of half of a billion dollars.

Ultimately, however reimbursement changes occurred and many doctors could no longer get paid for doing the test. The company's revenues began to drop in 2007. Gozani fought the byzantine reimbursement system to restore payment for the technology. While he eventually had some success, "it was too little too late to salvage the business," he says. "That business was not coming back."

Fortunately, Gozani realized that there was a better, bigger business—fo-

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zani and his MIT team took advantage of innovations in electronics to miniaturize and automate the technology, creating a product that many different types of doctors could use to detect nerve damage. It works by stimulating the nervous system with a small electrical stimulus, then measuring how fast that signal trav-

eling on the 25.8 million Americans (and the 258 million people around the world) with diabetes. That's because one of the major complications of diabetes is nerve damage. Some 60-70% of diabetes patients suffer from it. More precisely, the nerves leading to their extremities—primarily the feet—degenerate, a condi-



Dr. Shai Gozani shown demonstrating the NC-stat® DPNCheck™

tion called diabetic peripheral neuropathy, or DPN. Interesting, DPN is not just a predictor of nerve related complications in diabetes, but is a leading predictor of mortality. People with diabetes and DPN have much higher near term mortality than those without DPN.

One of the key reasons: When their nerves degenerate, diabetics can no longer feel what's happening with their feet. So it's easy for them to get cuts, blisters, and other wounds. Then, once a foot is injured and the skin broken, the wound can become an ulcer that fails to heal. When the ulcers get bad enough, the only recourse is amputation which is associated with high mortality. "The enemy here is foot ulcers," explains Gozani.

The problem is many patients don't know their nerves are failing until foot ulcers develop. "Nerve damage is the most common complication of diabetes—and yet it is often ignored," says Gozani.

NeuroMetrix knew it could solve this problem by using its existing nerve signal detection technology to create a device focused solely on measuring a key nerve in DPN. "It was obvious that our nerve testing products are well suited to diabetes, and that we could also diversify into therapeutics," Gozani explains. So starting in mid 2010, the company's engineers developed a simpler, more specialized product, called NC-stat® DPN-Check™. "By only testing one nerve, we were able to lower the cost of the device," says Gozani. For just \$15 for the needed biosensor, doctors can check patients for worrisome neuropathy. Then physicians can take steps to slow down the progression of the nerve damage and lower the risk of its consequences such as wounds

that lead to ulcers. "We're completely changing the game in how neuropathy is assessed," says Gozani. "I think there is an opportunity for our device to eventually become the standard of care."

NeuroMetrix launched the product in September 2011. By the end of the year, it had sold 131 devices. "The nice thing about this business is that it builds rapidly once you create a growing base of customers," says Gozani. The company's sales target is 1000 devices in 2012. Once 10,000-20,000 devices are in doctor's offices, managed care organizations, retail medical clinics and pharmacies, and other settings, the revenues from the disposable biosensor used in the test may make the company profitable again, Gozani expects. Sales are also expected to get a boost if drugs that can treat nerve degeneration make it to the market. Once the drugs are available, doctors will have an even greater need to detect nerve

damage early—so that they can prevent further damage.

But the company isn't stopping there. Even as their nerves degenerate, more than 10% of people with diabetes suffer from often-excruciating pain. "There is an unmet need in pain," says Gozani. NeuroMetrix can help here as well. The same type of electrical stimulation that's used in the nerve test can also be used to reduce pain. So the company is developing a wearable device that patients can use to manage chronic pain such as due to diabetic neuropathy. Gozani is hoping for FDA clearance for the product, named SENSUS™, by the fourth quarter of 2012. "I think it will be pretty revolutionary—and could generate significant revenue," he says.

Having gotten NeuroMetrix back on track with its new strategy and products, Gozani's last big challenge was keeping the company going until the expected new revenues and profits kick in. By the end of 2011, the company was consuming a bit under \$2 million cash per quarter and had only enough cash on hand to last for about a year. Investors didn't like that. "You get this morbid bankruptcy watch, where investors look not at your strategy but how close you are to running out of money," says Gozani.

To solve the problem, the company sold more stock in February 2012, raising about \$8.5 million. "Now we have about two years of cash on hand," Gozani explains. "That gives us a chance to build out the business."

And with the new strategy, that business is likely to be a very good one. Says Gozani: "We're feeling bullish about where we are now." ■

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<sup>1</sup> <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>

<sup>2</sup> <http://www.worlddiabetesfoundation.org/composite-35.htm>