



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Emvision Medical Devices

By TIM BOREHAM

ASX code: EMV

Share price: \$1.315

Market cap: \$83.8 million

Shares on issue: 63,759,832 (16,789,351 in ASX escrow)

Chief executive officer: Dr Ron Weinberger

Board: John Keep (chairman), Dr Weinberger, Scott Kirkland, Ryan Laws, Geoff Pocock, and Tony Keane

Financials (March quarter 2020): receipts \$46,000, cash outflows \$798,000, cash balance \$6.06 million, quarters of available funding 7.6

Identifiable major shareholders: Uniquet Pty Ltd 9.41%, Scott Kirkland 5.87%, Ryan Laws 5.19%.

Emvision chief Ron Weinberger brings a rarefied perspective to the prospective device maker: he was a mover and shaker behind the \$2 billion market cap probe sterilizing house Nanosonics.

As one could imagine, Dr Weinberger learnt a few do's and don't's during Nanosonics' elongated evolution, including the importance of focusing on one or two applications instead of trying to solve all the world's health challenges.

“You will have significant successes and also face significant issues,” he says. “I’m five foot four and I’m bald. When I started at Nanosonics I was six feet two and had lots of hair.”

Emvision’s challenge is to perfect and commercialize a portable helmet-like device to detect strokes and other brain injuries in a timely and non-invasive manner, as well as to provide more interpretation as to what’s going on in the grey matter.

But true to Dr Weinberger’s ethos of not taking on the world, Emvision does not aspire to replace the current stroke imaging methods: computer tomography (CT) or magnetic resonance imaging (MRI) scans.

Based on electromagnetic microwave imaging, Emvision’s devices are intended to be used in hospitals as an adjunct to these accepted methods. But much of the sizzle in the company’s story lies with the devices being used in ambulances and other “first responder” situations (as the yanks would put it).

According to the World Health Organisation, strokes are the second biggest cause of death and the leading cause of permanent disability.

Incorrect or delayed diagnoses can result in permanent disability and death.

One in six people will have a stroke and five million will die. One third of stroke patients will have another stroke and stroke patients who enter hospital for other indications account for roughly 10 percent of all strokes.

A stroke of fortune ... and hard work

Emvision is the culmination of a decade of research at the University of Queensland.

The underlying algorithm and antenna technology was co-invented by Professors Amin Abbosh and Stuart Crozier. The former is a leader in electromagnetic microwave imaging; the latter created technology central to MRI machines.

Emvision was formed in July 2017 by Scott Kirkland and Ryan Laws, for the purpose of acquiring this tech from the university’s commercialization arm, Uniquist.

Mr Kirkland held senior sales positions at San Francisco’s Quantcast, while Mr Laws has a history of investing in - and arranging funding for - emerging companies.

Emvision listed in mid-December 2018, having raised \$6 million at 25 cents apiece. Dr Weinberger has been the CEO since the listing, but in April this year was elevated to the board as managing-director (at the same time, executive chairman John Keep became ‘normal’ chair).

Emvision has other strong Nanosonics links: head of design and development Robert Tiller worked on the original Trophon, while regulatory affairs head Ruth Cremin held an identical role at Nanosonics.

Thirty-second stroke detection

Once fitted, the helmet devices can take an image in about 30 seconds and interpret it in less than three minutes. The entire process can be done on a laptop.

Dr Weinberger says CT/MRI scans are “Very well-established utilities and do a very good job”.

But the truth is they very heavy and bulky - and very fixed. The machines are also heavily in demand in hospitals, which need to prioritize use, strictly.

“We are trying to provide different data that can be done by the bedside,” Dr Weinberger says.

The ‘algorithms’ create an image which is compared to the “ground truth”: the pictures from the MRI-CT scans.

“We are able to provide very high contrast images between damaged and normal tissue, whereas an MRI/CT without contrast agents is pretty grey,” Dr Weinberger says.

“In one particular patient we not only picked up the effects of the new stroke, but could identify damaged tissue surrounding an old stroke.”

The device has the potential to detect cellular changes by monitoring the electrical properties of the tissue as they change in response to the injury.

While much of the company’s intellectual property is based on the imaging algorithms, the company’s “secret sauce” lies in how the software integrates with the hardware.

The view from the clinic

Having done trials on healthy humans, the company launched a pilot clinical trial at Brisbane’s Princess Alexandra Hospital.

The trial kicked off in January 2020, just in time for the coronavirus to put a shuddering halt to trials on April 2. It has been restarted.

The trial aims to enroll both haemorrhagic (bleed) and ischemic (blockage) stroke patients - 30 in all - and is about halfway through this process. Dr Weinberger says the primary purpose of the trial is to generate data on the electromagnetic scattering effects in the brain, so that the algorithms can be improved and refined.

In April, the company reported clinical results from two patients, showing a “strong correlation” between Emvision’s imaging and the “ground truth” scans.

The images were reconstructed by creating a map of electromagnetic wave “scattering” that results from the contrast between the ischemic (blood flow deprived) and healthy brain tissue.

