



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Polynovo

**By Tim BOREHAM**

**ASX code:** PNV

**Market cap:** \$1,870.8 million

**Share price:** \$2.83

**Shares on issue:** 661,088,044

**Chief executive officer:** Paul Brennan

**Board:** David Williams (chairman), Bruce Rathie, Dr David McQuillan, Max Johnston, Philip Powell, Leon Hoare, Dr Robyn Elliott

**Financials (year to June 30 2019):** revenue \$13.7 million (up 128%), sales revenue \$9.35 million (up 435%), loss of \$3.2 million (previous \$6.0 million deficit), cash \$13.9 million

**Identifiable major holders:** Moggs Creek Pty Ltd (David Williams) 2.4%, Lateral Innovations (David Kenley) 1.6%, Monash Investment Holdings 1.4%, Trust Company Australia (The Merchant Group) 1.4%, Dr John Greenwood 1.4%.

As with fellow ASX listed burns house, Avita Medical, the decade ended on a high for Polynovo after European regulators in December gave the nod to its lattice-style device to treat serious burns and other horrendous wounds.

So far, the Twenties have been roaring for Polynovo as well, with its shares surging 11 percent to a fresh record high on January 22.

The catalyst was German artificial skin outfit Polymedics Innovations lodging first orders for Polynovo's lead product, the Novosorb Burns Temporising Matrix (BTM) and the first German use of the product.

The company also said it had wined and dined 70 top burns surgeons at the DAV\* Burns Conference in Austria, with many of them promising to use the product "in the near future".

Further validating the technology, Novosorb was used to treat several burns patients from New Zealand's White Island volcano disaster.

The US Food and Drug Administration approved Novosorb way back in 2015 and the product is also available in Australia, New Zealand, South Africa, India, Malaysia, Singapore and Israel.

### **Lest we forget**

Polynovo was previously known as Calzada and, before that, 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 was infamous for a failed obesity trial using the peptide AOD9604, later made even more infamous in the Essendon and Cronulla drug scandals. Then CEO Dr Roland Scollay corrected Biotech Daily at that time: "Oh, no, David. The trial was very successful. It showed that our drug didn't work.")

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 chairman and changed its name to Polynovo in 2014.

In 2015, Calzada offloaded the right to AOD9604 - which remains popular with body builders who source the stuff illicitly - to former director David Kenley's Lateral Pharma Pty Ltd for \$1.5 million.

Chairman Williams is also well known as chair of Medical Developments, which is successfully selling the Pentrox (green whistle) front-line pain relief product. He also runs advisory company Kidder Williams with Bega Cheese as a major client. On the clinical side, leading burns surgeon and 1.4 percent shareholder Prof John Greenwood is a certified Polynovo fan.

### **Novosorb explained**

Novosorb is a 2.0mm thick biodegradable polymer foam wound scaffolding that is claimed to provide a better result than rival lattice products, or skin grafts. The material can be produced as a fibre, a cardiac stent or films and foams.

Novosorb looks like a piece of foam but has three intricate layers: a sealing membrane, a bonding layer and the foam scaffolding that enables integration.

Novosorb provides a 'home' for cells to migrate and disrupts the ability of collagen protein fibres to form knots and bundles. Unlike rival products, it covers the full dermis.

As a dermal scaffold, the foam-like material is placed in the wound area where it forms a closed protective zone.

Eventually, the material biodegrades and is excreted via the usual channels (urine or respiration).

### **You BarDA believe it**

As with Avita, Polynovo is receiving support from the US Biomedical Advanced Research and Development Authority (BARDA), the agency that stockpiles medicine and medical equipment for use in a disaster.

"They are keen to make sure the product works and also make sure we are commercially viable so their investment in getting it to market is safe," Mr Brennan says.

The BARDA-funded full thickness burns feasibility trial in the US involves 19 patients across four hospitals, with four enrolled so far. While plenty of US surgeons have used Novosorb for full-thickness burns, the use is off-label which means that Polynovo can't promote it.

BARDA is stumping up about \$US18 million (\$A22 million) for the trial, with a further \$US35 million to \$US40 million for a pivotal trial.

Results from six sites participating in the feasibility trial are expected in March, with the pivotal trial expected to kick off in June.

"They are our friends," Mr Brennan says of BARDA. "We have a very good relationship with them, they help us in all sorts of ways."

### **Approved for use where it counts**

The US Food and Drug Administration 510k (device) clearance was for use in reconstructive and surgical wounds.

