

Interview - Galvani wants to get on patients' nerves



[Elizabeth Cairns](#)

GlaxoSmithKline had already signalled its interest in bioelectronics by starting an investment group three years ago that focused on this area. Now it is beginning to develop these devices directly, through Galvani Bioelectronics, a joint venture it has established with Google's life sciences arm Verily.

The partners intend to invest £540m (\$709m) in Galvani over the next seven years, dependent on milestones, and test bioelectronics in areas like diabetes. "Formation of Galvani Bioelectronics is a huge undertaking by both GSK and Verily," says Kris Famm, president of the new group.

"There's definitely a degree of outstanding risk. But it behoves companies in general to look at the long-term horizon and see what can have meaningful impact not only on one or two products but what could open up a whole new class."

Glaxo will hold 55% of the equity interest in the UK-based group and Verily 45%.

Bioelectronics is similar to neuromodulation, involving the use of implanted devices to stimulate or block neural impulses. Neuromodulation is well established for neurological conditions such as chronic pain and the tremor associated with Parkinson's disease. Bioelectronics seeks to adapt the technique to a much wider range of disorders.

Galvani is going where the money is, with development programmes in metabolic, inflammatory and endocrine disorders, with type 2 diabetes being one example. Galvani contends that there are several ways in which altering neural function can treat this condition.

"You can shift pancreatic function through modulation of the nervous signals to the pancreas," says Mr Famm. "You can shift the sensitivity to insulin in different tissues through modulating the sensing of insulin in the body; you can shift, potentially, storage of glucose through innervation to organs such as the liver; you can shift the uptake of nutrition and satiety through innervation of the stomach and the gastrointestinal tract.

"There are many different potential points of attack. We've been exploring several of those and have good reason to believe, in animal models, that we can get some powerful effects."

Read and write

Animal models is as far as the company has got. It has bold ambitions: data from the first clinical proof of concept trials in three years and a finished device ready for regulatory review seven years from now.

Still, 2023 is a while away, and another company has already reached the clinical stage with a similar technology. Last month SetPoint Medical reported encouraging, if not definitive, results with its vagus nerve stimulation device in patients with rheumatoid arthritis ([Interview - SetPoint off to a good start in the clinic, July 21, 2016](#)).

Far from being left behind, however, GlaxoSmithKline in fact stands to benefit from SetPoint's success. It is one of SetPoint's venture backers, having sunk \$5m into the start-up three years ago through its dedicated bioelectronics investment fund, Action Potential Venture Capital.

Galvani intends to employ a similar initial clinical strategy to SetPoint, using a third-party device at first - SetPoint has adapted a vagus nerve stimulator from Cyberonics, while Galvani is using a device from Nuviant Medical. It will simultaneously work on a proprietary version.

There are differences, however. SetPoint's implant is miniaturised compared with traditional neuromodulation devices, Mr Famm says. But Galvani is even further along on that trajectory, building smaller and smaller devices, thanks to Verily's engineering expertise.

The company wants "devices that can stimulate not just a particular waveform, but devices that can record the underlying neuro signals as well," he says. A [video dating from 2014](#) suggests that Glaxo wants to "read

and write action potentials". The collaboration has mentioned incorporating Verily's data analytics capacity – perhaps Galvani needs this in order to better understand neural impulses as well as altering them.

Galvanise

Another difference between Galvani and SetPoint is the positioning of the modulators. "SetPoint have this stimulating on the cervical vagus," Mr Famm says. "Our view is that the closer we can be to the end organ the more specific an effect we can have, without affecting the many other functions that run through the trunk or the vagus nerve in the neck."

But this presents problems of its own, not least how to power the device. "It will be wirelessly charged," says Mr Famm. "It is critical to do deep tissue charging without too much power loss." Again, Verily will be contributing technology and knowhow here.

As for the competitive landscape, there are several device companies working on peripheral neurostimulation. CVRx is developing a device to simulate the carotid sinus to treat hypertension and heart failure and ImThera Medical is working on stimulating the hypoglossal nerve in the neck as a therapy for obstructive sleep apnoea.

And then there are the big players: Medtronic and Boston Scientific, St Jude, Cyberonics and LivaNova all have neuromodulation franchises, though as Mr Famm points out, "they haven't pursued – at least publicly – the realm of neuromodulation in the viscera for the sort of indications that are traditionally treated with medicines."

Glaxo is the first pharma company to show an interest in this approach. Mr Famm believes it will not be the last.

He says that it is inevitable that other large pharmaceutical companies will see the potential of bioelectronics and begin to investigate this technique. Presumably the looming threat of biosimilar competition to blockbusters like Sanofi's diabetes drug Lantus and J&J's arthritis antibody Remicade will spur the search for alternative products.

"Who moves in remains to be seen, and in what sort of partnerships, but if the field has the potential we believe it has, and we continue to be successful in the next few years, of course there will be other players," says Mr Famm.

The success or otherwise of bioelectronics in general and Galvani in particular will naturally hinge on clinical data. Come 2019, Glaxo will have a decent idea of whether its faith has been justified.

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