



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Polynovo

**By TIM BOREHAM**

**ASX code:** PNV

**Share price:** \$2.33

**Shares on issue:** 661,388,044

**Market cap:** \$1.54 billion

**Chief executive officer:** Paul Brennan

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

**Financials: (December half 2020):** revenue \$12.8 million (up 24%), net loss \$3.54 million (previous \$2.42 million deficit), operating loss \$200,000 (previously \$1 million loss) cash of \$7.66 million (down 5%)

**Identifiable major holders:** David Williams 2.9%, Vanguard Group 4.9%

As many life science companies have discovered during the pandemic, every cloud has a silver lining.

For device-maker Polynovo, the silvery upside of the latter-day plague is discovering that business-building can still take place via webinars, video calls and other non-personal channels.

“I think business has permanently changed,” says chief executive Paul Brennan.

“It’s a higher mix of digital and that’s going to be beneficial in the long-term in relation to costs and our ability to reach [customers],”

During the pandemic, the company signed up 22 new customers for its surgical reconstruction device in the US; and more than 30 in Germany, Australia and Switzerland. A further 30 evaluation programs are underway.

The core product is called Novosorb BTM (as in biodegradable temporizing matrix).

Not that Covid-19 has been an overall positive for the Melbourne-based Polynovo, given restricted access to hospitals and surgeons who won’t change suppliers in a hurry.

While burns and other traumas were attended to, revenue was affected by postponed elective surgeries and there are “probably years of catch-up growth”.

Mr Brennan says the US Covid experience has been “all over the shop, with 50 states acting like 50 individual countries”.

Having said that, most of the US is open for trade - after all, the business of America is business - and physical access is about 60 percent of normal levels.

### **Don’t mention the (drug) war**

Polynovo has an interesting history - to put it mildly - having morphed from companies known as Calzada and Metabolic Pharmaceuticals.

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. Metabolic owned AOD9604, a peptide that failed a large, randomized, controlled obesity trial and was then involved in the drug scandal engulfing the Essendon and Cronulla footy clubs.

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 is also chair of Medical Developments and runs advisory company Kidder Williams, among numerous other pursuits.

## **About Novosorb**

Polynovo's core product, Novosorb BTM is a bioresorbable lattice for complex wounds and 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 biodegrades and is excreted via the usual channels (urine or respiration).

Apart from costing less, Novosorb is the only synthetic surgical matrix product on the market and thus obviates the risks around rejection and bacteria.

The other products are made from animal products such as ovine or bovine collagen, shark fin cartilage, pigs' bladders and bowels, fish skins or cadavers.

As Mr Brennan says: "Pick an animal".

The US Food and Drug Administration approved Novosorb BTM for burns in 2015, while European authorities followed suit in 2019.

## **That just about covers the world ...**

Polynovo has been active on the distribution front, having recently inked deals this year covering Denmark, Iceland, Norway, Italy, Turkey and Poland.

The company already has arrangements in other countries including Sweden, Finland, Taiwan, Greece, Germany, Austria, South Africa, Saudi Arabia, Israel and India.

The company sells directly in Australia, New Zealand, Singapore, Malaysia, the UK, Ireland and the US.

In the US, the company has signed up its third group purchasing organization, or GPO. GPOs are not a venue for buying stamps but procure supplies on behalf of member hospitals.

The latest deal is with Premier Inc, which services around 4,100 facilities including 2,000 acute care hospitals.

Polynovo now has compacts with three of the top five GPOs that account for 90 percent of the market— and is keen to sign up the remaining two.

Currently, 60 percent of Novosorb's use is in burns and the remainder in wounds.

Mr Brennan says the longer-term aim is to get burns down to about 20 percent, with growth in other areas (such as scar revision, reconstructive surgery, traumas skin cancer excisions).

"The more non-burns you get the more predictable revenue stream it is, because you never know when a burn is going to happen or where," he says.

"We can respond to such happenstances but you can't bank them on a predictable monthly basis."

### **You BARDA be prepared**

As with fellow ASX-listed US-focused burns house Avita Medical, Polynovo has the support of the US doomsday preparation house, the Biomedical Advanced Research and Development Authority (BARDA).