The CE mark approval covers broad indications: full thickness burns, reconstructive surgery, scar revision, venous leg ulcers, diabetic foot ulcers and "any loss of dermis needing repair".

That just about covers the world

Mr Brennan estimates the European market at \$300 million to \$330 million, one-third the size of the US market. The reason for this is that reimbursement is limited to hospital use, whereas in the US private insurers will fund out-of-hospitals use.

Notably, the approval covers the Europhobic Brits, as well as Ireland. The reason for this is that while Britain has executed its Brexit along with Megxit, the Poms have decreed they will accept European registration for the next three years.

Polynovo has also done the rounds of European burns conferences and is girded to launch in Austria in January.

The distributor for Germany, Austria and Switzerland, Polymedics Innovations says it has 14 hospitals ready to evaluate Novosorb.

The European approval also enables fast track approval in a number of South East Asian geographies, with applications also lodged in South Korea, Taiwan, Mexico and Kuwait.

## **Finances and performance**

Polynovo doesn't intend to issue quarterly statements but in early January management trumpeted December as its first \$2 million month sales-wise.

The company hit \$1 million of monthly sales last April, "which gives some feel for the acceleration of sales in the US, Australia and New Zealand."

The first (December) half results on February 26 will show revenue of \$8.57 million, 129 percent better than the previous \$3.75 million.

The company achieved \$9.35 million of product sales in 2018-'19, 435 percent higher and narrowed its loss from \$5.97 million to \$3.19 million.

At its November annual general meeting management advised the company was "on track" to more than double sales in the current (2019-'20) year: "however cash flows will continue to be reinvested to drive growth".

The company expects "accelerated" revenue from its direct marketing in the US, UK, Ireland, Australia and New Zealand.

But Mr Brennan cautions sales will continue to be "lumpy" as new staff are signed on, with "natural disasters such as fires and volcanoes" adding to the unpredictability.

Broker Baillieu Holst forecasts current-year revenue of \$24 million and net earnings of \$2.2 million (earnings per share of 0.3 cents).

Polynovo shares have climbed from 61 cents to a peak of \$2.83 over the last 12 months, a 364 percent increment. Just over three years ago they were trading at a mere 19c and the company was more worried about cash burn than third degree burns.

In September 2019, the ASX bestowed Polynovo its highest honor - well, almost - by elevating the stock to the ASX200 index.

So, investors are smiling like the proverbial moggies from Cheshire. But hang on - why the long faces at active stock picker Regal Funds Management?

The answer is that Regal certainly picked Polynovo - but as a short-sold position. This means the fund was betting on the share price declining rather than soaring with the gods.

Oops.

### **What's next?**

Polynovo's next target is the hernia repair market, with a planned entry into the US and New Zealand markets in 2021 (the Kiwis recognize US registration).

"The hernia market is twice the size as the skin market and that's where we see a real transformation of Polynovo," Mr Brennan says. "We move from being a one-shot-in-the-locker company to a platform technology."

The company's Port Melbourne facility is currently a construction site, as an extension is built to accommodate production of the hernia variant.

The hernia product is based on the same foam as Novosorb, but otherwise is a complete rebuild.

As with Novosorb, a key selling point is that 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.

The company plans to run post-marketing trials in the US over the next two years, to assess the longer-term progress of the patients.

Beyond hernias, Polynovo is eyeing applications for type two diabetes, involving transplanting pancreatic islet cells into the dermal depot created by the matrix.

The company also mentions breast reconstruction and - intriguingly - breast augmentation which implies potential cosmetic applications (boob jobs).

Polynovo's technology platform might also be relevant for repairing bone fractures and damaged cartilages and for subcutaneous drug delivery.

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

It's tempting to compare Polynovo and Avita, both of which have won US Food and Drug Administration approval and have enjoyed powerful price rallies.

Both bear beefy market valuations: \$1.8 billion for Polynovo and circa \$1.5 billion for Avita (which we covered on December 20, last year).

In truth, there's room for both, in that Avita's Recell spray-on skin is more suitable for less severe burns. Novosorb and Recell have also been used alongside each other.

A corporate match made in heaven? Just sayin'.

We agree with Regal that Polynovo's valuation looks toppish relative to its current revenues and there's no margin for error.

We'll get a better feel when it starts selling in European markets.

The hernia roll-out will also establish whether the company's valuation is strained, or merely the beginning.

(\* DAV is an abbreviation of Jahrestagung der Deutschsprachigen für Verbrennungsbehandlung. Thanks for asking.)

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His grasp of German is pretty scheiße as well.***