Doctor and biomedical engineer team up on nerve stimulation device

February 22 2017, by Alex Van Abbema, Star Tribune (Minneapolis)

Daniel Romo and Daniel Gulick, the young scientists behind the Minneapolis-based startup Aucta Technologies, are used to being flexible with their research.

After spending last year wading through the field of noninvasive neuron stimulation, they made a discovery in December that led them to change the entire course of their development.

They had spent months planning a device to regulate appetite. The gadget would send an ultrasound signal to the nervous system that would mimic the sensation of fullness. It would be an inexpensive device that could be used by individuals at home.

But when they tested the effect of their prototype on the vagus nerve, which connects to many organs, they found it reduced the level of glucose in the blood.

As a result, the pair shifted from appetite regulation to the prospect of a creating a noninvasive device for diabetes therapy and inflammation control. The focus of their research, the vagus nerve, allows unique access to the brain and can be the regulator of inflammatory diseases like sepsis, rheumatoid arthritis and psoriasis.

"If you can control that specifically, you can alleviate a bunch of symptoms in these people," Romo said.

Before Aucta Technologies, Gulick, the company's chief executive, earned his doctorate in biomedical engineering at Arizona State and worked briefly at the University of Minnesota. Romo, its chief scientist, earned his medical degree in Mexico and moved to Minnesota to research neuromodulation.

They met in November 2015 as Romo was looking for a partner to work on an idea related to ultrasound. The pair initially didn't get along as Romo pitched his preliminary ideas. "He thought I was too crazy, and I thought he wasn't crazy enough to work together," Romo said.

The first idea they developed involved using ultrasound as a form of anesthesia to block nerves. After pitching the idea to investors, the two were surprised at how seriously they took the technology and business plan. They then started to work in developing a prototype.

After officially starting Aucta in March 2016, they were invited to Y Combinator, a Mountain View, Calif.-based provider of seed money for startups, for an interview.

But they were rejected in a second round of discussions, an experience that helped persuade them to pivot from nerve-blocking. "If we'd been accepted by YC, we would have been stuck with pain, which is a terrible application," Gulick said.

Because it is easier to stimulate the nerve than to block it, they zeroed in on noninvasive nerve simulation, working with the vagus nerve in particular.

Aucta also reached out to the Minneapolis-based Metropolitan Economic Development Association to find initial capital sources. It has also raised funds from an angel investor in California. Romo and Gulick said they are holding costs down in the initial stages so they don't have to give up

large shares of the company.

"If we were to get an investment in the early stages, we would have given away 30 percent to 40 percent because the risk would have been so much higher," Romo said.

Aucta Technologies is also getting some help from the Economic Development Fellows Consulting Program at the University of Minnesota, which provides graduate students who help Romo and Gulick do market research, IP research and building the business plan.

Their testing lab consists of several machines in Gulick's apartment in Minneapolis. They use an imaging system originally designed for pregnancy tests on pigs to locate the vagus nerve for testing. They used their rough prototype of the device for the pivotal glucose test, and will use it again for their definitive test on inflammation.

They are still working on final designs for the nerve stimulation device. One possibility is a handheld version, which they envisioned for appetite control. A bigger machine for use in hospitals may be in the offing to treat inflammatory conditions.

Since nerve stimulation is a relatively new area, they are still deciding the best course to obtain clearance from the Food and Drug Administration. Aucta would likely pursue what's known as a 510(k) premarket notification, the fastest path to regulatory approval.

For that, the pair must show that their device is "substantially equivalent" to one the agency has already approved to be on the market.

The pair are considering product trials in South America, where they can run tests faster and accumulate more initial data. If the trials work as expected, they would pursue the premarket approval from the FDA.

At the moment, their aim is to get patents and regulatory approvals lined up to be selling products in 2020.