Emvision's clinical adviser and stroke expert Prof Michael O'Sullivan dubbed the results as "highly promising", adding: "In both cases the scans were clearly positive and provided a good guide to the extent of brain tissue damaged or under threat."

Keepin' it real

Dr Weinberger says it's one thing to get a nice image of the injured tissue, but it's little more than a pretty picture if the clinicians can't do anything about it. In the first aid context, in-situ detection could enable a paramedic to identify the stroke as clot-based and dispense a clot-dissolving drug.

"There's a golden hour once you have had a stroke - and that's when there's the ability to make the biggest impact with intervention," he says.

"You can have tremendously improved outcomes. The longer these things go on, the more damage there can be."

Once in hospital, the patient may have to wait between 24 and 48 hours for a follow-up MRI/CT scan and there's no way of bedside monitoring in this critical period.

"One third of patients with a primary stroke will have a recurrence or a new stroke," Dr Weinberger says. "Sometimes the clot is pulled out, but this can damage the blood vessel."

What's next?

Emvision plans to seek marketing approval from the local Therapeutic Goods Administration, but also tackle the US Food and Drug Administration "in parallel".

European device regulation is in disarray post-Brexit and can wait.

Not, surprisingly the company dispatched regulatory affairs head Ruth Cremin to the FDA for a preliminary chat.

Dr Weinberger says the company will need to carry out a pivotal trial, enrolling "a few hundred" patients across multiple sites.

"We will have well-defined objectives that we are in the process of determining," he says.

"I've been around long enough in our industry to see companies shoot for the stars with five objectives. Then one fails and the share price plummets."

Dr Weinberger says the company hopes to kick off its pivotal trial within the next 12 months, in view of a regulatory submission in late 2021 and commercial launch in 2022.

Also in alliance with the University of Queensland, Emvision has a secondary program to develop a torso scanner to monitor the severity of non-alcoholic fatty liver disease.

Finances and performance

Last November, Emvision tapped the market for \$4.5 million in a placement at 74 cents, a 13 percent discount to the prevailing price.

With \$6 million in the bank, Dr Weinberger says there's enough dosh to complete the trial and the company is "well capitalized at this point".

Emvision spent \$1.08 million on research and development funding, but received \$237,000 in Cooperative Research Centre (CRC) funding.

Emvision was awarded a \$2.6 million government CRC grant in late 2017.

By March 2020, CRC program partners - including GE Healthcare, the University of Queensland and Queensland's Metro South Hospital and Health Services - had chipped in a further \$910,000.

As with Nanosonics - and sorry to stretch the comparison - Emvision envisages a "razor blade" model by which the company generates substantial revenue from consumables and servicing the units.

The consumable in this case is a flexible single-use cap worn by the patient under the helmet, for infection control and improved signaling.

On back-of-the-envelope sums, the dollars add up: Princess Alexandra admits an average of five stroke patients per day, or 1,825 a year (ok – 1,830 in a leap year).

Charge, say, \$20 per cap and that's \$35,000 a year just for one ward in one hospital - assuming the patients are scanned only once.

Dr Weinberger notes that in the US, preventative maintenance accounts for 14 percent of the annual cost of running a typical device.

Shares have run strongly on April's initial trial results and are trading around record levels, having slumped from 90 cents to 43 cents during the February/March overall market selloff.

The next 'Packer Whacker'?

Dr Weinberger's ultimate ambition is to see the devices installed in every ambulance: the stroke version of the Packer Whackers (the late tycoon funded defibrillators for all NSW ambos after suffering a near fatal heart attack in 1990).

As with Nanosonics Trophons that can be operated by nurses, Emvision's devices will be designed to be used easily in the field.

A paramedic could conduct the scan and send the images to the hospital via telemetry, ahead of the patient's arrival.

Ambulance organizations and the Royal Flying Doctor Service are keen. Speaking of the latter, the device has particular appeal in regional areas where a high-end CT or MRI scan is about as proximate as an Uber Eats delivery.

Dr Boreham's diagnosis:

Dr Weinberger says one of the keys to succeeding in device development is not to strive for perfection, but to keep in mind the practical considerations of everyday usage.

For example: where will the device be stored at night?

While devices need not be revolutionary, they do have to offer something that others can't - and on this note Emvision does have 'same but different' competitors.

For instance, an Austrian company has a mobile stroke imaging device with around 200 antennae compared to 16 for the Emvision device. "It's very large by comparison and you have to pull the bed away from the wall," Dr Weinberger says.

Other device makers have "portable" CT scanners weighing around 600 kilograms.

"There's always going to be someone having a crack at this, but we think we have a very good advantage in terms of price and our value proposition," he says.

As with Dr Weinberger, your columnist can remember when Nanosonics - apologies, again - had a similar market cap of a modest \$80 million.

"Nothing happens overnight," he says. "But eventually the fairy godmother will turn up and you get turned from a pumpkin to a prince and everyone forgets you were a pumpkin for a while."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's still trying to find the damn shoe that fits properly, but fortunately he is partial to pumpkin soup in the winter months.