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Dr Boreham's Crucible: Polynovo

By **TIM BOREHAM**

ASX code: PNV

Share price: \$1.545; **Shares on issue:** 690,232,751; **Market cap:** \$1.07 billion

Chief executive officer: Swami Raote

Board*: David Williams (chair), Dr Robyn Elliott, Christine Emmanuel-Donnelly, Leon Hoare, Bruce Rathie, Andrew Lumsden

* Dr David McQuillan resigned from the board in September 2022 and became chief technology and scientific officer

Financials: (December half 2022): revenue \$29.5 million (up 63%), underlying net loss \$3.8 million (previous \$2.5 million deficit), cash of \$50.5 million (previous cash of \$3.3 million)

Identifiable major holders: David Williams 3.1%, Lateral Innovations 1.65%, Kittel Family super account 1.22%, Simone Maree Beks 0.63%, Paul Gerard Brennan 0.63%, CSIRO 0.62% (Apart from Mr Williams, these numbers are from the company's 2022 annual report and ahead of the \$53 million capital raising.)

When he was tapped for the top job at Polynovo a year ago, Swami Raote had a clear vision of where the wound care house should be headed.

"I saw an amazing technology that really needed to reach many more patients as quickly as possible," the Florida-based CEO says of Novosorb, the company's bio-resorbable lattice for complex wounds, burns and reconstructions.

Mr Raote certainly knows a good medical device from a dud, having had a 30-year career at Johnson & Johnson in roles including over-the-counter goods and pharmaceutical products and devices.

He most recently headed J&J Vision Care, where he boosted revenue by 30 percent and profits by 50 percent over four years. He is also a senior advisor supporting the rollout of a digital health platform to Indian citizens.

“Work is not work, it is a joy,” Mr Raote says.

It is a case of so-far-so-good for Mr Raote, with the company recording its highest monthly product sales of \$7.2 million in May.

In September last year, the US Food and Drug Administration (FDA) approved the company’s treatment for soft tissue regeneration, Novosorb MTX, under the 510(k) pathway.

The long-awaited approval expands the application of Novosorb from the company’s core burns-oriented Novosorb BTM (as in biodegradable temporizing matrix).

More specifically, this global masterplan involves lessening reliance on the US market and expanding from burns to other forms of trauma.

Not-so-great moments in sport

In its previous iterations, Polynovo has been involved in some great - or infamous - moments in sporting and biotechnology history.

Polynovo evolved from companies known as Calzada and, earlier, Metabolic Pharmaceuticals.

Metabolic owned AOD9604, a peptide that failed a large and very expensive obesity trial and then was central to the drug scandals engulfing the Essendon and Cronulla football clubs in 2013.

The Novosorb technology itself was developed by the Commonwealth Scientific and Industrial Research Organisation and spun-off in 2004 as Polynovo Materials, in a joint venture with Xceed Biotechnology.

Metabolic bought 60 percent of this venture in 2008.

In 2009, Metabolic changed its name to Calzada and moved to full ownership of Polynovo in 2010. Calzada appointed David Williams, first as a director, and shortly afterwards as chair and changed its name to Polynovo in 2014.

Mr Williams runs his advisory company Kidder Williams and until recently was on the board of the pain-relief house Medical Developments.

Mr Raote replaced Paul Brennan, who over seven years built the company from a \$30 million market cap minnow to a peak valuation of \$2.7 billion.

He also navigated the company through the Covid shoals, but according to chair David Williams' unusually frank disclosure, the departure resulted from "increasing differences with the board in relation to Paul's interaction with the company's senior management team and his management style".

A lot to absorb about Novosorb

Novosorb BTM is a bio-resorbable lattice for complex wounds, burns and reconstructions.

Only two millimetres thick, the foam looks like something you would wrap a parcel in, but in reality, it's a complex product. The material can be produced as a fibre, a cardiac stent or films and foams.

In essence, Novosorb provides a 'home' for cells to migrate and disrupts the ability of collagen protein fibres to form knots and bundles. Eventually, the material bio-degrades and is excreted via the usual channels (urine or respiration).

As a synthetic surgical matrix, Novosorb obviates the risks around rejection and bacteria - and religious and other objections towards biological products made from ovine or bovine collagen and porcine parts.

The FDA approved Novosorb BTM for burns in 2015, while European authorities followed suit in 2019.

The company claims Novosorb BTM has become the market leader in Australia and has "quickly become the standard-of-care for burns and trauma surgeons in the US, the UK and Germany".

In the nine months to March 2023, about 9,000 patients had been treated, compared with 10,000 in the full 2021-'22 year.

As of the end of April, Polynovo was doing business directly with 570 hospitals in Australia, New Zealand, Singapore, Hong Kong, Ireland, India, Canada and the US.

It also has distributor arrangements in other jurisdictions, including Germany, Scandinavia and South Africa.

Going places

Furthering what Mr Williams describes as the company's "disruptive mood", in November last year Polynovo availed of the annual get together of Indian plastic surgeons to enter the sub-continental market.

The company notes there are 140,000 deaths and 240,000 injuries caused by burns in India annually, mainly affecting women and children.