BARDA has extended \$US15.5 million to a fund pivotal full thickness burns trial, enrolling 100 patients over 25 sites including the US and Canada.

Polynovo supplies material as an 'in kind' contribution.

The idea, of course, is that BARDA stockpiles Novosorb for a disaster. But as a US health agency it can't exactly order a product for an unregistered indication, so it needs Polynovo to win the label claim from the FDA.

Hence the trial...

### **Straining to help hernia sufferers**

Polynovo is in the process of launching a hernia repair product and is expanding the capacity of its Port Melbourne facility (where it makes its material).

Described as an "ultrasonically welded film/foam construct" the device is dissolved by the body, unlike the permanent current standard-of-care meshes that are sutured on to the offending area where the bowel is trying to push through.

Meanwhile a chronic wounds trial is underway, with the first 10 patients recruited.

These patients are expected to be healed by July, after which the trial will be expanded to 40 patients. The idea of this phase is to collect health economic data to win reimbursement for US private insurers.

“It will give us a lot of good clinical evidence from a marketing point of view, as well,” Mr Brennan says.

Meanwhile, the company is eyeing studies into healing diabetic foot ulcers, venous leg ulcers and arterial ulcers - a collective \$400 million opportunity. Work at Adelaide’s Flinders University shows the device resulted in “remarkable” healing and saved limbs from being amputated.

“A lot of anecdotal studies are coming in,” Mr Brennan says. “We will be doing more formal trials in some of these indications as well.”

Polynovo’s other pursuits also include the US alternate care sector and the potentially lucrative plastics and reconstruction industry. The latter is an in-house project with a development timeline of three or more years.

## **Finances and performance**

In the December 2020 (first) half, Polynovo increased sales by 24 percent to \$12.8 million, which is creditable under the Covid circumstances.

The net loss of \$3.54 million was higher than the previous \$1 million deficit, but the operating loss of \$200,000 signifies the company’s edging towards break-even status.

Belying their simplicity, the standard patches sell for around \$US950 (\$A1,270) and deliver a 90 percent margin, so the path to profit is clearly there if the company can achieve adequate volumes.

“We are not only half the price [of rival biologic products] but we have a better outcome,” company chair David Williams says. “We are not worried about our competition at all, but some are reducing prices by 20 to 40 percent.”

Polynovo pocketed \$US1.35 million from BARDA during the half year and expects \$US5 million in the current year.

The importance of the US market cannot be underestimated, as it accounted for 80 percent of Polynovo’s revenue during the half (the local market chipped in 14 percent). But given the number of distribution agreements recently inked - especially in Europe - expect the ‘rest of world’ line item to become more substantive.

Polynovo shares fared well during Covid, peaking at \$4 on Christmas Eve last year. But Santa’s munificence proved fleeting and the shares have lost 40 percent of their value since then.

Mr Brennan is baffled by the market’s behavior.

“You grow your business by 40 percent during a pandemic with no travel and no elective surgery and that’s very unimpressive,” he says with just an inkling of sarcasm.

## **Dr Boreham's diagnosis:**

Mr Brennan rues that Australian life science success is often judged by the price paid by an offshore acquirer.

But Polynovo is determined to continue to fly the Australian flag, in the same manner as Cochlear or CSL.

“Ultimately the best thing is not to focus on ‘are you for sale’ but ‘how you are going to grow your business’,” he says.

Besides, he says, with a substantive \$1.6 billion market capitalization, the company is “not exactly a plum acquisition target”.

In revenue terms, Polynovo looks far from cheap, even after the recent valuation pull-back. But expect sales to grow exponentially, especially given the company's market share still barely registers in the US.

“We think long term we should be the market-dominant matrix and it's a matter of time and penetration to achieve that,” Mr Brennan says.

Chairman Williams says no surgeon has ever failed to buy a Novosorb product after trialling it.

“It makes money and makes you look beautiful,” he says. “It's like a gift from God.”

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He knows a few people who think they are a gift from God but are more like the work of the Devil.***