In the Western world, the incidence of burns is flat to declining because of improving safety standards.

“In India every minute there is a burns incident and every three minutes someone gets horribly disfigured and every five minutes someone dies,” Mr Raote says. “We want to find the right model for India because our model for the US won’t work there.”

Meanwhile, China and Japan are also attractive markets: the former for sheer scale and the latter for sophistication and “the skills of its surgeons with respect to tissue sparing and restoring form, function and aesthetics”.

In October last year, Canadian authorities approved Novosorb BTM, while other markets of interest include France, Spain, and Brazil.

Tackling diabetic foot ulcers

In August last year, the company said it had enrolled the first patient in a randomized, controlled trial of Novosorb Synpath, its candidate to treat diabetic foot ulcers (DFUs).

In February this year, 25 of the targeted 138 patients had been signed up, with enrolment completion pushed out from April to the end of June.

Earlier work at Adelaide’s Flinders University shows the device resulted in “remarkable” healing and saved limbs from being amputated. DFUs affect 300,000 people in the US, at an annual cost to the health system of \$US9 billion.

According to Mr Williams, many surgeons already are using Novosorb BTM “but the time has come for a specific product to treat diabetic foot ulcers and venous leg ulcers”.

Better with BARDA

Polynovo’s biggest trial is a co-funding arrangement for full thickness burns with the US doomsday preparation authority, the Biomedical Advanced Research and Development Authority (BARDA).

To date, 54 patients have been enrolled at US sites. But to meet the requisite 120 patients, the company is expanding the trial to India.

The idea of BARDA is that it stockpiles medical supplies for a time of need, but understandably the products need to have been approved.

“BARDA has been a terrific partner,” Mr Raote says. “Some of the BARDA team members have been associated with Polynovo even longer than our own program managers.”

Sizing up the market

Polynovo cites a \$US3.6 billion market for trauma (degloving) and \$US1.2 billion for deep dermal and full-thickness burns.

The company is tackling these markets directly. It is also open to alliances to enter the \$US2.3 billion hernia market, the \$US1 billion breast reconstruction sector and the \$US318 million ortho-biologics sector.

Cut another way, the company cites a US addressable market of \$A500 million for Novosorb MTX.

Mr Raote says the company is not constrained about the availability of material for the products, which are made at the company's Port Melbourne factory, which is being expanded from the current single to unit to three units.

"We can scale our manufacturing to satisfy global demand," he says. "Unlike biologics, we are not constrained by supply chain vicissitudes or cleansing and processing challenges."

"The question is whether we can grow faster than that, so we can bring on another manufacturing plant elsewhere."

Finances and performance

In the six months to December 31, 2022, Polynovo recorded revenue of \$29.5 million, 62 percent higher than previously.

The company also recorded an underlying net loss of \$3.29 million, compared with a \$2.5 million deficit previously.

But in the nine months to March 2023, revenue stood at \$45.2 million, 48 percent higher than the previous corresponding period.

Of this, the US accounted for \$33.4 million, up 42 percent, with the rest of the world chipping in \$7.6 million (double the previous tally).

The company has followed up with monthly sales reports, culminating in a record \$7.2 million in May. This took revenue for the 11 months to \$59.1 million, 55 percent higher.

The company's robust cash position is explained by an institutional placement and share purchase plan in November last year, which was oversubscribed and raised \$53 million despite the gnarly market conditions.

Polynovo shares have had an up-and-down ride over the last 12 months, peaking at \$2.65 in early February this year and bottoming at \$1.27 in early September last year.

The stock hit an all-time peak of \$3.95 on Christmas Eve 2020.

Dr Boreham's diagnosis:

In its pursuit of broader markets, Polynovo is taking a cue from surgeons who provide feedback on how they use the Novosorb products and how they can be improved.

“Surgeons are coming up with multiple uses for Novosorb MTX and have suggestions such as increasing the pore size or thickness of the product,” Mr Raote says.

He says Polynovo is also willing to partner with other companies or groups that know the various markets better than the company.

“We are pretty humble about what we know and equally about what we don't know,” Mr Raote says.

We should be clear that Polynovo faces no shortage of competition, from both biologic and synthetic products. One quasi rival is the burns-focused, ASX listed Avita Medical, which earlier this month won FDA assent to treat the skin condition vitiligo.

Mr Raote says while Polynovo's US revenues keep growing, 'rest of the world' revenue is expanding three times faster - but from a much lower base.

“There is still a humungous amount of need in terms of where Novosorb as a platform can travel to, within the US and elsewhere,” he says.

Of course, there's revenue growth and there's profit, with the company still deficient with the latter.

But Mr Raote says profitability is “in sight”. The analysts at Macquarie concur, forecasting a strong rebound to \$10 million net profit in the 2023-'24 financial year and \$25 million in the following year.

Mr Raote says that prior to his signing-on, the Polynovo board outlined its “ambitious” plans to create a Melbourne-based genuine global force in wound care.

“That's where our interests converged,” he says. “I told them that if you are ambitious, I am willing to make it work.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is also humble about what he does and doesn't know – and has much to be humble about.